IRLAB

Q2.2022

# Interim report January – June 2022

## Transforming life for people with Parkinson's and other CNS disorders

# Interim report January – June 2022

## Positioned to enable growth and leverage commercial opportunities

### Summary of the second quarter

- The management team strengthened by appointing Richard Godfrey as new CEO and Nicholas Waters as Executive Vice President and Head of Research & Development, effective July 1, 2022.
- Know-how acquired to support a strong patent application for chemical matter claims related to the P003 research project. The P003 project aims to offer a once-daily Parkinson's treatment without the troublesome complications associated with chronic levodopa treatment.
- IRLAB presented at several investor events during the period to communicate updates of the company's strategy and pipeline. Public recordings are available on the website, irlab.se.
- Viktor Siewertz, CFO, was a guest speaker at the Expert session at the BioStock Life Science Summit 2022, talking about the licensing agreement with Ipsen (one of the larger in the Swedish biotech space in decades).

### After end of period

- The Phase IIb PD-LIDs study with mesdopetam has been expanded to include 154 patients, top-line data is anticipated around the year-end.
- The share issue of 120,000 Class A shares relating to the acquisition of know-how related to the P003 discovery project was registered. After the registration, the total number of registered shares is 51,868,406 (51,748,406).

### Financial highlights in the second quarter

- Net sales recorded in Q2 SEK 23.4m (SEK0m)
- Total operating expenses during the quarter SEK 50,6m (SEK 26.5m)
- The operational loss for the quarter SEK -27.1m (SEK -26.6m)
- Cash flow from operations SEK -44.0m (SEK -23.4m)
- Cash and cash equivalents amounted to SEK 322.6m 2022 (SEK 229.4m)
- The total number of registered shares 51,748,406 (51,748,406)

*Figures in brackets = same period 2021, unless otherwise stated*

## Financial summary

| SEK thousand | Apr–Jun 2022 | Apr–Jun 2021 | Jan–Jun 2022 | Jan–Jun 2021 | Jan–Dec 2021 |
|---|---|---|---|---|---|
| Net sales | 23,410 | 0 | 32 452 | 0 | 207,782 |
| Operating profit | –27,015 | –26,520 | –56,103 | –46,487 | 52,576 |
| Profit/loss for the period | –27,115 | –26,629 | –56,285 | –46,670 | 51,781 |
| Earnings per share before and after dilution, SEK | –0.52 | –0.51 | –1.09 | –0.90 | 1.00 |
| Cash and cash equivalents | 322,615 | 229,383 | 322,615 | 229,383 | 401,897 |
| Cash flow from operating activities | –44,010 | –23,430 | –76,793 | –45,800 | 128,641 |
| Equity per share at end of period, SEK | 6.63 | 5.82 | 6.63 | 5.82 | 7.72 |
| Equity ratio at end of period, % | 87 | 92 | 87 | 92 | 85 |
| Average number of employees | 28 | 21 | 27 | 20 | 22 |
| – of which in R&D | 25 | 19 | 24 | 18 | 20 |
| Number of registered shares at end of period | 51,748,406 | 51,748,406 | 51,748,406 | 51,748,406 | 51,748,406 |
| Share price at the end of period, SEK | 34.95 | 38.20 | 34.95 | 38,20 | 44.00 |

*"Going forward, I will concentrate on the strategic commercial, business development and financing aspects of IRLAB. My priorities are to increase the awareness and visibility of IRLAB and our pipeline programs both in the Nordics and internationally, focus our messaging on the potential significant patient benefits that our drug candidates offer to different stakeholders."*

RICHARD GODFREY, CEO

# Comments from the CEO

I am delighted to provide an update on IRLAB's progress over the last quarter, my first update since joining the Company as CEO on July 1, 2022. I am grateful for the warm welcome I have received, and during the summer I have been working with Nicholas Waters, the senior management team, and the Board to get up to speed and take a deep dive into the business.

My first impressions are very encouraging, and now having had a chance to examine our data and speak candidly with some of our patient-facing clinical team, I am even more optimistic that our pipeline of drug candidates will bring meaningful benefit to patients with Parkinson's.

In my initial consideration of IRLAB, my analysis highlighted some very compelling strategic rationales that provide the foundation of our strong business case.

Firstly, our R&D pipeline of drug candidates is strategically designed and focused to address patients' needs during their Parkinson's journey, offering chronic symptomatic relief from the most troublesome of Parkinson's symptoms including dyskinesias, trips and falls, apathy and psychosis. Not only does this meet the severe unmet medical needs for the millions of patients living with Parkinson's, it also represents a very attractive pharmaceutical business case.

Secondly, our Phase IIa proof-of-concept data for mesdopetam and pirepemat provides encouraging safety and efficacy signals in Parkinson's patients.

Thirdly, our global license with Ipsen to develop and commercialize mesdopetam is a strong clinical and commercial validation of our business.

And of course last, but not least, is our deep and profound understanding of the biology of Parkinson's and other CNS disorders rooted in the Nobel Prize-winning research of Prof. Arvid Carlsson and his research group. This knowledge and expertise are harnessed in our proprietary ISP drug discovery platform that can discover truly unique drug candidate molecules with unique neuropharmacological activity to address the disease biology.

Going forward, I will concentrate on the strategic commercial, business development and financing aspects of IRLAB; and Nicholas Waters in his new role as EVP and Head of R&D will focus on the delivery of our pipeline programs. My priorities are to increase the awareness and visibility of IRLAB and our pipeline programs both in the Nordics and internationally and to focus our messaging on the potential significant patient benefits that our drug candidates offer to different stakeholders.

I have also been impressed with the way in which IRLAB has remained focused during the Covid-19 pandemic and its associated challenges. Solid progress was made during the second quarter in our Phase IIb clinical trial with mesdopetam in PD-LIDs. Levodopa-induced dyskinesias (LIDs) is a severely limiting treatment-related symptom affecting 30 percent of Parkinson's patients. We saw an uptick in the recruitment into the study and recently announced that we, in collaboration with Ipsen, have expanded the study from 140 to 154 patients and have opened additional sites in the US and Poland. It is most encouraging that interest in the study have remained high and consistent among investigators and patients given the imposed restrictions in many regions due to Covid-19. We look forward to reporting top-line data around the year-end.

Also during the quarter, in our Phase IIb, randomized and placebo-controlled study evaluating efficacy of pirepemat on falls frequency in Parkinson's patients, we continued to activate sites across Europe and screened and enrolled patients. We aim to report top-line data by the end of 2023.

The cash flow for the second quarter of 2022 was SEK –45 million; our balance sheet remains strong with a cash position of SEK 323 million at the end of the quarter.

In summary, I believe we are very well positioned as a biotech business with late-stage clinical assets, commercial validation and a strong pipeline – and increased awareness should deliver value growth to you, our shareholders. I look forward to meeting as many of you as possible at one or more of the several upcoming events during the fall such as the Q2 presentation and investor events. Do follow us on LinkedIn and check the website to keep updated on our events and activities.

Richard Godfrey, CEO, IRLAB

# Overview and strategic priorities

**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 the various stages of Parkinson's as they worsen over time throughout the patient's journey of neurodegeneration. Having a full range of effective disease management options for Parkinson's patients is regarded as essential by both the medical and patient communities – and at the same time potentially a blockbuster pharmaceutical business.**

Parkinson's is the most common primary neurodegenerative disease after Alzheimer's disease, and the number of affected persons is expected to rise as the world's population is ageing. At present, nearly nine million people have Parkinson's. By 2040, this figure is expected to double.

To meet this challenge, IRLAB has developed a unique, disruptive technology platform called ISP to discover new CNS drug candidates. Leveraging ISP is a major competitive advantage of IRLAB and increases both the pace of drug candidate discovery and probability of success. Based on advanced machine learning techniques, ISP first interrogates our extensive proprietary CNS pharmacology database and that informs our chemists on the optimal molecular design of potential drug candidates with the desired symptom correcting pharmacology or therapeutic effect.

Over the last eight years, the ISP technology platform has gained significant validation, discovering three drug candidates currently in clinical development, from Phase I-III, and two additional drug candidates pending Phase I development next year.

The company's current clinical candidates, mesdopetam (IRL790) and pirepemat (IRL752), both of which have successfully gone through Phase I safety and Phase IIa efficacy proof-of-concept studies, are now in Phase IIb trials. These drug candidates are intended to treat patients with some of the most challenging symptoms associated with Parkinson's – troublesome dyskinesias (PD-LIDs), psychosis (PD-P) and symptoms linked to cognitive decline, such as impaired balance and an increased risk of falls (PD-Falls). In addition, we are developing two preclinical drug candidates to address PD-cognitive impairment (IRL942) and PD-apathy (IRL757), earlier yet still debilitating symptoms of Parkinson's etiology.

Mesdopetam has already been successfully out-licensed to Ipsen, in addition to revenue, we believe this deal also brings further validation of the commercial value of our pipeline. Pirepemat and the preclinical candidates (IRL942 and IRL757) remain wholly-owned unencumbered assets of IRLAB and we retain full strategic autonomy to develop and / or commercialize these assets. It is anticipated that compelling clinical efficacy of these drug candidates for Parkinson's patients will make them attractive targets for the pharmaceutical industry and in turn yield substantial value for shareholders.

Therefore our strategic priorities are to:

1. Pursue the timely completion of the Phase IIb study of mesdopetam in PD-LIDs and pirepemat in PD-Falls
2. Progress IRL942 and IRL757 into Phase I clinical studies
3. Increase the awareness of IRLAB and our pipeline in the wider global pharmaceutical and financial markets

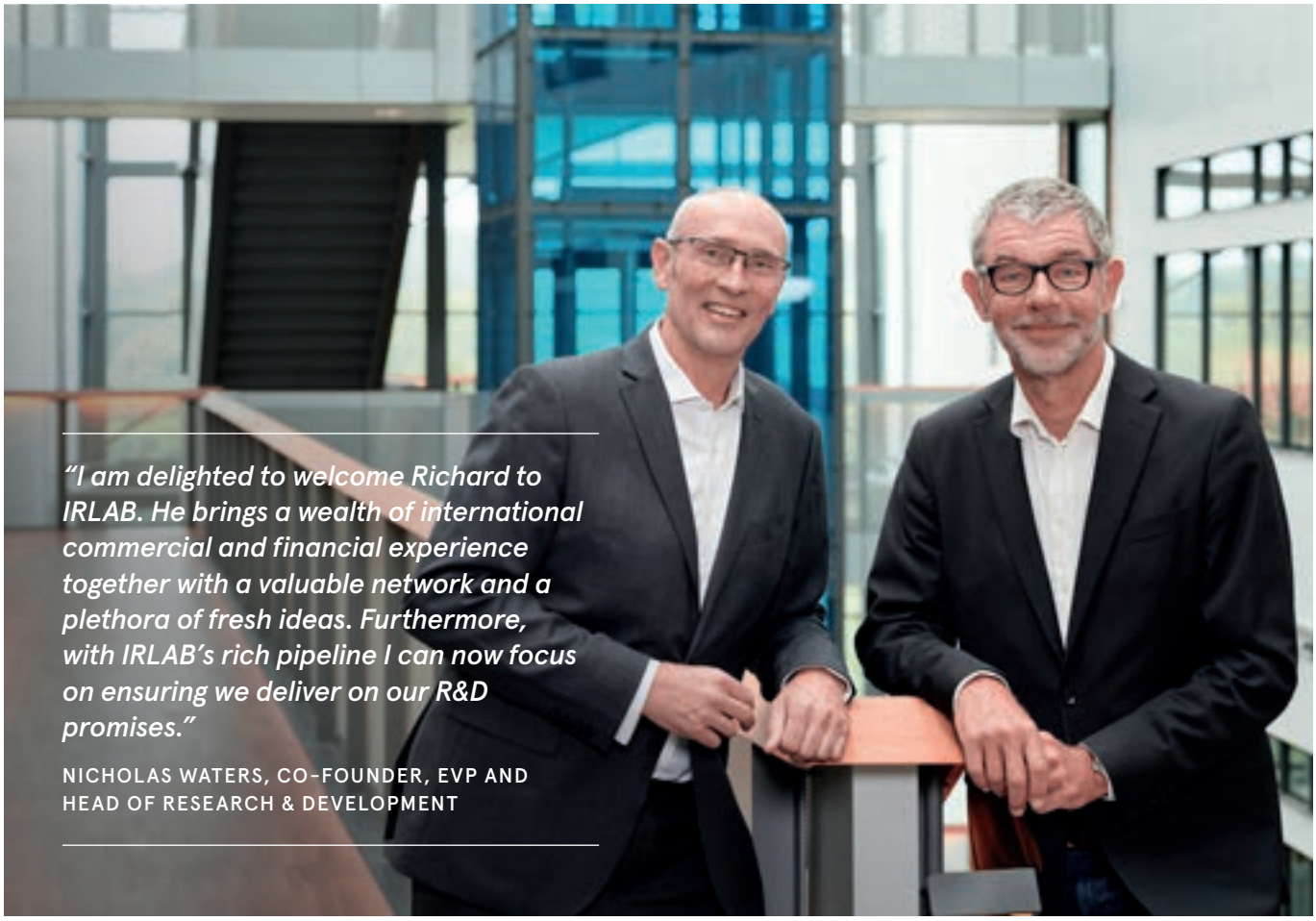
**IRLAB A**
**IRLAB has been listed on Nasdaq Stockholm's main list Mid Cap since 2020.**

# IRLAB's pipeline

## First-in-class drug candidates to treat symptoms of Parkinson's throughout the patient journey


PFC enhancer = noradrenaline and serotonin antagonists In the prefrontal cortex

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




# Update on R&D

**IRLAB's pipeline consists of drug candidates in clinical and preclinical development phases. It is focused on developing novel treatments for people with Parkinson's and other CNS disorders. All drug candidates have been generated by the company's proprietary technology platform, ISP.**

## Clinical phase

### Mesdopetam

Mesdopetam (IRL790) is a dopamine D3-receptor antagonist being developed to prevent and treat Parkinson's disease levodopa-induced dyskinesias (PD-LIDs), a severe form of troublesome dysjinesia (involuntary movements) commonly occurring in Parkinson's. In Phase IIa studies, mesdopetam has shown to reduce time spent with troublesome dyskinesia and thereby extend the daily time with good and controlled mobility in patients with Parkinson's, referred to as "good ON"-time.

Mesdopetam has a wide clinical potential for unmet medical needs in neurology. Firstly, the drug candidate is intended to treat people with Parkinson's who develop LIDs, which is more than 30 percent of all people living with Parkinson's. In the eight major markets worldwide, this equates to one million affected individuals. Mesdopetam also has potential in treating Parkinson's disease Psychosis (PD-P), which affects about 1.5 million people with Parkinson's across the eight major markets worldwide.

Following a successful Phase Ib study, a completed Phase IIa study with 75 patients demonstrated compelling proof-of-concept with potential for superior efficacy, improving daily hours of ON-time without troublesome dyskinesias, versus current treatment options.

*Ongoing Phase IIb study*

The Phase IIb study with mesdopetam is designed as a randomized, double-blinded and placebo-controlled study with the aim of evaluating the effects of mesdopetam or placebo in patients with Parkinson's affected by troublesome dyskinesias. The primary outcome measure is change in daily hours of ON-time without troublesome dyskinesia as assessed with 24-hour patient home diaries. The study is designed to randomize approximately 154 patients distributed across four groups, three dose levels of mesdopetam and a placebo group with approximately 38-39 patients in each group with a treatment period of three months. The study is conducted at 46 clinics and sites in Europe, Israel and in the US.

Patient enrollment is expected to be completed during the summer 2022, and thus, the last patient will complete treatment in late fall 2022. The study's top-line results are expected around the year-end, subsequent to database lock and data analyses. More information can be found on clinicaltrials.gov: NCT04435431 and EudraCT number: 2020-002010-41.

*Collaboration with Ipsen*

In 2021, exclusive global rights to the development and commercialization of the mesdopetam program was licensed to global

specialty pharma company Ipsen. IRLAB remains responsible for the ongoing Phase IIb study while Ipsen is responsible for Phase III preparatory activities as well as all remaining clinical development and worldwide commercialization.

### Pirepemat

Pirepemat (IRL752) is being developed to improve balance and reduce falls, and thus injuries from falls, in people living with Parkinson's. Falls are a significant consequence of Parkinson's that has severe complications, such as fractures, impaired mobility and a reduced quality of life. 45 percent of all people with Parkinson's fall recurrently, leading to a significantly reduced quality of life due to a fear of falling affecting their daily life. There are no available treatments at present despite it representing a great unmet medical need. The societal burden for falls is also significant with the cost of treatment for a fall injury in the US is estimated to be USD 30 thousand in people over the age of 65.

Pirepemat is designed to improve balance and reduce falls by strengthening nerve cell signalling in the prefrontal cortex via action at 5HT7 and alpha-2 receptors. Pirepemat also has potential as a treatment for dementia in Parkinson's disease (PD-D).

#### *Ongoing Phase IIb study*

Following successful completion of Phase I studies, an exploratory Phase IIa study was completed in 32 patients with advanced Parkinson's including cognitive impairment. Pirepemat was found well tolerated in this patient population. Compelling treatment effects were reported indicating improvement in balance and reduced risk of falling, in concert with cognitive and psychiatric benefits. These results suggest that pirepemat has the potential to strengthen the frontal cortical function and be a valuable, first-of-its-kind treatment to prevent falls in people living with Parkinson's.

The Phase IIb study with pirepemat is designed as a randomized, double-blind and placebo-controlled study with the aim to evaluate the effect of pirepemat on fall frequency in Parkinson's patients, as compared to a placebo, over a three-month treatment period. The study is designed to randomize 165 patients distributed across three groups with 55 patients respectively; two groups with different dose levels of pirepemat and one placebo group. The study is conducted at 39 European sites. Patient recruitment and enrollment in the study is ongoing and the top-line data is expected by the end of 2023. More information can be found on EudraCT number: 2019-002627-16 and clinicaltrials.gov: NCT05258071.

## Preclinical phase

### IRL942

Preclinical drug candidate IRL942 aims to improve cognitive function and brain health in people living with CNS disorders. There is about 12 percent of adults aged 65 years or more experiencing cognitive decline greatly affecting their quality of life.

Non-clinical development activities related to CMC and toxicology safety studies to prepare for submission to start Phase I studies are ongoing. The Phase I study is planned to begin in 2023, provided positive results from the preparatory studies and regulatory approvals are obtained.

### IRL757

IRL757 is in preclinical development and aims to treat apathy in neurological disorders. Apathy is a debilitating condition affecting over 10 million people in the US and EU respectively. The prevalence is high, occurring in 20–70 percent of people with Parkinson's and in 20–90 percent of people with Alzheimer's disease and other CNS disorders.

Non-clinical development activities related to CMC and toxicology safety studies to prepare for submission to start Phase I studies are ongoing. The Phase I study is planned to begin in 2023, provided positive results from the preparatory studies and regulatory approvals are obtained.

### P003

The P003 project is currently in discovery stage. The project aims to discover and develop a once-daily Parkinson's treatment without the complications associated with chronic levodopa treatment, that could replace levodopa as the treatment of the hallmark symptoms of Parkinson's, i.e., the next generation Parkinson's treatment. At present, lead optimization is ongoing for the 1st generation molecules and drug candidate identification through structural chemistry is ongoing for the 2nd generation. Nomination of a drug candidate is expected towards year-end 2022.

## Research technology platform ISP

IRLAB's pipeline is generated with the unique proprietary drug discovery platform Integrative Screening Process, called ISP, which has proven to enable discovery of truly novel first-in-class compounds. The ISP methodology combines systems biology screening models, an extensive database and modern machine learning analytical methods. This means that IRLAB obtains unique insights into the overall effect of the studied molecules at an early stage. The platform can at that stage already predict which drug candidates that have the greatest potential to be developed into a promising drug with the lowest risks, based on the biological fit. The ISP platform provides an improvement in probability of drug discovery success in translation between clinical phases, compared with industry standard.

This 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. New perspectives are also added through close cooperation with universities and academic researchers so that IRLAB can keep leading the development of cutting-edge technology.

# The group's performance January – June 2022

IRLAB Therapeutics AB 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. Generated by ISP, IRLAB's two promising drug candidates in preclinical development, IRL942 and IRL757, are currently in Phase I study preparation.

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

The research and development work has advanced according to plan. In the period January to June, the total costs for research and development were SEK 75,741 thousand (38,500), corresponding to 85 percent (83) of the group's total operating expenses. Development costs vary over time, depending on where in the development phase the projects are.

## Comments on the income statement

The loss for the period January 1 – June 30, 2022 was SEK –56,285 thousand (–46,670). Earnings per share were –1.09 SEK (–0.90). The group's revenue during the period was SEK 23,601 thousand (0).

Of the SEK 239.6 million that was received up-front in 2021 under the mesdopetam license agreement, SEK 185.3 million was recognized as license revenue and SEK 54.3 million was recognized as deferred income for the finalization of the ongoing Phase IIb study and will be recognized as income during 2022 in parallell with the study's completion. In the second quarter of 2022, SEK 13.368 million (0) was recognized as such income. Revenue for other services provided to Ipsen was SEK 10.042 million (0).

In the second quarter 2022, the group's operating expenses were SEK 50,616 thousand (26,520) of which SEK 10,042 thousand (0) were costs referring to services provided to Ipsen. The increase compared with the previous year was primarily due to increased clinical research activities and an increased organization.

## Financing and cash flow

Cash flow from operating activites were SEK –76,793 thousand (–45,800) during the first six months 2022 and SEK –44,010 thousand (–23,430) in the second quarter 2022. Cash and cash equivalents were SEK 322,615 thousand (229,383) on June 30, 2022. On June 30, 2022, equity was SEK 343,196 thousand (301,210) and the equity ratio was 87 percent (92).

The Board of Directors and CEO determines that there are sufficient cash and cash equivalents to cover working capital needs over the next twelve months, given the current business activities and financing plan.

## Investments

Investments for the period January 1 – June 30, 2022 were SEK 991 thousand (424). Investments mainly related to tools and machinery in the laboratories.

## Significant events January–March 2022

In March, new drug candidate IRL757 was nominated for the treatment of apathy in neurological diseases.

## Significant events April–June 2022

In April, know-how was acquired to support a strong patent application for chemical matter claims related to the P003 research project. The P003 project aims to offer a once-daily Parkinson's treatment without any complications.

In June, it was announced that the management team was strengthened by appointing Richard Godfrey as new CEO and Nicholas Waters as Executive Vice President and Head of Research & Development, effective July 1, 2022.

## Significant events after the end of the period

In July, it was reported that the Phase IIb PD-LIDs study with mesdopetam was expanded to include 154 patients, top-line data is anticipated around the year-end.

The share issue of 120,000 Class A shares relating to the acquisition of know-how related to the P003 discovery project was registered. After the registration in July, the total number of registered shares is 51,868,406 (51,748,406).

# Consolidated income statement in summary

| Amounts in SEK thousand | 2022 Apr–Jun | 2021 Apr–Jun | 2022 Jan–Jun | 2021 Jan–Jun | 2021 Jan–Dec |
|---|---|---|---|---|---|
| **Operating income** | | | | | |
| Net revenue | 23 410 | 0 | 32 452 | 0 | 207 782 |
| Other operating income | 191 | 0 | 278 | 0 | 124 |
| *Total income* | *23 601* | *0* | *32 730* | *0* | *207 906* |
| **Operating expenses** | | | | | |
| Other external costs | –39 461 | –18 084 | –66 673 | –31 302 | –81 737 |
| Personnel costs | –9 744 | –7 456 | –19 418 | –13 506 | –31 024 |
| Outlicensed capitalized developent projects | 0 | 0 | 0 | 0 | -39 091 |
| Depreciation of intangible and tangible fixed assets | –958 | –915 | –1 903 | –1 551 | –3 474 |
| Other operating cost | –454 | –66 | –839 | –128 | –4 |
| *Total operating expenses* | *–50 616* | *–26 520* | *–88 833* | *–46 487* | *–155 330* |
| **Operating result** | **–27 015** | **–26 520** | **–56 103** | **–46 487** | **52 576** |
| **Result from financial items** | | | | | |
| Financial income | 0 | 0 | 0 | 0 | 1 |
| Financial costs | –100 | –108 | –182 | –183 | –796 |
| *Total financial items* | *–100* | *–108* | *–182* | *–183* | *–795* |
| **Result after financial items** | **–27 115** | **–26 629** | **–56 285** | **–46 670** | **51 781** |
| Tax on income | 0 | 0 | 0 | 0 | 0 |
| **Result for the period** | **–27 115** | **–26 629** | **–56 285** | **–46 670** | **51 781** |
| Earnings per share before and after dilution (SEK) | –0.52 | –0.51 | –1.09 | –0.90 | 1.00 |
| Average number of shares, before and after dilution | 51 748 406 | 51 748 406 | 51 748 406 | 51 748 406 | 51 748 406 |

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

# Consolidated statement of comprehensive income in summary

| Amounts in SEK thousand | 2022 Apr–Jun | 2021 Apr–Jun | 2022 Jan–Jun | 2021 Jan–Jun | 2021 Jan–Dec |
|---|---|---|---|---|---|
| Result for the period | –27 115 | –26 629 | –56 285 | –46 670 | 51 781 |
| Other comprehensive income | 0 | 0 | 0 | 0 | 0 |
| **Total result for the period** | **–27 115** | **–26 629** | **–56 285** | **–46 470** | **51 781** |

# Consolidated statement of financial position in summary

| Amounts in SEK thousand | | 06/30/2022 | 06/30/2021 | 12/31/2021 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Fixed assets** | | | | |
| Intangible fixed assets | | 42 531 | 81 881 | 42 661 |
| Tangible fixed assets | | 7 566 | 9 857 | 8 348 |
| **Total fixed assets** | | **50 097** | **91 738** | **51 009** |
| **Current assets** | | | | |
| Short-term receivables | | 23 291 | 5 997 | 19 542 |
| Cash and cash equivalents | | 322 615 | 229 383 | 401 897 |
| **Total current assets** | | **345 906** | **235 381** | **421 440** |
| **TOTAL ASSETS** | | **396 003** | **327 119** | **472 449** |
| **EQUITY AND LIABILITIES** | | | | |
| **Equity** | Note 5 | | | |
| Share capital | | 1 035 | 1 035 | 1 035 |
| Other contributed capital | | 685 450 | 685 630 | 685 450 |
| Retained earnings incl. results for the period | | –343 289 | –385 455 | –287 004 |
| **Total equity** | | **343 196** | **301 210** | **399 481** |
| **Long-term liabilities** | | | | |
| Leasing debt | | 1 993 | 5 102 | 3 566 |
| **Total long-term liabilities** | | **1 993** | **5 102** | **3 566** |
| **Short-term liabilities** | | | | |
| Leasing debt | | 3 109 | 2 961 | 3 034 |
| Other liabilities | | 47 705 | 17 845 | 66 367 |
| **Total short-term liabilities** | | **50 814** | **20 806** | **69 402** |
| **TOTAL EQUITY AND LIABILITIES** | | **396 003** | **327 119** | **472 449** |

# 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, 2021** | **970** | **65** | **685 630** | **-338 785** | **347 880** |
| Total result for the period | | | | -46 670 | -46 670 |
| *Transactions with owners in their capacity as owners:* | | | | | |
| Rights issue | 65 | -65 | 0 | | 0 |
| **Equity June 30, 2021** | **1 035** | **0** | **685 630** | **-385 455** | **301 210** |
| Total result for the period | | | | 98 451 | 98 451 |
| *Transactions with owners in their capacity as owners:* | | | | | |
| Rights issue | | | | | |
| 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** |
| Total result for the period | | | | -56 285 | -56 285 |
| **Equity June 30, 2022** | **1 035** | **0** | **685 450** | **-343 289** | **343 196** |

# Consolidated statement of cash flows in summary

| Amounts in SEK thousand | 2022 Apr–Jun | 2021 Apr–Jun | 2022 Jan–Jun | 2021 Jan–Jun | 2021 Jan–Dec |
|---|---|---|---|---|---|
| **Operating activities** | | | | | |
| Operating result | –27 015 | –26 520 | –56 103 | –46 487 | 52 576 |
| Adjustment for items not included in the cash flow | 958 | 915 | 1 903 | 1 551 | 42 564 |
| Paid interest | –100 | –109 | –182 | –183 | –796 |
| **Cash flow from operating activities before changes in working capital** | **–26 157** | **–25 714** | **–54 382** | **–45 119** | **94 345** |
| **Cash flow from changes in working capital** | | | | | |
| Change in operating receivables | -6 875 | 113 | -3 749 | 734 | -12 811 |
| Change in operating liabilities | -10 978 | 2 171 | –18 662 | –1 415 | 47 107 |
| **Cash flow from operating activities** | **–44 010** | **–23 430** | **–76 793** | **–45 800** | **128 641** |
| **Investment activities** | | | | | |
| Acquisition of tangible fixed assets | –668 | –374 | –991 | –424 | –708 |
| **Cash flow from investment activities** | **–668** | **–374** | **–991** | **–424** | **–708** |
| **Financing activities** | | | | | |
| Amortization of financial liabilities, leasing debt | –754 | –718 | –1 499 | –1 402 | –2 865 |
| Issue of new shares | 0 | 0 | 0 | 0 | -180 |
| **Cash flow from financing activities** | **–754** | **–718** | **–1 499** | **- 1 402** | **–3 045** |
| **Cash flow for the period** | **–45 432** | **–24 522** | **–79 282** | **–47 626** | **124 888** |
| Cash and cash equivalents at the start of the period | 368 047 | 253 905 | 401 897 | 277 009 | 277 009 |
| **Cash and cash equivalents at the end of the period** | **322 615** | **229 383** | **322 615** | **229 383** | **401 897** |

# Parent company income statement in summary

| Amounts in SEK thousand | 2022 Apr–Jun | 2021 Apr–Jun | 2022 Jan–Jun | 2021 Jan–Jun | 2021 Jan–Dec |
|---|---|---|---|---|---|
| ***Operating income*** | | | | | |
| Net revenue | 877 | 994 | 1 771 | 1 792 | 4 059 |
| *Total income* | *877* | *994* | *1 771* | *1 792* | *4 059* |
| ***Operating expenses*** | | | | | |
| Other external costs | –3 292 | –2 563 | –6 275 | –4 662 | –16 805 |
| Personnel costs | –2 311 | –2 069 | –5 817 | –3 450 | –8 705 |
| *Total operating expenses* | *–5 603* | *–4 632* | *–12 092* | *–8 112* | *–25 510* |
| ***Operating result*** | ***–4 726*** | ***–3 637*** | ***–10 321*** | ***–6 320*** | ***–21 451*** |
| ***Result from financial items*** | | | | | |
| Interest costs | 0 | -1 | 0 | -1 | –3 |
| *Total financial items* | *0* | *–1* | *0* | *–1* | *–3* |
| ***Result after financial items*** | ***–4 726*** | ***–3 638*** | ***–10 321*** | ***–6 321*** | ***–21 454*** |
| Tax on the period's result | 0 | 0 | 0 | 0 | 0 |
| **Result for the perioden** | **–4 726** | **–3 638** | **–10 321** | **–6 321** | **–21 454** |

# Parent company statement of comprehensive income in summary

| Amounts in SEK thousand | 2022 Apr–Jun | 2021 Apr–Jun | 2022 Jan–Jun | 2021 Jan–Jun | 2021 Jan–Dec |
|---|---|---|---|---|---|
| Profit/loss for the period | –4 726 | –3 638 | –10 321 | –6 321 | –21 454 |
| Other comprehensive income | 0 | 0 | 0 | 0 | 0 |
| ***Comprehensive income for the period*** | ***–4 726*** | ***–3 638*** | ***–10 321*** | ***–6 321*** | ***–21 454*** |

# Parent company balance sheet in summary

| Amounts in SEK thousand | 2022-06-30 | 2021-06-30 | 2021-12-31 |
|---|---|---|---|
| **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 | 1 705 | 966 | 1 755 |
| Cash and cash equivalents | 102 692 | 128 256 | 112 970 |
| **Total current assets** | **104 397** | **129 222** | **114 725** |
| **TOTAL ASSETS** | **454 717** | **479 542** | **465 045** |
| **EQUITY AND LIABILITIES** | | | |
| **Equity** | | | |
| ***Restricted equity*** | | | |
| Share capital | 1 035 | 1 035 | 1 035 |
| | *1 035* | *1 035* | *1 035* |
| ***Unrestricted equity*** | | | |
| Share premium fund | 739 463 | 739 643 | 739 560 |
| Retained earnings including total result for the period | -290 569 | -265 114 | -280 345 |
| *Total Unrestricted equity* | *448 894* | *474 529* | *459 215* |
| **Total equity** | **449 929** | **475 564** | **460 250** |
| **Short-term liabilities** | | | |
| Other liabilities | 4 788 | 3 979 | 4 795 |
| **Total liabilities** | **4 788** | **3 979** | **4 795** |
| **TOTAL EQUITY AND LIABILITIES** | **454 717** | **479 542** | **465 045** |

# The parent company's statement of cash flows

| Amounts in SEK thousand | 2022 Apr–Jun | 2021 Apr–Jun | 2022 Jan–Jun | 2021 Jan–Jun | 2021 Jan–Dec |
|---|---|---|---|---|---|
| Cash flow from operating activities | -4 177 | 82 242 | –10 278 | –26 437 | –126 543 |
| Cash flow from investment activities | 0 | –85 000 | 0 | –85 000 | 0 |
| Cash flow from financial activities | 0 | 0 | 0 | 0 | -180 |
| **Cash flow for the period** | **–4 177** | **–2 758** | **–10 278** | **–111 437** | **126 723** |
| Cash and cash equivalents at the start of the period | 106 870 | 131 013 | 112 970 | 239 693 | 239 693 |
| **Cash and cash equivalents at the end of the period** | **102 692** | **128 256** | **102 692** | **128 256** | **112 970** |

# Key financial ratios for the group

| | 2022 Jan-Jun | 2021 Jan-Jun | 2021 Jan-Dec | 2020 Jan-Dec | 2019 Jan-Dec |
|---|---|---|---|---|---|
| Net sales | 32 452 | 0 | 207 782 | 0 | 26 |
| Operating result, TSEK | -56 103 | -46 487 | 52 576 | -91 458 | -95 848 |
| Result for the period, TSEK | -56 285 | -46 670 | 51 781 | -91 653 | -96 120 |
| Earnings per share before and after dilution, SEK | -1,09 | -0.90 | 1,00 | -1.92 | -2.37 |
| R&D costs, TSEK | 75 741 | 38 500 | 129 748 | 75 989 | 79 381 |
| R&D costs as a percentage of operating costs, % | 85 | 83 | 84 | 83 | 82 |
| Cash and cash equivalents at the end of the period, TSEK | 322 615 | 229 383 | 401 897 | 277 009 | 110 527 |
| Cash flow from operating activities, TSEK | -76 793 | -45 800 | 128 641 | -89 214 | -91 201 |
| Cash flow for the period, TSEK | -79 282 | -47 626 | 124 888 | 166 482 | -23 915 |
| Equity, TSEK | 343 196 | 301 210 | 271 999 | 347 880 | 181 827 |
| Equity per share, SEK | 6,63 | 5.82 | 7,72 | 6.72 | 4.22 |
| Equity ratio, % | 87 | 92 | 85 | 94 | 87 |
| Average number of employees | 27 | 20 | 22 | 18 | 17 |
| Average number of employees in R&D | 24 | 18 | 20 | 17 | 16 |

Of the above key financial ratios, only the key ratio Earnings per share before and after dilution, and R&D costs, are defined in accordance with IFRS. Of the other key financial ratios, Result for the period, Liquid assets at the end of the period, Cash flow from operating activities, Cash flow for the period, and Equity are drawn from from a financial statement defined by IFRS. For the derivation of key financial ratios, as well as definitions and justifications for the selected key financial ratios, please refer to IRLAB Therapeutics AB (publ) annual report 2021.

# 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 2021 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 1,034,968 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.

## 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 corres-ponded 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 328,806 thousand (229,593).

## 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.

## Revenue in Q2

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. At present, the primary revenue is related to the licensing agreement with specialty pharma Ipsen for the global exclusive development and commercialization rights to drug candidate mesdopetam.

| Net sales by revenue category | 2022 Jan–Jun | 2021 Jan–Jun | 2021 Jan–Dec |
|---|---|---|---|
| Licensing revenue | 20 223 | 0 | 185 261 |
| Service revenue | 12 229 | 0 | 22 521 |
| **Total revenue** | **32 452** | **0** | **207 782** |

## Segment information

| Net sales by geographic market | 2022 Jan–Jun | 2021 Jan–Jun | 2021 Jan–Dec |
|---|---|---|---|
| Sweden | 0 | 0 | 0 |
| United Kingdom | 32 452 | 0 | 207 782 |
| **Total revenue** | **32 452** | **0** | **207 782** |

All invoicing was in EUR. 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 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.

To date, the global Covid-19 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. 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.

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 pos-sibility 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.

## Nomination Committee

Prior to the 2022 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 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, 2022.

## Employees

The average number of employees in the group from April–June was 28 (21). At the end of the period, the number of full-time positions was 28 (22), distributed over 31 (25) people.

The number of full-time positions, including long-term contracted consultants, was 32 (27) at the end of the period, distributed over 36 (32) 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 2022 – November 9, 2022.
Year-end report 2022 – February 23, 2023.

# Glossary

| | |
|---|---|
| **Dyskinesias** | 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-Falls** | 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. |
| **CNS disorders** | Central nervous system (CNS) disease is a broad category of conditions in which the brain does not function as it should, limiting health and the ability to function. |

## Presentation to investors and media

A presentation will be held on August 24, 2022, at 10:00 CET at the Infront Direkt Studio, Kungsgatan 33, in Stockholm. CEO Richard Godfrey, EVP and Head of R&D Nicholas Waters and CFO Viktor Siewertz will comment the interim report for the period January-June 2022. The presentation will be held in English and followed by a Q&A session.

To attend in-person, please register via email to ir@irlab.se.

It is also possible to follow the presentation online on: https://youtu.be/NHxs1EViwIM

## 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 24, 2022

GUNNAR OLSSON
Chair of the Board

CAROLA LEMNE
Vice Chairperson

REIN PIIR
Board member

AN VAN ES-JOHANSSON
Board member

CATHARINA GUSTAFSSON WALLICH
Board member

RICHARD GODFREY
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 IRL757 in development for Phase I studies.

# Contact information


FOR FURTHER INFORMATION, PLEASE CONTACT

Richard Godfrey, CEO
+46 730 70 69 00
richard.godfrey@irlab.se

Viktor Siewertz, CFO
+46 727 10 70 70
viktor.siewertz@irlab.se

HEAD OFFICE

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