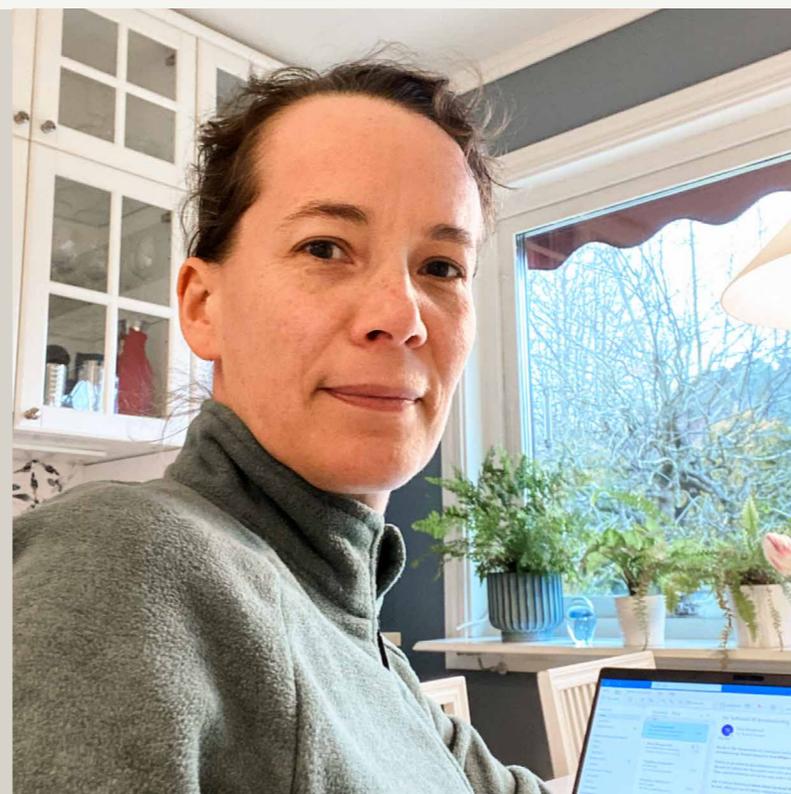




Q3



“The license agreement with Ipsen is a milestone for IRLAB – our business model is validated and our scalable research platform ISP provides the conditions to increase the pace in our value creation.”

IRLAB THERAPEUTICS AB (PUBL)

Interim report July – September 2021

Calendar

Februari 23, 2022	Year-end-report 2021
April 4-8, 2022	Annual report 2021
May 11, 2022	Annual general meeting
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	Year-end-Report 2022

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“The mesdopetam deal is transformational for IRLAB – we have shown that our business model works and that our ISP research platform is an effective tool for developing drug candidates that are attractive to the market.”

REIN PIIR – BOARD MEMBER AND CHAIRMAN OF THE AUDIT COMMITTEE

IRLAB in brief

IRLAB is a Swedish research and development company that develops novel drugs for the treatment of Parkinson’s disease with the aim of transforming the lives of those affected and their families.

Mesdopetam & Pirepemat

IRLAB’s two drug candidates, which have concluded Phase IIa studies:
Mesdopetam for the **prevention and treatment of dyskinesias** (involuntary movements) in Parkinson’s caused by long-term treatment with levodopa.
Pirepemat to **treat impaired balance and reduce falls** in Parkinson’s.

9 million have Parkinson’s

At present, nearly nine million people have Parkinson’s, **by 2040 this is expected to have doubled**. The need for new and better treatments is therefore very large. The understanding of Parkinson’s disease, its causes and the symptoms people with Parkinson’s experience is growing fast. IRLAB focuses its research on developing new knowledge and to design and develop novel drugs which can do the greatest good for these patients.

IRLAB A

IRLAB Therapeutics is **listed on Nasdaq Stockholm’s Main Market** under the ticker IRLAB A.

Integrative Screening Process

IRLAB generates drug candidates using the company’s unique systems biology and machine learning research platform Integrative Screening Process, **ISP**.

January – September in brief

Significant events during first six months (January 1– June 30, 2021)

- In January, new preclinical data were presented that indicates that not only can mesdopetam treat, but also prevent, the development of levodopa-induced dyskinesias (LIDs) in Parkinson's. The new results increase the commercial potential of mesdopetam.
- In January, results were also presented from a collaboration with Chalmers University of Technology, AI-company Smartr and IRLAB about the application of deep learning on multi-dimensional effects of CNS drugs. A summary of the interesting results were presented at the leading congress Society of Neuroscience (SfN) Global Connectome: A Virtual Event.
- At the beginning of March, it was announced that the first European patients had been dosed in the Phase IIb/III clinical trial with mesdopetam. Regulatory authorities across Europe have approved the study and Poland is the first European country where patients have been dosed with mesdopetam. 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 compound 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 signed a new and extended lease agreement the company's premises. The new premises are located in direct connection to the current premises. As a result, the right of use 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 paper reporting the clinical phase I study results for drug candidate mesdopetam was published in the journal Pharmacology Research & Perspectives (PR&P). The published paper 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 initiates coverage of the company.
- In mid-June, a scientific publication reporting the results from the clinical first-in-human study with pirepemat was published in the journal Clinical Pharmacology in Drug Development (CPDD). 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 broadly academically as well as in the industry.

Significant events during third quarter (July 1–September 30, 2021)

- In July, it was announced that the global biopharmaceutical company Ipsen and IRLAB entered a licensing agreement, providing Ipsen exclusive worldwide development and commercial rights to mesdopetam, a novel investigational drug candidate for the treatment of dyskinesia and psychosis in Parkinson. IRLAB will continue to be responsible for the ongoing Phase IIb trial that started in autumn 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 \$363m and royalties. Payments include a \$28m upfront payment, corresponding to approximately SEK 240m, and up to 335m in potential development, regulatory and sales-based milestones, plus tiered low double-digit royalties on worldwide net sales.
- In September, it was announced that IRLAB has been granted an increased 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 after end of period

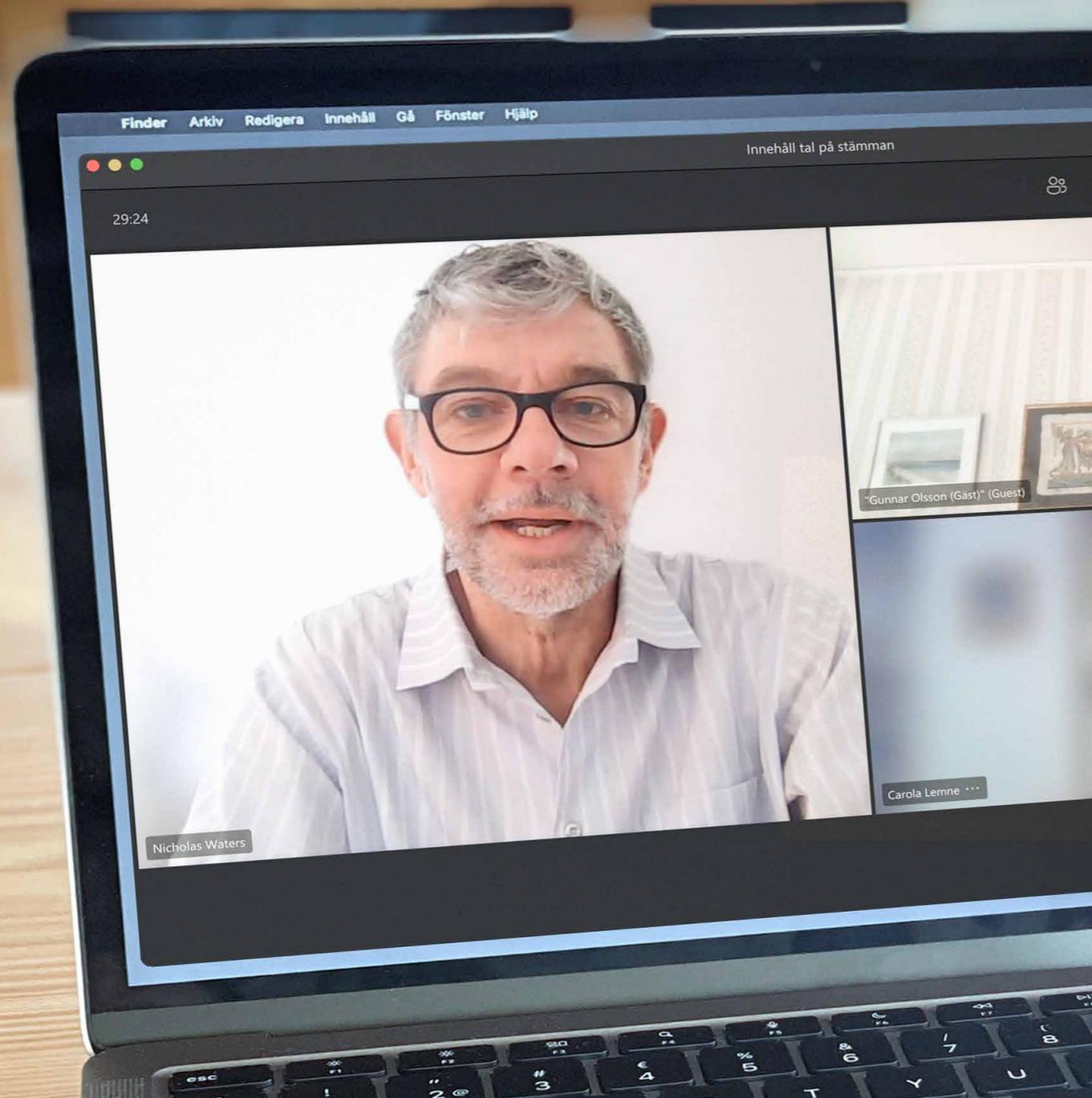
- After the end of the period, no significant events that have affected the group's financial results or position has occurred.

Financial overview

(TSEK)	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Operating result	121 665	-26 869	75 177	-72 033	-91 458
Result for the period	121 567	-26 915	74 897	-72 187	-91 653
Earnings per share before and after dilution attributable to the parent company's shareholders	1.45	-0.55	1.45	-1.52	-1.92
Number of shares at end of period including subscribed but not yet registered and bonus issue	51 748 406	48 498 406	51 748 406	48 498 406	47 677 734
Cash and cash equivalents	431 168	169 693	431 168	169 693	277 009
Equity per share	8.17	5.03	8.17	5.03	6.72
Average no. employees	22	18	21	19	18
of which are in R&D	20	16	18	17	17

“IRLAB is now situated in a much better position than at any earlier phase. We have a partnership with a global pharmaceutical company, a strong cash position, and new projects and drug candidates with very exciting characteristics on their way to clinical development. We have also received attention and expressions of interest from our biotech and pharma sphere in a completely different way than earlier. We have every reason to view the future with confidence.”

NICHOLAS WATERS, CEO



CEO's comment

For the third quarter of 2021 IRLAB has shown a positive result of SEK 120m, primarily due to the licensing of our drug candidate mesdopetam to Ipsen, a global pharmaceutical firm. The mesdopetam deal is transformational for IRLAB – we have shown that our business model works and that our ISP research platform is an effective tool for developing drug candidates that are attractive to the market. At the same time, we have laid the foundation for taking the next step towards our vision of creating a sustainable and profitable drug development company. The deal is one of the largest ever made within Swedish biotech, and gives us completely new opportunities for increasing and broadening our ISP research activities, focusing on the pirepemat project and taking new drug candidates from our preclinical project into clinical studies.

After the mesdopetam deal – focus on P001, P003 and pirepemat

From the very start, IRLAB's business has been focused on our two clinical drug projects, mesdopetam and pirepemat. At the same time it has been important to further develop ISP, our research platform, to enable early research and continually discover new drug candidates. Thanks to the focused and goal-directed efforts of our research team, we now have several very promising drug candidate projects that are rapidly approaching clinical Phase I studies.

The mesdopetam agreement enables completely new opportunities for adding value for shareholders by developing pioneering treatments of a number of CNS illnesses. The license agreement means significant revenues and reduced costs, as Ipsen will be responsible for investments in the remaining developmental stages of mesdopetam, except for the current Phase IIb/III study. Moreover, internal resources tied to mesdopetam will be freed up. IRLAB will now expand preclinical activities in the P001 and P003 projects and focus on developing substances that have the best potential for being safe and effective for patients, and therefore attractive for future partners.

P001 – for better cognitive function

This project aims to develop new drugs that improve the interconnection and signals between nerve cells in the

cerebral cortex, in order to strengthen patients' cognitive functions – and to do it in a way that not only eases their symptoms but may also slow down the course of the illness. Using ISP, we have developed several substances with varying inherent characteristics that can be appropriate for treatment of Parkinson's as well as other broader disease groups in neurology and psychiatry. We believe that this new class of potential drugs should be able to improve treatment of dementia-related illnesses, depression, schizophrenia and even ADHD.

IRLAB has already nominated IRL942 as a candidate drug and generated preclinical proof of concept in several disease models for cognitive improvement. We have initiated scaling up manufacture of IRL942 in order to carry out the animal studies required for regulatory approval to begin clinical Phase I studies. Additional candidate drugs are expected to be nominated from this project.

P003 – transforming treatment of Parkinson's

In the treatment of the basic symptoms of Parkinson's disease, the most effective drugs today are based on levodopa or apomorphine in different preparations. These two substances deliver a good effect, but with varying absorption from the gastrointestinal tract and very short effect durations, which leads to poor treatment results. It has long been an explicit goal in the field to find a better, longer-acting alternative to these two drugs.

CEO's comment

As part of IRLAB's P003 project, we have discovered long-acting substances that have the same or better effectiveness than levodopa or apomorphine in animal studies. Here we see a great opportunity to transform the treatment of the core symptoms of Parkinson's disease with new candidate drugs. The project has achieved pre-clinical proof of concept, and we are now optimizing the first drug candidates.

Pirepemat

Pirepemat is a unique development program. Today there are no drugs that specifically address the problem of falls in Parkinson's disease. Problems with balance and falls are one of biggest issues for these patients, and it is estimated that about 50% of all diagnosed patients fall often. This gives rise to reduced quality of life for the individual as well as very high societal costs and a which means there is a very large need for an effective treatment. Pirepemat has shown very promising results in preclinical and clinical studies.

Cutting a new path of our own requires, however, that we are thorough in planning our studies and charting the regulatory journey forward. After considerable efforts together with government authorities and research experts in both Europe and the US, we have an elaborate study plan. We will begin a Phase IIb study as soon as authorities approve our application.

Our cooperation with Ipsen on Mesdopetam

It's very exciting for us to work together with a global partner, and thus far the cooperation has exceeded all expectations. This quarter we worked together with Ipsen to create the working groups and processes required for continued successful development of mesdopetam towards a market launch. A technology transfer of all data and knowhow took place early this fall, and Ipsen is now forging ahead with preparations for the Phase III studies.

IRLAB continues to be responsible for completing the current international Phase IIb/III study, while Ipsen

handles all the other activities and costs associated with them. It is important for both Ipsen and us, however, that IRLAB's accumulated experience and knowledge of mesdopetam benefit the project, which is why IRLAB staff will continue to engage in the working groups that are driving developments toward Phase III and a market launch.

A deal resonating around the world

A relatively small northern European research firm like ours usually demands enormous efforts to gain the attention of potential business partners. The agreement with Ipsen, however, has put us in the spotlight of our entire industry, and we are now experiencing inquiries from a great many actors regarding our projects and ISP, our research platform

Accounting of upfront revenues from the mesdopetam deal

The mesdopetam deal gave IRLAB an initial payment of SEK 240m, which was paid during the third quarter, contributing to a cashflow exceeding SEK 200m. The revenue and results for IRLAB is, however, will differ due to two factors.

Revenues are affected by the fact that IRLAB is responsible for carrying out the ongoing Phase IIb/III study, which means that revenues to a certain degree will be deferred and continuously recognized during the study period. A total of about SEK 55m has been deferred, of which SEK 5m will be recognized in the third quarter, and the remaining SEK 50m is to be recognized in the remainder of 2021 and 2022.

Costs are affected by the fact that the booked value of the mesdopetam project must be reversed, which increases booked costs by SEK 39m.

Neither the deferred revenues nor the reversal of the booked value have any effect on IRLAB's cash flow.

Effects of the Covid-19 pandemic

Within the clinical program we see signs that the health-care situation in certain countries and regions is stressed,

and that regulatory authorities now have longer decision times for approvals. We also see that hospitals' capacity for participating in and carrying out clinical tests is limited, due to the need for acute care for Covid-19 patients. While this can affect IRLAB's clinical studies, we are following the situation closely and are taking measures to minimize the effects on our projects and schedules.

A new and stronger position

IRLAB is now situated in a much better position than at any earlier phase. We have a partnership with a global pharmaceutical company, a strong cash position, pirepemat on its way into Phase IIb and new projects and drug candidates with very exciting characteristics on their way to clinical development. We have also received attention and expressions of interest from our biotech and pharma sphere in a completely different way than earlier. We are now in a position to accelerate the development of IRLAB and strengthen ourselves with important core competencies in R&D, business development, finance and IR, in order to continue building a strong, business-oriented organization.

We have every reason to view the future with confidence.

November 2021

Nicholas Waters, CEO IRLAB Therapeutics

IRLAB's research and development portfolio

	DISCOVERY	PRE CLINICAL	PHASE I	PHASE IIA	PHASE IIB	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 & 1009	P001 program					
PARKINSON'S DISEASE						
P003	Dopamine substitution					

PFC = prefrontal cortex

*In development in partnership with Ipsen who has the global rights for development and commercialization

Project portfolio

IRLAB's project portfolio consists of drug candidates in the clinical and preclinical development phase. The project portfolio is focused on developing new treatments for patients with Parkinson's disease. The project portfolio comprises a combination of the fully-funded mesdopetam program, run in collaboration with global partner Ipsen, as well as innovative in-house programs from preclinical to Phase IIB. All drug candidates have been developed with the help of 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, so-called "good ON-time". Mesdopetam also has antipsychotic properties, and is even being developed for Parkinson's (PD-P) psychoses.

Pirepemat

Pirepemat (IRL752) is being developed to improve balance and reduce 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.

IRLAB's P001 project is aimed at developing new drugs that improve the connection and the signalling between nerve cells in the cortex to strengthen 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, IRL942 and IRL1009, is to treat mental illness, as well as cognitive and motor disorders associated with neurodegenerative and age-related CNS diseases.

Discovery phase

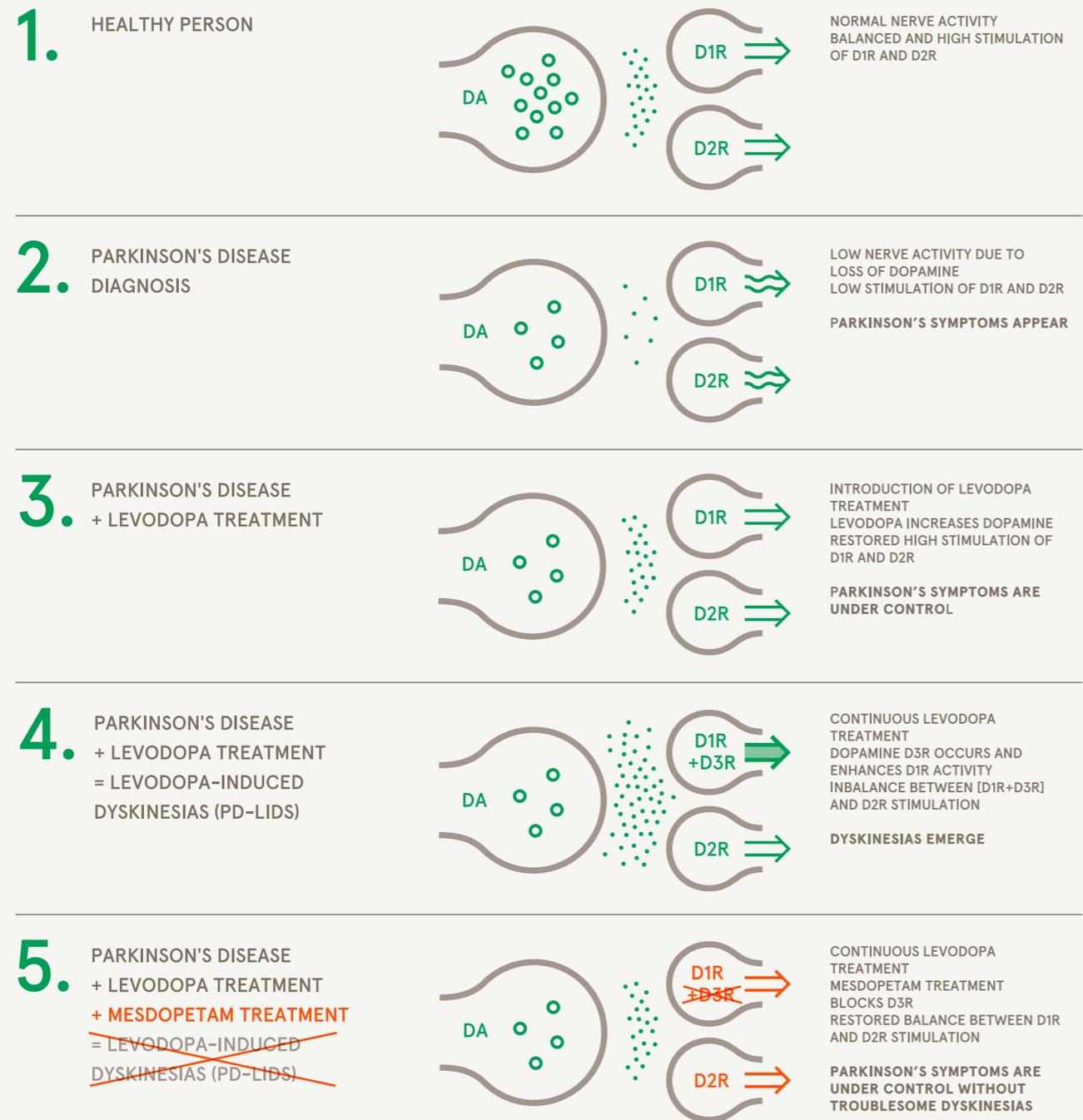
Laboratory tests for discovering drug candidates. The P003 research program includes a group of molecules with the potential to be developed into drugs for the treatment of the hallmark symptoms of Parkinson's disease.

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. These two substances can show good efficacy but have a short duration, which leads to poor treatment results.

For a long time, it has been a goal to find better, long-acting, alternatives to these two drug substances.

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

Mechanism of action (MoA) of mesdopetam



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

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 in collaboration with the global partner Ipsen. The aim of mesdopetam is to increase the time of day when patients have the optimal effect of their standard treatment with levodopa, i.e. good mobility and control of the basic 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.

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 image of the mechanism of action of mesdopetam on the left.

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 time of day when levodopa treatment helps with the basic symptoms (called "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 started at the end of 2020, and initial top-line results are expected during the first half of 2022. The study is designed to potentially form part of the final pivotal pro-

gram, ie Phase III studies, which form the basis for regulatory marketing approval. 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 number of hours daily with good mobility without troublesome dyskinesias, so-called "good ON-time", which is measured through a patient diary. The study is conducted at clinics in both Europe and the United States and through the start of the study, the company's clinical development work was expanded to the US, which was an important strategic goal for the company.

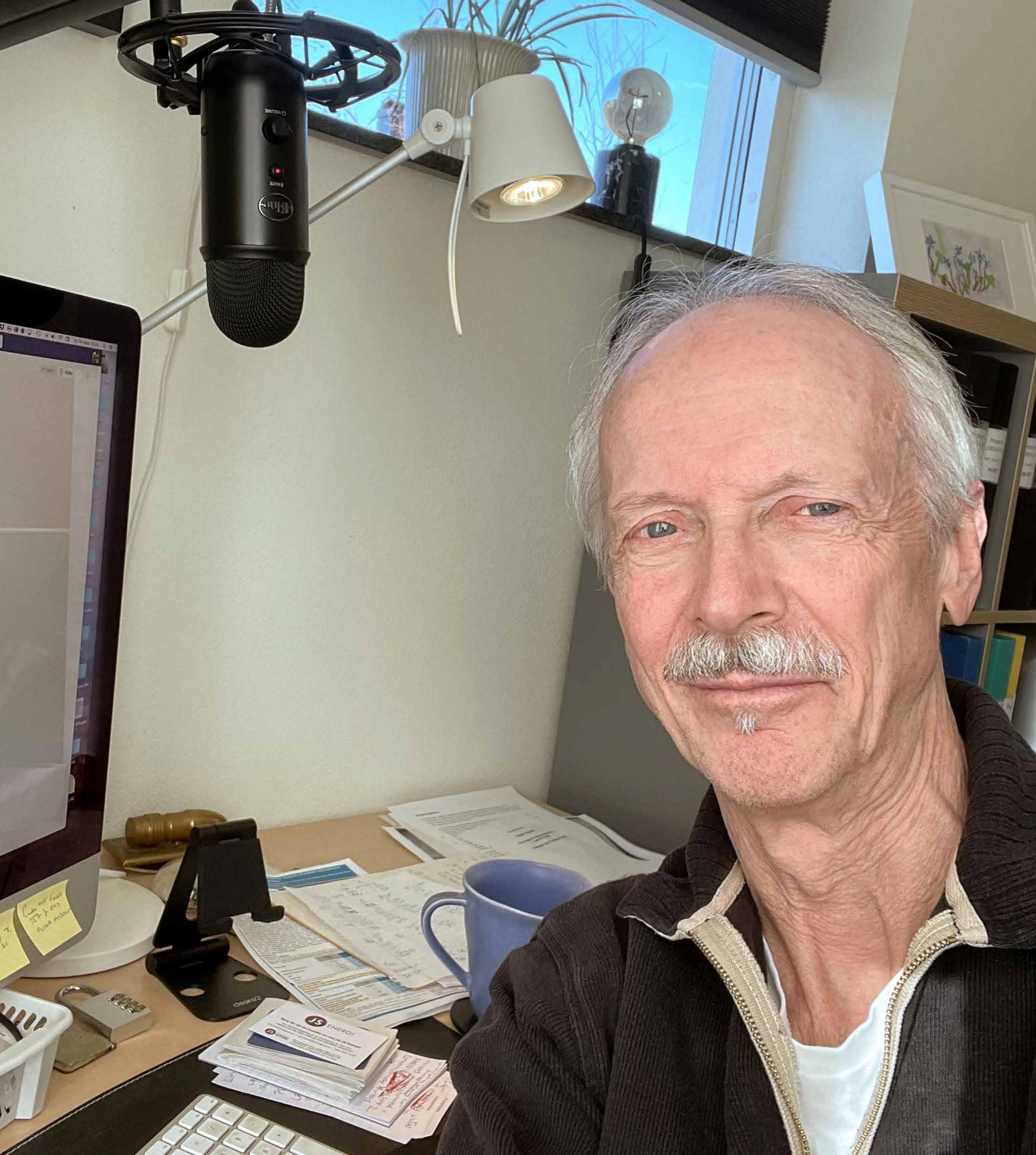
The development plan for mesdopetam includes further clinical studies to evaluate the effect of mesdopetam also on psychosis symptoms (PD-P).

Patent overview for mesdopetam

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

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

Source: The company's statement



Clinical drug candidate mesdopetam

Mesdopetam extends the daily time experienced as “good ON”-time through reducing dyskinesias as shown in Phase IIa data

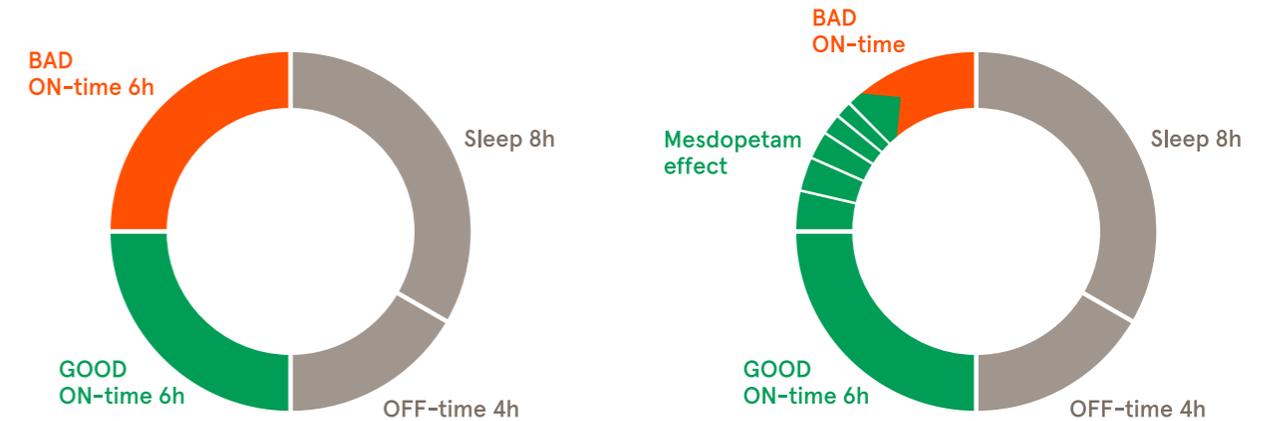


Illustration of a day for a Parkinson's patient with standard anti-Parkinson's medication (levodopa). The time is aggregated and grouped according to categories.

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 categories.

Competitive advantage

- Indications of better efficacy and a better safety profile than competitor drugs and projects in the completed Phase Ib and IIa studies.
- 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, and which has the possibility of becoming 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.
- Obtained mesdopetam as International Non-proprietary Name (INN, generic substance name).
- Development within two indications; dyskinesias and psychosis in Parkinson's.
- Study results published in highly ranked scientific journals.
- Strong IP protection: global patent protection and patent registrations can provide exclusivity until 2042.

The group's performance January – September 2021

IRLAB Therapeutics AB (publ) (with prior names Integrative Research Laboratories Holding AB and Integrative Invest AB) is the parent company of Integrative Research Laboratories Sweden AB (IRL Sweden), a research and development company with the aim of transforming life for patients with Parkinson's through novel treatments. The company's most advanced candidates, mesdopetam (IRL790) and pirepemat (IRL752), intends to treat some of the most difficult symptoms related to Parkinson's: levodopa-induced dyskinesias (PD-LIDs), psychosis (PD-P) and impaired balance leading to falls (PD-Falls). Both drug candidates have completed Phase IIa studies. In July 2021, an license agreement regarding the global and exclusive rights to develop and commercialize the drug candidate mesdopetam was entered with drug company Ipsen. IRLAB will continue to be 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 \$363m in up-front and milestone payments, whereof \$28 was paid out during 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 for developing new drug substances. The two most recently generated drug substances IRL942 & IRL1009 are both in preclinical phase and intended to improve motor function as well as mental and cognitive health in age-related diseases of the central nervous system (CNS). The project portfolio comprises a combination of the fully-funded mesdopetam program, run in collaboration with global partner Ipsen, as well as innovative in-house programs from preclinical to Phase IIb.

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

operations are conducted in the wholly owned subsidiary Integrative Research Laboratories Sweden AB.

Research and development work

The research and development work has advanced according to plan. Total costs for research and development during the period, including TSEK 39,093 relating to the reversal of acquired development projects connected to the licensing agreement with mesdopetam, amounts to TSEK 99,968 (59,553), which corresponds to 83% (82%) of the group's total operating costs.

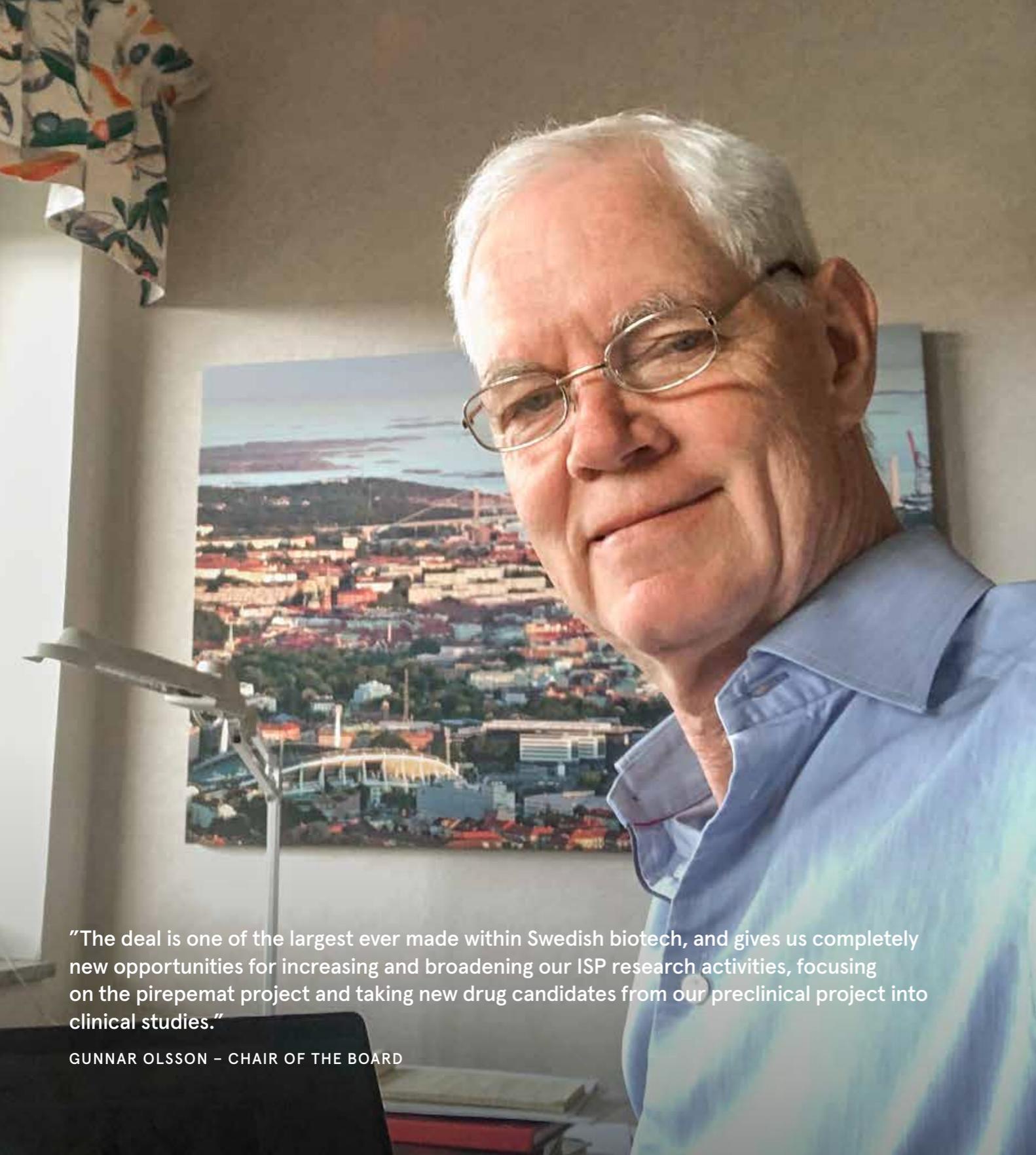
Development costs vary over time, depending on where in the development phase the projects are.

Comments on the income statement

The result for the period January 1 – September 30, 2021 amounts to TSEK 74,897 (TSEK -72,187). Earnings per share amount to SEK 1.45 (SEK 1.52).

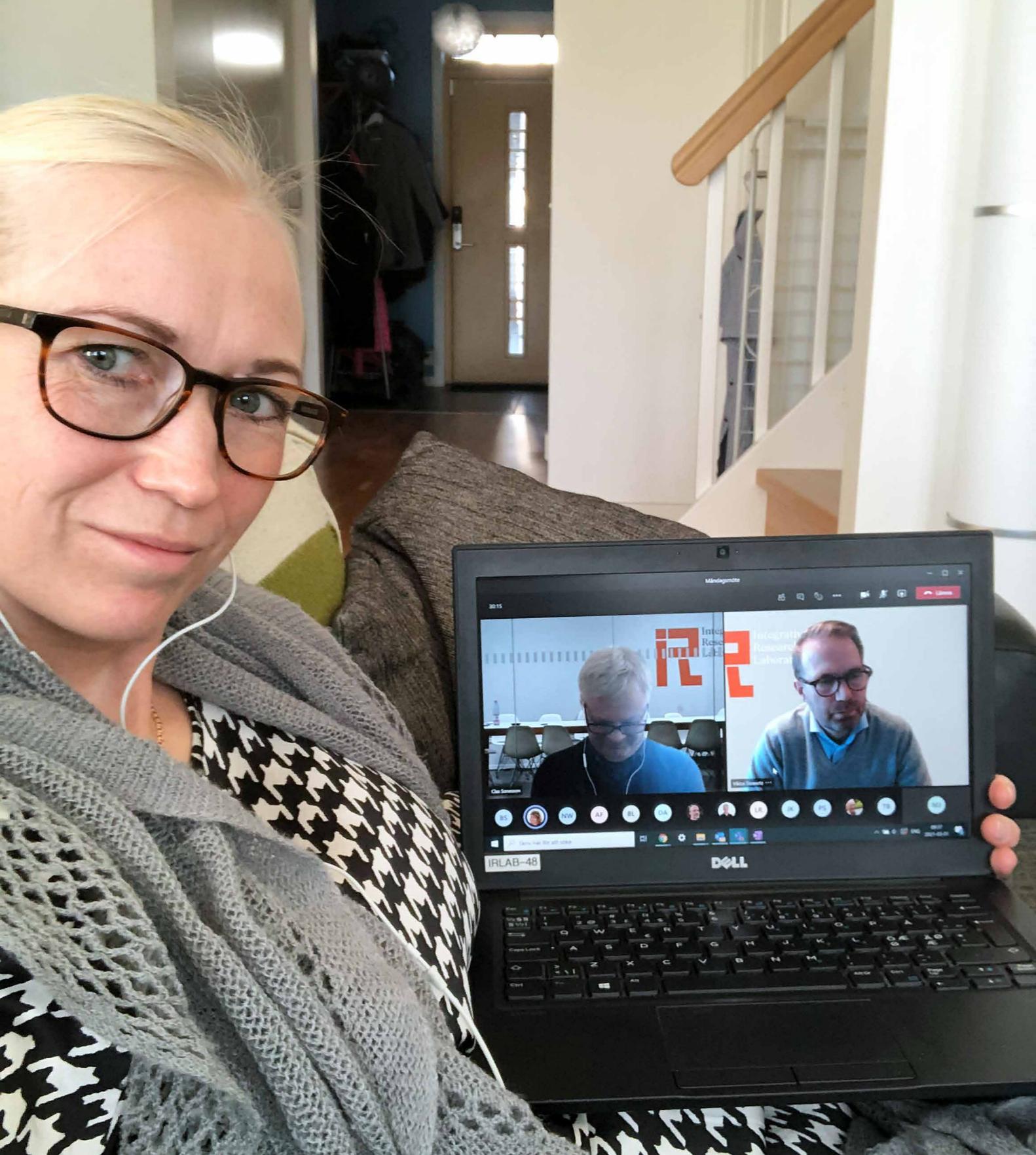
The company's net revenues during the period amounted to TSEK 195,794 (TSEK 0). TSEK 54,335 of the TSEK 239,596 that was paid out as up-front under the license agreement regarding mesdopetam, has been allocated to the finalization of the ongoing Phase IIb/III study and will be recognized as income over time until during the study period which is estimated to the remainder of 2021 and 2022. Therefore, the income from the license agreement is TSEK 185, 262. During the third quarter 2021, TSEK 5,377 has been recognized as income connected to the ongoing Phase IIb/III study and income from other services to Ipsen amounts to TSEK 5,003.

The company's operating expenses during the period amounted to TSEK 120,588 (TSEK 72,333), which was an increase of TSEK 48,255 compared to the same period in 2020. The increase can mainly be attributed to the reversal of intellectual property rights connected to the licensing of mesdopetam, contributing with TSEK 39,091 (TSEK 0) and transaction cost in connection with the mesdopetam license amounting to TSEK 8,982 (TSEK 0).



"The deal is one of the largest ever made within Swedish biotech, and gives us completely new opportunities for increasing and broadening our ISP research activities, focusing on the pirepemat project and taking new drug candidates from our preclinical project into clinical studies."

GUNNAR OLSSON – CHAIR OF THE BOARD



The group's performance January – September 2021

The transaction cost consists of remuneration to external parties and is depending on total revenues from the licensing agreement. The remaining increase compared to last year is attributable to the company having a higher activity in ongoing studies and thereby higher costs during than during the same period in 2020.

Share data

The number of registered shares at the end of the reporting period 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.

Financing and cash flow

Cash flow from operating activities January 1 to September 30, 2021 amounts to TSEK 157,029 (TSEK -72,785) and the cash flow for the period amounts to TSEK 200,234 (TSEK 59,167). Cash and cash equivalents as of September 30, 2021 amount to TSEK 431,168 (TSEK 169,693).

Equity at September 30, 2021 was TSEK 422,598 (TSEK 244,105) and the equity/assets ratio was 85% (92%).

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

Investments

Investments for the period January 1 – September 30, 2021 amounted to TSEK 561 (TSEK 394).

Personnel

The average number of employees in the group during the period January 1 – September 30, 2021 was 21 (19). At the end of the period, the number of full-time positions, including long-term contracted consultants, was 28 (21), divided between 32 (26) people.

Share capital development

Year	Event	Issued amount (SEK)	Total share capital (SEK)	Change (SEK)	Total number of shares	Change i shares	Quota value (SEK)
2013	Formation	25 000 000	50 000	50 000	100 000	100 000	0.50
2015	Rights issue	24 106 969	84 473	34 473	168 946	68 946	0.50
2015	Rights issue	14 772 000	104 169	19 696	208 338	39 392	0.50
2015	Rights issue	8 407 125	115 379	11 210	230 757	22 419	0.50
2015	Share division	0	115 379	0	2 307 570	2 076 813	0.05
2015	Cash issue	54 515 644	181 358	65 980	3 627 162	1 319 592	0.05
2016	Rights issue	41 350 000	231 358	50 000	4 627 162	1 000 000	0.05
2016	Rights issue	15 350 195	249 919	18 561	4 998 388	371 226	0.05
2016	Rights 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	0.05
2017	Rights issue	115 800 000	699 994	193 000	6 999 939	1 930 000	0.10
2018	Rights issue	138 600 000	809 994	110 000	8 099 939	1 100 000	0.10
2019	Share split (Split) 5:1	0	809 994	0	40 499 695	32 399 756	0.02
2019	Rights issue	70 470 000	862 194	52 200	43 109 695	2 610 000	0.02
2020	Rights issue	145 495 197	917 768	107 774	45 888 406	5 388 711	0.02
2020	Rights issue	130 000 000	1 034 968	65 000	51 748 406	3 250 000	0.02
At the end of the period		784 593 373	1 034 968		51 748 406		0.02

The issued amount above is the total issued amount incl. share premium but before issue costs.

Owners	Shares	Share of capital/vote
Försäkringsbolaget Avanza Pension	4 078 424	7.9%
Ancoria Insurance Public Ltd	3 826 638	7.4%
FV Group AB	3 665 626	7.1%
Fjärde AP-fonden	3 134 366	6.1%
Johnsson, Daniel	2 690 000	5.2%
Pension, Futur	2 046 869	4.0%
Tredje AP-fonden	1 847 994	3.6%
Nordnet Pensionsförsäkring AB	1 622 523	3.1%
Diklev, Philip	1 595 550	3.1%
Unionen	1 416 250	2.7%
Total ten largest shareholders	25 924 240	50.1%
Other shareholders	25 824 166	49.9%
Total	51 748 406	100.0%

Share and owners

The largest owners as of September 30, 2021

The group's
income statement
in summary

Amount in TSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Operating income					
Net revenue Note 5	195 641	0	195 641	0	0
Other operating income	124	0	124	300	404
<i>Total income</i>	<i>195 765</i>	<i>0</i>	<i>195 765</i>	<i>300</i>	<i>404</i>
Operating expenses					
Other external costs	-26 046	-22 055	-57 348	-52 710	-65 630
Personnel costs	-7 918	-4 193	-21 424	-17 912	-23 968
Outlicenced balanced development projects	-39 091	0	-39 091	0	0
Depreciation of intangible and tangible fixed assets	-926	-569	-2 477	-1 686	-2 256
Other operating cost	-120	-52	-248	-25	-8
<i>Total operating expenses</i>	<i>-74 100</i>	<i>-26 869</i>	<i>-120 588</i>	<i>-72 333</i>	<i>-91 862</i>
Operating result	121 665	-26 869	75 177	-72 033	-91 458
Result from financial items					
Financial income	0	0	0	1	1
Financial costs	-98	-46	-280	-155	-196
<i>Total financial items</i>	<i>-98</i>	<i>-46</i>	<i>-280</i>	<i>-154</i>	<i>-195</i>
Result after financial items	121 567	-26 915	74 897	-72 187	-91 653
Tax on income	0	0	0	0	0
Result for the period	121 567	-26 915	74 897	-72 187	-91 653
Earnings per share before and after dilution (SEK)	2.35	-0.55	1.45	-1.52	-1.92
Average number of shares, before and after dilution	51 748 406	48 498 406	51 748 406	47 357 730	47 677 734

The result for the period is in its entirety attributable to the parent company's shareholders.

Amount in TSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Result for the period	121 567	-26 915	74 897	-72 187	-91 653
Other comprehensive income	0	0	0	0	0
Total result for the period	121 567	-26 915	74 897	-72 187	-91 653

The group's report
on comprehensive income
in summary

The group's report
on financial position
in summary

Amount in TSEK	2021-09-30	2020-09-30	2020-12-31
ASSETS			
Fixed assets			
Intangible fixed assets	42 726	82 076	82 011
Tangible fixed assets	9 133	4 822	4 317
Total fixed assets	51 859	86 898	86 327
Current assets			
Short-term receivables	15 365	8 256	6 732
Cash and cash equivalents	431 168	169 693	277 009
Total current assets	446 534	177 949	283 741
TOTAL ASSETS	498 392	264 847	370 068

Amount in TSEK	2021-09-30	2020-09-30	2020-12-31
EQUITY AND LIABILITIES			
Equity Note 6			
Share capital	1 035	970	970
Unregistered share capital	0	0	65
Other contributed capital	607 659	562 454	685 630
Retained earnings incl. results for the period	-186 097	-319 319	-338 786
Total equity	422 598	244 105	347 880
Long-term liabilities			
Leasing debt	4 339	769	1 270
Total long-term liabilities	4 339	769	1 270
Short-term liabilities			
Leasing deb	2 998	1 654	1 657
Other liabilities	68 458	18 319	19 261
Total short-term liabilities	71 456	19 973	20 918
TOTAL EQUITY AND LIABILITIES	498 392	264 847	370 068

The group's report
on changes in equity
in summary

Amount in TSEK	Share capital	Unregistered share capital	Other capita contributed equity	Retained earnings incl. total result for the period	Total equity
Equity January 1, 2020	862		428 097	-247 132	181 827
Total result for the period				-72 187	-72 187
Registration of share capital					0
<i>Transactions with owners in their capacity as owners:</i>					
Rights issue	108		145 387		145 495
Issue costs			-11 030		-11 030
Equity September 30, 2020	970		562 454	-319 319	244 105
Total result for the period				-19 466	-19 466
<i>Transactions with owners in their capacity as owners:</i>					
Rights issue		65	129 935		130 000
Issue costs			-6 759		-6 759
Equity December 31, 2020	970	65	685 630	-338 786	347 880
Equity January 1, 2021	970	65	685 630	-338 786	347 880
Total result for the period				74 897	74 897
<i>Transactions with owners in their capacity as owners:</i>					
Rights issue	65	-65	0		0
Issue costs			-180		-180
Equity September 30, 2021	1 035	0	685 450	-263 888	422 598

The group's report
on cash flows in summary

Amount in TSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Operating activities					
Operating result	121 665	-26 869	75 177	-72 033	-91 458
Adjustment for items not included in the cash flow	40 017	568	41 568	1 685	2 256
Received interest	0	1	0	1	1
Paid interest	-98	-47	-280	-155	-196
Cash flow from operating activities before changes in working capital	161 584	-26 347	116 465	-70 502	-89 397
Cash flow from changes in working capital					
Change in operating receivables	-9 368	-1 147	-8 634	1 095	2 620
Change in operating liabilities	50 613	-2 411	49 198	-3 378	-2 437
Cash flow from operating activities	202 829	-29 905	157 029	-72 785	-89 214
Investment activities					
Acquisition of tangible fixed assets	-137	-25	-561	-394	-394
Cash flow from investment activities	-137	-25	-561	-394	-394
Financing activities					
Amortization of financial liabilities, leasing deb	-727	-1 182	-2 129	-2 119	-1 616
Issue of new shares	-180	-979	-180	134 465	257 706
Cash flow from financing activities	-907	-2 161	-2 309	132 346	256 091
Cash flow for the period	201 786	-32 091	154 160	59 167	166 482
Cash and cash equivalents at the start of the period	229 382	201 784	277 009	110 527	110 527
Cash and cash equivalents at the end of the period	431 168	169 693	431 168	169 693	277 009

The parent company's
income statement
in summary

Amount in TSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Operating income					
Net revenue	995	683	2 788	2 384	3 274
<i>Total income</i>	995	683	2 788	2 384	3 274
Operating expenses					
Other external costs	-9 994	-2 223	-14 656	-5 897	-8 052
Personnel costs	-2 120	-1 182	-5 570	-6 231	-7 794
<i>Total operating expenses</i>	-12 114	-3 405	-20 226	-12 128	-15 845
Operating result	-11 119	-2 722	-17 439	-9 743	-12 572
Result from financial items					
Result from shares in group companies	0	-10 000	0	-35 000	-35 000
Interest income	0	0	0	1	1
Interest costs	0	-1	-1	-1	0
<i>Total financial items</i>	0	-10 001	-1	-35 001	-35 000
Result after financial items	-11 119	-12 724	-17 440	-44 744	-47 571
Result for the perioden	-11 119	-12 724	-17 440	-44 744	-47 571

Amount in TSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Result for the period	-11 119	-12 724	-17 440	-44 744	-47 571
Other comprehensive income	0	0	0	0	0
Total result for the period	-11 119	-12 724	-17 440	-44 744	-47 571

The parent company's
report on comprehensive
income in summary

The parent company's
balance sheet in summary

Amount in TSEK	2021-09-30	2020-09-30	2020-12-31
ASSETS			
Fixed assets			
Financial fixed assets			
Shares in group companie	350 320	350 320	350 320
Total fixed assets	350 320	350 320	350 320
Current assets			
Other receivables	3 605	1 522	1 232
Cash and cash equivalents	114 900	164 061	239 693
Total current assets	118 504	165 583	240 926
TOTAL ASSETS	468 825	515 903	591 246

Amount in TSEK	2021-09-30	2020-09-30	2020-12-31
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1 035	970	970
Unregistered share capital	0	0	65
	1 035	970	1 035
Unrestricted equity			
Share premium fund	739 560	616 564	739 740
Retained earnings including total result for the period	-276 330	-106 062	-258 891
	463 230	510 501	480 849
Total equity	464 265	511 471	481 884
Short-term liabilities			
Other liabilities	4 560	4 432	109 362
Total liabilities	4 560	4 432	109 362
TOTAL EQUITY AND LIABILITIES	468 825	515 903	591 246

The parent company's report on cash flows in summary

Amount in TSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Cash flow from operating activities	-98 176	-2 160	-124 614	-14 571	-12 179
Cash flow from investment activities	85 000	-10 000	0	-35 000	0
Cash flow from financial activities	-180	-979	-180	134 465	172 706
Cash flow for the period	-13 356	-13 138	-124 794	84 895	160 527
Cash and cash equivalents at the start of the period	128 256	177 199	239 693	79 166	79 166
Cash and cash equivalents at the end of the period	114 900	164 061	114 900	164 061	239 693

Key financial ratios for the group

	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec	2019 Jan-Dec	2018 Jan-Dec
Operating result, TSEK	75 177	-72 033	-91 458	-95 848	-73 897
Result for the period, TSEK	74 897	-72 187	-91 653	-96 120	-74 099
Result for the period attributable to parent company shareholders, TSEK	74 897	-72 187	-91 653	-96 120	-74 099
Earnings per share before and after dilution, SEK	1.45	-1.52	-1.92	-2.37	-1.94
R&D costs, TSEK	99 968	59 553	75 989	79 381	58 927
R&D costs as a percentage of operating costs, %	83	82	83	82	80
Cash and cash equivalents at the end of the period, TSEK	431 168	169 693	277 009	110 527	134 442
Cash flow from operating activities, TSEK	157 029	-72 785	-89 214	-91 201	-70 790
Cash flow for the period, TSEK	154 160	59 167	166 482	-23 915	59 733
Equity, TSEK	422 598	244 105	347 880	181 827	212 476
Equity per share, SEK	8.17	5.03	6.72	4.22	5.25
Equity ratio, %	85	92	94	87	94
Average number of employees	21	19	18	17	15
Average number of employees in R&D	18	17	17	16	14

Of the above key financial ratios, only the key ratio Earnings per share before and after dilution, and R&D costs, are defined in accordance with IFRS. Of the other key financial ratios, Result for the period, Liquid assets at the end of the period, Cash flow from operating activities, Cash flow for the period, and Equity are drawn from from a financial statement defined by IFRS. For the derivation of key financial ratios, as well as definitions and justifications for the selected key financial ratios, please refer to IRLAB Therapeutics AB (publ) annual report 2020.

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 rendered 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 from participations in group companies.

The management in the parent company thereby reflects the accounting in the group, where all costs for research are charged to the result. The opening balance remains unchanged as the company's assessment is that there is no need for impairment. Applied accounting principles corresponds to what appears in the Annual report 2020.

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

New and amended standards adopted from 2021 have not had any significant impact on the group's financial position.

Revenue recognition

Net sales consist of income from the sale of products or licensing of products, e.g. in the form of drug development projects (candidate drugs) and services.

In accordance with IFRS 15, revenue recognition occurs when control of the goods/service 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 to what extent 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 use the product or service separately or together with other resources that are available for the customer; and
- the Group's obligation to transfer the product or service to the customer can be distinguished from other obligations 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 payments only if it is highly likely that a substantial reversal of the income is not expected to occur for a future period.

When entering a drug candidate license agreement, the income is allocated between the different performance obligations that is recognized in the agreement. Revenues 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 an independent sale price. The independent sale price is the price at which the group would sell the product or service separately to the customer. IRLAB recognizes the income when the group fulfills a performance obligation by transferring a product or service to a customer, i.e. when the customer

takes 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. For services that take place over a shorter period of time, the revenues are 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 described on pages 99–100, of the Annual Report 2020. No significant changes have occurred that affect the reported risk.

Covid-19

To date, 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 the situation at healthcare providers in certain countries and regions is under pressure, which affects the hospitals' ability to participate in clinical trials. Additionally, interactions have shown that regulatory authorities currently have longer processing times. Combined, this may come to affect IRLAB's clinical programs if the outbreak of covid-19 continues to strain global healthcare resources, and restrictions on individuals' freedom of movement is extended beyond what is known today. We therefore follow the situation closely and evaluate measures to minimize the impact on our projects and timelines.

Note 3. Related party transactions

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

Note 4. 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 TSEK 436,284 (TSEK 169,693).

Note 5. Net sales

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

Income distributed by income category	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
License income	185 261	0	185 261	0	0
Service income	10 380	0	10 380	0	0
Total income	195 641	0	195 641	0	0

Note 6. Equity

Incentive program

In April 2016, a decision was taken on a share and warrant program for key personnel, both employees and board members.

A total of 39 355 warrants (196 775 after split) were subscribed for in the program to a subscription price that corresponded to the market value.

Notes

Warrant program

Each warrant entitles the holder to subscribe for one Class A ordinary share at a subscription price of SEK 82.70 after split. The warrants may be exercised up to and including June 30, 2023. Upon full exercise of the warrants, share capital increases by SEK 3 935.50 through the issue of 196 775 Class A ordinary shares.

Note 7. Segment information

Income by geographic market	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Sweden	0	0	0	0	0
Great Britain	195 641	0	195 641	0	0
Total income	195 641	0	195 641	0	0

100 % of the income in the period consist of sales to Ipsen. All of the group's fixed assets are located in Sweden.

Note 8. Significant events after the closing date

After the end of the period, no significant events that have affected the group's financial results or position has occurred.

This interim report has 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 the companies included in the group.

Gothenburg, November 10, 2021

GUNNAR OLSSON
Chair of the Board

CAROLA LEMNE
Vice Chair

LARS ADLERSSON
Board member

MARTIN NICKLASSON
Board member

REIN PIIR
Board member

LENA TORLEGÅRD
Board member

NICHOLAS WATERS
CEO

Auditor's report

IRLAB Therapeutics AB (publ.) reg. no. 556931-4692

Introduction

We have reviewed the condensed interim financial information (interim report) of IRLAB Therapeutics AB (publ.) as of 30 September 2021 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

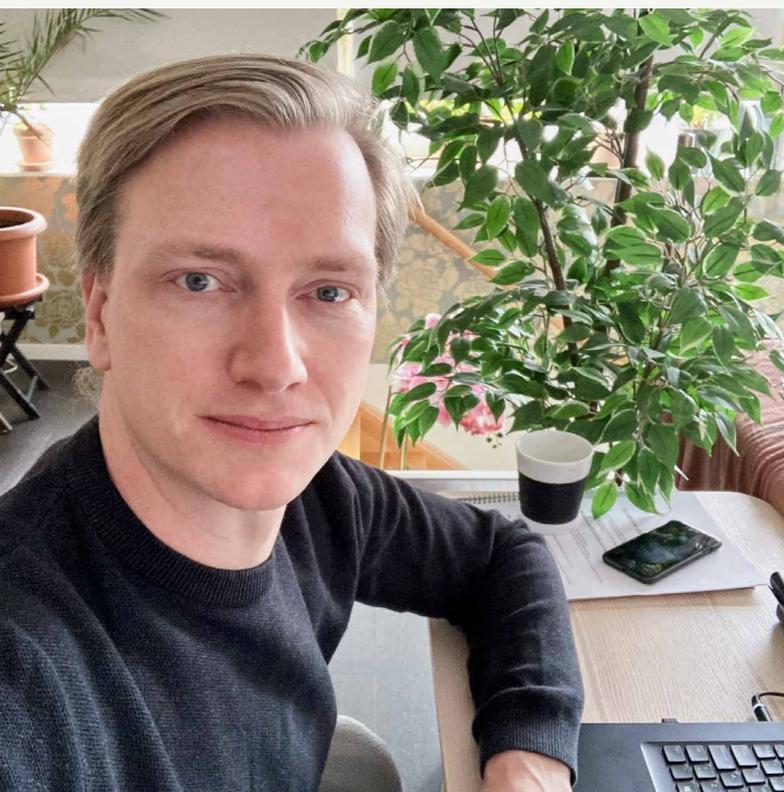
Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Gothenburg, November 10, 2021

Öhrlings PricewaterhouseCoopers AB

Johan Rippe
Authorized Public Accountant
Auditor in charge

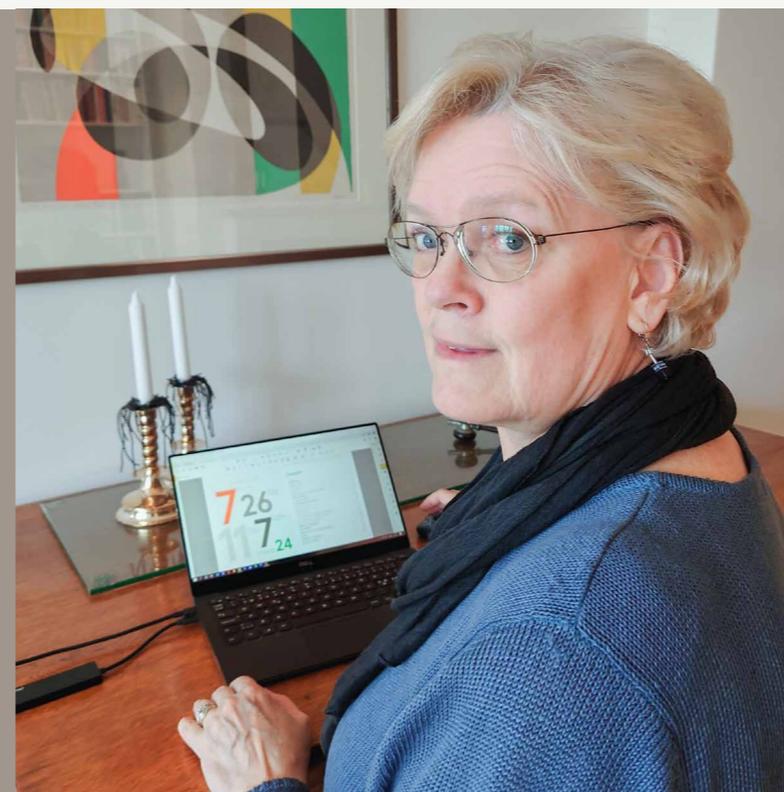
Martin Oscarsson
Authorized Public Accountant



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

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

The company's most advanced candidates, mesdopetam (IRL790) and pirepemat (IRL752), both of which completed Phase IIa-studies, intends 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 increased risk of falls (PD-Falls).

The project portfolio comprises the fully-funded mesdopetam program, run in collaboration with global partner Ipsen, as well as innovative in-house programs, generated by the ISP platform, from pre-clinical programs in P001 and P003 to pirepemat that has finalized Phase IIa.

IRLAB is listed on Nasdaq Stockholm Main Market. More information on www.irlab.se.

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