IRLAB

Q1.2022

Interim report
January – March 2022

Interim report January – March 2022

JANUARY–MARCH 2022
compared with January–March 2021 and the full year 2021

SEK thousand	January–March 2022	January–March 2021	January–December 2021
Net sales	9,042	0	207,782
Operating profit	–29,088	–19,967	52,576
Profit/loss for the period	–29,170	–20,041	51,781
Earnings per share before and after dilution, attributable to the parent company's shareholders	–0.56	–0.39	1.00
Number of shares at the end of the period, including subscribed but not yet registered shares	51,748,406	51,748,406	51,748,406
Cash and cash equivalents	368,047	253,905	401,897
Equity per share	7.16	6.34	7.72
Equity ratio, %	85	93	85
Average number of employees	26	19	22
Of which in R&D	23	18	20

"In the first quarter of the year, we accelerated the development in our preclinical programs with an additional drug candidate, IRL757. The major license agreement that was concluded with Ipsen in 2021 regarding the development and commercialization of mesdopetam placed us in a strong position and gave us a cash injection. We therefore have the resources needed to continue building our uniquely effective R&D operations."

NICHOLAS WATERS, CEO

Three quick facts

What we do

IRLAB is developing novel drugs for the treatment of disorders of the central nervous system, with a focus on Parkinson's disease.

Why we do it

IRLAB wants to transform life for people with Parkinson's disease and other disorders of the central nervous system and their loved ones. The aim is to offer an increased quality of life with fewer complications from the disease.

How we do it

IRLAB uses the research platform ISP to create effective and successful drug candidates at a considerably lower cost and in considerably less time compared with traditional drug development.

Important to know

- A novel drug candidate for the treatment of apathy in neurological diseases, IRL757, has been selected for further clinical studies. This is an important step in the development of the development portfolio, and it is estimated that Phase I studies will begin in the second half of 2023, provided positive results from the preliminary studies and regulatory approvals are obtained.
- IRLAB's first annual capital markets day was held at the end of March. Many investors, analysts and media representatives participated in the presentations about the company and its future development. A recording of the day is available on our website.
- Know-how related to the P003 project was acquired to improve the possibility of obtaining strong patent protection and making several patent applications for the substances studied in the P003 project. The P003 project is aimed at an innovative treatment of Parkinson's.

At the core of 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 novel and better drugs. Through the ISP platform, IRLAB discovers and develops drug candidates for disorders of the central nervous system (CNS), where there are significant growing medical needs. All clinical drug candidates in the portfolio were generated by the ISP platform. Several preclinical programs and discovery projects also originated on the research platform.

Mesdopetam and pirepemat

The company's clinical 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). Mesdopetam is being developed by the partner Ipsen in a Phase IIb/III study, while pirepemat is undergoing a Phase IIb study carried out by IRLAB.

9 MILLION

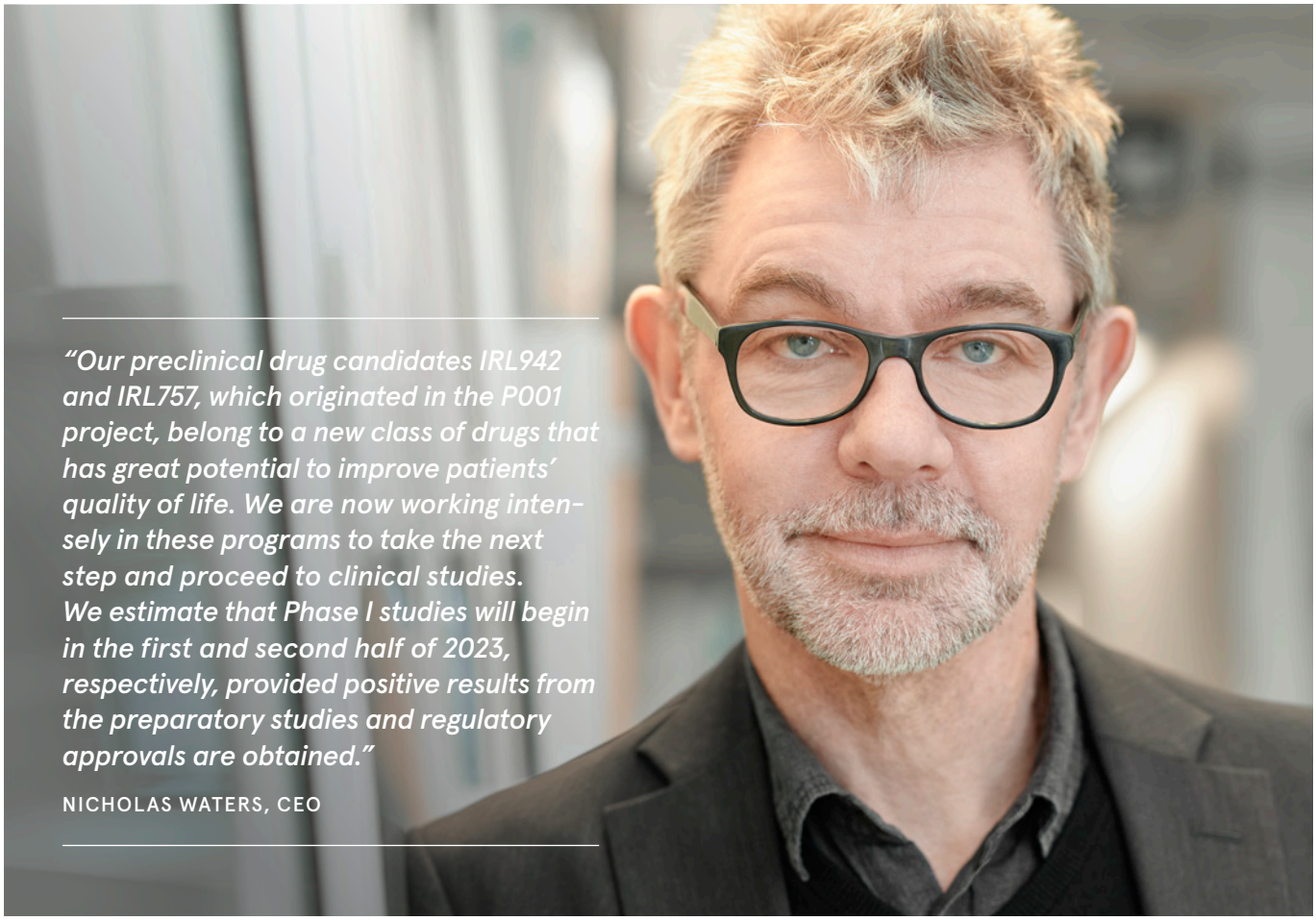
At present, nearly nine million people have Parkinson's. By 2040, this figure is expected to double. The need for new and better treatments is therefore huge. IRLAB focuses its research on developing better drugs and is developing them in areas where they can do the greatest good for these patients.

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

NICHOLAS WATERS, CEO

IRLAB A

IRLAB has been listed on Nasdaq Stockholm's main list Mid Cap since 2020.



Comments from the CEO

In the first quarter, IRLAB achieved several new milestones. We presented a new drug candidate, IRL757, with high hopes that it will improve the quality of life for all those who currently have apathy – a debilitating symptom in many neurological diseases, such as Alzheimer's and Parkinson's. The strengthened cash position after the mesdopetam deal and the resources that were freed up in the R&D organization allow an increased focus on our preclinical operations, and we are very pleased to have been able to deliver a new drug candidate in our project portfolio so soon.

During the period, we continued to grow and added additional expertise to our business, and the response on our capital markets day in March was very positive, which confirmed our growth strategy. We are approaching the second half of 2022, and we have already added several important building blocks in the continued exciting progress towards better drugs for those living with Parkinson's.

One of our key strategic goals is to widen our portfolio and start additional clinical development programs. In the first quarter of the year, we therefore accelerated the development in our preclinical programs with an additional drug candidate, IRL757. The major license agreement* that was concluded with Ipsen in 2021 regarding the development and commercialization of mesdopetam placed us in a strong position and gave us a cash injection. We therefore have the resources needed to continue building our uniquely effective R&D operations.

Our development programs are expanding

We are currently investing fully in our two promising drug candidates from the P001 research project: IRL942, for the treatment of cognitive impairment, and IRL757, for the treatment of apathy in people with neurological disorders. Both drug candidates represent an entirely novel class of drugs, discovered by IRLAB, and addresses neurological conditions for which there is no approved treatment at present or where the treatment is ineffective or causes side effects that limit its use. Our drug candidates in this novel class of drugs have great potential to improve the quality of life for these patients. We are now working intensely in the IRL942 and IRL747 programs to take the next step and proceed to clinical studies. We estimate that Phase I studies will begin in the first and second half of 2023, respectively, provided positive results from the preparatory studies and regulatory approvals are obtained.

The development in our other preclinical research project, P003, which aims to develop an entirely novel treatment for the hallmark symptoms of Parkinson's, with the potential to replace levodopa, was the reason we made into an important acquisition after the end of the quarter. Our acquisition of know-how, specific knowledge linked to innovative chemistry and patents, will increase our chances of obtaining strong patent protection and filing more patent applications of relevance to the substances included in the P003 projects. This also means that we can now invest in the development of potentially ground-breaking drugs for all people with Parkinson's.

The Phase IIb/III study with mesdopetam continues

The development of mesdopetam towards a future marketing authorization progresses well in collaboration with our partner Ipsen. Our collaboration with Ipsen is well organized, and Ipsen is now taking over an increasing amount of the operational work in the preparation for the next development stage. The recruitment of patients for the study continues around Europe and in the US, with the aim of reporting the topline results from the ongoing Phase IIb/III study in the second half of 2022.

The Phase IIb study with pirepemat has begun

Our other clinical drug candidate, pirepemat, is being developed to reduce falls and injuries from falls in people with Parkinson's. Having received regulatory approvals last winter from the countries in Europe that will participate in this important study, we have now initiated the Phase IIb clinical trial in France, Germany, Poland, Spain, Sweden.

External impact on our studies

From a global perspective, biotech companies had to delay the start of studies or interrupt studies prematurely in 2021–2022, and many studies were hampered by slow patient recruitment. In connection with the spreading of the Omicron variant of Covid-19 in the beginning of the year, it became clear that patient recruitment for clinical trials declined. All companies in the industry also experienced longer response times from regulatory authorities during this period. We are therefore particularly pleased that the mesdopetam study was able to proceed and that we were granted regulatory approvals for the pirepemat study, even though people with Parkinson's belong to the elderly at-risk group who were advised to isolate and avoid unnecessary medical appointments.

We must be prepared for the impact of a potential increase in the rate of infection and the war in Ukraine may have on the recruitment rate for our clinical studies, chiefly in Europe. Delays in global trade may also impact the supply of input goods that are necessary for our operations. We are continuously taking measures to reduce the risk of impact on our research and clinical studies.

A growing organization

In the first quarter of the year, our organization kept growing. Additional expertise was added that strengthens our operations in various ways, including in the calculation team, which is central to our AI-based research methodology, and a broadening of our IR function, now with a stronger focus on activities in the US.

I would also like to mention that we received plenty of positive feedback from various players in the market after our very first capital markets day. A recording of the event is available on our website for those who missed it. The international experts in our prioritized therapeutic areas who participated as speakers were particularly well received, and they attested to the actual potential of our drug candidates to meet major patient needs in the future. For me, this is an important signal that we are taking the right actions and have high credibility. We look forward to making this an annual event, so that we can offer shareholders, analysts and media more insights into the company and our growth strategy.

Progress in 2022

To conclude, I am happy to say that the beginning of 2022 involved significant progress. We strengthened our organization as well as our preclinical programs and research projects. We are constantly aiming for our strategic goal of expanding our clinical development portfolio while supporting our business goals and creates value for patients, shareholders and society.

Nicholas Waters, CEO, IRLAB

* Mesdopetam is developed in partnership with Ipsen, who has licensed global and exclusive rights from IRLAB to develop and commercialize mesdopetam.

Project portfolio

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

Clinical phase

Tolerability, safety and efficacy studies.

Mesdopetam

Mesdopetam (IRL790) is being developed to prevent and treat levodopa-induced dyskinesias (troublesome involuntary movements, PD-LIDs) in Parkinson's. The aim is to reduce troublesome dyskinesias and 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) . Mesdopetam is being developed in collaboration with Ipsen, who has exclusive global development and commercialization rights to the program.

Pirepemat

Pirepemat (IRL752) is being developed to improve balance and reduce falls, and thus injuries from falls, in Parkinson's. Falls are a particularly difficult problem in Parkinson's that has severe complications, such as fractures, impaired mobility and a reduced quality of life. Pirepemat is also being developed for the treatment of dementia in Parkinson's disease (PD-D).

Preclinical phase

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

IRL942

IRL942 is intended to improve cognitive function and brain health associated with neurodegenerative and age-related disorders of the central nervous system. IRL942 originated in the P001 research project.

IRL757

The aim of IRL757 is to treat apathy in neurological diseases. Apathy is an enormous problem for patients and their families and is currently untreatable. IRL757 originated in the P001 research project.

Discovery phase

Laboratory tests for discovering drug candidates.

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

IRLAB's research and development portfolio

PFC = prefrontal cortex

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

ISP, IRLAB's unique research platform, gives us a major head start in the race to market

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

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

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

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

More about the systems biology approach

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

More about the database

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

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

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

Continued investments in artificial intelligence (AI)

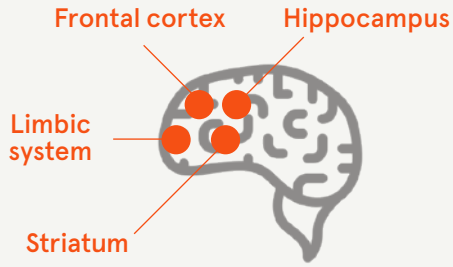
It is important to IRLAB to constantly refine and develop its research methods and always remain at the forefront of modern calculation methods, such as artificial intelligence, to further increase the efficiency in the development of drugs.

In the first quarter of 2022, IRLAB expanded the company's expertise in the area through new recruitments of experts, which increases the focus on the application of artificial intelligence in the scope of the ISP platform.

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

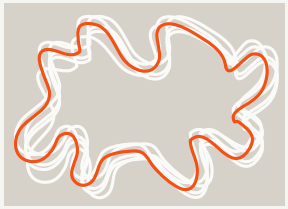
Data flow in the ISP research platform

Tissue samples

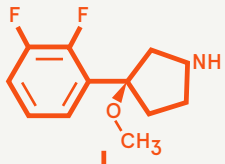


Animal models

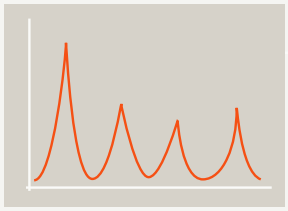
Movement patterns, nerve signal transfer and genetic expression



In silico data
Physiochemical properties, quantitative structure-effect relationships (QSAR) and structure-based drug design



Neurochemical analysis



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

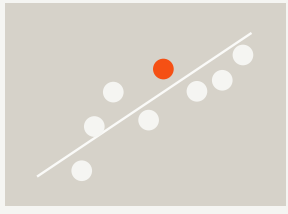
ISP DATABASE
~1,000 proprietary molecules
~370 known reference molecules

In vitro data
Binding capacity & metabolism

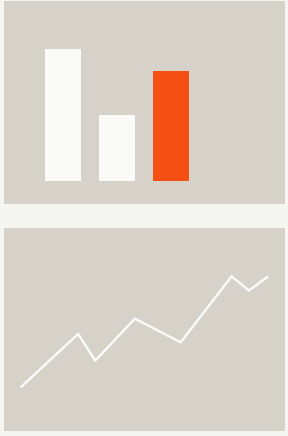
In vivo DMPK

Microdialysis (analysis of signal transfer between nerve cells)

New molecule composition



Graphs & statistics



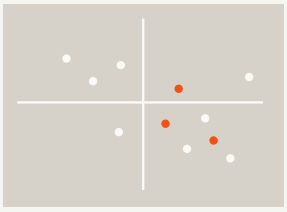
Data matrices

Machine learning

Quantitative analysis

Multivariate analysis

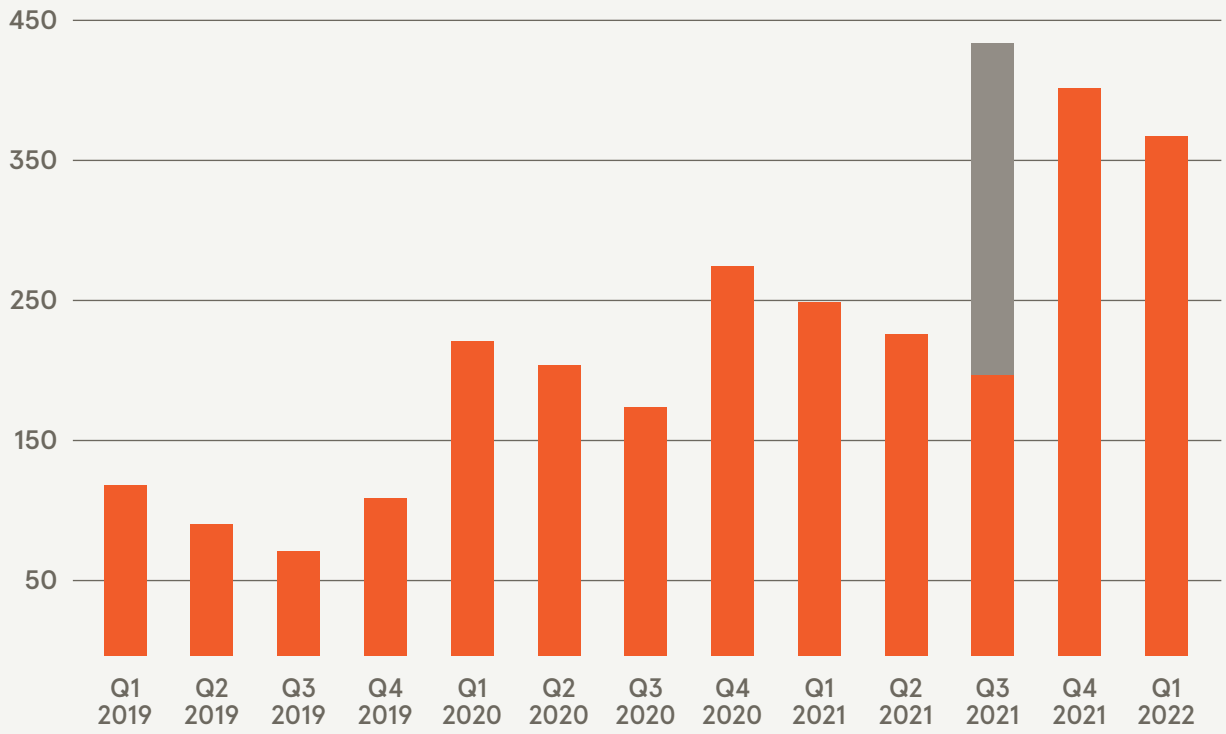
Mapping



"Our starting point is that cost control is highly important to reduce the risk in biotech companies that have no regular revenue. Our business model therefore builds on the fact that a large part of the costs in IRLAB are allocated to research and development activities. In addition to our clinical projects, we are currently investing in creating a strong development portfolio. We are now preparing IRL942 and IRL757 for Phase I clinical studies."

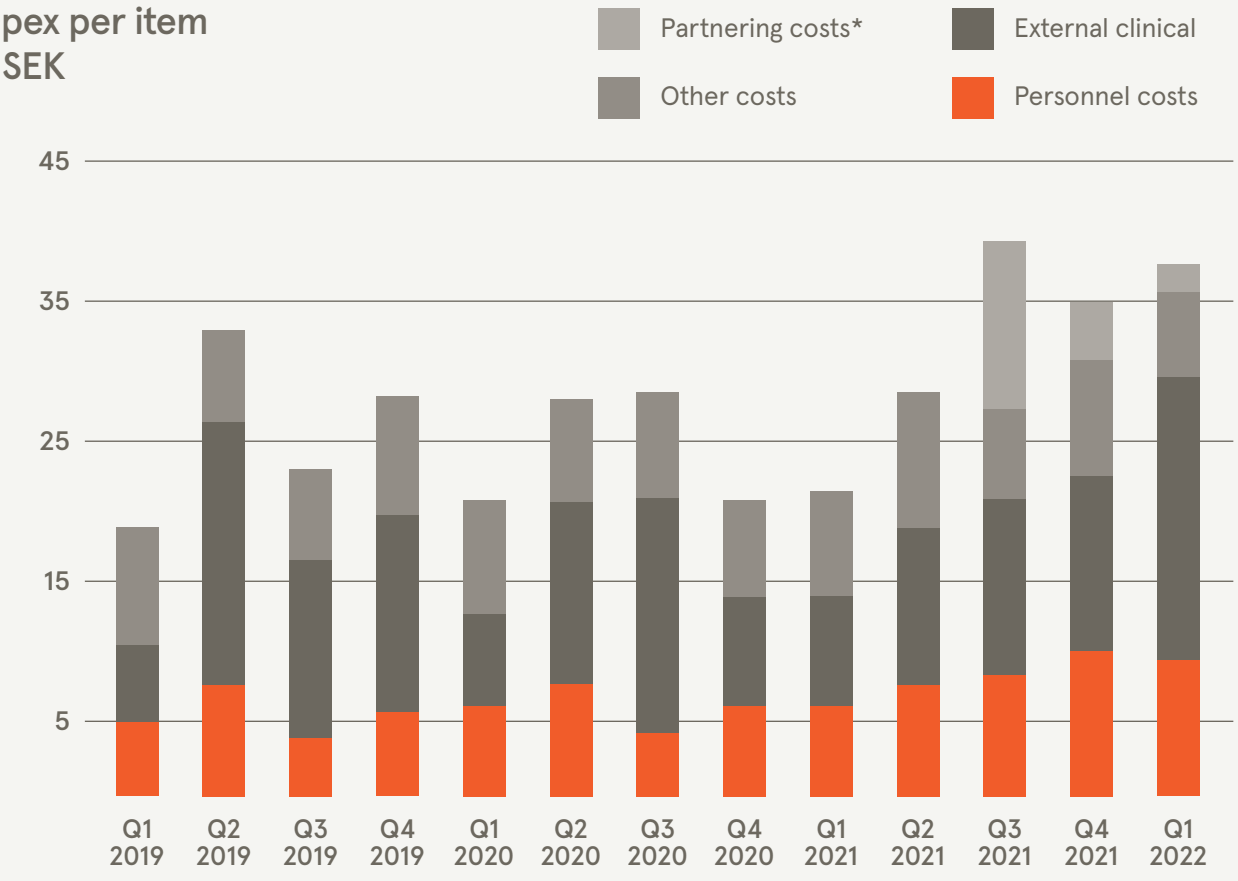
VIKTOR SIEWERTZ, CFO

Cash balance
MSEK



- Cash position SEK 368m
- Roughly SEK 230m net impact of license agreement (grey bar)

Opex per item
MSEK



* Partnering cost are cost for entering licensing agreements and costs which are covered by a corresponding revenue from partners

The group's performance January – March 2022

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 and other disorders of the brain 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 dyskinesias (PD-LIDs) and psychosis (PD-P). Pirepemat is being developed for the treatment of balance impairment 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 received 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 novel drug substances. IRLAB has several such substances in 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). Thanks to ISP, IRLAB was able to nominate the substance IRL757 as a new drug candidate in the first quarter of 2022, which means that IRLAB now has two drug candidates in preparation for Phase I studies: IRL757 and the previously nominated IRL942.

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 31,243 thousand (16,454), corresponding to 82 percent (82) of the group's total operating expenses.

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

Comments on the income statement

The loss for the period January 1–March 31, 2022 was SEK –29,170 thousand (–20,041). Earnings per share were –0.56 SEK (–0.39). The group's revenue during the period was SEK 9,129 thousand (0).

Of the SEK 239,596 thousand that was received up-front in 2021 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 the first quarter of 2022, SEK 6,855 thousand was taken up as income. In the first quarter of 2022, revenue for other services provided to Ipsen was SEK 2,187 thousand.

The group's operating expenses were SEK 38,217 thousand (19,967) in the first quarter 2022. The increase compared with the previous year was chiefly 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 2021.

Financing and cash flow

Cash flows from operating activities were SEK –32,783 thousand (–22,370) in the first quarter. Cash and cash equivalents were SEK 368,047 thousand (253,905) on March 31, 2022.

On March 31, 2022, equity was SEK 370,311 thousand (327,839) and the equity ratio was 85 percent (93).

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–March 31, 2022 were SEK 323 thousand (50).

Significant events January–March 2022

In March, IRLAB nominated a new drug candidate, IRL757, for the treatment of apathy in neurological diseases. This is an important step in the development of the development portfolio, and the new drug candidate, IRL757, originated in the P001 research program. IRL757 will be developed for the treatment of apathy in people with neurological diseases. Between 20 and 80 percent of all those with neurological diseases suffer from apathy, and there are no approved treatments at present.

Significant events after the end of the period

In April, know-how associated with the development of innovative chemistry and patents in the P003 project was acquired from Per Lindberg Consulting AB. This newly acquired knowledge will reinforce IRLAB's P003 project and the associated intellectual property rights. The total purchase price was SEK 0.5 million

in cash and 120,000 newly issued Class A shares in IRLAB, corresponding to approximately SEK 4.8 million based on 10 days VWAP.

The IRLAB share

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

Share capital, number of shares and number of votes

At the end of the period, IRLAB's share capital was SEK 1,034,968 divided into 51,748,406 shares with a quota value of SEK 0.02. There were 51,668,630 Class A shares and 79,776 Class B shares. All shares, including shares in Class B, gives the holder one vote.

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–March was 26 (19). At the end of the period, the number of full-time positions was 24 (18), distributed over 26 (21) people.

The number of full-time positions, including long-term contracted consultants, was 27 (20) at the end of the period, distributed over 30 (25) people.

Executive management

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

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.

The company's financial risks are described on pages 77–78 and its risk management is described on page 110 of the 2021 Annual Report. No significant changes have occurred that affect the reported risks.

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 are available on the company's website, irlab.se.

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 (chair of the Nomination Committee), Bo Rydlinger, Clas Sonesson and Gunnar Olsson, the Chair of the Board. They represent 46 percent of the votes and capital in IRLAB as at 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 its sustainability efforts in the following three focus areas: Employees, Responsible dealings, Community involvement.

Consolidated income statement in summary

Amounts in SEK thousand	2022 Jan–Mar	2021 Jan–Mar	2021 Jan–Dec
Operating income, etc.			
Net sales	9,042	0	207,782
Other operating income	87	0	124
Total income	*9,129*	*0*	*207,906*
Operating expenses			
Other external expenses	–27,213	–13,219	–81,737
Personnel costs	–9,674	–6,051	–31,024
Outlicensed capitalized development projects	0	0	-39,091
Amortization, depreciation and impairment	–944	–636	–3,474
Other operating expenses	-386	-62	–4
Total operating expenses	–38,217	*–19,967*	*–155,330*
Operating profit/loss	**–29,088**	**–19,967**	**52,576**
Profit/loss from financial items			
Finance income	0	0	1
Finance costs	–81	–74	–796
Total financial items	–81	*–74*	*–795*
Profit/loss after financial items	**–29,170**	**–20,041**	**51,781**
Income tax	0	0	0
Profit/loss for the period	**–29,170**	**–20,041**	**51,781**
Earnings per share before and after dilution (SEK)	–0.56	–0.39	1.00
Average number of shares, before and after dilution	51,748,406	51,748,406	51,748,406
Number of shares at the end of the period	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	2022 Jan–Mar	2021 Jan–Mar	2021 Jan–Dec
Profit/loss for the period	–29,170	–20,041	51,781
Other comprehensive income	0	0	0
Comprehensive income for the period	**–29,170**	**–20,041**	**51,781**

Consolidated statement of financial position in summary

Amounts in SEK thousand		03/31/2022	03/31/2021	12/31/2021
ASSETS				
Non-current assets				
Intangible assets		42,596	81,946	42,661
Property, plant and equipment		7,791	10,334	8,348
Total non-current assets		**50,387**	**92,280**	**51,009**
Current assets				
Current receivables		16,416	6,111	19,542
Cash and cash equivalents		368,047	253,905	401,897
Total current assets		**384,463**	**260,015**	**421,440**
TOTAL ASSETS		**434,850**	**352,295**	**472,449**
EQUITY AND LIABILITIES				
Equity	Not 5			
Share capital		1,035	1,035	1,035
Other contributed capital		685,450	685,630	685,450
Retained earnings including comprehensive income for the period		−316,174	−358,826	−287,004
Total equity		**370,311**	**327,839**	**399,481**
Non-current liabilities				
Lease liabilities		2,805	5,856	3,566
Total non-current liabilities		**2,805**	**5,856**	**3,566**
Current liabilities				
Lease liabilities		3,051	2,925	3,034
Other liabilities		58,684	15,674	66,367
Total current liabilities		**61,734**	**18,600**	**69,402**
TOTAL EQUITY AND LIABILITIES		**434,850**	**352,295**	**472,449**

Consolidated statement of changes in equity in summary

Amounts in SEK thousand	Share capital	Unregistered share capital	Other contributed capital	Retained earnings incl. total comprehen-sive income for the period	Total equity
Equity January 1, 2021	**970**	**65**	**685,630**	**–338,786**	**347,879**
Comprehensive income for the period				–20,041	–20,041
Transactions with owners in their capacity as owners:					
Rights issue	65	–65			
Equity March 31, 2021	**1,035**	**0**	**685,630**	**–358,826**	**327,839**
Comprehensive income for the period				71,822	71,822
Transactions with owners in their capacity as owners:					
Rights issue					0
Issue costs			–180		–180
Equity December 31, 2021	**1,035**	**0**	**685,450**	**–287,004**	**399,481**
Equity January 1, 2022	**1,035**	**0**	**685,450**	**–287,004**	**399,481**
Comprehensive income for the period				–29,170	–29,170
Equity March 31, 2022	**1,035**	**0**	**685,450**	**–316,174**	**370,311**

Consolidated statement of cash flows in summary

Amounts in SEK thousand	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Operating activities			
Operating profit/loss	-29,088	-19,967	52,576
Adjustments for non-cash items	944	636	42 564
Interest received	0	0	0
Interest paid	-81	-74	-796
Taxes paid	0	0	0
Cash flows from operating activities before changes in working capital	**-28,226**	**-19,405**	**94,345**
Cash flows from changes in working capital			
Changes in operating receivables	3,126	621	-12,811
Changes in operating liabilities	-7,684	-3,586	47,107
Cash flows from operating activities	**-32,783**	**-22,370**	**128,641**
Investing activities			
Acquisition of property, plant and equipment	-323	-50	-708
Cash flows from investing activities	-323	**-50**	**-708**
Financing activities			
Repayment of financial liabilities	-745	-684	-2 865
New issue	0	0	-180
Cash flows from financing activities	**-745**	**-684**	**-3 045**
Profit/loss for the period	**-33,850**	**-23 ,104**	**124,888**
Cash and cash equivalents at the beginning of the period	401,897	277,009	277,009
Cash and cash equivalents at the end of the period	**368,047**	**253,905**	**401,897**

Parent company income statement in summary

Amounts in SEK thousand	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Operating income, etc.			
Net sales	894	798	4 059
Total income	*894*	*798*	*4 059*
Operating expenses			
Other external expenses	–2,982	–2,097	–16,805
Personnel expense	–3,506	–1,382	–8,705
Total operating expenses	*–6,487*	*–3,479*	*–25,510*
Operating profit/loss	***–5,593***	***–2,681***	***–21,451***
Profit/loss from financial items			
Interest expenses	-1	0	–3
Total financial items	*0*	*0*	*-3*
Profit/loss after financial items	***–5,594***	***–2,681***	***–21,454***
Profit/loss for the period	**–5,594**	**–2,681**	**–21,454**

Parent company statement of comprehensive income in summary

Amounts in SEK thousand	2022 Jan–Mar	2021 Jan–Mar	2021 Jan–Dec
Profit/loss for the period	–5,594	–2,681	–21,454
Other comprehensive income	0	0	0
Comprehensive income for the period	***–5,594***	***–2,681***	***–21,454***

Parent company balance sheet in summary

Amounts in SEK thousand	03/31/2022	03/31/2021	12/31/2021
ASSETS			
Non-current assets			
Financial assets			
Participations in group companies	350,320	350,320	350,320
Total non-current assets	**350,320**	**350,320**	**350,320**
Current assets			
Other receivables	1,844	1,127	1,755
Cash and cash equivalents	106,870	131,013	112,970
Total current assets	**108,713**	**132,140**	**114,725**
TOTAL ASSETS	**459,033**	**482,461**	**465,045**
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1,035	1,035	1,035
Total restricted equity	*1,035*	*1,035*	*1,035*
Non-restricted equity			
Share premium reserve	739,560	739,740	739,560
Retained earnings including profit/loss for the period	–285,938	–261,572	–280,345
Total non-restricted equity	*453,622*	*478,168*	*459,215*
Total equity	**454,657**	**479,203**	**460,250**
Current liabilities			
Other liabilities	4,377	3,258	4,795
Total liabilities	**4,377**	**3,258**	**4,795**
TOTAL EQUITY AND LIABILITIES	**459,033**	**482,461**	**465,045**

The parent company's statement of cash flows

Amounts in SEK thousand	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Cash flows from operating activities	–6,100	-108,680	–126,543
Cash flows from investing activities	0	0	0
Cash flows from financing activities	0	0	-180
Profit/loss for the period	**–6,100**	**-108,680**	**-126,723**
Cash and cash equivalents at the beginning of the period	112 ,970	239,693	239,693
Cash and cash equivalents at the end of the period	**106,870**	**131,013**	**112,970**

Key financial ratios for the group

	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec	2020 Jan-Dec	2019 Jan-Dec
Net sales, SEK thousand	9,042	0	207,782	0	26
Operating profit/loss, SEK thousand	-29,088	-19,967	52,576	-91,458	-95,848
Profit/loss for the period, SEK thousand	-29,170	-20,041	51,781	-91,653	-96,120
Profit/loss attributable to the parent company's shareholders, SEK thousand	-29,170	-20,041	51,781	-91,653	-96,120
Earnings per share before and after dilution, SEK	-0.56	-0.39	1.00	-1.92	-2.37
R&D costs, SEK thousand	31,243	16,454	129,748	75,989	79,381
R&D costs as a percentage of operating expenses, %	82	82	84	83	82
Cash and cash equivalents at the end of the period, SEK thousand	368,047	253,905	401,897	277,009	110,527
Cash flows from operating activities, SEK thousand	-32,783	-22,370	128,641	-89,214	-91,201
Cash flows for the period, SEK thousand	-33,850	-23,104	124,888	166,482	-23,915
Equity, SEK thousand	370,311	327,839	399,481	347,880	181,827
Equity attributable to the parent company's shareholders, SEK thousand	370,311	327,839	399,481	347,880	181,827
Equity per share, SEK	7.16	6.34	7.72	6.72	4.22
Equity ratio, %	85	93	85	94	87
Average number of employees	26	19	22	18	17
Average number of employees in R&D	23	18	20	17	16

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 2021 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 2021 Annual Report.

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

New and amended standards adopted from 2022 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 (drug candidates) 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 satisfied either over time or at a point in 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 and licensing of products is recognized as revenue when control of the product is transferred to the customer, which normally occurs in conjunction with the transfer of rights to use IRLAB's patents, study results and other rights connected to the product to the customer. Services are recognized over time as the services are provided. For services that 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's financial risk exposure and risk management are described on pages 77–78 and the company's risk management is described on page 110 of the 2021 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. Impact of Covid-19

As of March 31, 2022, the global pandemic has not had any significant direct effects on IRLAB's operational activities, results or financial position.

Effects in the medium to long term cannot yet be assessed, but the company is monitoring and evaluating the situation regularly. There are, however, indications that healthcare providers in certain countries and regions are under pressure, which affects certain hospitals' ability to participate in clinical trials. Additionally, interactions have shown that regulatory authorities currently have longer processing times. Combined, this may affect IRLAB's

clinical programs if the Covid-19 outbreak continues to put a strain on global healthcare resources and if restrictions on individuals' freedom of movement are extended beyond what is known today. We are therefore monitoring the situation closely and evaluating measures to minimize the effects on our projects and schedules.

Note 5. Impact of the war in Ukraine

The war in Ukraine, the subsequent geopolitical instability in Eastern Europe in particular, and its effect on people in the affected areas may impact the speed of patient recruitment and the possibility for already recruited patients to get to the clinics for the requisite visits. IRLAB's Phase IIb/III study with mesdopetam and the Phase IIb study with pirepemat are both partially carried in clinics in Poland, a country that may be more affected than other countries due to its geographical proximity to Ukraine. So far, IRLAB has only noticed a minor impact on the ongoing studies. The company is continuously monitoring the developments so that appropriate measures can be taken if necessary.

Note 6. Financial instruments

The group currently has no financial instruments that are valued at fair value, rather all financial assets and liabilities are valued at accrued acquisition value. It is judged that there are no significant differences between fair value and book value regarding the financial assets and liabilities. On the closing date, the carrying amount of financial assets was SEK 368,292 thousand (254,091).

Note 7. 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 by revenue category	2022 Jan–Mar	2021 Jan–Mar	2021 Jan–Dec
Licensing revenue	0	0	185,261
Service revenue	9,042	0	22,521
Total revenue	**9,042**	**0**	**207,782**

Note 8. Equity

Incentive programs

In April 2016, it was decided to introduce a share and warrant program for 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 9. Segment information

Net sales by geographic market	2022 Jan–Mar	2021 Jan–Mar	2021 Jan–Dec
Sweden	0	0	0
United Kingdom	9,042	0	207,782
Total revenue	**9,042**	**0**	**207,782**

All invoicing was in EUR. Revenue is recognized in SEK.

Glossary

Dyskinesia	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.
Good ON-time	The part of the day when the patient does not have troublesome symptoms of Parkinson's disease.
ISP	Integrative Screening Process, IRLAB's proprietary research platform used to generate drug candidates.
PD-LIDs	Parkinson's Disease levodopa-induced dyskinesias, involuntary movements (dyskinesias) caused by long-term medication with levodopa.
PD-P	Parkinson's Disease Psychosis, psychic symptoms such as delusions and/or hallucinations caused by Parkinson's disease.
PD-Fall	Parkinson's Disease Falls, falls due to postural dysfunction (balance impairment) and impaired cognition in Parkinson's disease.
Preclinical Proof of Concept	Is achieved when a drug candidate has shown safety, tolerability and efficacy in preclinical model systems and when the effect shown can be connected to a medical need. At IRLAB, the preclinical development starts when these requirements are fulfilled.
Clinical Proof of Concept	Prove the effectiveness of a concept. At IRLAB, this means when a drug candidate has achieved clinical proof of concept after a successful Phase II program..

Calendar

May 11, 2022	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	2022 Year-end report

Presentation to investors and media

A conference call will be held on Wednesday May 11, 2022, at 10:30 CET where Nicholas Waters, CEO, and Viktor Siewertz, CFO, will present the report. The presentation will be held in English 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 +46 850 558 369
UK +44 333 300 9260
US +1 631 913 1422

It will also be possible to follow the conference call via link:
https://tv.streamfabriken.com/irlab-q1-2022

Review and the Board's assurance

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, May 11, 2022

GUNNAR OLSSON
Chair of the Board

CAROLA LEMNE
Vice Chair

REIN PIIR
Board member

LARS ADLERSSON
Board member

LENA TORLEGÅRD
Board member

NICHOLAS WATERS
CEO

IRLAB

IRLAB discovers and develops novel drugs for the treatment of Parkinson's disease and other disorders of the brain. The company's most advanced drug candidates, mesdopetam (IRL790) and pirepemat (IRL752), both of which are currently subject to Phase IIb studies, were designed to treat some of the most difficult symptoms associated with Parkinson's disease. In 2021, IRLAB entered into an exclusive global license agreement with Ipsen regarding the development and commercialization of mesdopetam.

Through its proprietary research platform, ISP (Integrative Screening Process), IRLAB has discovered and developed all its projects and keeps discovering innovative drug candidates for the treatment of disorders of the central nervous system (CNS). In addition to IRLAB's strong clinical development portfolio, IRLAB runs several preclinical programs, with IRL942 and IRL747 in development for Phase I studies.

Contact information

FOR FURTHER INFORMATION, PLEASE CONTACT

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