IRLAB

Q2.2023
Interim report
January – June 2023

DAVID BLIMAN, works with design and manufacturing of candidate drugs in our laboratory.

World-leading portfolio of drug candidates with the aim of transforming life for people living with Parkinson's disease and other CNS disorders

Interim report January – June 2023

Summary of the second quarter

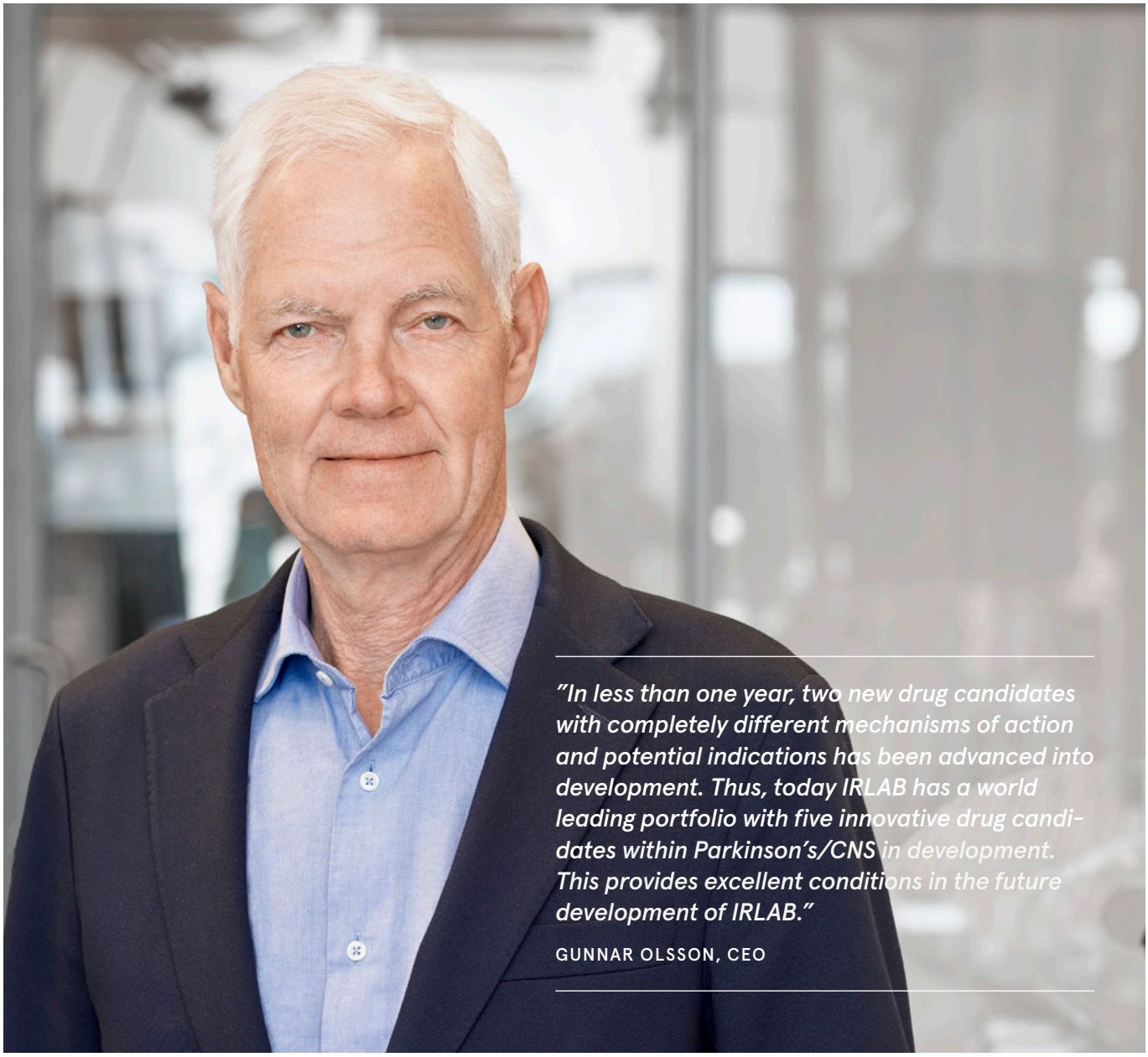
- On May 3, IRLAB became aware that Ipsen's Universal Registration Document 2022, published on April 6, 2023, contained the incorrect information that the development and commercialization rights for mesdopetam had been transferred back to IRLAB. This error was corrected by Ipsen, who published an updated Universal Registration Document 2022.
- During May 2023, a discussion was initiated with Ipsen to mutually agree on the best way forward to ensure that the mesdopetam program are given the best chance of achieving registration and to ensure that mesdopetam can be made available to all people living with Parkinson's disease.
- On May 16, IRLAB and the McQuade Center for Strategic Research and Development (MSRD), part of the global pharmaceutical company Otsuka, signed an agreement that gives MSRD an exclusive right to evaluate, for a period of time, IRLAB's neuropsychiatric programs IRL757 and IRL942. The objective is to investigate whether IRLAB and MSRD, after the evaluation, can agree to enter into a collaboration to develop the compounds into medicines.
- At the end of May, it was announced that all 38 clinics are activated and recruits patients in the Phase IIb study with pirepemat. Pirepemat is developed with the goal of improving balance and reducing falls in Parkinson's disease.
- On June 13–16, IRLAB participated with a presentation at the scientific conference XIV Triennial Meeting of the International Basal Ganglia Society (IBAGS) held in Stockholm. IBAGS XIV is a major event that brings together researchers who study the basal ganglia of the brain at all levels (from molecule to behavior) in both neurological and neuropsychiatric disorders originating in the basal ganglia that also include Parkinson's disease.
- On June 20, the company's annual general meeting was held where, among other things, three new members were elected to the board; Daniel Johnsson, Christer Nordstedt and Veronica Wallin.
- IRLAB presented at several national investor conferences during the period and has ongoing discussions with potential national and international investors to continuously provide updates on the company and its development. Recordings are available on IRLAB's website, irlab.se.

Events after the period

- In mid-July, the DSMB for the pirepemat Phase IIb study unanimously recommended the company to continue the study in accordance with the approved study protocol, following their first planned review. The DSMB continuously reviews the clinical study data generated during an ongoing study. This is to ensure the safety of study participants and the validity and integrity of data. This scheduled review was performed after the first 25 patients had completed the entire treatment and follow-up period of the study.
- On August 21, the company announced that the rights to the now Phase III-ready mesdopetam project had been transferred to IRLAB. IRLAB has secured the ownership of the mesdopetam project. This includes, among other things, all technology, all rights, know-how, intellectual property and study drugs for upcoming Phase III studies. IRLAB will also control continued clinical development and commercialization. As compensation, IRLAB pays a low single digit royalty based on future product sales, to Ipsen.
- On August 21, IRLAB communicated an update of the mesdopetam project, which included additional information on the results of mesdopetam's Phase IIb clinical trial in PD-LIDs and the Phase III preparatory Phase I studies conducted by Ipsen. The results show that mesdopetam has a dose-dependent anti-dyskinetic and anti-parkinsonian effect in combination with a tolerability and safety profile on par with placebo, giving mesdopetam a unique position. The results from the extensive data package developed by IRLAB and Ipsen provides a strong basis for the continued development of mesdopetam to Phase III. IRLAB now continue with preparations for Phase III by compiling documentation for an end-of-Phase 2 meeting with the US FDA to define the Phase III study program.
- During the MDS congress, held August 25-28, IRLAB presented further results from the analyses of the Phase IIb study with messdopetam. The scientific poster is available at irlab.se.

Financial summary

SEK thousand	Apr–Jun 2023	Apr–Jun 2022	Jan–Jun 2023	Jan–Jun 2022	Jan–Dec 2022
Net sales	6,870	23,410	6,870	32,452	61,136
Operating profit	–44,872	–27,015	–104,379	–56,103	–113,110
Profit/loss for the period	–44,905	–27,115	–104,461	–56,285	–113,406
Earnings per share before and after dilution, SEK	–0.87	–0.52	–2.01	–1.09	2.19
Cash and cash equivalents	156,413	322,615	156,413	322,615	401,897
Cash flow from operating activities	–52,798	–44,010	–94,294	–76,793	–142,612
Equity per share at end of period, SEK	3.59	6.63	3.59	6.63	7.72
Equity ratio at end of period, %	81	87	81	87	90
Average number of employees	31	28	31	27	29
– of which in R&D	27	25	27	24	25
Number of registered shares at end of period	51,868,406	51,748,406	51,868,406	51,748,406	51,868,406
Share price at the end of period, SEK	8.66	34.95	8.66	34.95	38.30



Comments from the CEO

IRLAB continues to make significant progress in its efforts to develop innovative treatments for Parkinson's and other neurological disorders. During the second quarter of this year, we achieved important milestones in our development programs. After the period, on August 21, IRLAB secured the full ownership of the now phase III ready mesdopetam project. Our broad and world-leading project portfolio in Parkinson´s disease, addresses the great majority of complications and symptoms that the person living with Parkinson may experience after diagnosis and during the continued progression of the condition. We remain confident in the potential of our portfolio of drug candidates to address the unmet medical needs for those living with Parkinson's and other CNS diseases.

Building a world-leading portfolio in Parkinson's

By utilizing our proprietary and unique research platform - ISP, we have built a world-leading portfolio of drug projects focused on unmet needs in Parkinson's. The portfolio includes completely new treatments based on novel mechanism of actions, that can address the majority of complications and symptoms across all stages of the disease, and which could simultaneously generate value for our shareholders. Following the recent securing of the ownership of mesdopetam, we have further strengthened our position. The portfolio projects now span from preclinical to phase III preparation stage products. Over the next 1-2 years, we could have up to five drug candidates in clinical development phase I-III – an impressive and highly possible development of the company.

Clear anti-dyskinetic effects by mesdopetam

In the Phase IIb study with mesdopetam, the efficacy and safety of three dose levels of mesdopetam were evaluated in individuals with Parkinson's disease experiencing troublesome dyskinesia. One of the key aims for the study was to evaluate dose-response relationship for mesdopetam in order to be able to

determine the appropriate dose for Phase III. Following a comprehensive analysis of all data we have concluded that mesdopetam has a dose-dependent anti-dyskinetic and anti-parkinsonian effect without compromising normal motor function coupled with a safety and tolerability profile on par with placebo for all doses tested. Based on the results of the phase IIb study, the dose 7.5 mg twice daily is the preferred dose to be investigated in Phase III. An update of the mesdopetam project was communicated on a webcast on the 22nd of August and can be viewed here [LINK]. A comprehensive analysis of the Phase IIb study data was presented at the International Congress of Parkinson's Disease and Movement Disorders, MDS Congress, in Copenhagen on August 28.

Securing ownership of mesdopetam and Planning for end-of-Phase 2 meeting with the FDA

Following a contact by Ipsen on May 1, discussions between Ipsen and IRLAB were initiated on the best way forward for mesdopetam in order to reach the market and become available for patients in need. These discussions were concluded on August 21, resulting in IRLAB securing all rights and full ownership of mesdopetam. We will now pursue the regulatory path toward Phase III and request an end-of-Phase 2 meeting with the FDA as soon as a briefing book including all available information has been compiled. The purpose with the meeting is to define the design of a Phase III program for mesdopetam. Ipsen will support us in the preparation of the briefing book. In parallel, we will evaluate options for the execution of Phase III. External key opinion leaders and advisors share IRLAB's view that the profile of mesdopetam provides both the prerequisites for a successful treatment in Parkinson's and that it has a significant commercial potential.

With the new agreement, IRLAB has full ownership of all data generated by Ipsen, including the three Phase I clinical studies performed during 2022 and 2023, CMC development, and manufactured drug product for a Phase III program. The full transfer of the project to IRLAB will be completed during the fall 2023.

Ongoing Phase IIb study of pirepemat

In the ongoing Phase IIb study with pirepemat, the efficacy, safety, and tolerability of two doses of pirepemat are evaluated in people living with Parkinson's disease in order to identify the optimal dose for Phase III. By the latter part of May all participating clinics were activated. By mid-July, the first planned DSMB review took place following 25 patients having completed the study. The DSMB unanimously recommended the study to continue according to plan. Recruitment of patients has been slightly slower than anticipated and actions are being taken to facilitate patient recruitment with the aim to complete recruitment by the end of 2023, followed by a three-month treatment period. Based on the current timeline estimate, top-line results are expected in H1 2024.

In previous interactions with the FDA, IRLAB was advised to frontload the development plan for pirepemat with preclinical in vivo as well as specific in vitro studies. This, as a result of the transient liver enzyme elevations observed in a few subjects in early clinical studies. The frontloaded preclinical studies have been performed with no sign of new previously undetected metabolites of pirepemat, nor negative effects on liver cells by pirepemat or its metabolites.

Preclinical programs has potential to address major needs

Our drug candidates in the preclinical development phase are progressing according to plans to be made ready for entering into clinical Phase I trials. IRL757 aims to treat apathy in Parkinson's and other neurological disorders, and IRL942 targets the improvement of cognitive dysfunction in people with Parkinson's and other neurological disorders. Key ongoing activities for these projects include CMC development and IND/CTA enabling studies with the aim to have a formulation of the compound ready for human dosing, as well as having demonstrated safety for the dose levels to be used in Phase I. Reassuringly, no unexpected findings have been observed, and we anticipate to reach the Phase I ready stage as previously communicated.

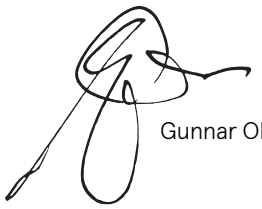
On May 16, an agreement was signed with MSRD, a company within the Otsuka family, giving MSRD the exclusive right to evaluate IRL757 and IRL942 for a potential drug development collaboration for the two neuropsychiatric projects.

Our IRL1117 project has the objective to develop a treatment for the hallmark symptoms of Parkinson's (tremors, stiffness, and bradykinesia) without causing the troublesome effect fluctuations and the complications associated with current mainstay levodopa-based treatments. A drug with this profile has the potential to replace levodopa treatment for Parkinson's. The project continues according to plan.

Forward-looking

In the beginning of 2023, we defined priorities for the year. With the mesdopetam project transfer to IRLAB, we will review our internal priorities to optimally support our product development activities. This includes evaluations of the best way to finance the further development of our assets - through licensing/collaboration agreements and/or through the capital market. We anticipate that the strengthening of our project portfolio with the Phase III ready mesdopetam program will improve our partnering and financing opportunities to advance our world-leading portfolio of treatments in Parkinson's disease. We remain vigilant on our financial stability as we continuously evaluate our opportunities.

I am looking forward to continuing to develop the company and the exciting portfolio of drug candidates together with our employees and the Board, and I want to express my gratitude to all shareholders for the support and trust you have placed in us.



Gunnar Olsson, CEO, IRLAB

IRLAB's unique offering and position

IRLAB discovers and develops novel treatments to transform the life of patients living with Parkinson's and other CNS disorders. Rooted in Nobel Prize-winning research, IRLAB has grown rapidly to become recognized and respected as a world-leader in understanding the complex neuropharmacology of CNS disorders and especially Parkinson's. We have a well-defined, strategically focused R&D pipeline of powerful new treatments targeting various stages of Parkinson's. Having a full range of effective treatments for the disease's different complications and symptoms is regarded as essential by both the medical and patient communities and is at the same time potentially a possibility for a successful pharmaceutical business.

Pioneering biologi & ISP

IRLAB has deep profound understanding of Parkinson's based on research conducted by the research group of Nobel laureate Prof. Arvid Carlsson. IRLAB has a unique proprietary research platform – Integrative Screening Process (ISP) – that has generated all of the company's first-in-class drug candidates.

Focused strategy

Drugs developed by IRLAB should be able to treat people with Parkinson's throughout all phases of the disease. IRLAB has blockbuster potential as a pharma business.

Validated proof-of-concept

IRLAB has validated the R&D and business strategy by:

- Discovering and developing investigational drugs from drug discovery to Phase III ready projects.

Organization positioned for success

IRLAB is an organization with very a experienced team. IRLAB is listed on the Nasdaq Stockholm main market (IRLAB A).

Broad & solid portfolio

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

Phase III-ready

- Mesdopetam: to counteract levodopa-induced dyskinesias in Parkinson's (PD-LIDs).

Fas IIb

- Pirepemat: to improve balance and reduce falls in Parkinson's (PD-Falls).

Preclinical

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

Therefore our strategic priorities are to:

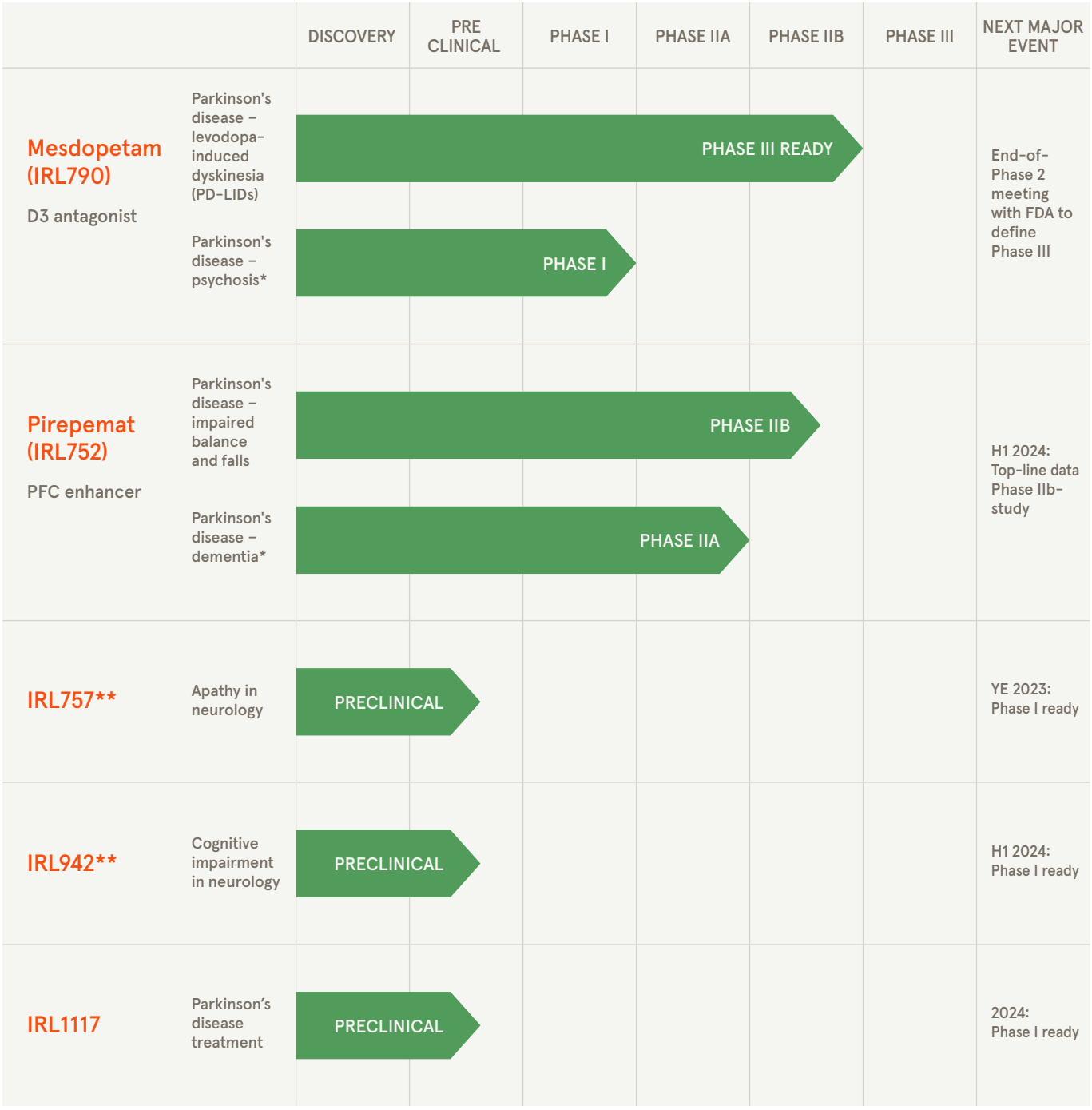
1. Ensure an end-of-Phase 2 meeting with FDA to define the Phase III program for mesdopetam.
2. Continue and intensify dialogues with potential investors, partners, and licensees for IRLAB's development projects to secure future financing of the development programs.
3. Ensure that Phse III development is initiated in a timely manner with the appropriate resources.
4. Complete recruitment for the Phase IIb study of pirepemat and present top-line results in H1 2024.
5. Drive the development of IRL757, IRL942 and IRL1117 towards clinical Phase I studies.
6. Continue to document the opportunity for our drug candidates and pipline, focusing on commercial potential and differentiation vs. existing treatments to highlight medical, commercial and shareholder values.

IRLAB A

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

IRLAB's portfolio

First-in-class drug candidates to treat people with Parkinson's across all stages of disease.



PFC enhancer = noradrenaline and serotonin antagonists In the prefrontal cortex.

*Currently no active clinical development in this indication.

** Under evaluation under exclusivity by MSRD, an Otsuka company.

Read more about our development programs on irlab.se

"In 2023 and especially in recent months, our entire portfolio has progressed well. This, in combination with the fact that IRLAB has now secured control of the continued development of the mesdeoptam project means that IRLAB now has a broad and solid project portfolio, from discovery through Phase I-ready, Phase IIb to Phase III-ready. The results from the mesdeoptam studies show that we discovered a tolerable and effective treatment, with a completely new mechanism of action, for people living with Parkinson's and dyskinesia. The patent protection has the potential to span into the 2040-ies. The next important milestone for mesdeoptam is an end-of-Phase 2 meeting with the FDA to define an upcoming Phase III study program.

In our ongoing Phase IIb study of pirepemat, all participating clinics have now been activated and the forecast is that all study participants will be recruited by the end of the year.

Our preclinical development candidates, IRL757 and IRL942, represent completly novel strategies to treat apathy and cognitive impairment, symptoms that occur in Parkinson's and other brain disorders, for which there is currently no treatment. We are now working with Otsuka/MSRD in order to evaluate the possibility of building a broadere collaboration for the development of these unique drug candidates. In parallell, we carry out the studies required to make the drug canddidates ready for Phase I.

Our discovery and research activities have a focus on patent-related work and development of IRL1117 into a completly new type of treatment for the hallmark symptoms of Parkinson's. Overall, we are making big and meaningful advancements across our R&D portfolio."

NICHOLAS WATERS, EVP AND HEAD OF R&D

R&D update

Mesdopetam

- In the Phase IIb study of mesdopetam in people with Parkinson's disease levodopa-induced dyskinesias (PD-LIDs) mesdopetam demonstrated clear anti-dyskinetic effects with an adverse event and tolerability profile on par with placebo. IRLAB held a webcast on August 22 where further information about the Phase IIb study results were discussed, which is available on IRLAB's website. Further results were later presented at the scientific conference MDS Congress 2023 in Copenhagen. In summary, the results from the study indicates that mesdopetam has the rare combination of having both dose-dependent anti-dyskinetic and anti-parkinsonian effects without untoward effect on the normal motor function, combined with a tolerability and safety profile not different from placebo.

  This givies mesdopetam a unique and strong position in the competitive landscape of other strategies for the management of dyskinesias. The results of the comprehensive data package developed provides IRLAB with a solid foundation for continuing the development of mesdopetam to Phase III. The results from the study have made it possible to identify the optimal dose, 7.5 mg, twice daily, for a Phase III program.

Pirepemat

- The ongoing study is recruiting patients at the planned study sites in France, Poland, the Netherlands, Spain, Sweden and Germany. Patient recruitment and randomization is planned to be completed by the year-end 2023 and top-line results are thus expected in H1 2024.

- A unanimous recommendation to continue the ongoing Phase IIb study was obtained following a planned review by the independent Data Safety Monitoring Board (DSMB). The DSMB evaluated data from the first 25 patients who completed the entire treatment and follow-up period in the study.
- The FDA has recommended that IRLAB frontloads preclinical studies relating to the drug candidate's uptake, distribution, metabolism and excretion, including studies with radioactively labeled pirepemat, so-called mass balance studies (or DMPK studies), in the development plan for pirepemat. Recommendation to conduct in vitro studies to support the documentation of the pharmacokinetic, safety and tolerability profile of pirepemate in different cell types has also been given. During the period, these preclinical DMPK and in vitro studies were completed with good results. The results generated, show that pirepemat is fully metabolized and excreted. Furthermore, no metabolites are formed that can be linked to the safety of pirepemat in these studies. In vitro studies based on human hepatocyte preparations developed to study drug metabolism and safety over longer periods (up to 14 days of in vitro exposure) did not indicate the occurrence of adverse effects in hepatocytes of pirepemat or its metabolites.
- New patent application for pirepemat (IRL752) has been submitted to the European Patent Office as a first priority region. If granted, it may further strengthen the IP situation.

IRL757

- IRLAB works with MSRD in their evaluation and scientific review of the IRL757 project in accordance with the agreement signed in May 2023.
- All preparatory Phase I toxicology and safety studies neccessary for the submission to a regulatory authority are completed. GMP manufacturing of drug substance (API) and development of drug product is completed.
- Preparatory work and compilation of the documentation for the application to conduct a Phase I study is ongoing.
- IRL757 is expected to be Phase I ready by year-end 2023.
- Two patent applications for IRL757 have been filed during the period which, if granted, could further strengthen the IP situation and extend the protection of IRL757 into the early 2040s.

IRL942

- IRLAB works with MSRD in their evaluation and scientific review of the IRL942 project in accordance with the agreement signed in May 2023.
- Development proceeds according to the set plan for preclinical development, toxicology, safety studies and GMP manufacturing of API. Development of drug product has started and IRL942 is expected to be Phase I ready during H1 2024.

IRL1117

- IRL1117 continues with in-house activities during 2023/2024. Activities related to substance manufacturing and planning for preclinical regulatory studies neccessary for Phase I preparations are ongoing.
- The patent situation for IRL1117 has strengthened during Q2 by the submissions of additional international patient applications.

Integrative Screening Process (ISP)

- IRLAB's portfolio is generated with the unique proprietary drug discovery platform Integrative Screening Process, called ISP, which has proven to enable the discovery of truly novel first-inclass compounds. The ISP methodology combines systems biology screening models, an extensive database, and modern machine learning-based analytical methods. This means that IRLAB obtains unique insights into the overall effect of the studied molecules at an early stage. The platform can already at that stage predict the drug candidates with the greatest potential in a certain indication, as well as the lowest risks. ISP provides an improvement in probability of drug discovery success in translation to clinical phases, compared with industry standard. This is also exemplified by higher probability to demonstrate positive clinical proof-of-concept in patients and reach later stages of clinical development for an ISP generated drug candidate compared with the industry standard.
- This discovery and development strategy provides IRLAB with a strong competitive advantage in the discovery of novel treatments for Parkinson's and other CNS disorders. It is important to IRLAB to constantly refine and develop its technology-base and remain at the forefront of modern drug discovery. A close cooperation with universities and academic researchers also contribute to IRLAB being able to keep leading the development of cutting-edge technology.
- During Q2, IRLAB has performed advanced molecular modeling of the receptors (target molecules) through which IRLAB's drug candidates act. This provides a better understanding on how the interaction between the drug candidate and the receptors works. A focus in this work has been on the receptors through which IRL1117 acts. This knowledge is important to prepare both the development program and the commercial positioning of the IRL1117 project.

The group's performance January – June 2023

IRLAB Therapeutics AB, corporate identity number 556931-4692, is the parent company in a group that carries out research and development with the aim of transforming life for people with Parkinson's and other CNS disorders 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.

The company's unique proprietary research platform ISP generates novel, high-potential drug substances that make up the company's pipeline. IRLAB has two drug candidates in clinical phase, mesdopetam, where data from a Phase IIb study was reported in January and August 2023, and pirepemat where a Phase IIb study is ongoing. Generated by ISP, IRLAB's three promising preclinical drug candidates IRL942, IRL757 and IRL1117, are currently in developmet toward clinical Phase I studies in respective preclinical development programs.

The parent company's operations mainly consist of providing management and administrative services to the group's operating companies, and activities related to the stock market. The research and development operations are conducted in the wholly-owned subsidiary Integrative Research Laboratories Sweden AB. IRLAB has offices in Gothenburg (main) and Stockholm, Sweden.

Research and development work

In the period January to June, the total costs for research and development were SEK 86 684k (75 741), corresponding to 78 percent (85) of the group's total operating expenses. Development costs vary over time, depending on where in the development phase the projects are.

During the period 1 January – 30 June 2023, the percentage proportion of R&D cost is lower, mainly due to increased personnel costs attributable to one-off costs in connection with the former CEO being dismissed.

Comments on the income statement

The loss for the period January 1 – June 30, 2023 was SEK –104 461k (-56 285). Earnings per share were –2.01 SEK (-1.09). The group's revenue during the period was SEK 6 871k (32 730).

The personnel costs during the period was SEK 32 289k (19 418). The increase is primarly due to one-off costs associated with the removal of the former CEO, which amounted to SEK 10 580k.

Of the SEK 239 596k that was received up-front in 2021 under the mesdopetam license agreement, SEK 185 262k was recognized as license revenue and SEK 54 335k was recognized as deferred income for the finalization of the Phase IIb study and was recognized as income during 2022. No such income has been recognized during 2023.

During the period 1 January – 30 June 2023, the group's operating expenses were SEK 51 743k (50 616).

Financing and cash flow

Cash flow from operating activites were during the period 1 january to 30 June 2023 SEK –94 294k (-76 793) and during the second quarter SEK –52 798k (-44 010). Cash and cash equivalents were SEK 156 413k (322 615) on June 30, 2023.

On June 30, 2023, equity was SEK 186 370k (343 196) and the equity ratio was 81 percent (87).

IRLAB is a research and development company with no regular income. The company is primarily financed via the capital market or through the sale or out-licensing of projects, with an initial payment at signing of the agreement, as another financing option. The financing strategy is based on continuously ensuring that the company is sufficiently financed via the capital market to be able to operate the business efficiently and make rational business decisions. The board and the CEO determine that the activities IRLAB runs in parallel gives an opportunity to ensure the funding need and has several opportunities such as a potential research collaboration regarding IRL942 and/or IRL757, a new license deal regarding mesdopetam, pirepemat or IRL1117 or various forms of share issues.

Investments

Investments in intangible assets for the period January 1 – June 30, 2023 were SEK 293k (991).

Significant events April–June 2023

On May 3, IRLAB became aware that Ipsen's Universal Registration Document 2022, published on April 6, 2023, contained the incorrect information that the development and commercialization rights for mesdopetam had been transferred back to IRLAB. This error was corrected by Ipsen, who published an updated Universal Registration Document 2022.

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At the end of May, it was announced that all 38 clinics are activated and recruiting patients in the Phase IIb study with pirepemat. Pirepemat is developed with the goal of improving balance and reducing falls in Parkinson's disease.

On June 13–16, IRLAB participated with a presentation at the scientific conference XIV Triennial Meeting of the International Basal Ganglia Society (IBAGS) held in Stockholm. IBAGS XIV is a major event that brings together researchers who study the basal ganglia of the brain at all levels (from molecule to behavior) in both neurological and neuropsychiatric disorders originating in the basal ganglia that also include Parkinson's disease.

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

On June 20, the company's annual general meeting was held where, among other things, the three new members were elected to the board Christer Nordstedt, Daniel Johnsson and Veronica Wallin.

IRLAB presented at several national investor conferences during the period and holds ongoing discussions with potential national and international investors to continuously provide updates on the company and its development. The conferences were arranged by, among others ABGSC and Redeye. Recordings are available on IRLAB's website, irlab.se.

Significant events after the end of the period

In mid-July, the DSMB for the pirepemat Phase IIb study unanimously recommended the company to continue the study in accordance with the approved study protocol, following their first planned review. The DSMB continuously reviews the clinical study data generated during an ongoing study. This is to ensure the safety of study participants and the validity and integrity of data. This scheduled review was performed after the first 25 patients had completed the entire treatment and follow-up period of the study.

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During the MDS congress, held August 25-28, IRLAB presented further results from the analyses of the Phase IIb study with messdopetam. The scientific poster is available at irlab.se.

IRLAB participated in an international competition focusing on applying Machine Learning (ML) to describe animal behaviour – Behavioural Representation Learning Competition. The competition was arranged by a consortium of machine learning and neuroscience researchers at Northwestern and Caltech Universities. IRLAB was awarded 2nd place in the competition illustrating that IRLAB is in the absolute forefront in the application of ML in its discovery and drug development. An article describing the results was published during the period at the Fortieth International Conference on Machine Learning, July 23, Honolulu, USA. https://proceedings.mlr.press/v202/sun23g.html
MABe22: A Multi-Species Multi-Task Benchmark for Learned Representations of Behavior.

Consolidated income statement in summary

Amounts in SEK thousand	2023 Apr–Jun	2022 Apr–Jun	2023 Jan–Jun	2022 Jan–Jun	2022 Jan–Dec
Operating income					
Net revenue	6,870	23,410	6,870	32,452	61,136
Other operating income	1	191	1	278	141
Total income	*6,871*	*23,601*	*6,871*	*32,730*	*61,277*
Operating expenses					
Other external costs	-38,737	-39,461	-75,866	-66,673	-125,906
Personnel costs	-11,199	-9,744	-32,289	-19,418	-42,481
Depreciation of intangible and tangible fixed assets	-1,085	-958	-2,165	-1,903	-4,779
Other operating cost	-722	-454	-930	-839	-1,220
Total operating expenses	*-51,743*	*-50,616*	*-111,250*	*-88,833*	*-174,387*
Operating result	**-44,872**	**-27,015**	**-104,379**	**-56,103**	**-113,110**
Result from financial items					
Financial income	4	0	7	0	0
Financial costs	-37	-100	-89	-182	-297
Total financial items	*-33*	*-100*	*-82*	*-182*	*-297*
Result after financial items	**-44,905**	**-27,115**	**-104,461**	**-56,285**	**-113,406**
Tax on income	0	0	0	0	0
Result for the period	**-44,905**	**-27,115**	**-104,461**	**-56,285**	**-113,406**
Earnings per share before and after dilution (SEK)	-0.87	-0,52	-2,01	-1,09	-2,19
Average number of shares, before and after dilution	51,866,406	51,748,406	51,868,406	51,748,406	51,831,913
Number of shares at end of period	51,866,406	51,748,406	51,868,406	51,748,406	51,866,406

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	2023 Apr–Jun	2022 Apr–Jun	2023 Jan–Jun	2022 Jan–Jun	2022 Jan–Dec
Result for the period	−44,905	−27,115	−104,461	−56,285	-113,406
Other comprehensive income	0	0	0	0	0
Total result for the period	**-44,905**	**-27,115**	**-104,461**	**-56,285**	**-113,406**

Consolidated statement of financial position in summary

Amounts in SEK thousand		06/30/2023	06/30/2022	12/31/2022
ASSETS				
Fixed assets				
Intangible fixed assets		46,862	42,531	46,862
Tangible fixed assets		6,137	7,566	8,009
Total fixed assets		**52,999**	**50,097**	**54,871**
Current assets				
Short-term receivables		20,575	23,291	15,908
Cash and cash equivalents		156,413	322,615	252,776
Total current assets		**176,988**	**345,906**	**268,684**
TOTAL ASSETS		**229,987**	**396,003**	**323,555**
EQUITY AND LIABILITIES				
Equity	Note 5			
Share capital		1,037	1,035	1,037
Other contributed capital		690,205	685,450	690,205
Retained earnings incl. results for the period		−504,872	−343,289	−400,411
Total equity		**186,370**	**343,196**	**290,831**
Long-term liabilities				
Leasing debt		249	1,993	381
Total long-term liabilities		**249**	**1,993**	**381**
Short-term liabilities				
Leasing debt		1,951	3,109	3,595
Other liabilities		41,417	47,705	28,748
Total short-term liabilities		**43,368**	**50,814**	**32,343**
TOTAL EQUITY AND LIABILITIES		**229,987**	**396,003**	**323,555**

Consolidated statement of changes in equity in summary

Amounts in SEK thousand	Share capital	Unregistered share capital	Other capital contributed equity	Retained earnings incl. total result for the period	Total equity
Equity January 1, 2022	**1,035**	**0**	**685,450**	**–287,005**	**399,481**
Total result for the period				–56,285	–56,285
Equity June 30, 2022	**1,035**	**0**	**685,630**	**–343,289**	**343,196**
Total result for the period				-57,122	-57,122
Transactions with owners in their capacity as owners:					
Rights issue					
Issue costs	2		4,754		4,757
Equity December 31, 2022	**1,037**	**0**	**690,205**	**–400,411**	**290,831**
Equity January 1, 2023	**1,037**	**0**	**690,205**	**–400,411**	**290,831**
Total result for the period				-104,461	-104,461
Equity June 30, 2023	**1,037**	**0**	**690,205**	**-504,872**	**186,370**

Consolidated statement of cash flows in summary

Amounts in SEK thousand	2023 Apr–Jun	2022 Apr–Jun	2023 Jan–Jun	2022 Jan–Jun	2022 Jan–Dec
Operating activities					
Operating result	–44,872	–27,015	–104,379	–56,103	–113,110
Adjustment for items not included in the cash flow	1,085	958	2,165	1,903	4,779
Interest	4	0	7	0	0
Paid interest	–38	–100	–89	–182	–297
Cash flow from operating activities before changes in working capital	**–43,821**	**–26,157**	**–102,296**	**–54,382**	**–108,627**
Cash flow from changes in working capital					
Change in operating receivables	–7,309	–6,875	–4,667	–3,749	3,634
Change in operating liabilities	–1,668	–10,978	12,668	–18,662	–37,619
Cash flow from operating activities	**–52,798**	**–44,010**	**–94,294**	**–76,793**	**–142,612**
Investment activities					
Acquisition of intangible fixed assets	0	0	0	0	–500
Acquisition of tangible fixed assets	0	–668	–293	–991	–2,876
Cash flow from investment activities	**0**	**–668**	**–293**	**–991**	**–3,376**
Financing activities					
Amortization of financial liabilities, leasing debt	–894	–754	–1,776	–1,499	–3,134
Cash flow from financing activities	**–894**	**–754**	**–1,776**	**– 1,499**	**–3,134**
Cash flow for the period	**–53,690**	**–45,432**	**–96,363**	**–79,282**	**–149,121**
Cash and cash equivalents at the start of the period	210,103	368,047	252,776	401,897	401,897
Cash and cash equivalents at the end of the period	**156,413**	**322,615**	**156,413**	**322,615**	**252,776**

Parent company income statement in summary

Amounts in SEK thousand	2023 Apr–Jun	2022 Apr–Jun	2023 Jan–Jun	2022 Jan–Jun	2022 Jan–Dec
Operating income					
Net revenue	1,236	877	2,822	1,771	4,531
Total income	*1,236*	*877*	*2,822*	*1,771*	*4,531*
Operating expenses					
Other external costs	–3,608	–3,293	–7,952	–6,275	–12,187
Personnel costs	–3,213	–2,311	–17,143	–5,817	–14,402
Other operating expences	-9	0	-18	0	-25
Total operating expenses	*–6,830*	*–5,603*	*–25,113*	*–12,092*	–26,614
Operating result	***–5,594***	***–4,726***	***–22,290***	***–10,321***	***–22,083***
Result from financial items					
Interest income	0	0	1	0	0
Interest costs	0	0	-1	0	–7
Total financial items	*0*	*0*	*0*	*0*	*–7*
Result after financial items	***–5,594***	***–4,726***	***–22,290***	***–10,321***	***–22,090***
Tax on the period's result	0	0	0	0	0
Result for the perioden	**–5,594**	**–4,726**	**–22,290**	**–10,321**	**–22,090**

Parent company statement of comprehensive income in summary

Amounts in SEK thousand	2023 Apr–Jun	2022 Apr–Jun	2023 Jan–Jun	2022 Jan–Jun	2022 Jan–Dec
Profit/loss for the period	–5,594	–4,726	–22,290	–10,321	–22,090
Other comprehensive income	0	0	0	0	0
Comprehensive income for the period	–5,594	–4,726	–22,290	–10,321	–22,090

Parent company balance sheet in summary

Amounts in SEK thousand	06/30/2023	06/30/2022	12/31/2022
ASSETS			
Fixed assets			
Financial fixed assets			
Shares in group companies	350,320	350,320	350,320
Total fixed assets	**350,320**	**350,320**	**350,320**
Current assets			
Other receivables	7,196	1,705	8,535
Cash and cash equivalents	77,312	102,692	92,814
Total current assets	**84,508**	**104,397**	**101,349**
TOTAL ASSETS	**434,829**	**454,717**	**451,669**
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1,037	1,035	1,037
	1,037	*1,035*	*1,037*
Unrestricted equity			
Share premium fund	744,314	739,463	744,314
Retained earnings including total result for the period	–324,724	–290,569	–302,434
Total Unrestricted equity	*419,590*	*448,894*	*441,880*
Total equity	**420,627**	**449,929**	**442,917**
Short-term liabilities			
Other liabilities	14,202	4,788	8,752
Total liabilities	14,202	4,788	8,752
TOTAL EQUITY AND LIABILITIES	**434,829**	**454,717**	**451,669**

Parent company statement of cash flows in summary

Amounts in SEK thousand	2023 Apr–Jun	2022 Apr–Jun	2023 Jan–Jun	2022 Jan–Jun	2022 Jan–Dec
Cash flow from operating activities	-8,597	-4,177	-15,502	-10,278	-24,913
Cash flow from financial activities	0	0	0	0	4,757
Cash flow for the period	**-8,597**	**-4,177**	**-15,502**	**-10,278**	**-20,156**
Cash and cash equivalents at the start of the period	85,909	106,870	92,814	112,970	112,970
Cash and cash equivalents at the end of the period	**77,312**	**102,692**	**77,312**	**102,692**	**92,814**

Key financial ratios for the group

	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec	2021 Jan-Dec	2020 Jan-Dec
Net sales	6 870	32 452	61 136	207 782	0
Operating result, TSEK	-104 379	-56 103	-113 110	52 576	-91 458
Result for the period, TSEK	-104 461	-56 285	-113 406	51 781	-91 653
Earnings per share before and after dilution, SEK	-2.01	-1.09	2.19	1.00	1.92
R&D costs, TSEK	86 684	75 741	146 178	129 748	75 989
R&D costs as a percentage of operating costs, %	78	85	84	84	83
Cash and cash equivalents at the end of the period, TSEK	156 413	322 615	252 776	401 897	277 009
Cash flow from operating activities, TSEK	-94 294	-76 793	-142 612	128 641	-89 214
Cash flow for the period, TSEK	-96 363	-79 282	-149 121	124 888	166 482
Equity, TSEK	186 370	343 196	290 831	399 481	347 880
Equity per share, SEK	3.59	6.63	5.61	7.72	6.72
Equity ratio, %	81	87	90	85	94
Average number of employees	31	27	29	22	18
Average number of employees in R&D	27	24	25	20	17

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 2022 Annual Report.

Other information

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 2022 Annual Report.

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

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 votes

At the end of the period, IRLAB's registered share capital was SEK 1,037,368 divided into 51,868,406 shares with a quota value of SEK 0.02. There were 51,788,630 Class A shares and 79,776 Class B shares. All shares, including shares in Class B, gives the holder one vote.

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.

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 161,078k (328,806).

Transactions with related parties

IRLAB has during the period January - June 2023 paid salaries and other remuneration to the executive management and board fees to the board, in accordance with the resolution of the Annual General Meeting. IRLAB has also during the period paid remuneration to a company related to the board member Catharina Gustafsson Wallich. The remuneration has not been considered significant for neither IRLAB nor the recipient, and has been on market conditions.

Revenue January - June 2023

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	2023 Jan–Jun	2022 Jan–Jun	2022 Jan–Dec
Service revenue	6 870	32 452	61 136
Total revenue	**6 870**	**32 452**	**61 136**

Segment information

Net sales by geographic market	2023 Jan–Jun	2022 Jan–Jun	2022 Jan–Dec
Sweden	0	0	0
United Kingdom	2 650	32 452	61 136
USA	4 220	0	0
Total revenue	**6 870**	**32 452**	**61 136**

All invoicing was in euro or american dollars. Revenue is recognized in SEK.

Risks and uncertainties

The nature 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. It is therefore important to take the risks into account when assessing IRLAB's future potential in addition to the opportunities that are inherent in both projects and operations. IRLAB's business model entails high development costs that do not generate potential revenues connected to licensing, sales or partnerships until the majority of the drug development has been completed. The company's financial risks are described on pages 88-89 and its risk management is

described on page 124 of the 2022 Annual Report. No significant changes have occurred that affect the reported risks.

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

Nomination Committee

Prior to the 2023 Annual General Meeting and until a new nomination committee is elected, and pursuant to the instructions applicable to IRLAB's Nomination Committee, the nomination committee comprised Hans-Peter Ostler, Anders Vedin (Chair of the Nomination Committee), Clas Sonesson and Carola Lemne, the Chair of the Board. The members of the nomination committee represent about 43 percent of the votes and shares in IRLAB as per August 31, 2022.

Management

On February 21, 2023, the then CEO was dismissed and replaced by the then chairman of the board, Gunnar Olsson. Olsson is CEO until further notice, but with a short notice period and no special compensation upon termination of the employment. A process to replace him with a new CEO was initiated during the spring of 2023 and is still ongoing.

Employees

The average number of employees in the group from January – June was 31 (28). At the end of the period, the number of full-time positions was 31 (28), distributed over 33 (31) people.

The number of full-time positions, including long-term contracted consultants, was 33 (32) at the end of the period, distributed over 37 (36) people.

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.

Financial calendar

Interim report Q3 2023	October 25, 2023.
Year-end report 2023	February 7, 2024.

Presentation to investors and media

The presentation will be held on August 30, 2023, at 10:00 CEST through an online webcast. Gunnar Olsson, CEO, Nicholas Waters, EVP and Head of R&D, and Viktor Siewertz, CFO, will comment the interim report for the period January–June 2023. The presentation will be held in English and followed by a Q&A session.

Follow the presentation online on:
https://youtube.com/live/tmtQrel7r_s

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, August 30, 2023

CAROLA LEMNE
Chair of the Board

GUNNAR OLSSON
CEO
Board member

CATHARINA GUSTAFSSON WALLICH
Board member

REIN PIIR
Board member

DANIEL JOHNSSON
Board member

VERONICA WALLIN
Board member

CHRISTER NORDSTEDT
Board member

IRLAB

IRLAB discovers and develops novel treatments of Parkinson's disease and other CNS disorders. The company's most advanced drug candidates, mesdopetam (IRL790) and pirepemat (IRL752), are in Phase IIb and are designed to treat some of the most difficult symptoms related to Parkinson's. In 2021, Ipsen, a specialty pharma company, acquired exclusive global rights to the development and commercialization of mesdopetam.

IRLAB has discovered and generated all its drug candidates and continues to discover innovative drug candidates for the treatment of CNS disorders through its proprietary systems biology-based Integrative Screening Process (ISP) research platform. In addition to IRLAB's strong clinical pipeline, the company is also progressing three preclinical programs, IRL942, IRL757, and IRL1117, towards Phase I studies.

Contact information

FOR FURTHER INFORMATION, PLEASE CONTACT

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