

"Cases of Parkinson's disease are increasing as more and more people are getting older, worldwide. We want to offer a better future with a high quality of life for everyone affected by Parkinson's."



IRLAB THERAPEUTICS AB (PUBL)

Annual Report

2020

Calendar

6

Annual general meeting 2021:
May 6, 2021

25

Interim report
April – June 2021:
August 25, 2021

10

Interim report July – September 2021:
November 10, 2021

6

Interim report
Januari – March 2021:
May 6, 2021

23

Year-end report 2021:
February 23, 2022

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“It has been an unusual year, characterized by the pandemic and remote working. We have quickly adapted the business and established new ways to collaborate effectively, and consequently we are taking part in the annual report with selfies. During the year, the work was guided by a clear vision where we met important milestones, such as the launch of studies with mesdopetam in the US. We have worked to broaden the clinical and commercial potential of our drug candidates, and have also identified several new indications for mesdopetam during 2020. A number of new qualified employees have also joined us, with the aim of strengthening the transition to a commercial phase.”

NICHOLAS WATERS, CHIEF EXECUTIVE OFFICER (CEO)



IRLAB in brief

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

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

Phase IIb/III: Mesdopetam Pirepemat

9 million

At present, nearly nine million people have Parkinson’s, by 2040 this is expected to have doubled. It is not known exactly what causes Parkinson’s. There is currently no way to prevent the onset or slow down the development of the disease.

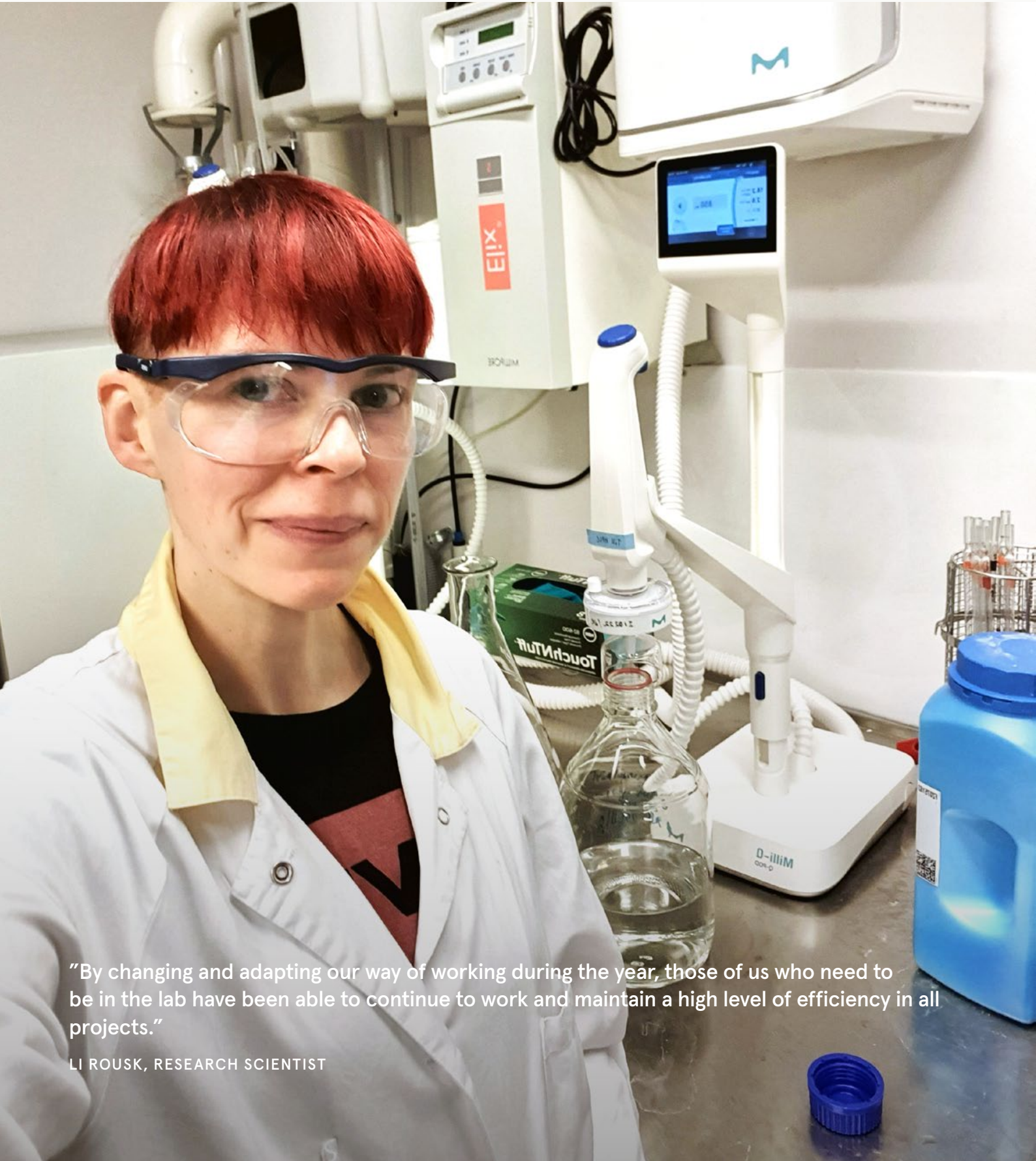
IRLAB A

Listed on Nasdaq Stockholm’s Main Market under the ticker IRLAB A.

Integrative
Screening
Process

ISP

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



“By changing and adapting our way of working during the year, those of us who need to be in the lab have been able to continue to work and maintain a high level of efficiency in all projects.”

LI ROUSK, RESEARCH SCIENTIST

The operations

IRLAB is a Swedish research and development company that develops novel drugs for the treatment of Parkinson’s disease with the aim of transforming the lives of those affected and their families. The clinical development portfolio today consists of two drug candidates; mesdopetam in an ongoing Phase IIb/III study and pirepemat that is being prepared to start a Phase IIb study. Preparations for Phase III studies are ongoing in parallel.

Parkinson’s is the second most common neurological disease after Alzheimer’s disease and is growing rapidly due to an aging population. The treatment alternatives are few and the unmet medical needs are huge.

Two drug candidates in clinical phase

The company’s clinical drug candidates have so far undergone full development programs up to and including Phase IIa studies. The study results show clear efficacy on symptoms that previously have not been possible to effectively treat in patients with Parkinson’s.

Troublesome dyskinesias in Parkinson’s occur after long-term treatment with levodopa, a drug all patients with Parkinson’s are treated with. The troublesome dyskinesias that can occur up to 6 hours a day are linked to overactivity of the dopamine D3 receptor in the brain – a target that mesdopetam inhibits. In the initial clinical studies, mesdopetam significantly improves the daily time during which the levodopa treatment alleviates the cardinal symptoms, so-called “good ON”-time, by reducing the time patients’ experience troublesome dyskinesias. This gives a significantly improved quality of life.

Newly published preclinical results show that mesdopetam has the potential to also prevent the development of dyskinesias. This discovery could lead to many more patients benefiting from treatment with mesdopetam.

The Phase IIa study of pirepemat in patients with Parkinson’s and dementia indicated improved balance and reduced risk of falls. The results are well in line with the hypothesis that pirepemat will improve balance and cognitive symptoms by strengthening nerve activity in the frontal

parts of the cerebral cortex and subsequently reduce the risk of falls.

In the autumn of 2020, an international Phase IIb/III study with mesdopetam was initiated. IRLAB also plans to start a Phase IIb study with pirepemat. These studies in a larger group of patients aim to confirm the dose and the efficacy that previous studies have demonstrated, as another step in the process toward marketing authorization.

In addition to the two clinical drug candidates, there is a strong pipeline of preclinical drug candidates generated with IRLAB’s proprietary research platform; Integrative Screening Process (ISP).

The ISP research platform

IRLAB’s ISP platform is based on a unique combination of a systems biology approach and effective machine learning methods. This means that the evaluation of the potential of different substances takes into account holistic effects and the interaction that takes place in the brain when controlling movements and emotions. This differs from focusing primarily on individual mechanisms, so-called “target-based discovery”, which is the dominant method in industry at present. With ISP, IRLAB can discover drug candidates with new mechanisms that have unique systems biology effects, and which would not be possible to detect with traditional methodology. The ISP platform also entails a greatly improved cost efficiency as it can predict which molecules could successfully transition through development phase with a high probability.

Changing the lives of patients with Parkinson’s

An article recently published in *The BMJ* identified ten prioritized areas in the management of Parkinson’s. These included treatment of motor complications, such as levodopa-induced dyskinesias (LIDs), non-motor symptoms, such as psychosis and anxiety, and impaired balance and falls, as well as cognitive impairment. This highlights major clinical needs and the difference IRLAB’s drug candidates can potentially make for patients.

Year of 2020

Study start with mesdopetam

The Phase IIb/III clinical study to evaluate mesdopetam in patients with levodopa-induced dyskinesias in Parkinson’s is ongoing in both Europe and the US. The aim of the study is to show that mesdopetam reduces dyskinesias and thus increases the time of day when the patient experiences good mobility, which is the goal of all Parkinson’s treatments. The study includes 140 patients and initial study results are expected during the first half of 2022.

Prevent, not just treat, dyskinesias

Results from preclinical studies with mesdopetam carried out in 2020 indicate that mesdopetam can, in addition to treating already developed dyskinesias, also be used to prevent them. This needs to be confirmed in clinical studies and may mean that mesdopetam could help in slowing the progression of disease symptoms, which has long been a highly sought-after goal in the treatment of Parkinson’s. This could lead to an increase in the number of Parkinson’s patients treated with mesdopetam as well as the length of treatment, which could lead to a significantly greater market potential for the compound.

Listing on Nasdaq Stockholm’s Main Market

IRLAB’s share was traded for the first day on Nasdaq Stockholm’s Main Market on September 30, 2020, and has since been traded in the MidCap segment.

Two clinical candidates first-in-class

During the year, the WHO concluded that both mesdopetam and pirepemat are completely unique in their mechanisms of action, and have therefore assigned both unique generic names, International Nonproprietary Name (INN), that may mark two wholly new substance classes in the existing classification system. This would mean that both candidates are first-in-class substances.

Strengthened financial position

After raising capital in 2020, IRLAB has a strong cash position, which primarily provides an opportunity to increase resources in clinical studies and expedite the important preparatory work for Phase III studies, with the aim of minimizing the time to regulatory approval and launch.

Leading in technology development

IRLAB leads the technology development in systems biology-based drug discovery in the CNS area with modern artificial intelligence (AI) based methods. The goal is to develop new and better drugs, while at the same time strengthening the company’s competitive advantage through a successful combination of IRLAB’s systems biology ISP database and advanced AI-based calculations. In collaboration with experts and scientific advisors, the company continues to upgrade the ISP research platform.

Financial overview

All figures refer to the group	2020	2019	2018	2017
Operating result, tSEK	-91 458	-95 848	-73 897	-54 218
Result for the year, tSEK	-91 653	-96 120	-74 099	-56 225
Earnings per share before and after dilution, SEK	-1,92	-2,37	-1,94	-1,67
Cash and cash equivalents, tSEK	277 009	110 527	134 442	74 709
Equity per share, SEK	6,72	4,22	5,25	4,43
Solidity, %	94	87	94	95
Average number of employees	18	17	15	12
of which are within R&D	17	16	14	11



Conversation between the CEO and board members

Nicholas Waters, Gunnar Olsson and Carola Lemne talk about IRLAB’s research, development projects and future to improve the lives of those with Parkinson’s disease.

If you were to summarize, how was 2020 for IRLAB?

– **Nicholas Waters (NW):** An intense year with many important milestones that will add value to our projects, IRLAB and our owners. One highlight was the approved IND and launching the Phase IIb/III clinical trial with mesdopetam. The first patients began treatment as early as the end of 2020. We were also delighted with the new preclinical results which indicate that mesdopetam can slow down the development of Parkinson’s symptoms, which has long been a highly sought-after goal. From a commercial perspective, the new patent applications, for both mesdopetam and pirepemat, are very important as they increase the potential of our drug candidates.

The listing on Nasdaq Stockholm’s Main Market and well-executed financing during the year create prerequisites for us to broaden the clinical work with the aim of minimizing the time to launch approved drugs. We have worked intensively to expand our capacity within communication and administration, and to attract new expertise in clinical development and research, based on our unique ISP platform.

– **Gunnar Olsson (GO):** Despite the pandemic and its effects, the year has, as Nicholas mentions, offered many positive and impressive results. What I think is most important is an accepted IND for mesdopetam in the US, i.e. FDA approval to conduct a clinical study in the US, and the subsequent start of the Phase IIb/III study. Furthermore, successful financing of the operations and promotion to Nasdaq Stockholm’s Main Market has also contributed to, to say the least, an exciting year.

– **Carola Lemne (CL):** Yes, it really has been a year with both a great deal of hard work, and many great

achievements. Just as Nicholas and Gunnar say, our projects have moved forward in a decisive way, and the fact that the uniqueness of our drug candidates has been noticed by many external players is something I would like to highlight a little extra. Add to this that we have managed the challenge of covid-19 in a good way, and also made successful rounds of financing, one can conclude that it has not exactly been a standard year!

It has been just over a year since the covid-19 pandemic began, how would you say IRLAB has handled this and how have you been affected during this time?

– **CL:** The pandemic has been a challenge on two different levels – both internally within IRLAB, and our external activities. When it comes to the internal situation, this has been handled very well – the employees have adapted very professionally to the situation, and the work has not suffered. However, it has required a significant effort – it has been intense! When it comes to the external activities, this has worked better than one might have expected, but we have certainly noticed that certain things have taken longer than usual. How this unfolds in the future is difficult to say – unfortunately, it seems there are delays with vaccinations etc. around the world.

– **GO:** My assessment is that the company has handled the situation exemplary. Very quickly, the working methods switched to digital solutions with working from home, video meetings, email and telephone. Our goals for the year were able to be delivered thanks to the quick and efficient adjustment of all our employees. It has been impressive to follow.

– **NW:** I agree with Carola and Gunnar that we have managed to handle the situation in a good way. We have

Samtal mellan VD och styrelseledamöter

continuously adapted to the effects of the pandemic on our industry, the burden on the pharmaceutical authorities, and the patients’ situation. Despite the external circumstances, we have organized and carried out our goal-oriented work without any major impact during the year.

An expressed goal of the 2020 capital raising has been to expedite the preparations for Phase III studies of the drug candidates mesdopetam and pirepemat and to grow the company. How is this implemented in practice, especially with regard to the pandemic?

– **GO:** The ongoing pandemic has presented us with a new situation – regulatory authorities have, for obvious reasons, had a strong focus on covid-19, and hospital clinics’ procedures are changing as a result of heavy workload due to covid-19-related healthcare. Taken together, this affects all companies that carry out drug development for medical conditions that are not directly linked to covid-19. At IRLAB, we have focused on what we can do to ensure the implementation of the ongoing study with mesdopetam, which includes an expansion of participating hospitals. In parallel, the best implementation plan for the intended Phase IIb study with pirepemat is being discussed to ensure sufficient patient recruitment so that conclusive results come out of the study.

– **NW:** As Gunnar says, we have, together with our partners in regulatory affairs, clinical development, and production and distribution of drug substances, drawn up plans to adapt as effectively as possible to the effects of the pandemic on healthcare systems in the countries where we are working on the mesdopetam study. We have now engaged more clinics so that we can control recruitment during what we all hope will be the final phase of the pandemic.

How does IRLAB differentiate itself from competitors – and other drug development companies? Is there a clear strategy for this?

– **NW:** Basically, what differentiates us from others is our leading role in technology development and our systems-biological research methodology, ISP, which delivers new and potentially very effective drug candidates. During the year, we have had this confirmed by our study results being highlighted in highly ranked journals, by independent research groups, and by WHO-INN recommending the creation of completely new drug classes for both mesdopetam and pirepemat. This is the result of long-term focused work, and our strategy to use ISP to develop drug candidates with better efficacy and fewer side effects than competing drugs, or, perhaps better yet, to be able to treat diseases and symptoms where there is currently no treatment.

– **GO:** One of IRLAB’s biggest differentiations from other companies in the industry – and strength – is that we use our own ISP platform to generate new drug candidates. ISP is a so-called systems biological screening method supported by computerized selection criteria (artificial intelligence). Through this approach for finding new molecules as drug candidates, we have greatly improved the possibility to choose molecules that really give the expected effect in patients. This strategy has been very successful – both mesdopetam and pirepemat, both of which have shown beneficial effects in Phase IIa clinical studies, have been generated by IRLAB with the ISP. It is here we differ significantly in relation to the vast majority of other companies that still only use so-called target-based screening.

– **CL:** I quite agree that it is our unique ISP platform and the benefits it provides when it comes to producing unique substances that differentiate us. The fact our first two substances both represent completely new drug classes, and have a very favorable tolerability and efficacy profile is solid proof of that.

What is the most important thing for IRLAB in 2021 in order to continue to deliver on the long-term vision to take the first-in-class drug candidates towards market approval?

– **GO:** In 2021, it is important that we can carry out the Phase IIb/III study with mesdopetam – despite the ongoing pandemic. We also see a need to update the project strategy for this substance as we have just received experimental data which suggest that mesdopetam not only can be used to treat, but also to prevent the troublesome levodopa-induced dyskinesias which a large proportion of patients suffer from. This means both that the number of patients in need of treatment can increase considerably and that individual patients can receive the treatment for a significantly longer period of time. It is important that we study this further in order to be able to help all the patients who can benefit from treatment with mesdopetam.

a whole, and it is important that we match that development by replenishing and further strengthening all relevant expertise. This is another important focus for the year.

How do you intend IRLAB to look in a year, compared to today?

– **NW:** Our goals are clear; the company is currently in an important transition phase towards commercialization. The organization needs to grow with additional key expertise. We are approaching the important steps into Phase III studies, and activities for market preparation are ongoing.

Despite the pandemic and its effects, the year has offered many positive and impressive results. What I think is most important is an accepted IND for mesdopetam in the US, i.e. FDA approval to conduct a clinical study in the US, and the subsequent start of the Phase IIb/III study.

– **NW:** We are also working intensively on broadening the clinical and commercial potential of our drug candidates, and during the year have identified several new possible indications for mesdopetam, which may result in greater use than previous forecasts. Gunnar mentions the possibility that mesdopetam can prevent the onset of severe symptoms in Parkinson’s disease. Another interesting possibility is that mesdopetam may have potential in cases of tardive dyskinesia, which is a serious complication in more than three million patients who are chronically treated with antipsychotics.

– **CL:** Moving forward, it is important to be fully focused on carrying out the intended studies professionally and to work on developing new substances, at the same time as we also need to continuously review which expertise we need in the company. We are in a very exciting development phase for both our projects, and the company as

– **GO:** Our goal is to have results available to be able to enter Phase III studies with mesdopetam. We will prepare different scenarios – so that, together with a partner or by ourselves, we can initiate the last part of the drug documentation. In a year, we expect the Phase IIb study with pirepemat will be ongoing and preparations for Phase III trials will be progressing. We also expect to have our third drug candidate in a Phase I clinical study. It will definitely be an exciting year!

– **CL:** I really want to emphasize what Nicholas is saying – we are in an exciting transition phase, and I think the year will include some crucial milestones along the way. We must not lose focus on carrying out the clinical studies in the best possible way, but at the same time we have to broaden our commitment in all aspects of the future commercialization. A challenge – but also very motivating!

IRLAB’s vision to deliver strong growth



Goals & Strategy

IRLAB’s strength is in discovering new drug candidates with the help of ISP and developing them to so-called clinical “Proof of Concept” when clear indications of efficacy, tolerability and safety are achieved. IRLAB’s business model, competence and experience are designed to utilize this strength. By developing innovative drugs, IRLAB helps patients to a better life, which is a great benefit to society. This will, over time, lead to substantial value creation for our shareholders.

Two routes to shareholder value

IRLAB’s business model has the potential to generate revenue by licensing drug candidates and by entering into collaborations based on the ISP platform.

Drug candidates

IRLAB’s drug candidates can provide shareholder value through licensing/partnership or sale of projects. Revenue is then received in the form of a payment when signing an agreement, milestone payments, and royalties. IRLAB’s main focus is to develop unique drug candidates up to and including Phase II studies and achieve clinical “Proof of Concept”. After that, collaboration agreements will be entered into for further development in Phase III, primarily through license agreements with licensees who have the necessary resources to complete development and to market the drug after regulatory approval.

The ISP research platform

In preclinical research, the ISP platform can be used in collaboration with other pharmaceutical companies. It creates opportunities for revenue in the form of market cooperation agreements, as well as milestone payments and royalties on the products that the partner chooses to develop. IRLAB’s current strategy is to utilize the internal resources in order to develop its own drug candidates and thereby maximize the value in these. ISP has high precision and is resource and cost efficient, which means that only development of molecules with very good prerequisites for success takes place. To the extent that the company believes that there are additional resources within the

framework of the ISP, these can be offered to external parties.

What does IRLAB need to succeed?

Competent employees

Well-educated and motivated personnel is a prerequisite for conducting research and development activities in the best possible manner. IRLAB needs to maintain a high level of qualifications of employees and external consultants.

Well-planned clinical development

Successful studies are necessary in order to move forward with the company’s drug candidates. Good prerequisites for this are created through careful and detailed work on development plans and design of studies, which are validated together with area experts and through interactions with regulatory pharmaceutical authorities.

Innovative research

IRLAB needs to promote continuous development of knowledge and methodology around the company’s research platform, ISP. IRLAB’s drug candidates have originated from ISP, and it is important to continuously develop the method in order to maintain a continued high level of innovation in the creation of the company’s future pipeline.

Effective collaboration

Good relations with partners and external expertise are needed to be able to effectively carry out the company’s research and development, as well as strategic and

“We work according to an IR strategy that stands for consistent messages with the goal of allowing shareholders to get to know the company and those who work here. We strive to maintain an open dialogue with our shareholders and market players by communicating newsworthy events, and with ‘softer updates’ in the form of financial reports and investor meetings.”

TOVE BERGENHOLT, WORKS WITH IRLAB’S IR (MSC NORDICS)



Goals & Strategy

operational activities. By using the best partner or area expert for each important area, IRLAB can obtain the best prerequisites.

Strong IP protection

IRLAB works continuously to protect the company’s technologies and innovations. This is done through continuous work in processes aimed at protecting the intellectual property rights of the ISP platform and the company’s drug candidates.

Optimized organization

In order to create the best prerequisites for developing new treatments for Parkinson’s patients, IRLAB needs to maintain continuous focus on constantly optimizing the organization with regard to effectiveness, quality and flexibility.

Strong financial position

IRLAB needs to constantly work with the capital structure to secure development of the company’s projects and pipeline. This also entails managing budget and costs responsibly in order to best manage shareholders’ trust.

What?

IRLAB strives to meet the need for novel drugs for the treatment of diseases of the central nervous system, with a focus on Parkinson’s disease.

IRLAB wants to transform the lives of patients with Parkinson’s disease. The goal is to give patients the possibility of more time without troublesome symptoms and consequently increased quality of life.

Why?

“IRLAB is a research company without regular income, and we have a responsibility to the shareholders to ensure that the company continually has sufficient funding to be able to conduct its operations in an efficient and rational manner. We are also at the beginning of two Phase IIb studies with mesdopetam and pirepemat, which will entail quite significant costs, for which we secured full funding during 2020.”

VIKTOR SIEWERTZ, CHIEF FINANCIAL OFFICER (CFO)



Financing

IRLAB is a research and development company with no regular income. The company is primarily financed via the capital market or through future out-licensing or sales of projects. The financing strategy is to continuously ensure that the company is sufficiently financed via the capital market to be able to operate the business efficiently and make rational business decisions, for example to enter into agreements on out-licensing or sales once clinical “Proof of Concept” has been achieved. Activities to obtain financing via the capital market are ongoing in parallel and in interaction with processes to be able to enter into agreements on out-licensing or sales.

Viktor Siewertz, CFO, on the work with the company’s financing and listing on Nasdaq Stockholm’s Main Market:

IRLAB moved to NASDAQ Stockholm Main Market in September 2020, how has this affected the business?

– Our main activity, to discover and develop drug candidates, has of course not been affected in any significant way. On the other hand, we have established an internal control structure that is considerably more formalized than previously, where our long-term strategy forms the basis and we set goals in the short and long term. We subsequently assess the risks we see in the business that may affect achievement of our goals. Finally, we have continuous monitoring and reporting structures to ensure the management team and the Board of Directors have control of the operations and the risks associated with them. I believe that the quality of corporate governance has improved significantly through this, and we now have the possibility to intercept any problems and risks in order to be able to remedy them in a better way. The division of work between the Board of Directors and management team has also become clearer, and with new and more distinct interfaces for information between the different aspects of the company, the work can be conducted more efficiently.

In 2020, we saw two capital raising instances, where a total of MSEK 345 was generated, can you comment on the idea behind the two instances?

– IRLAB is a research company without regular revenue, and we have a responsibility to ensure that we continuously have sufficient funding to be able to operate our business in an efficient and rational manner. We are also at the beginning of two Phase IIb studies with mesdopetam and pirepemat, which will entail quite significant costs. It is important that these studies are fully funded before they begin, so as not to jeopardize their completion. Prior to any future discussions with potential buyers or licensees of our projects, it is also important to be able to show that we have a strong financial position and the ability to raise capital that places us in a good negotiation position. For the shareholders, it is therefore important to ensure that we are financially strong, while, of course, a balance must always be struck against dilution and the needs of the business.

How does IRLAB work at present to secure the company’s continued capital need?

– We have always been clear that we work in parallel with both discussions about licensing and financing via the capital market. It is important for us not to be too dependent on one or the other alternative, it is also important to ensure that the decisions on how we want to operate the company further lie in our own hands. Processes therefore constantly take place in parallel with discussions and disclosures to both potential buyers/licensees of our projects and institutional investors.

“I believe that the quality of the corporate governance has been strengthened through the improved internal control, and that we now have the opportunity to capture possible risks at an early stage in order to be able to redress them in a better way.”

VIKTOR SIEWERTZ, CHIEF FINANCIAL OFFICER (CFO)



Financing

345

In 2020, three capital raisings were registered where shares of a total of MSEK 345 was generated.

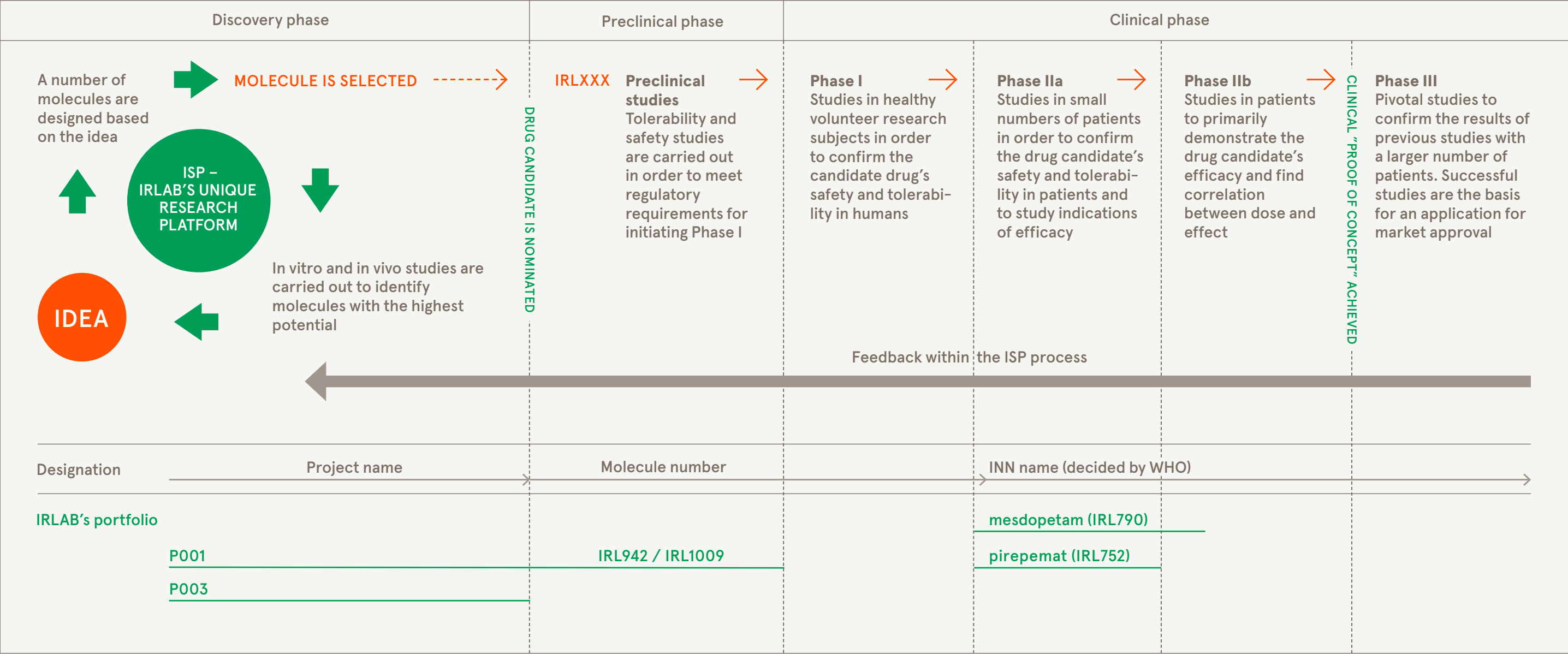
The Phase IIb studies are fully financed before study start.

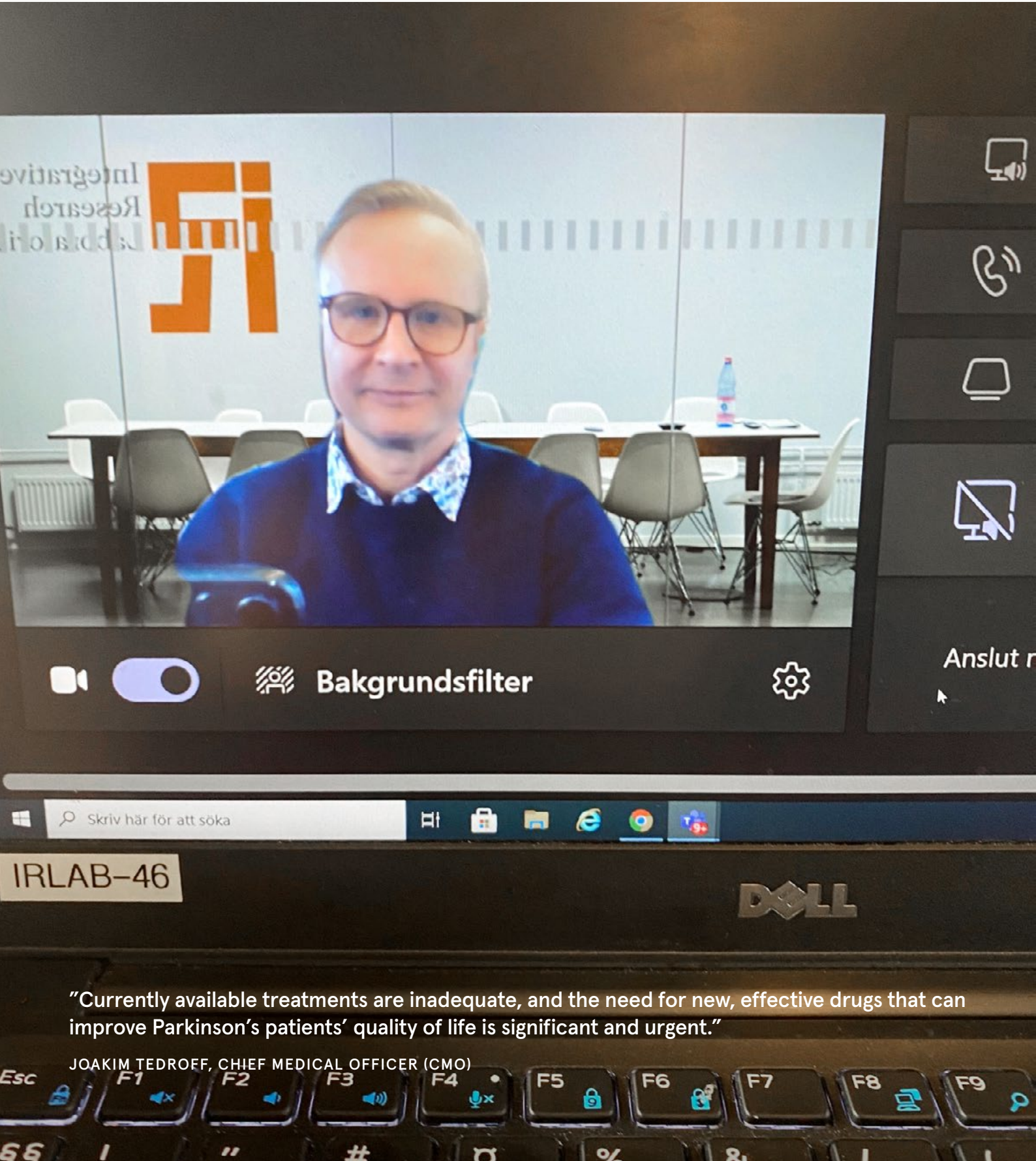
Phase IIb

In a licensing agreement, the following revenue generally arises:

- Remuneration when signing agreements
- A number of one-off payments when certain development phases, milestones, have been achieved, such as the initiation of Phase III studies, regulatory applications, marketing approval, and first sales in various markets
- Royalties on drug sales (following marketing approval of new drug)

Drug development is complex and the road to approval of a new drug can be perplexing. There is no single route forward, but rather many possibilities where, among other things, aspects such as chemical structure, mechanisms of action, analytical methods and regulatory requirements govern. The illustration below shows IRLAB’s vision of the development process and where IRLAB’s project is in this process.





“Currently available treatments are inadequate, and the need for new, effective drugs that can improve Parkinson’s patients’ quality of life is significant and urgent.”

JOAKIM TEDROFF, CHIEF MEDICAL OFFICER (CMO)

Parkinson’s disease

Parkinson’s disease is the second most common neurodegenerative disease after Alzheimer’s disease. Globally, it is believed nearly nine million people are living with the disease, and that the number will more than double by 2040. Today’s available treatments are insufficient and the need for new, effective drugs that can improve the quality of life of Parkinson’s patients is significant and urgent.

Parkinson’s disease is a neurological disease, which means that nerve cells that use the neurotransmitter dopamine slowly disappear and cause a reduced level of dopamine in the brain. Parkinson’s develops slowly and is not normally diagnosed until close to 80 percent of the dopamine cells have disappeared. The disease is both chronic and progressive, in other words, it is both lifelong and worsens over time. Parkinson’s symptoms usually appear after the age of 60 but can also affect younger people. It is not known exactly what causes the disease, and at present there is no way to prevent its onset or slow its development.

Motor and non-motor symptoms

Parkinson’s is associated with characteristic motor symptoms, such as tremors, muscle stiffness, mobility impairment and balance problems (so-called postural dysfunction). These symptoms result in difficulty in walking, starting movements and performing repeated motions (such as writing or brushing teeth), decreased facial expressions, weakened voice, impaired balance and recurring falls. The movements become less automated, slower, and require more mental effort.

Parkinson’s also causes so-called non-motor symptoms, such as problems related to cognition (for example, memory, the ability to think or plan, decision-making and learning) or to mental health, such as depression, anxiety, fatigue and sleep problems. The so-called autonomic nervous system may also be affected, which can cause problems such as a drop in blood pressure, impotence and incontinence. Furthermore, patients with Parkinson’s may develop psychotic symptoms in the form of hallucinations and delusions.

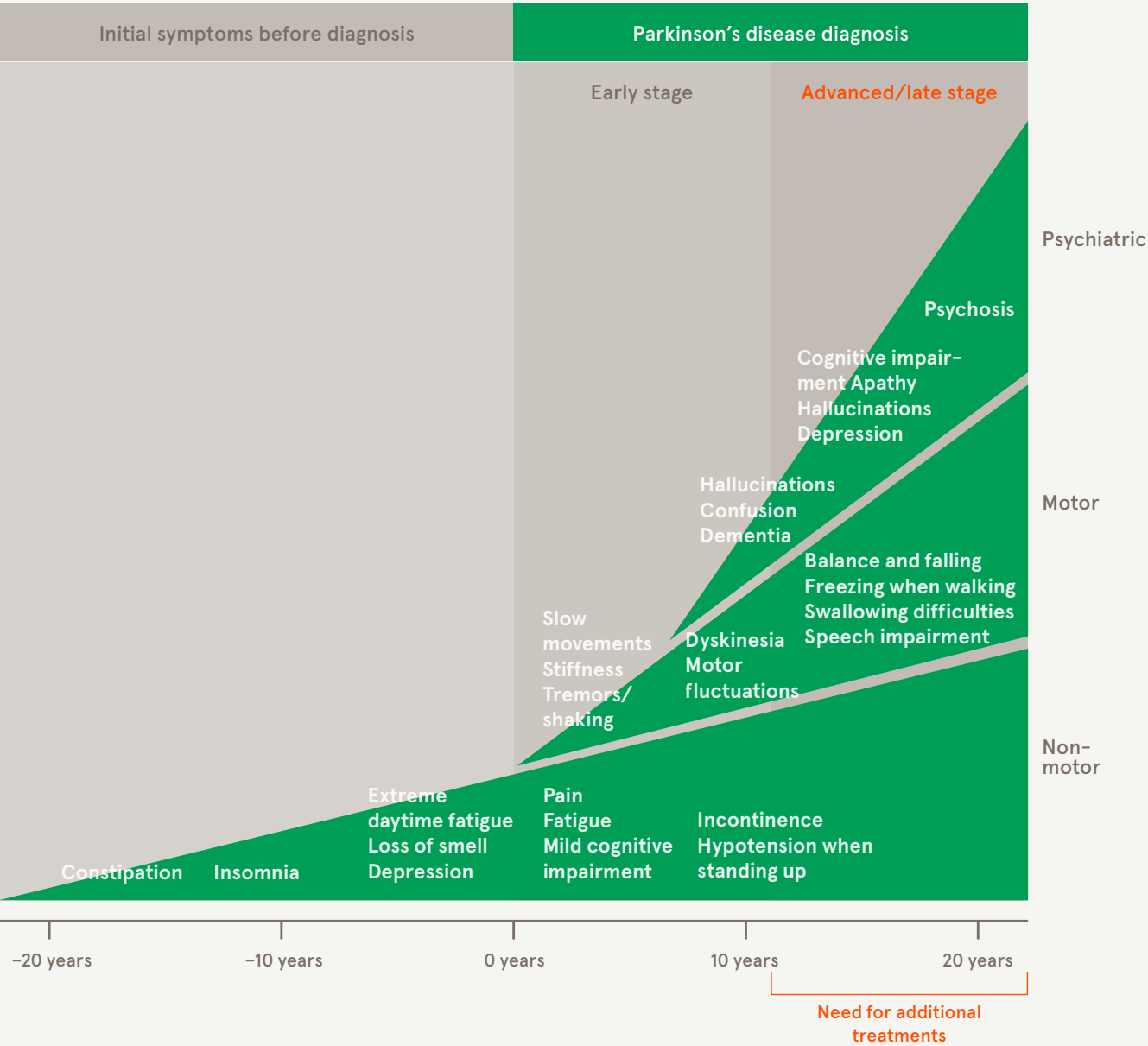
Current treatments for Parkinson’s

Today’s available treatments for Parkinson’s aim to alleviate motor symptoms, such as tremors, muscle stiffness and mobility impairment. The aim of all Parkinson’s treatment is to achieve good symptom control with as few treatment complications as possible. Since the 1970s, almost all patients have been treated with levodopa, a drug that is converted in the brain to dopamine. However, as the disease progresses, it will be necessary to add more drugs to deal with side effects caused by long-term treatment with levodopa. They currently consist of enzyme inhibitors (for example, COMT inhibitors and MAO-B inhibitors), dopamine inhibitors (agonists) and amantadine, a compound that inhibits NMDA receptors. However, these have additional side effects and are not fully effective in controlling the symptoms.

Dyskinesias, involuntary movements

A common and difficult-to-treat complication of chronic levodopa treatment are dyskinesias, often referred to as PD-LIDs (Parkinson’s Disease Levodopa-Induced Dyskinesias). Dyskinesias refers to involuntary movements which are caused by the levodopa treatment the patient has to take to stay mobile. Dyskinesias are often very troublesome, and as such overshadow the benefit of the levodopa treatment that is necessary to treat the underlying symptoms. The resulting dyskinesias consequently reduce the time of day when patients have good mobility and can control the symptoms. More than 30 percent of people with Parkinson’s develop such dyskinesias within five years and about 60 percent after 10 years of starting treatment with levodopa.¹ The concern of increasing the time

Diagnosis of Parkinson’s disease



Parkinson’s disease is diagnosed often at the onset of motor symptoms (0 years) but may be preceded by a premotor phase or premonitory symptoms for as many as 20 or more years. This premonitory phase is characterised by specific non-motor symptoms. After diagnosis, additional non-motor symptoms present that cause tangible impairment in functions. Axial motor symptoms, such as imbalance accompanied by frequent falling and slowing down/freezing while walking, tend to present in advanced stages of the illness. Long-term L-dopa treatment causes side effects that lead to further complications such as dyskinesias and psychosis. Based on Kalia, LV. and Lang, AE. Lancet 2015;386-912.

Parkinson’s disease

with troublesome dyskinesias often leads to doctors being forced to prescribe a lower dose of levodopa than would have been optimal for the treatment of the underlying symptoms.

In Europe today there is no approved drug for the treatment of PD-LIDs. The drug amantadine has long been used to control PD-LIDs, although it is not approved for that indication. In the United States, amantadine ER, a long-acting formulation of amantadine, was approved for the treatment of PD-LIDs in 2017. Amantadine can work well for some patients, but is also associated with side effects, primarily psychiatric, and it has been questioned whether it works for longer than 6-12 months. Other options for patients with PD-LIDs are surgical methods, but these are only considered for the most severe cases due to the side effects of the treatments and high costs.

There is a great need for drugs that can help people with Parkinson’s reduce dyskinesias, or at best slow down the development of symptoms, and thereby provide an increased time of day where patients have good mobility without being bothered by dyskinesias, so-called “good ON-time”.

Impaired balance and falls

Impaired balance and a fear of falling substantially impair the daily lives of many Parkinson’s patients. Linked to a balance impairment, there is a markedly increased risk of falls. People with Parkinson’s have a two to three times greater risk of falling compared to healthy people of the same age. Injuries related to falls are one of the biggest reasons people with Parkinson’s seek hospital care. About 60 percent of people with Parkinson’s suffer falls each year, and about 70 percent of them fall regularly. This leads to significant increases in injuries and consequently healthcare and social costs. In the United States, healthcare costs are esti-

mated at approximately SEK 250 000 (recalculated from US \$ 30 000) for each fall injury in people over the age of 65. Complications that can be associated with falls are fractures, reduced mobility, and a lower quality of life.

There is currently no complete treatment for balance impairment and the falls that affect people with Parkinson’s disease. There is therefore an extremely great need for effective medical treatment.

Psychosis

Parkinson’s patients often develop psychotic symptoms (PD-P) in the form of hallucinations and delusions. It is estimated that 20 – 40 percent of people with Parkinson’s are at risk of developing psychotic symptoms over time.² This means more than 750 000 patients in the United States, the EU5 (France, Germany, Italy, Spain and the United Kingdom) and Japan.

There is currently one approved drug for the treatment of PD-P. This drug is approved in the United States for the treatment of hallucinations and delusions, but not in Europe. In the absence of approved drugs, patients are often treated with antipsychotic drugs for the treatment of schizophrenia, even though they are not documented for the treatment of PD-P.

¹ Turcano et al. 2018. Neurology 91:1-6
² Spears C. (n.d.) Hallucinations/Delusions. Parkinson’s Foundation
<https://www.parkinson.org/Understanding-Parkinsons/Symptoms/Non-Movement-Symptoms/Hallucinations-Delusions>



“IRLAB applies a systems biology methodology, which is based on examining a wide range of effects in the brain. The ISP platform provides a unique opportunity to capture holistic effects linked to the interaction that takes place in the intricate signaling system in the brain, one of the body’s most complex organs.”

SUSANNA WATERS, DIRECTOR OF BIOLOGY & BIOSTATISTICS

ISP research platform

IRLAB uses a unique proprietary research platform called ISP to generate new drug candidates. The ISP platform is based on comprehensive, high-quality and relevant data in combination with effective machine learning methods. This unique combination of a systems biology approach and modern AI-based methods provides a powerful competitive advantage in the development of new treatments for brain diseases.

ISP captures integrated effects

The most common principle for evaluating drug candidates today is so-called target-based screening.¹ The method is based on first identifying substances that typically act on a single protein (target) or by a single mechanism, which is expected to have a certain effect on diseases or symptoms. Instead, IRLAB applies a systems biology methodology, based on examining a wide range of effects in the brain of each substance tested.² The ISP platform provides a unique ability to capture the integrated net effects of tested compounds linked to the interactions that takes place in the intricate signaling network of the brain, one of the body’s most complex organs. In practice, this means that the effects of new drug candidates are studied directly in living systems with detailed analysis methods, which results in a powerful basis for finding new effective drugs. The company’s structured, systems biology approach enables the discovery of new profiles and mechanisms of action that are extremely difficult to find with conventional screening methodology. All in all, it is with this drug development strategy that IRLAB believes it can produce successful drug candidates in a resource-efficient way.

How the platform works

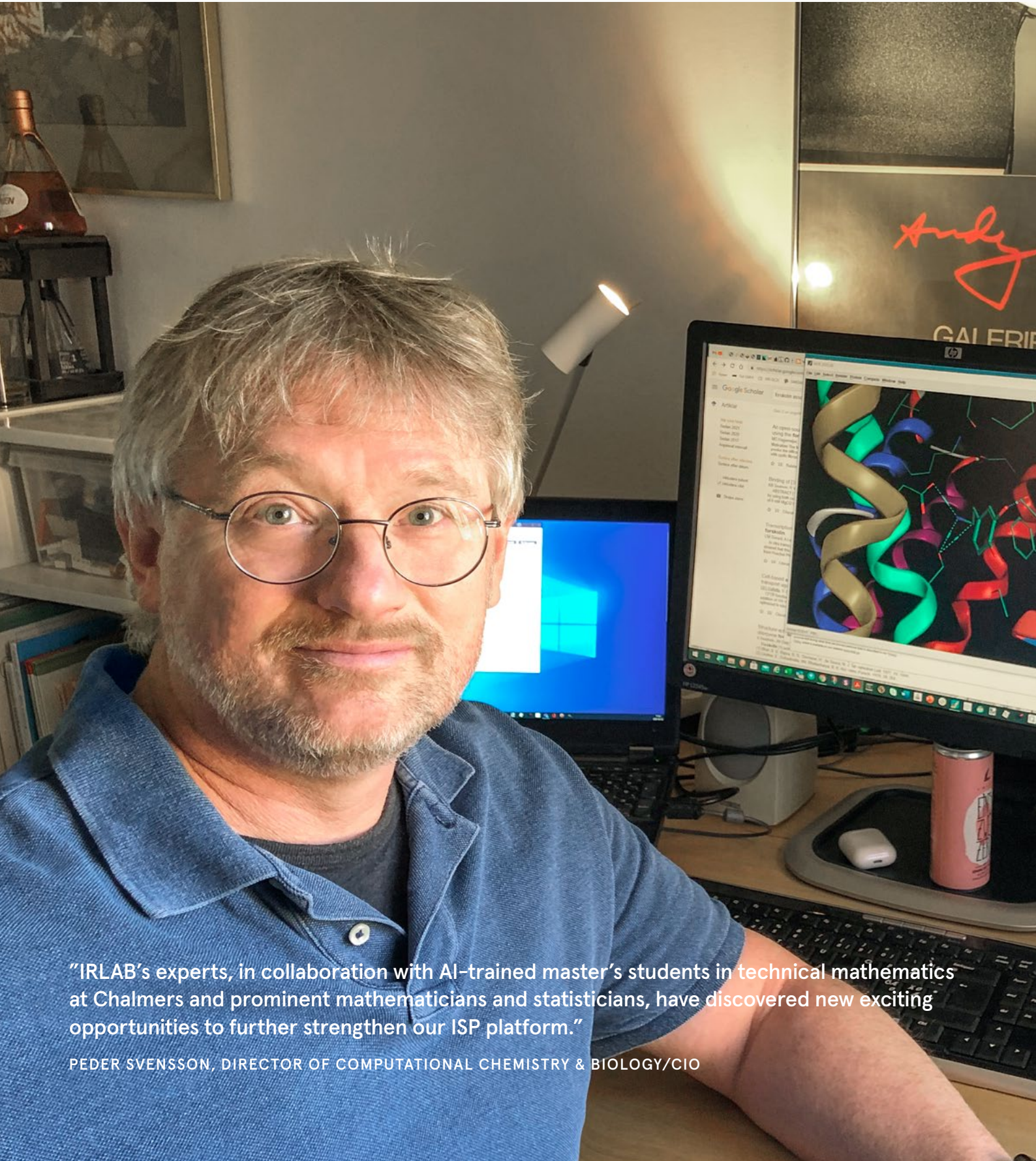
ISP is a platform that includes systems biology screening models, database, software, analysis models and working methods. The database consists of profiles of measured and calculated data, of the following types:

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

These data profiles are analyzed in parallel in order to capture the underlying connections and groupings in the data. This is done using a machine learning process.

The database is an ever-growing reference library that is used to compare and evaluate the composition and effect profile of new, proprietary molecules. At present, data for about 1 100 own substances and more than 300 reference substances (known drugs, competing substances, etc.) are in the company’s database. Early in the process, IRLAB’s research platform captures properties of central importance for the continued development of new drug products, such as pharmacological effects, pharmacokinetics, chemical properties and safety. Thereby, many development risks are managed at an early stage.

¹ Swinney, D.C. and Anthony, J. How were new medicines discovered? Nat Rev Drug Discov. 2011 Jun 24;10(7):507-19.
² Waters, S. et al. In Vivo Systems Response Profiling and Multivariate Classification of CNS Active Compounds: A Structured Tool for CNS Drug Discovery. ACS Chem Neurosci. 2017 Apr 19;8(4):785-797.



“IRLAB’s experts, in collaboration with AI-trained master’s students in technical mathematics at Chalmers and prominent mathematicians and statisticians, have discovered new exciting opportunities to further strengthen our ISP platform.”

PEDER SVENSSON, DIRECTOR OF COMPUTATIONAL CHEMISTRY & BIOLOGY/CIO

Further development of ISP

Research is a cornerstone at IRLAB, and it is essential to continually refine and develop our methods. During 2020/2021, several master’s students have been involved in IRLAB’s research with the aim of contributing in various ways to the further development of the ISP platform. Furthermore, IRLAB had the opportunity during the year to start a collaboration with the internationally renowned mathematician Per Enflo. Through these collaborations, IRLAB has the opportunity to take advantage of new perspectives from students and academic researchers, as well as offer students practical and applicable experience before they enter working life.

Application of the deep learning-project

The project involved exploration of nonlinear machine learning methods for analysis of IRLAB’s systems biological data. More specifically, dimension reduction and classification methods were tested with the aim of further improving the precision of ISP. The work identified methods, showing great potential for discovering new indications for both drug candidates and already approved drugs in the CNS area.

A summary of the results was presented at one of the world’s leading conferences in neuroscience, the Society of Neuroscience (SfN) Global Connectome: A Virtual Event, in January 2021.

Klara Granbom, MSc, describes her research at IRLAB:

Who are you and how did you find your way to IRLAB?

– I am a civil engineer with a keen interest in data-driven decisions and everything where it is possible to apply mathematics. I previously did a student project with Smartr, a specialist agency in artificial intelligence (AI), who then had a proposal for a master’s thesis together with IRLAB. The proposal caught my interest when it came to machine learning and Parkinson’s, and seemed broad and exploratory. I applied and got the opportunity to take on this project together with IRLAB.

How would you describe your time at IRLAB?

– During my time at IRLAB, I have learned an incredible

amount about drug innovation. I have been introduced to IRLAB’s ISP platform and completed my master’s work with this as a starting point.

QSAR project

The purpose of the project was to investigate different methods for ‘quantitative structure–activity relationships’ (QSAR) modeling with the aim of finding statistical models that describe the relationship between chemical structure and affinity for D2 and D3 receptors. Using large amounts of chemical and biological data, we trained models that predict how molecules interact with the receptors. Various methods were investigated and evaluated in order to find a complement to IRLAB’s existing analysis methods.

Richard Martin, Sebastian Oleszko and Adrià Amell, in their final year of the master’s program ‘Engineering mathematics and Computational science’ at Chalmers, carried out the project:

How did you find your way to IRLAB?

– **Richard:** I first heard about IRLAB through private contacts but then got in touch via a course given by Chalmers, where IRLAB offered a project to a group of students.

– **Sebastian:** I’m currently doing my final year at Chalmers. Through a course in mathematical and statistical modeling, I and two fellow students have had the chance to work on a project in statistics and bioinformatics together with IRLAB over a few months.



“The statistical and mathematical part of ISP is based on the same methods used in artificial intelligence, AI. By applying more advanced mathematics and statistics, ISP may become even more accurate and give IRLAB opportunity to develop better medicines in less time.”

FREDRIK WALLNER, SENIOR RESEARCH SCIENTIST AND SOFTWARE DEVELOPER

Further development of ISP

– **Adrià:** I’m an international student at Chalmers interested in computer science and machine learning. As mentioned by the others, I also found IRLAB through the course in the program.

Beams2video-project

The aim of the project was to investigate signals from various measuring instruments used in behavioral studies, partly to be able to improve the analysis of the signals, partly to ensure the system’s robustness for future studies. Previously, a system with photocells connected to an analyzer was primarily used, but today, video with a higher resolution is also used. In the project, we have worked to recreate the filtering function used by the analyzer, so that in the future there will be better opportunities to compare results from video with older results from the analyzer.

Rickard Karlsson, student in Technical Physics with a focus on applied mathematics at Chalmers, and Axel Nathanson, student in Engineering Mathematics at Chalmers, who carried out the project:

How did you find your way to IRLAB?

– **Rickard:** My interest has always been in technology and science, where physics and mathematics in particular have dominated my studies. Recently, I have become aware of how mathematics and programming can be applied in other areas. It was in this way I discovered IRLAB, when I was looking to be able to use my knowledge in a new domain. In addition, it is undeniably inspiring to be able to participate and contribute to medical research.

– **Axel:** I’m in my final year of the master’s program “Engineering Mathematics and Computational Science”. During my master’s, I have mainly focused my studies on courses in Algorithms, Statistics and Machine Learning. I came in contact with IRLAB through the course Mathematical and Statistical Modeling.

My goal is to continue in the same field as IRLAB and work on investigating how new algorithms from the statistical field and machine learning can be used in the healthcare sector or medical research.

State dependence project

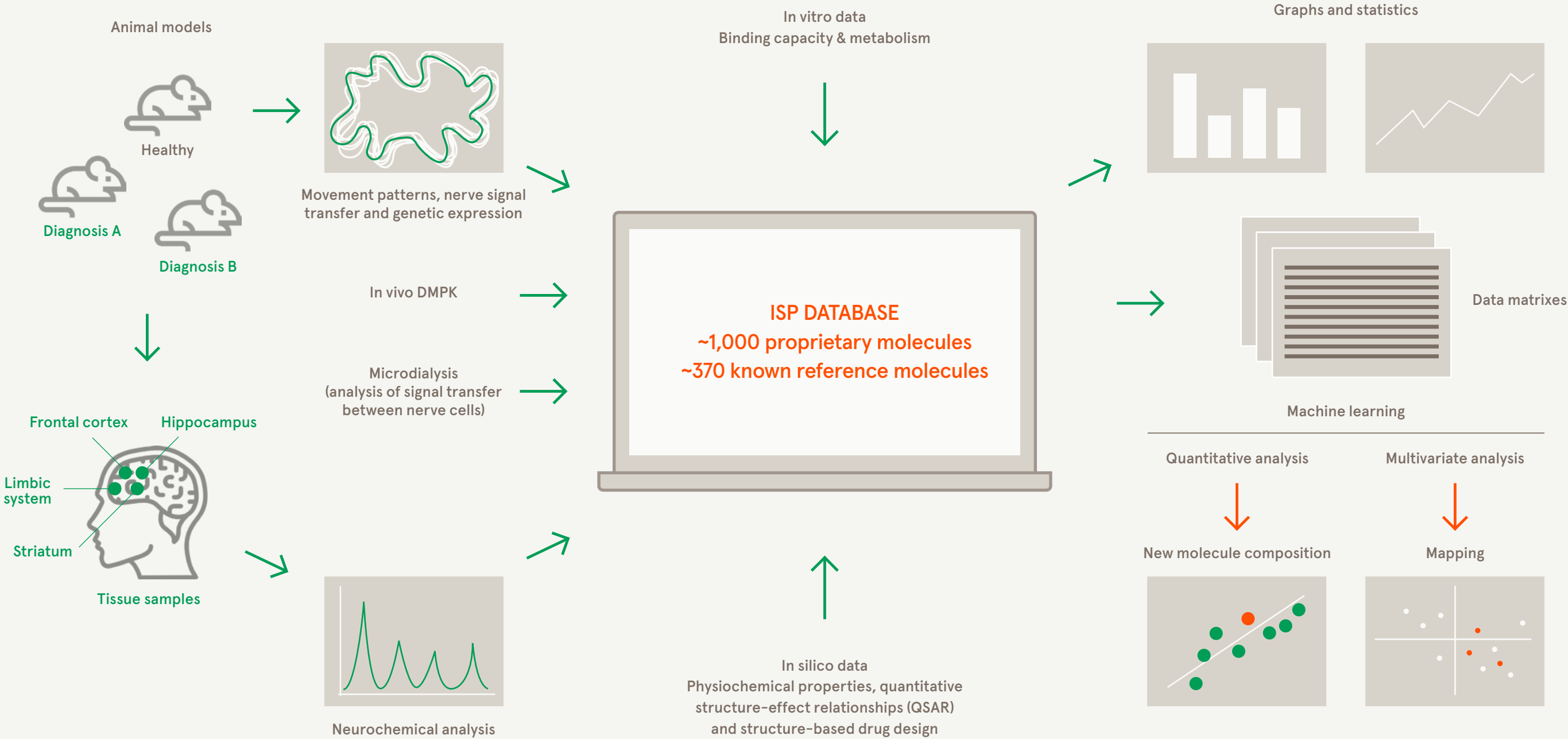
The project studies how the interrelations between neurochemistry and behavior differs between different conditions of the brain, such as different states of disease and healthy conditions. This involves an in-depth way of studying and comparing different conditions, which can also be applied to studying the effects of different treatments. The project resulted in several proposals for methods that IRLAB can use in the future. As part of the project, new ways of pre-processing the data before it was analyzed were also investigated.

Sara Nordin Hällgren is in her final year of the Engineering Physics program at Chalmers and completed the project together with two fellow students:

How did you find your way to IRLAB?

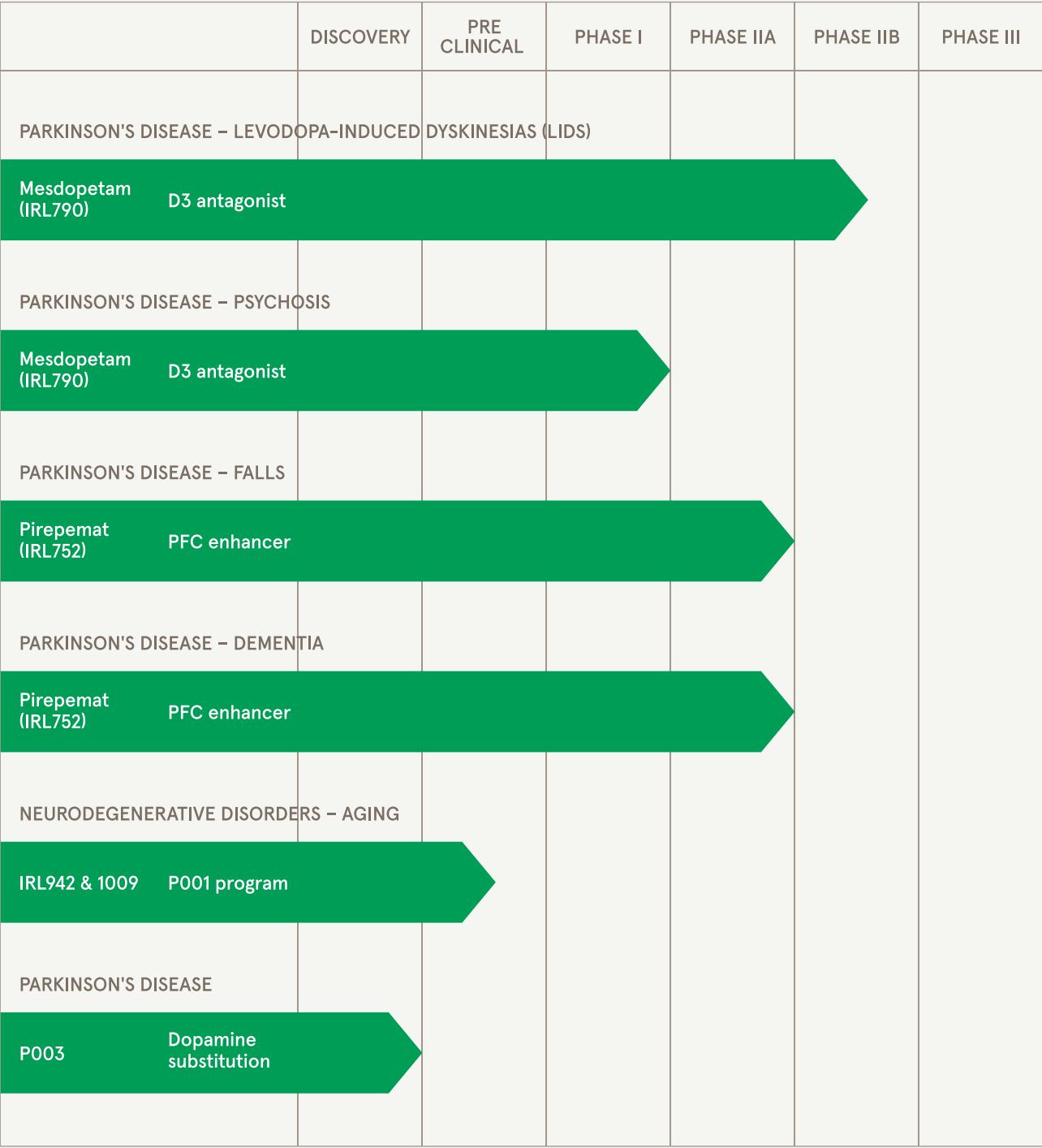
– I am studying a master’s program in applied mathematics, and as a final course before the master’s thesis we have a project course where we get to help a company with data analysis. I thought IRLAB’s project sounded interesting because I wanted to learn more about drug development.

Data flow in the ISP research platform



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

IRLAB’s research and development portfolio



PFC = prefrontal cortex

Project portfolio

IRLAB’s project portfolio consists of drug candidates in the clinical and preclinical development phase. The project portfolio is focused on developing new treatments for patients with Parkinson’s disease. All drug candidates have been developed with the help of the company’s proprietary research platform, ISP.

Clinical phase

Tolerability, safety and efficacy studies.

Mesdopetam

Mesdopetam (IRL790) is being developed to prevent and treat levodopa-induced dyskinesias (trouble-some involuntary movements, PD-LIDs) in Parkinson’s disease. The aim is to reduce troublesome dyskinesias and then extend the daily time with good and controlled mobility, so-called “good ON-time”. Mesdopetam also has antipsychotic properties, and is also being developed for Parkinson’s (PD-P) psychoses.

Pirepemat

Pirepemat (IRL752) is being developed to improve balance and reduce falls in Parkinson’s disease (PD-Falls). Pirepemat is also being developed for the treatment of dementia in Parkinson’s disease (PD-D).

Preclinical phase

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

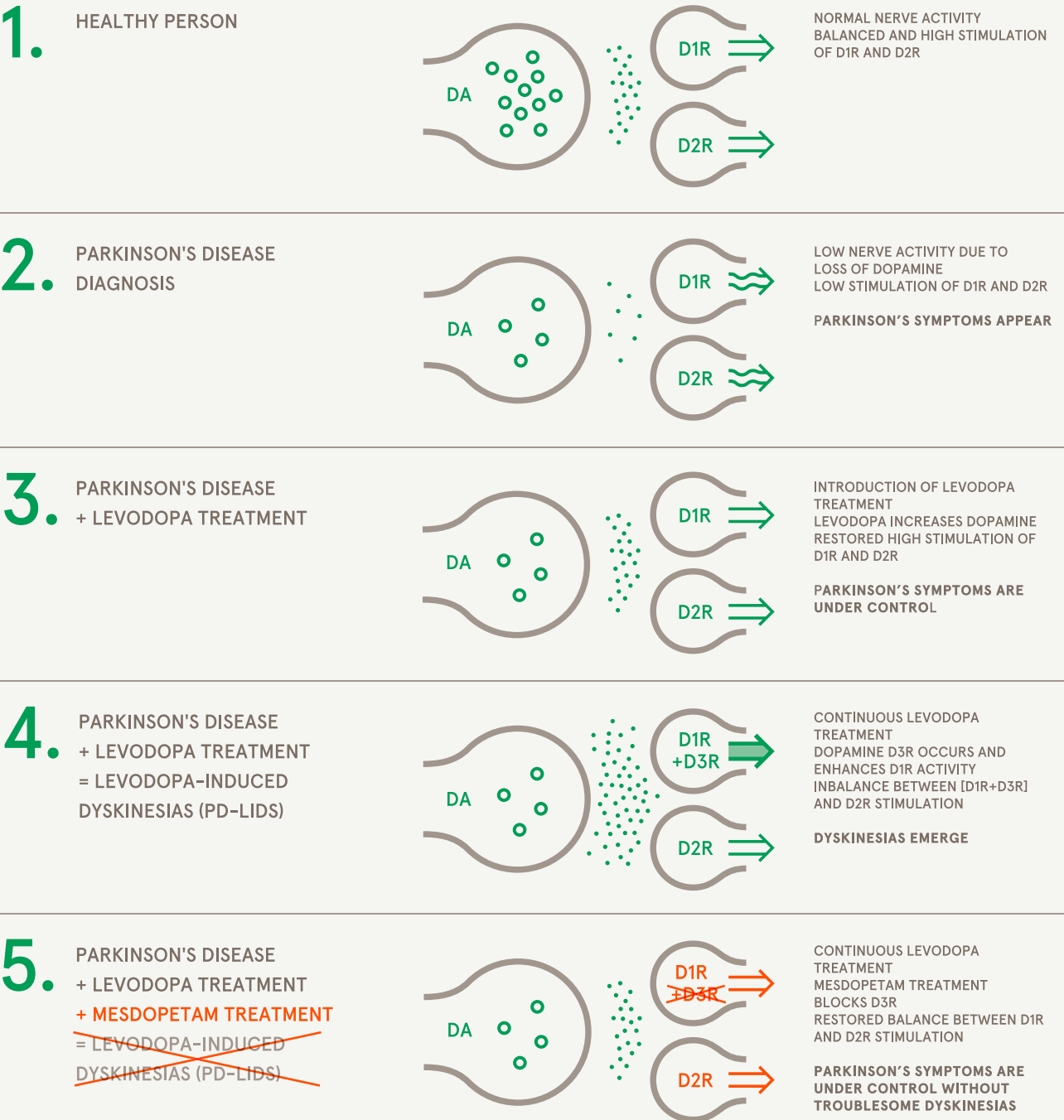
IRL942 & IRL1009

The aim of these two drug candidates is to treat mental illness, as well as cognitive and motor disorders associated with neurodegenerative and age-related CNS diseases.

Discovery phase

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

Mechanism of action (MoA) of mesdopetam



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

Clinical drug candidate mesdopetam

The drug candidate mesdopetam is being developed for the treatment of levodopa-induced dyskinesias (PD-LIDs) and psychosis (PD-P) in Parkinson’s disease. The aim of mesdopetam is to increase the time of day when patients have the optimal effect of their standard treatment with levodopa, i.e. good mobility and control of the basic symptoms, without being troubled by involuntary movements or psychoses. A Phase IIb/III study is currently being conducted in the US and Europe to investigate the effects of mesdopetam in patients with PD-LIDs.

Mesdopetam (IRL790) is an antagonist of the dopamine D3 receptor and reduces the overactivity which, via the D3 receptor, leads to dyskinesias (involuntary movements) in Parkinson’s disease. See the image of the mechanism of action of mesdopetam on the left.

Clinical development of mesdopetam

IRLAB has completed clinical Phase I, Phase Ib and Phase IIa studies with mesdopetam. Following positive results in the Phase I and Phase Ib studies, a clinical Phase IIa study was carried out on patients with Parkinson’s disease and dyskinesias. The aim was to study the efficacy, safety and tolerability of mesdopetam in approximately 70 patients. Analyses of efficacy data indicate that mesdopetam can reduce dyskinesias in Parkinson’s disease (PD-LIDs) without worsening other mobility in patients. The study results indicate that mesdopetam has good potential to help patients with Parkinson’s disease to optimize their treatment with levodopa without risking dyskinesias. This increases the time of day when levodopa treatment helps with the cardinal symptoms (called “good ON-time”) without the patient experiencing troublesome dyskinesias. Recent preclinical studies indicate that mesdopetam has further potential to be able to prevent the development of dyskinesias, and may therefore be relevant for a larger group of patients.

Ongoing Phase IIb/III study

A Phase IIb/III study with mesdopetam in PD-LIDs was started at the end of 2020, and initial top-line results are expected during the first half of 2022. In the study, a total of about 140 patients will be treated over three months,

divided into four different groups: three dose levels of mesdopetam and a placebo group. The study’s primary endpoint is the change in number of daily hours with good mobility without troublesome dyskinesias, so-called “good ON”-time, which is measured through a patient diary. The study is conducted at clinics in both Europe and the United States and through the start of the study, the company’s clinical development work was expanded to the US, which was an important strategic goal for the company.

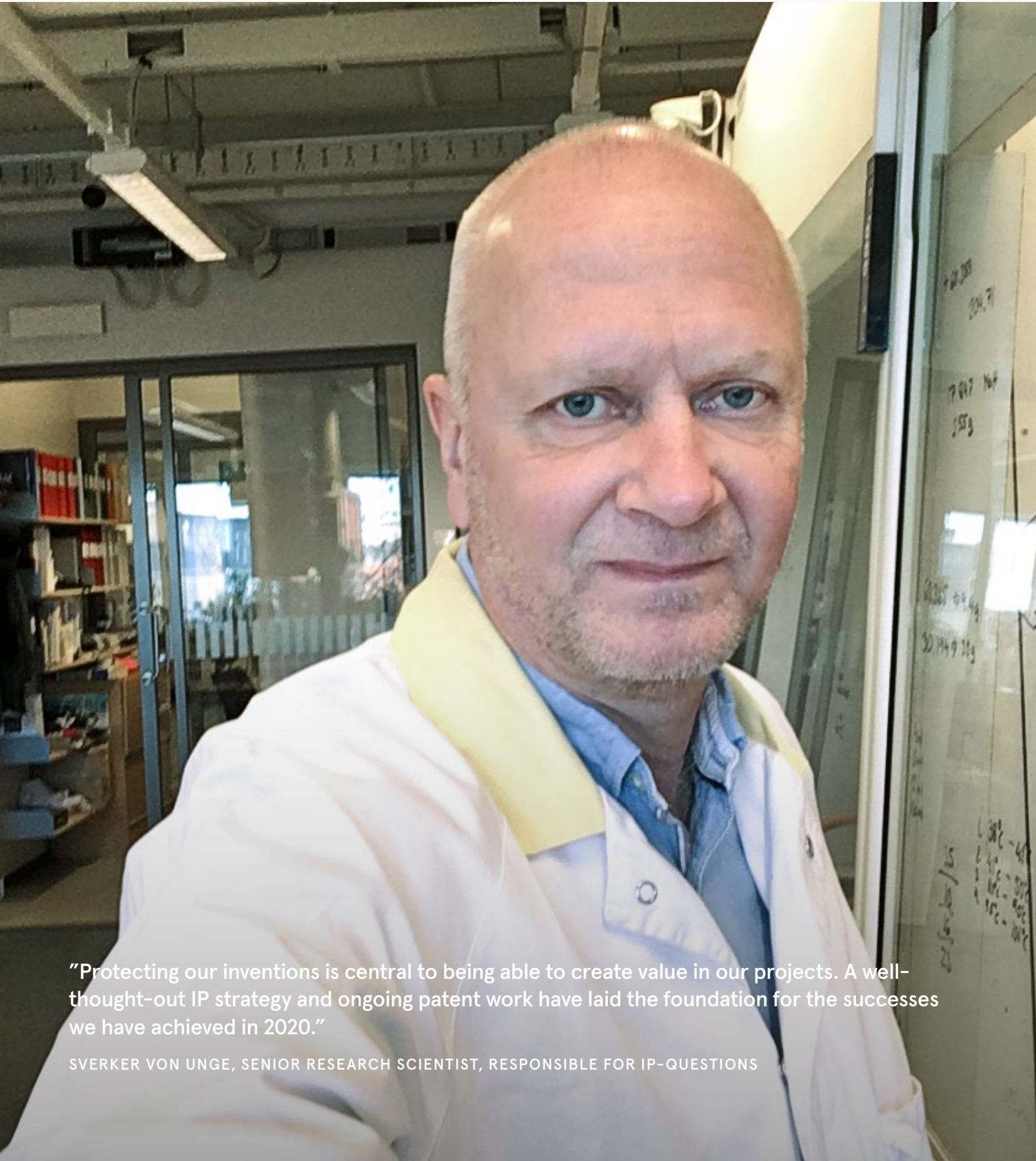
IRLAB’s development plan also includes further clinical studies to evaluate the effect of mesdopetam also on psychosis symptoms (PD-P). The start date for these is somewhat later than for the Phase IIb/III study within PD-LIDs.

Patent overview for mesdopetam

Molecule	IRL790
WO No.	WO2012/143337
Granted patents	All major markets in Europe, US, Canada, Australia and China
Patent expiration	Until 2037 in EU/JP/US based on: <ul style="list-style-type: none">• IND application strategies• Supplementary Protection Certificate (SPC)• Patent Term Extension (PTE)

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

Source: The company’s statement



“Protecting our inventions is central to being able to create value in our projects. A well-thought-out IP strategy and ongoing patent work have laid the foundation for the successes we have achieved in 2020.”

SVERKER VON UNGE, SENIOR RESEARCH SCIENTIST, RESPONSIBLE FOR IP-QUESTIONS

Clinical drug candidate mesdopetam

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

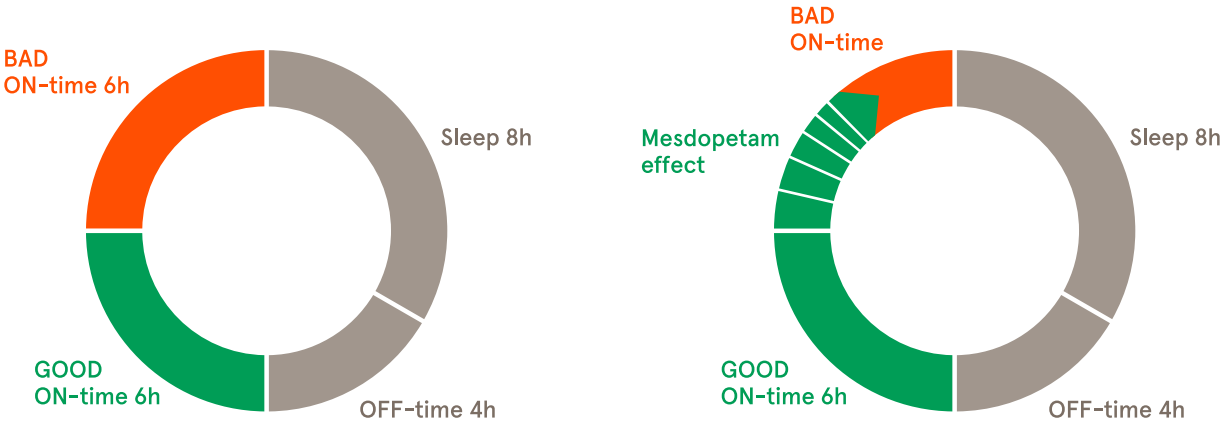


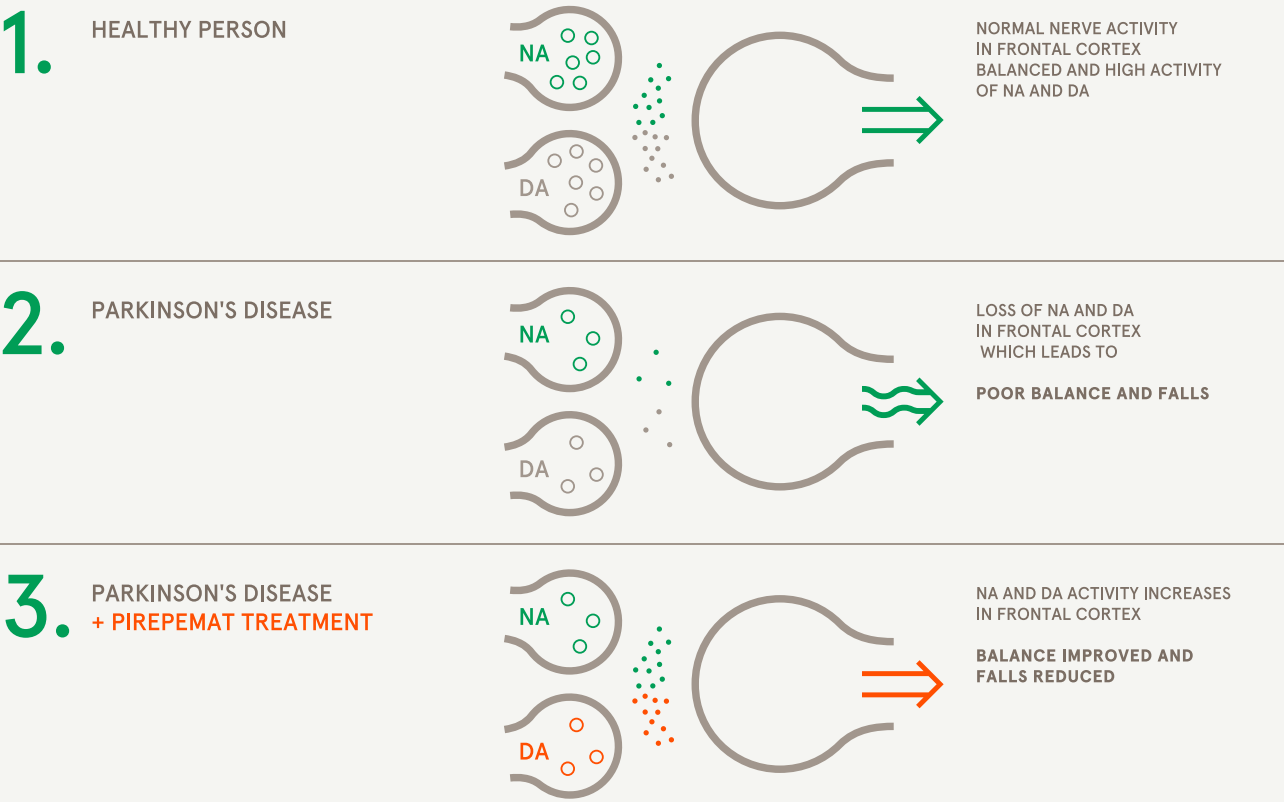
Illustration of a day for a Parkinson's patient with standard anti-Parkinson's medication (levodopa). The time is aggregated and grouped according to categories.

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

Competitive advantage

- Indications of significantly better efficacy and a better safety profile than competitor drugs and projects.
- Ongoing Phase IIb/III study within PD-LIDs in the most important markets: US and Europe.
- First-in-class: Mesdopetam is a drug candidate with a new mechanism of action, with potential to become the first in a completely new drug class for the treatment of complications in Parkinson's disease.
- Preclinical results also indicate the potential to prevent the development of dyskinesias, which distinguishes mesdopetam from currently available treatments.
- Obtained mesdopetam as International Non-proprietary Name (INN, generic substance name).
- Development within two indications; dyskinesias and psychosis in Parkinson's.
- Study results published in highly ranked scientific journals.
- Strong IP protection: global patent protection and patent registrations can provide exclusivity until approx. 2042.

Mechanism of action (MoA) of pirepemat



NA = noradrenergic; DA = dopamine

Clinical drug candidate pirepemat

Pirepemat is being developed for the treatment of impaired balance and falls in Parkinson’s disease, PD–Falls. Impaired balance and increased risk of falls are strongly associated with impaired cognition, such as memory and thinking capability, a problem where existing Parkinson’s medications do not help. The aim of pirepemat is to give Parkinson’s patients improved balance and fewer falls to provide them the opportunity for an increased quality of life in everyday life. Pirepemat is also being developed for the treatment of dementia in Parkinson’s disease (PD–D).

Injuries related to falls are one of the biggest reasons patients with Parkinson’s seek hospital care. Around 60 percent of Parkinson’s patients suffer falls each year, and about 70 percent of them fall regularly. Pirepemat (IRL752) has the ability to selectively improve the functions of the cerebral cortex by increasing the levels of the neurotransmitters norepinephrine and dopamine, and by activating genes involved in the nerve cells’ contacts. Pirepemat has its effect mainly on the cerebral cortex.

There is currently no specific treatment to reduce the risk of falls for Parkinson’s patients. An overview of ongoing development projects globally shows that there is no drug with a similar mechanism of action under development. IRLAB thereby estimates that with pirepemat the company is approximately 4–5 years ahead of other projects.

Clinical development of pirepemat

IRLAB has carried out Phase I and Phase IIa clinical studies with pirepemat where the results indicate good tolerability for the doses studied. Exploratory analyzes of efficacy data indicate that pirepemat improves symptoms that are strongly linked to cerebral cortex functions. These early indications of efficacy include improved balance, decreased tendency to fall, decreased apathy (lack of motivation and ability to take initiative), and improved results in cognitive tests (memory and thinking ability). The continued development program for pirepemat aims to demonstrate the safety and efficacy in Parkinson’s patients with symptoms consistent with a lack of signal transmission in the cerebral cortex.

Phase IIb study

IRLAB is now preparing for a Phase IIb study, in which pirepemat will be given for 12 weeks as adjunctive therapy to the patient’s normal Parkinson’s medication, and the efficacy of pirepemat on the frequency of falls will be compared with a placebo. The study is estimated to include a total of approximately 150 patients divided into three different groups: two dose levels of pirepemat and a placebo group. The Phase IIb study is expected to start in 2021 and be carried out at clinics in Europe and the US. Following efficacy and safety results it may progress to more extensive Phase III study.

IRLAB’s development plan also includes further clinical studies in order to evaluate the efficacy of pirepemat within dementia in Parkinson’s (PD–D). The plans for these are not yet as well developed as for the Phase IIb study within PD–Fall.

Patent overview for pirepemat

Molecule	IRL752
WO No.	WO2010/058018
Granted patents	All major marketsin Europe, US, Japan and China
Patent expiration	Until 2034 in EU/JP and 2035 in the US based on: <ul style="list-style-type: none">• IND application strategies• Supplementary Protecton Certificate (SPC)• Patent Term Extension (PTE)

Source: The company’s statement



“Working in clinical projects with significant drug candidates that have the possibility of making a real difference for Parkinson’s patients was important when I applied to IRLAB.”

JOHANNA LANDSTRÖM, CLINICAL PROJECT MANAGER

Clinical drug candidate pirepemat

60%

Approximately 60 percent of all Parkinson’s patients suffer falls each year, leading to fractures, limited mobility and a lower quality of life.

Around 76 percent of all falls in Parkinson’s patients require medical attention.

76%

Competitive advantage

- First-in-class treatment for impaired balance (postural dysfunction) and falls.
- New unique mechanism of action.
- Strong IP protection; global patent protection and patent registrations can provide exclusivity until approx. 2040.
- Good tolerability profile in Parkinson’s patients.
- Obtained pirepemat as International Nonproprietary Name (INN, generic substance name).
- Developed within two indications; treatment of impaired balance and falls in Parkinson’s (PD-Falls) and dementia in Parkinson’s disease (PD-D).
- Developed for a new market with significant clinical need and limited competition.
- Study results published in highly ranked scientific journals.



“As a researcher specializing in Parkinson’s disease, IRLAB, with its history and unique systems biology research platform, is a very exciting workplace. I look forward to contributing to the development IRLAB’s preclinical programs for studies in patients.”

DANIEL ANDERSSON, PRINCIPAL SCIENTIST

Preclinical phase and discovery phase

In addition to the two main projects – the drug candidates mesdopetam and pirepemat – IRLAB is working on two preclinical programs and a research project. These are also generated from the in-house developed research platform ISP.

IRL942 & IRL1009

The drug candidates IRL942 & IRL1009 originate from the research program P001 and are intended for the treatment of mental and cognitive illness, as well as impaired motor skills associated with neurodegenerative diseases and aging. IRL942 has been chosen as the project’s leading substance and is being developed in series with IRL1009, which has similar effects. As a new drug candidate, IRL942 will, in an initial stage, be taken further via a preclinical development program in order to meet the regulatory requirements for obtaining a permit to conduct Phase I clinical studies.

The research program P001 also continues to be run, in part to support the continued development of IRL942 & IRL1009, but also to find additional substances with similar properties.

P003

The P003 research program includes a group of substances with the potential to be developed into drugs for the treatment of newly diagnosed Parkinson’s disease. The program aims to develop new drug candidates that IRLAB can further develop towards clinical studies.

Overview of the candidate’s development

	DISCOVERY	PRE CLINICAL	PHASE I	PHASE II	PHASE III
NEURODEGENERATIVE DISORDERS – AGING					
IRL942 & 1009	P001 program				
NEURODEGENERATIVE DISORDERS – AGING					
P001	P001 program				
PARKINSON'S DISEASE					
P003	Dopamine substitution				



“The market for drugs related to brain diseases is one of the largest in the pharmaceutical industry. As the financial burden and medical needs are significant, the market potential for IRLAB’s drug candidates is considerable.”

JONAS LINDGREN, BUSINESS DEVELOPMENT

Market & competition

IRLAB focuses on areas within Parkinson’s disease where there is a significant need for new, effective drugs that can improve patients’ quality of life. After Alzheimer’s disease, Parkinson’s is the most common neurodegenerative disease and is expected to increase as more and more people age, worldwide.

Global trends

The world’s population is growing, yet at the same time people are getting older. The fastest growing proportion of the population globally is people over 65 years of age. The increase in people over 65 in the US and Europe between 2019 and 2050 will be as large as 48%.¹

The increase in the proportion of older people in turn creates a decrease in the proportion of younger and able-bodied people, which is predicted to create problems in many countries around the world. If you look at Europe, the number of able-bodied people in relation to each older person is estimated to decrease from four in 2015 to two in 2050. This will require the older generation to be able to work up to the age of 70, and require less care.

Parkinson’s symptoms usually appear after the age of 60 but can also affect younger people. In 2017, it was estimated that over 40 percent of Parkinson’s patients were 75 years or older, and only two percent were 49 years or younger. Due to the high societal costs and the increasingly aging population, the great need for new and effective drugs in Parkinson’s is believed to increase significantly in the coming years. Drugs that address difficult-to-treat symptoms that occur in Parkinson’s can provide valuable improvements in patients’ ability to function, as well as significant reductions in the societal costs associated with the disease.

The market for drugs related to the central nervous system (CNS) is one of the largest in the pharmaceutical industry. As the financial burden and medical needs are considerable for various adjunctive treatments to the current standard treatment of Parkinson’s, the market potential for IRLAB’s drug candidates is significant.

Success for a drug candidate largely depends on how quickly it enters the market, especially for first-in-class

substances, since the right of exclusivity can then be used to the maximum. With the high demands placed on drug development, this is a challenge at all stages. With IRLAB’s research platform, ISP, IRLAB expects to minimize the time spent on preclinical development and estimates a time saving of 2 to 3 years.

Market for IRLAB’s drug candidates

IRLAB develops drug candidates with a unique mechanism of action for symptoms associated with Parkinson’s in markets with great needs. The global market for Parkinson’s is estimated at approximately 5 billion USD, where the majority is generic drugs. Growth is expected to be around 6.5 percent annually. Mesdopetam and pirepemat are candidates in clinical phase, and have been shown to be promising for the treatment of several Parkinson’s related symptoms.

Mesdopetam

Mesdopetam is being developed to treat some of the most severe symptoms associated with Parkinson’s: levodopa-induced dyskinesias (PD-LIDs). Today, about 1 million patients are affected by PD-LIDs and for PD-P the number of patients is about 1.5 million in the 8 largest markets (8MM). Newly introduced drugs in this sector have prices of around USD 30,000/patient and year.

In the US, there is today a market-approved treatment that is specifically targeted at PD-LIDs, in other geographical regions there are no approved drugs. The treatment approved in the US is usually associated with several disabling side effects that impact the patient’s quality of life.

Wider potential in neurological diseases

Recent preclinical studies indicate that mesdopetam has the further potential to even prevent the development

Market & competition

of dyskinesias, which means that mesdopetam may be relevant for a larger group of patients and a longer duration of treatment.

Mesdopetam has also shown antipsychotic properties, and is thus being evaluated as a potential treatment for Parkinson’s psychosis (PD-P), which approximately 35 percent of Parkinson’s patients are at risk of developing over time.

The mechanism of action of mesdopetam indicates that the drug candidate may also have clinical potential in the neurological condition of tardive dyskinesia, which affects patients with psychosis and is caused by long-term treatment with antipsychotics. Globally, more than 3 million patients have tardive dyskinesia, which is approximately 25 percent of those treated with antipsychotic drugs.

Pirepemat

Pirepemat is intended to improve balance impairment and as such prevent falls in Parkinson’s (PD-Falls). About 60 percent of all Parkinson’s patients suffer falls each year, leading to fractures, limited mobility and a lower quality of life. Approximately 76 percent of all falls in Parkinson’s patients require hospital care. 33 percent of falls result in fractures. For people over 65, the cost of medical care for falls is estimated at \$ 30 000.² Balance impairment and consequently the risk of falling has been shown to be strongly linked to impaired cognition. There is currently no treatment approved for this major clinical problem.

As there is no approved drug, estimates of the market for balance impairments should be based on the costs of the Parkinson’s patients who fall and get fractures. Approximately 30 percent of all Parkinson’s patients will suffer a fall that causes a hip fracture in the first 10 years after diagnosis.³ The cost of treating a hip fracture is estimated at about 50,000 USD.⁴ Today, about 1 million patients in the US are diagnosed with Parkinson’s and the number patients are expected to increase steadily. Falls and fractures are thus becoming a significant burden on healthcare systems in the future.⁵ From a health economic perspective, the market potential is great for a balance-improving treatment.

Competition

Mesdopetam

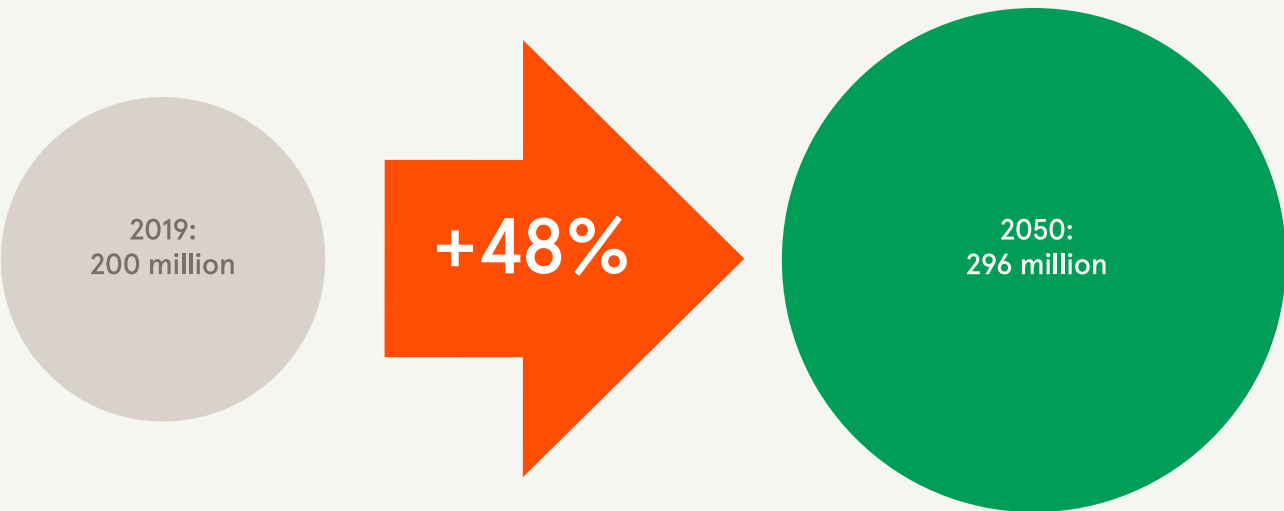
In addition to standard treatment with levodopa, there are a number of drugs available for Parkinson’s patients. These are used to support the effect of levodopa on the basic symptoms. Amantadine ER is available in the US for the treatment of dyskinesias. Amantadine may work well for some patients but is associated with side effects, with hallucinations being the most prominent. It is also discussed whether the drug works for longer than 6–12 months. Amantadine ER is a reformulation of amantadine and is approved for the treatment of PD-LIDs, but is only available in the US. There is therefore a great need for drugs that can help Parkinson’s patients reduce dyskinesias, at best slow down the development of symptoms, and thus provide increased daily time where patients have good mobility without being troubled by dyskinesias, so-called “good ON”-time. There are a number of development programs in the global pipeline for PD-LIDs in both the clinical and preclinical phases, but none with the same mechanism of action as mesdopetam.

Pirepemat

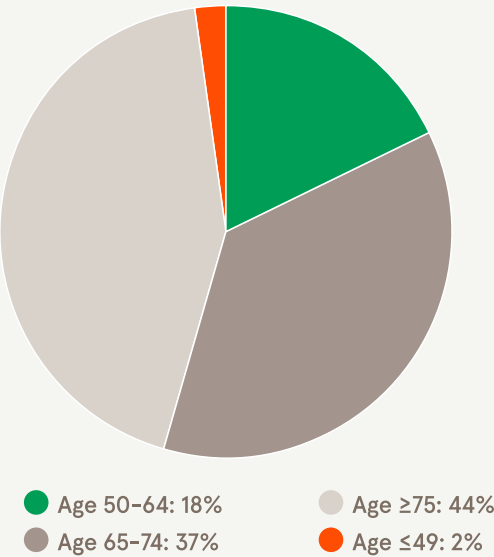
There is currently no approved drug that improves balance and reduces falls in Parkinson’s. IRLAB only knows of a small number of development projects in the clinical phase within the indications that may compete with IRLAB’s drug candidates. In addition to IRLAB’s pirepemat, there is only one candidate in the preclinical phase (CM-PK) and one in the clinical phase (droxidopa, which is being developed for the treatment of falls in orthostatic hypertension and Parkinson’s).

¹ United Nations, Department of Economic and Social Affairs, Population Division (2019). World Population Ageing 2019: Highlights (ST/ESA/SER.A/430)
² US CDC
³ Watts, J.J. et al. BMC Geriatr. 2008;8:23. Published 2008 Sep 30. doi:10.1186/1471-2318-8-23.
⁴ Adeyemi, A. et al. JBJS Open Access: March 28, 2019 – Volume 4 – Issue 1 – p e0045 doi: 10.2106/JBJS.OA.18.00045
⁵ Kalilani, L. et al. PLoS One. 2016;11(9):e0161689. Published 2016 Sep 1. doi: 10.1371/journal.pone.0161689

The growth of people over 65 in the US and Europe.



Parkinson’s prevalence, age distribution in the US 2017.



Illustrates candidates in development for PD-LIDs and PD-Falls, including IRLAB’s two candidates in orange.

	PRE-CLINICAL PHASE	PHASE I	PHASE II	PHASE III
PD-LIDs	<div><div></div><div></div><div></div><div></div></div>		<div><div></div><div></div><div></div><div></div><div></div><div></div></div>	
PD-Falls	<div><div></div><div></div></div>		<div><div></div><div></div></div>	

Parkinson’s disease is one of the fastest growing diseases

2015:
8.7 million patients diagnosed

2040:
16+ million patients diagnosed

Market & competition

2-3

With IRLAB’s research platform ISP, IRLAB expects to minimize the time spent in preclinical development and estimates a time saving of 2 to 3 years.

The market for drugs related to the central nervous system (CNS) is one of the largest within the pharmaceutical industry.

CNS

Market size

MESDOPETAM, PD-LIDs

REGION	PATIENT POPULATION ¹	TREATMENT PRICE
US	200 000	28 500 USD per year (amantadin ER)
EU5	230 000	No approved drug available
China	470 000	No approved drug available
Japan	115 000	No approved drug available

PIREPEMAT, PD-FALLS

REGION	PATIENT POPULATION (RISK FOR FALLS) ²	PATIENT POPULATION (RECURRING FALLS) ²
US	470 000	330 000
EU5	565 000	395 000
China	1 130 000	790 000
Japan	275 000	190 000

¹ GlobalData, Epidemiology database, 2020. Regards treatment of established LIDs, not preventative.
² Adamas Pharmaceuticals Annual Report, 2019.



“During 2020, we have worked to strengthen the organization with new skills and are now growing into larger premises. IRLAB strives to create good conditions for the company’s employees, with a pleasant work environment, independent and inspiring tasks with individual responsibilities, and a clear connection to the company’s development.”

CECILIA TIVERT STENBERG, EKONOMICHEF AND HUMAN RESOURCES MANAGER

Sustainability

IRLAB’s activities are permeated by the goal and the desire to contribute to a positive impact on society and individuals through increased knowledge. IRLAB does this through research, knowledge building, and drug development in order to contribute to a better life for individuals affected by impaired function, and consequently to a more sustainable society.

IRLAB’s sustainability work is based on the UN’s global sustainability goals that are essential for the business, and where the company can make the biggest difference: gender equality, decent working conditions and economic growth, sustainable industry, innovations and infrastructure, and sustainable consumption and production. IRLAB summarizes this sustainability work in the following three focus areas:

Employees

IRLAB wants to offer all employees a healthy work environment that is characterized by stability and development opportunities. People’s values and interests vary, and therefore IRLAB sees a great benefit in having an inclusive corporate culture at all levels of the business. The company’s research and development activities usually require specific expertise and training, but the main principle is that everyone shall be offered the same opportunity when recruiting and developing at work. IRLAB’s operations are at their best when many years of experience are combined with new ideas and perspectives in order to best help patients who are in need of new effective treatments.

IRLAB strives to create good conditions for the company’s employees with a pleasant work environment, independent and inspiring tasks with own responsibilities, and a clear connection to the company’s development. The well-being and safety of employees has been the focus in the current Covid-19 pandemic. The company largely switched to remote working, according to government guidelines. Digital communication with video conferencing has frequently been used and outdoor activities have been arranged to maintain community spirit in the company.

Responsible dealings

IRLAB shall act responsibly in all relationships and partner-

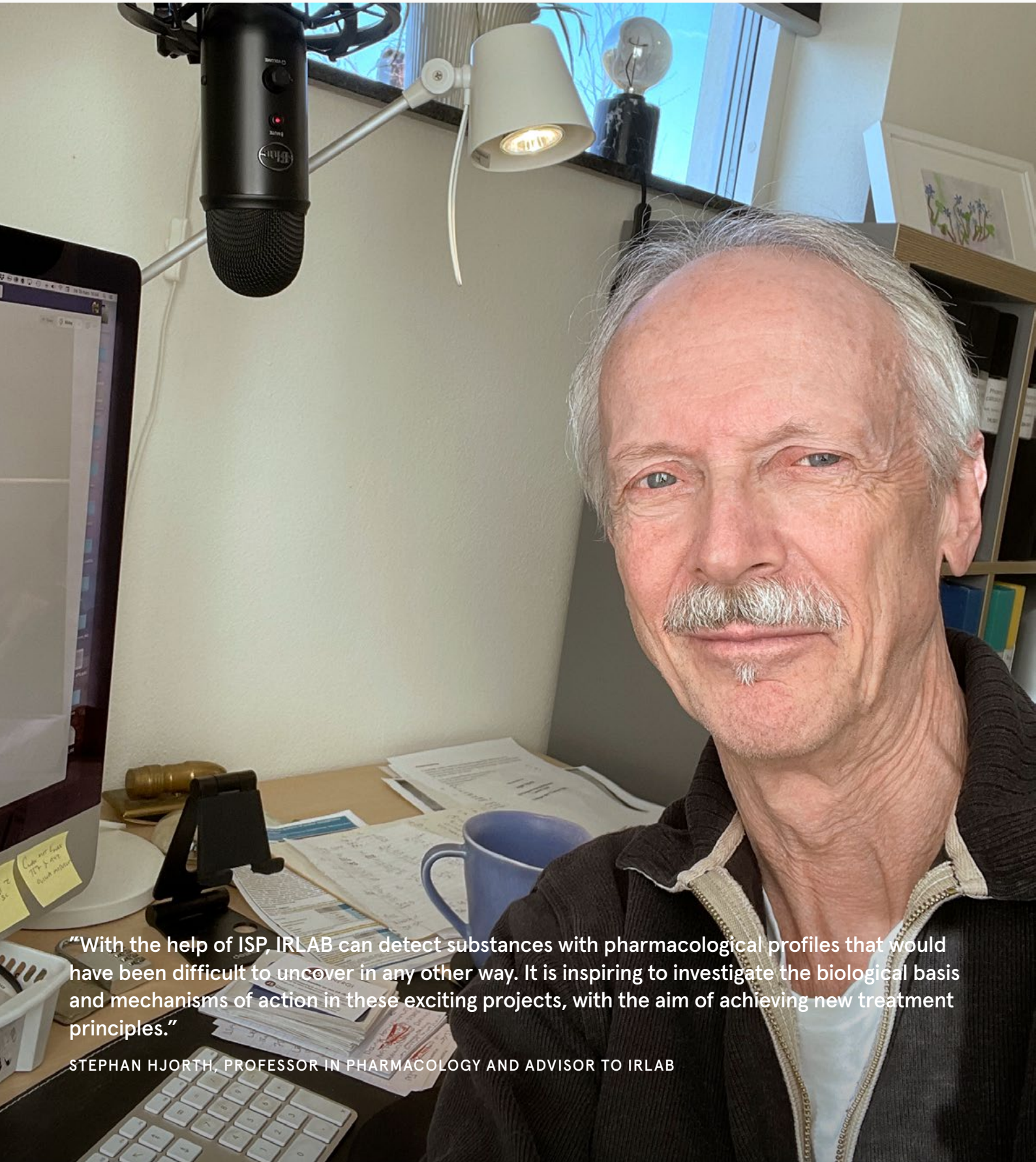
ships. In addition to the company’s own responsible behavior, IRLAB also places high demands on external suppliers and collaboration partners. They are required to meet and work according to the same guidelines as IRLAB. It is important that transparency permeates IRLAB’s work in order to create the best conditions for the company’s drug development projects. This means that suppliers and laboratories, contract research organizations and hospital clinics with which IRLAB collaborates shall have documented experience and strictly follow current regulations and regulatory requirements.

Where necessary, IRLAB receives support from area experts and Key Opinion Leaders (KOLs). These collaborations shall be characterized by sincerity, respect and the pursuit of a common understanding of the goal to productively contribute to the development of our drug candidates. Drug development is complex, and knowledge from experienced experts can contribute to creating the best possible prerequisites for achieving the sustainability goals.

Community involvement

Research is IRLAB’s core business, and knowledge is a key to innovation in drug development. Therefore, knowledge sharing is at the center of the company’s commitment. IRLAB regularly offers university students the opportunity to carry out degree work within the business and holds regular seminars in various research and development areas, which are open to everyone. The results and knowledge IRLAB produce are shared via its own website, through presentations at public events, and through the publication of articles in scientific journals.

In this way, IRLAB wishes to contribute to the development and visibility of the company’s areas of expertise, and raise awareness in society.



“With the help of ISP, IRLAB can detect substances with pharmacological profiles that would have been difficult to uncover in any other way. It is inspiring to investigate the biological basis and mechanisms of action in these exciting projects, with the aim of achieving new treatment principles.”

STEPHAN HJORTH, PROFESSOR IN PHARMACOLOGY AND ADVISOR TO IRLAB

Organization

IRLAB is established on competent employees in all parts of the business. This applies to the laboratory, the business functions, the clinical operations and the work with the ISP platform – everything that forms the core of the organization. The business is driven forward together with external consultants and area experts.

IRLAB’s operations are based at the office in the Biotech center in Gothenburg but have activities on all the world’s continents. The premises in Gothenburg contain both a laboratory and office space. During 2020, employees have primarily worked virtually in accordance with the guidelines recommended during the covid-19 pandemic different phases. At the end of the first quarter of 2021, the business consists of 29 employees, four of which were added in 2021, and consists of about 60 percent women and 40 percent men. All are university educated and a total of 41 percent have a doctorate.

In addition to the direct employees of the company, IRLAB has formalized collaborations with clinical research organizations (CROs), consultants and subject matter experts so the company is in practice a much larger organization than the figures show.

Scientific experts

IRLAB collaborates with a number of scientific experts:

- Dr. Bastiaan Bloem, Netherlands, Professor of Neurology, MD, PhD
- Dr. Camille Carroll, UK, Assistant professor in Neurology, MD, PhD
- Dr. Per Svenningsson, Sweden, Professor of Neurology, MD, PhD
- Dr. Anette Schrag, UK, Professor of Clinical Neuroscience, MD, PhD
- Prof. Alan Whone, UK, Assistant Professor and Consultant in Movement Disorders, MD, PhD

Regulatory experts

Clintrex is a clinical research company that collaborates with pharmaceutical organizations to establish development pathways for new treatments for CNS diseases. Clintrex is an integrated team of internationally renowned experts who collaborate with clients to identify, clarify and resolve preclinical, clinical, biostatistical and regulatory issues that are important for product development and approval. Mainly active in the US.

Consilium Salmonson and Hemmings support the development, approval and life cycle of drugs. Together, they have over 50 years of experience working with drug development and regulation. They offer unique insights into the science of drug development, regulatory standards, and processes for regulatory assessment and decision-making in the EU.

Long-term collaborations

Hjalmarsson & Partners supports IRLAB’s business development activities and is an independent financial advisor within mergers and acquisitions (M&A) and raising capital.

MAQS Advokatbyrå (legal firm) supports IRLAB with all legal services and participates in all company processes. MAQS is one of Sweden’s leading law firms specializing in business law.

MSC Nordics works with IRLAB’s IR and communications and are specialized in Nordic life science. MSC has experience from 80+ biotech companies.



“My work in investigating the complex chemical and biological issues in relation to how our substances are absorbed, broken down and excreted in the body is important for patient safety and a central part of a drug project’s development.”

THERESE KNUBBE, SENIOR RESEARCH SCIENTIST

Organization

40%

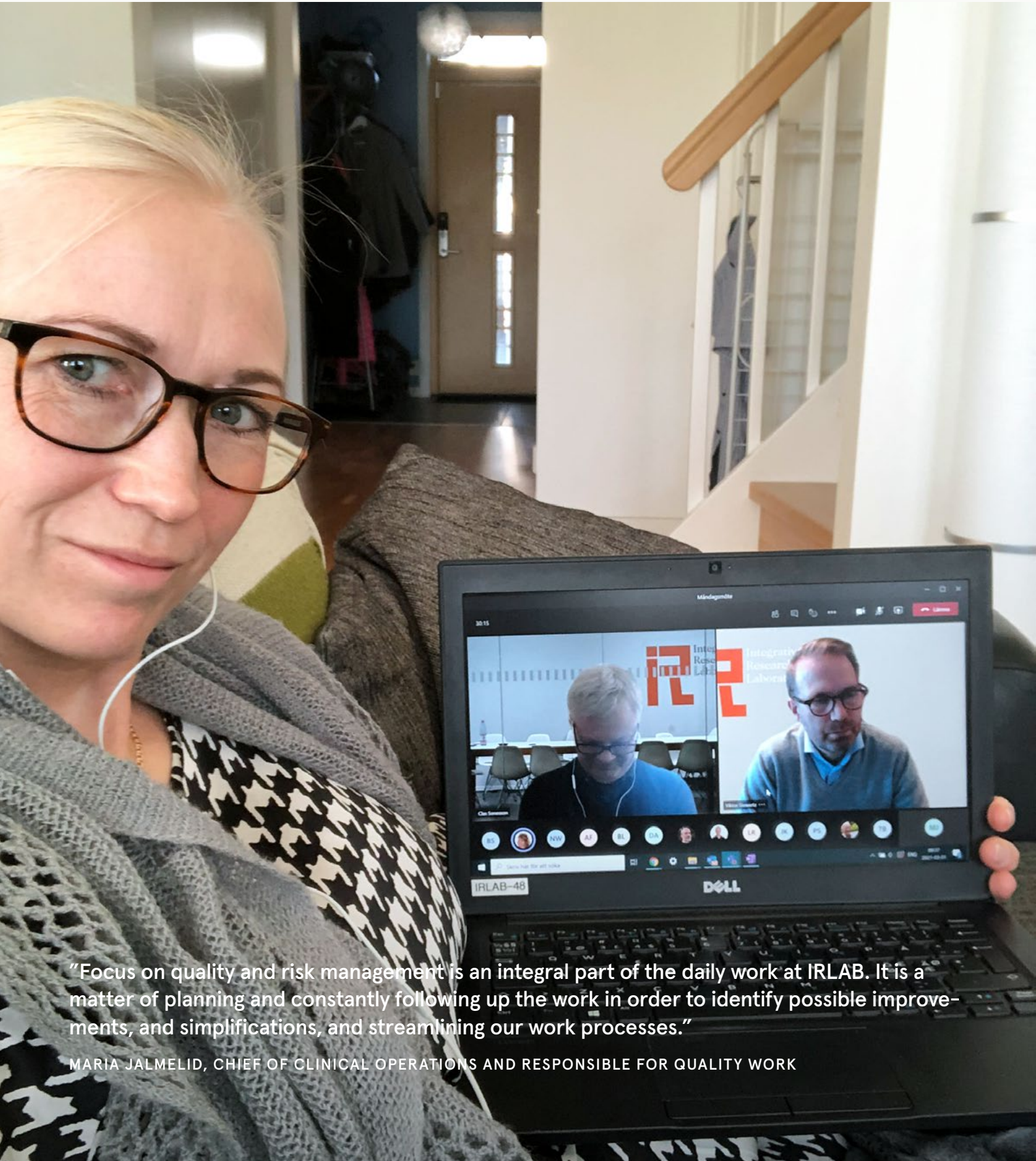
40 percent of the company’s employees have a doctorate. All are university educated.

29 employees, 60 percent women, 40 percent men.

60%

Partners for drug development

Toxicity studies, preclinical	TKT SVERIGE
Clinical studies	SELECTED INTERNATIONAL CLINICAL RESEARCH ORGANIZATIONS
Production of active substances for preclinical studies	ARDENA
Animal laboratory (rats)	UNIVERSITY OF GOTHENBURG
Cognition tests on rats	UNIVERSITY OF MANCHESTER AND ST ANDREWS
Production of drugs, manufacturing of API – Cambrex	CATALENT NOTTINGHAM
Licensing issues and business development	HJALMARSSON & PARTNERS
Project forecasting software	CAPTARIO
Patent registration	VALEA PATENTBYRÅ
Laboratory partner for metabolism studies	ADMESCOPE
Contract issues and law	MAQS ADVOKATBYRÅ
Certified advisor, Nasdaq Stockholm	FNCA
Investor relations	MSC NORDICS
Regulator, USA	CLINTREX
Regulator, EU/EMEA	CONSILIUM SALMONSON AND HEMMINGS



“Focus on quality and risk management is an integral part of the daily work at IRLAB. It is a matter of planning and constantly following up the work in order to identify possible improvements, and simplifications, and streamlining our work processes.”

MARIA JALMELID, CHIEF OF CLINICAL OPERATIONS AND RESPONSIBLE FOR QUALITY WORK

Quality work

IRLAB’s processes for internal control and systematic quality work are the pillar for ensuring compliance with applicable laws and ordinances, good quality throughout all activities, and effective governance of the operations. This is a prerequisite for being able to achieve our goals, in both the short and long term, ensure the reliability of internal and external financial reporting and, ultimately, protect our owners’ investments.

Business goals at the center

IRLAB works continuously with the processes for internal control in accordance with the requirements set out in the Swedish Companies Act, the Swedish Annual Accounts Act and the Swedish Corporate Governance Code. A cornerstone in the process is the company’s defined operational goals, which cover the entire business from research and clinical operations to control of financial data. Risks are defined as circumstances that may affect the likelihood that the company will achieve its goals.

The other components of internal control, which, among other things, deal with the internal work environment, systematic quality work and risk management, aim to ensure that the goals are achieved through efficient and effective operations, and that the Board of Directors has an overview of the company’s path towards fulfilled goals.

Risk awareness are the foundation

The internal work environment is built on a structured organization with well-defined areas of responsibility and reporting routes, and with governing documents that provide the business with a framework. The management team works actively to create a work climate with focus on integrity, ethical values and risk awareness, which determines the basis for how the organization’s employees view and respond to risks and possibilities. By identifying risks and considering them in relation to the business, control mechanisms can be identified and implemented in order to be able to identify as early as possible when the probability of a risk increases, and then be able to take measures to prevent or mitigate the impact on the business.

Systematic quality work

IRLAB’s system for quality assurance involves policy documents, standard operating procedures (SOPs) and work instructions that describe our core processes and form the framework for how our operations are conducted and governed. Focus on quality and risk management is an integral part of the daily work at IRLAB, and relates to planning and monitoring the work and thereby identifying possible areas for improvement, both in terms of preventing and detecting possible deficiencies. If necessary, changes are implemented in the business, and as such our processes are continuously improved. Employee commitment makes the process come alive, and our governing documents are under constant development and improvement. The management team is also responsible for regularly reviewing and evaluating the system for control activities and quality assurance to ensure efficiency and results in relation to established goals.

Evaluation of partners

An important aspect of quality assurance is our guidelines for evaluation and approval of our partners. For example, IRLAB outsources a large part of the practical implementation of the clinical studies to specialized collaboration partners (so-called Clinical Research Organizations, CRO), which requires careful evaluation to ensure that the partner we choose has the right competence and experience. Our processes also describe how IRLAB, during the implementation of the clinical studies, ensures continuous control and review of work and deliveries from the CRO.



“IRLAB has a well-developed system for policies, Standard Operating Procedures, and work instructions that make it easy to quickly get into how the operations are performed. After just a few weeks, I felt that I could really start contributing in the lab.”

KARIN ÖNNHEIM, SENIOR RESEARCH SCIENTIST

Quality work

Regular risk assessments

Within the framework of the systematic quality work, an assessment is regularly made of the most significant risks to the business and the opportunities to achieve our goals. All employees are involved in the work of identifying the risks that arise in the operations, and it is the management team’s responsibility to assess how likely it is that the risk will occur and how harmful the consequences of the risk may be. Based on the assessment, a plan is created to ensure that the risks are managed and/or eliminated in an appropriate and effective manner. The risks that are currently considered to be the most significant are presented on pages 67 – 69.

Annual cycle for internal control at IRLAB

Ultimately, the Board of Directors is responsible for internal control and risk management. Established procedures for reporting and communication in the form of an annual cycle ensure that the processes are kept alive and that the

Board of Directors has an overview of internal control, and is kept up to date with risks and opportunities identified in daily operations.

The annual cycle of the company’s internal control can be briefly described as beginning with an evaluation of the previous year and deciding on a strategy, as well as establishing goals for the coming year together with the Board of Directors. Based on the updated company goals, a risk assessment is performed on the entire company, governing documentation is reviewed and updated as necessary, and control activities are identified and documented. At the end of the cycle, the processes and control activities are evaluated with a focus on how they are designed and how effective they are at identifying when the likelihood of a risk increases at an early stage. This is done together with the Board of Directors and feeds into the discussions and decisions on strategy for the coming year. More about this can be found in the Corporate Governance Report on pages 123-139.

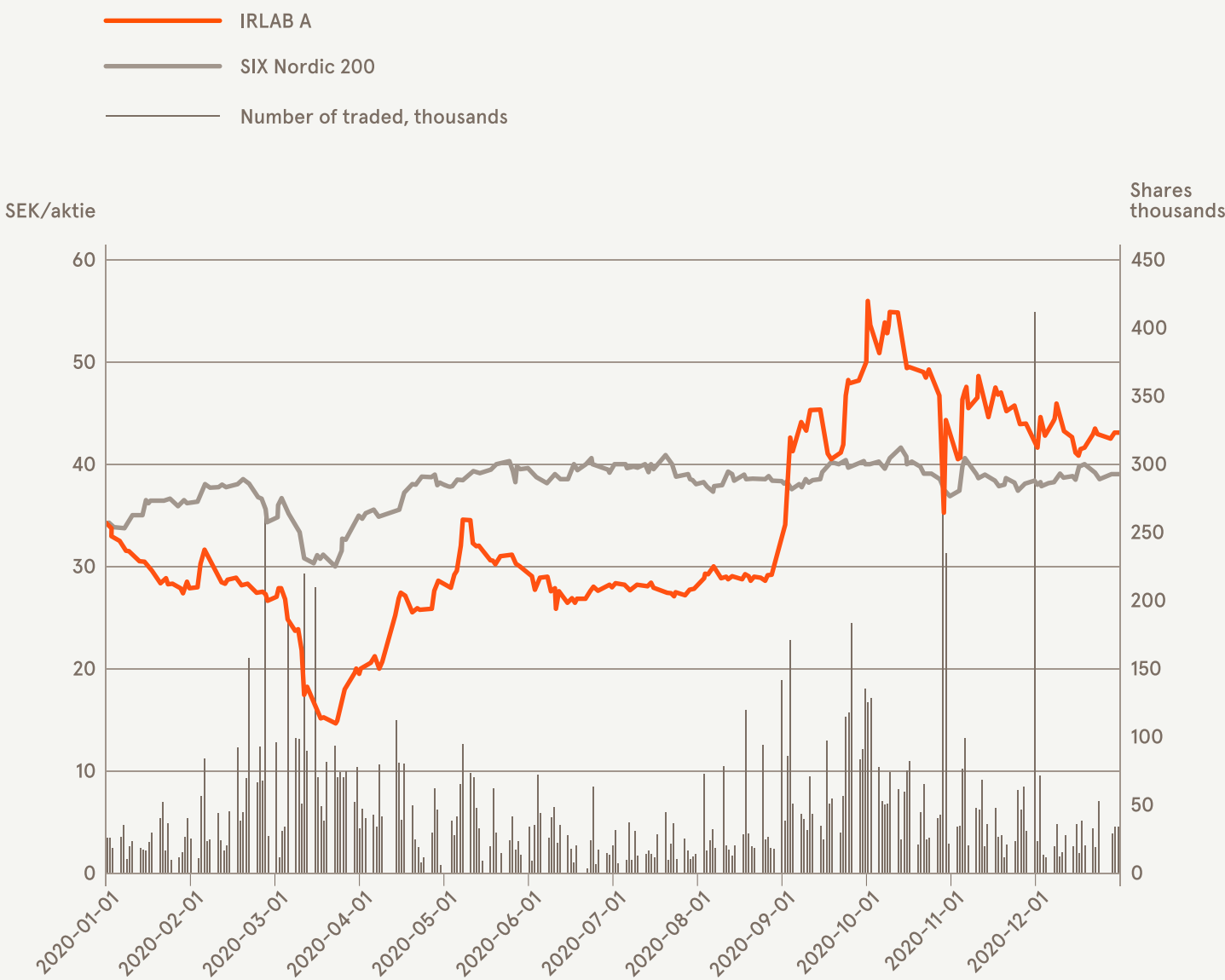
SOP

IRLAB’s system for quality assurance involves policy documents, standard operating procedures (SOPs) and work instructions that describe our core processes and form the framework for how our operations are conducted and governed.

IRLAB outsources a large part of the practical implementation of the clinical studies to specialized collaboration partners (Clinical Research Organizations, CRO).

CRO

IRLAB share price development in 2020



Source: Infront

The share

IRLAB’s Series A share has been listed on Nasdaq Stockholm’s Main Market since September 30, 2020, following a move from Nasdaq First North Premier Growth Market, where the company has been listed since February 28, 2017. At the turn of the year, the share capital in IRLAB amounted to SEK 1 034 968, divided into 51 748 406 shares with a quota value of SEK 0.02. All shares, including Series B shares, carry one vote. The number of shareholders with regard registered shares amounted to 3 405 as of December 31, 2020, an increase of just over 20 percent compared with the end of 2019. The ten largest shareholders held 49.09 percent of the number of shares. The new issue in December 2020 was not registered as of the balance sheet date, and as such is not reflected in the shareholder statistics.

Financing solution in two stages 2019/2020

In December 2019, the company announced a two-stage financing solution; a private placement of MSEK 70, which was carried out in the same month, and a fully underwritten rights issue of approximately MSEK 145, which was carried out during February 2020. Through the rights issue, which was registered in March 2020, IRLAB’s share capital increased by SEK 107 774 to SEK 969 968, and the number shares increased by 5 388 711 Series A shares. The number of shares in IRLAB after the rights issue amounts to 48 498 406, of which 48 418 630 are Series A shares and 79 776 are Series B shares.

Private placement in December 2020

During December, a private placement of MSEK 130 was carried out. The new issue, which was registered in January 2021, increased the number of shares in IRLAB from 48 498 406 to 51 748 406 shares, of which 51 668 630 are Series A shares and 79 776 are Series B shares. The company’s share capital increased from SEK 969 968.12 to 1 034 968.12 SEK. A total of 3 250 000 Series A shares were issued, which raised approximately tSEK 123 241 in liquid assets, after issue costs.

Incentive program

In April 2016, a decision was made on a share and subscrip-

tion warrant program for key personnel, both employees and board members. A total of 71 551 Series B ordinary shares (357 755 after split) and 39 355 subscription warrants (196 775 after split) were subscribed for in the program. The subscription price for the shares and the subscription warrants corresponded to the market value. Proceeds from the issue of the shares was paid by the group as a benefit to the key personnel.

During the month of July 2019, a conversion of B shares into A shares was called for by holders of B shares. 277 979 B shares were converted into A shares. The remaining 79 776 B shares are not subject to conversion as the holders may only convert B shares on one occasion, and all holders have now exercised this and carried out a conversion.

Subscription warrant program

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

Trading volume

In 2020, approximately 12,1 million IRLAB shares were traded on both Nasdaq First North Premier Growth Market and Nasdaq Stockholm’s Main Market. This corresponds to a turnover rate of approximately 33 percent, which is in line with the turnover rate in 2018.

Dividend

IRLAB is in a phase that requires the preclinical and clinical development of drug candidates be prioritized, which is why no dividend is deemed to be relevant in the coming years.

Analysts who follow IRLAB

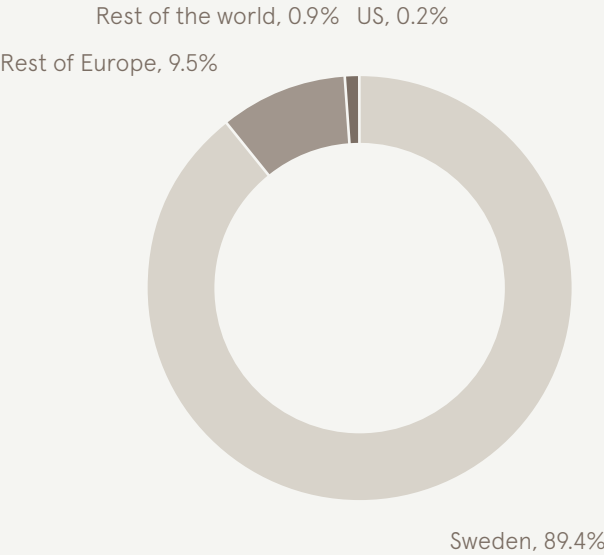
Anders Hedlund, RedEye

Breakdown by class of shares at 31 December 2020

	Number of shareholders	Number of class A shares	Number of class B shares	Totalt number of shares	Votes and capital (%)
1 - 500	1 787	281 158	0	281 158	0.58%
501 - 1000	542	407 922	0	407 922	0.84%
1001 - 5000	657	1 438 350	0	1 438 350	2,97%
5001 - 10000	158	1 110 273	0	1 110 273	2.29%
10001 - 25000	119	1 871 756	1 861	1 873 617	3.86%
25001 - 100000	94	4 896 075	18 656	4 914 731	10.13%
100001 -	58	38 413 096	59 259	38 472 355	79.33%
Totalt	3 415	48 418 630	79 776	48 498 406	100.00%

Source: Euroclear Sweden AB

Shares per region 31 December 2020



The 20 largest shareholders at 31 December 2020*

	Number of class A shares	Number of class B shares	Total number of shares	Votes (%)	Capital (%)
Försäkringsaktiebolaget, Avanza Pension	3 990 989	0	3 990 989	8.23%	8.23%
Ancoria Insurance Public Ltd	3 826 638	0	3 826 638	7.89%	7.89%
Fv Group AB	3 665 626	0	3 665 626	7.56%	7.56%
Johnsson, Daniel	2 690 000	0	2 690 000	5.55%	5.55%
Fjärde AP-fonden	2 419 366	0	2 419 366	4.99%	4.99%
Pension, Futur	1 756 639	0	1 756 639	3.62%	3.62%
Tredje AP-fonden	1 647 994	0	1 647 994	3.40%	3.40%
Diklev, Jens Philip	1 588 900	0	1 588 900	3.28%	3.28%
Marinvest Holding AB	1 208 250	0	1 208 250	2.49%	2.49%
Handelsbanken Läkemedelsfond	1 011 311	0	1 011 311	2.09%	2.09%
Olsson, Lars-Erik	895 000	0	895 000	1.85%	1.85%
Nordnet Pensionsförsäkring AB	845 554	0	845 554	1.74%	1.74%
Andra AP-fonden	758 493	0	758 493	1.56%	1.56%
Sonesson, Clas	748 589	8 946	757 535	1.56%	1.56%
Waters, Nicholas	736 200	8 946	745 146	1.54%	1.54%
Ekerholm,Lennart	651 005	0	651 005	1.34%	1.34%
Sandesjö, Claes	644 300	0	644 300	1.33%	1.33%
Holm Waters, Susanna	604 704	8 946	613 650	1.27%	1.27%
Tedroff, Joakim	602 839	8 946	611 785	1.26%	1.26%
Bassholmen Aktiebolag	562 500	0	562 500	1.16%	1.16%
20 largest shareholders, total	30 854 897	35 784	30 890 681	63.71%	63.71%
Other shareholders	17 563 733	43 992	17 607 725	36.29%	36.29%
Total	48 418 630	79 776	48 498 406	100.00%	100.00%

*The table refers to registered shares as of the balance sheet date. After the closing day the new share issue decided in December has been registered and Nordnet Pensionsförsäkringar AB and Unionen are ninth respectively tenth largest owner. The total number of registered shares increases in connection with the new issue with 3,250,000 Class A shares.

Source: Euroclear Sweden AB

Glossary

API – Active Pharmaceutical Ingredient, the active substance in a drug.

Bad ON-time – The part of the day the patient experiences troublesome dyskinesias.

CMC – Chemistry, Manufacturing and Controls, ensuring the production of the active substance and formulated drug.

COMT-inhibitors – Drugs that work by slowing down the metabolism of levodopa and dopamine.

CRO – Clinical Research Organization, contract research organization that conducts clinical studies.

Dyskinesia – Condition where the body or a part of the body performs uncontrolled involuntary movements. 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 the patient does not have troublesome symptoms of Parkinson’s disease.

IND – Investigative New Drug Application is an application to conduct drug studies in humans, usually referring to studies in the United States.

INN-name – International Nonproprietary Name, also called a generic substance name, is assigned by the World Health Organization based on the substance’s mechanism of action.

ISP – Integrative Screening Process, IRLAB’s proprietary research platform used to generate drug candidates.

MAO-B-inhibitors – Drugs that work by slowing down the breakdown of dopamine and have a certain symptom-relieving effect.

NMDA-receptor – The N-methyl-D-aspartate receptor. A receptor in the brain that is likely to be inhibited by the drug amantadine.

OFF-time – The part of the day the patient experiences classic Parkinson’s symptoms, such as muscle stiffness, mobility impairment and tremors.

PD-LIDs – Parkinson’s Disease levodopa-induced dyskinesia, 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.

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.

UDysRS (Unified Dyskinesia Rating Scale) – A standardized method for estimating movement patterns in dyskinesias.

UPDRS (Unified Parkinson’s Disease Rating Scale) – A method for qualitatively measuring the extent of the disease in a Parkinson’s sufferer, which consists of 42 measuring points, including behavior, mood, movement patterns and the complications they may experience during treatment.

Hauser diaries – A standardized method for patients to evaluate their health status, also called patient diaries.

Development process for drugs

Discovery phase

The early research phase is usually the stage where researchers have ideas on how to cure a disease or block processes that lead to a disease, or improve the efficacy of drugs, and where several tests in a laboratory environment are performed. A number of substances are developed to evaluate which has the best effect. A promising substance (drug candidate) then continues into the preclinical development phase.

Preclinical phase

The preclinical studies include a number of stages before studies on humans can begin, and evaluate chemistry (for example, possible manufacturing methods, the candidate’s solubility and stability, and the type of drug formulation to be used in clinical studies), toxicity and effects via studies in appropriate laboratory experiments and animal models. When the preclinical requirements on the substance are met, the substance can proceed to clinical development following a specific permit from the authorities.

Clinical phase

In the clinical phase, studies are carried out on humans. The clinical development is typically implemented in four phases, where each phase needs to show promising results, including safety, in order for the substance to be allowed to proceed to the next phase:

Phase I

Phase I studies are usually carried out on healthy study participants, but may, in some cases, include patients with the disease in question. The aim is to determine how the drug is tolerated, and how it is absorbed, distributed, metabolized and excreted in humans. The initial doses are often low and are gradually increased.

Phase II

The Phase II program often includes several studies and is carried out on a small number of patients with the relevant disease in order to study safety and tolerability, and to determine an appropriate dose for the Phase III studies. Phase II studies also aim to obtain preliminary but statistically reliable information on the efficacy of the substance, which usually occurs in the latter part of the Phase II program.

Phase IIa: Studies in patients with the aim of confirming the safety and tolerability of the drug candidate in patients, as well as obtaining indications of efficacy.

Phase IIb: Studies in patients to primarily demonstrate the drug candidate’s efficacy.

Phase III

The Phase III program, also known as the pivotal program, often consists of at least two independent studies and forms the basis of an application for market approval, and is carried out on a larger number of patients than in Phase II in order to confirm and document statistically significant efficacy of the treatment, as well as safety and tolerance in a large number of patients.

Phase IV

After approval of a new drug, the development of the drug usually continues through so-called Phase IV studies. There, additional information is collected from large patient groups over a long period of time, whereby unusual side effects can be detected and additional treatment effects evaluated. Sometimes the efficacy and tolerance between different drugs for a certain disease are compared.

“To see that the results of my work have a direct connection to both the preclinical and clinical development of our drug candidates gives meaning and motivation.”

JENNY GUNNERGREN, SENIOR RESEARCH SCIENTIST

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Administration report

The Board of Directors and the CEO hereby submit the annual report and consolidated financial statements for IRLAB Therapeutics AB, Org. No. 556931-4692, for the financial year 2020-01-01 – 2020-12-31.

Operations

IRLAB Therapeutics AB (publ) (with prior names Integrative Research Laboratories Holding AB and Integrative Invest AB) is the parent company of Integrative Research Laboratories Sweden AB (IRL Sweden), a research and development company with the aim of transforming life for patients with Parkinson’s through novel treatments. The company’s most advanced candidates, mesdopetam (IRL790) and pirepemat (IRL752), intends to treat some of the most difficult symptoms related to Parkinson’s: levodopa-induced dyskinesias (PD-LIDs), psychosis (PD-P) and impaired balance leading to falls (PD-Falls). Both drug candidates have completed Phase IIa studies. The company also has a unique and proprietary research platform, ISP, for developing new drug substances. The two most recently generated drug substances IRL942 & IRL1009 are both in preclinical phase and intended to improve motor function as well as mental and cognitive health in age-related diseases of the central nervous system (CNS).

The parent company’s operations mainly consist of providing management and administrative services for the group’s operative companies. In addition, the parent company manages group-wide issues, such as activities and information related to the stock market, as well as other group management issues. The research and development operations are conducted in the wholly owned subsidiary Integrative Research Laboratories Sweden AB.

Research and development work

The research and development work has advanced according to plan. Total costs for research and development during the period January to December amounts to TSEK 75 989 (TSEK 79 381), which corresponds to 83% (82%)

of the group’s total operating costs. Development costs vary over time, depending on where in the development phase the projects are.

Significant events during the financial year

In February 2020, a rights issue of TSEK 145 495 was carried out, and in December 2020 a directed share issue of TSEK 130 000 was carried out. Raised capital provides IRLAB with the prerequisites to continue developing mesdopetam and pirepemat based on the good results generated by these drug candidates in the completed Phase I and Phase IIa studies. At the same time, preclinical projects can be accelerated and the capacity of the ISP research platform can be expanded. Raised capital also resulted in greater institutional ownership in the company.

On September 30, IRLAB was listed on Nasdaq Stockholm’s main list.

The Phase IIb/III study with mesdopetam in levodopa-induced dyskinesias (PD-LIDs) received IND acceptance in October 2020 from the US Food and Drug Administration (FDA) to start the study in the US, which was done within one month.

During the year, both drug candidates mesdopetam and pirepemat were not only published in highly ranked scientific journals but also selected as covers in the journal *JPET, The Journal of Pharmacology and Experimental Therapeutics*.

Financial overview – the group

	2020	2019	2018	2017
Net revenue (TSEK)	0	26	18	109
Result after net financial items (TSEK)	-91 653	-96 120	-74 099	-56 225
Equity ratio (%)	94	87	94	95
R&D costs as a percentage of operating costs (%)	83	82	80	82

Financial overview – the parent company

	2020	2019	2018	2017
Net revenue (TSEK)	3 274	2 828	2321	2 053
Result after net financial items (TSEK)	-47 572	-38 201	-10 672	-8 444
Equity ratio (%)	82	98	99	99

Appropriation of result

Amount in SEK	
Proposal for appropriation of the company’s profit at the disposal of the Annual General Meeting are:	
premium fund	739 739 970
accumulated loss	-61 318 237
result for the year	-197 572 480
	480 849 253
The Board of Directors proposes that:	
is carried forward	480 849 253
	480 849 253

Comments on the income statement

The result for the period January 1 – December 31, 2020 amounts to TSEK -91,653 (TSEK -96,120). Earnings per share amounts to SEK -1.92 (SEK -2.37).

Financing and cash flow

Cash flow from operating activities in 2020 amounts to TSEK -89 214 (TSEK -91 201) and the cash flow for the period amounts to TSEK 166 482 (TSEK -23 915). Liquid assets as of December 31, 2020 amount to TSEK 277 009 (TSEK 110 527). On December 31, 2020, equity was TSEK 347 880 (TSEK 181 827) and the equity/assets ratio was 94% (87%). During the period, the company added, via issues, TSEK 257 706 (TSEK 65 471) net, after issue costs.

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

Administration report

Investments

Investments for the period January 1 – December 31, 2020 amounted to TSEK 394 (TSEK 137).

Personnel

The number of employees in the group during the period January – December averaged 18 (17). At the end of the period, the number of full-time positions, including long-term contracted consultants, was 20 (22), divided between 25 (27) people.

Share data

The number of registered shares at the end of the reporting period was 48 498 406 (40 499 695) shares, of which 48 418 630 (40 419 919) were A shares and 79 776 (79 776) were B shares.

The December new share issue resulted in an additional 3 250 000 A shares being registered during January 2021.

Nomination committee

Prior to the 2021 Annual General Meeting, and in accordance with the instructions that apply to IRLAB's Nomination Committee, the following Nomination Committee has been appointed. The Nomination Committee consists of Daniel Johnsson (Chair), Bo Rydlinger, Clas Sonesson, and the Chair of the Board Gunnar Olsson, who together represent approximately 53 percent of the votes and capital in IRLAB as of September 30, 2020.

Annual general meeting 2021

IRLAB's Annual General Meeting 2021 is planned to be held on May 6, 2021 in Gothenburg. As there is significant uncertainty about the development of the prevailing pandemic, a decision will be made at a later stage on the necessary precautionary measures that need to be taken in order for the Annual General Meeting to be conducted with the least possible risk to shareholders, employees and other participants. All general meeting documents, including the annual

report, will be available on the company's website no later than three weeks before the general meeting.

Parent company

The parent company in the group is IRLAB Therapeutics AB, organization number 556931-4692. The parent company's results for the period January 1 – December 31, 2020 amount to TSEK –38 201 (TSEK –10 672). Personnel costs amount to TSEK 6 793 (TSEK 5 983).

Risks and uncertainties

Risk in general in IRLAB's operations

Conducting operations within research and development of pharmaceuticals is associated with high risks, where the effects on the company's earnings and financial position cannot always be controlled by the company. IRLAB's business model entails high development costs followed by potential revenues connected to licensing, sales or partnerships only when a large part of the development has been completed. Taking the risks into account is important when assessing IRLAB's future potential, and are to be compared with the opportunities that exist in projects and operations. IRLAB's operations are based on continuous evaluation and analysis of available information with regard to risks in order to stay one step ahead and identify any problems at the earliest possible stage.

Risks related to the clinical projects

Safety and tolerability, as well as efficacy

Drug development is associated with the risk that drug candidates do not achieve an acceptable profile in terms of safety and tolerability, and efficacy. Results from early preclinical and clinical studies do not always correspond to results in more extensive studies, which may, for example, lead to requirements for further studies or, in the worst

case, an evaluation that the project should not be pursued further.

Large-scale production

Development of large-scale production of a drug is a complicated process, with high demands on reproducibility, robustness and quality. IRLAB continuously develops and improves its methods, but there is a risk that a production method will become unreasonably costly or provide unacceptable quality or efficacy, which may lead to a risk of increased costs, delays, or shutdown of projects. IRLAB has established close collaborations with partners who have the necessary expertise to develop large-scale production and, as far as possible, identify and mitigate the risks.

Regulatory approvals

In order to conduct clinical studies, manufacture, market and sell drugs, approvals from or registrations with relevant authorities are required for each geographical market in which IRLAB intends to be active. There is a risk that authorities' assessments deviate from IRLAB's assessments, requirements may differ between countries, and different authorities can also make different assessments. Furthermore, the rules and interpretations that currently apply for drugs to be approved may change in the future, which may affect the time frames or the possibilities of obtaining the necessary approvals. In order to be constantly updated regarding current regulations, guidelines and authorities' assessments, IRLAB collaborates with experienced players and advisers.

Impact of the covid-19 pandemic

Up until December 31, 2020, the global pandemic has not had any significant direct effects on IRLAB's operational activities, results or financial position. Effects in the medium to long-term cannot yet be assessed, but the company is monitoring and evaluating the situation on an ongoing basis. The circumstance that is deemed to pose

the greatest potential risk is that patient recruitment in future clinical studies may be delayed if the outbreak of covid-19 continues to strain global health care resources, and restrictions on individuals' freedom of movement is extended beyond what is known today. Delayed patient recruitment could mean that the company's costs during the period the studies are in progress will increase, and the company's possibility of implementing share issues is adversely affected, which could have an impact on its financial position.

Competition

A number of drug candidates are under development with the aim of treating the same or similar symptoms as IRLAB's drug candidates. There is a risk that these competing drug candidates will be approved for sale before IRLAB's, or that they have advantages regarding the efficacy and/or side effect profile in relation to IRLAB's drug candidates, which may make it harder for IRLAB's drugs to gain market share.

Risks related to operations

Product liability and insurance

Participants in clinical trials with IRLAB's drug candidates may experience side effects, which may lead to damage claims or other claims, including claims based on product liability, being directed at IRLAB. IRLAB has taken out product liability insurance, but there is a risk that any claims will exceed IRLAB's insured amount or that IRLAB will not be able to obtain or maintain insurance cover on reasonable terms in the future.

Partnership agreements

IRLAB's business model is largely based on entering into agreements in the form of licensing or collaboration agreements regarding the remaining development and commercialization of its drug candidates. There is a risk that expected revenues will decrease or disappear completely

Administration report

for IRLAB if a partnership agreement cannot be reached or if the partners do not succeed in bringing a drug candidate to the market.

Trade secrets, patents and intellectual property rights

IRLAB is dependent on protecting company and trade secrets. There is a risk that competitors will succeed in accessing sensitive information and use this in a way that has a negative impact on IRLAB. The company’s intellectual property rights are primarily protected through patents and patent applications. There is a risk that IRLAB’s patent applications will not be granted and/or that granted patents will be challenged by third parties, and/or that third parties will intentionally or unintentionally infringe on patents, trademarks and other intellectual property rights. Patent litigation can entail significant legal costs and if a patent is not granted, the conditions and revenues can be significantly reduced.

IRLAB maintains an active and continuous dialogue with our external Patent Attorney and works proactively to be well prepared in the event of a patent dispute. Internally, IRLAB works continuously with systematic quality work that includes policies and governing documents which describe how each employee shall handle and protect sensitive information for the company. There is also a continuous review of the IT environment and security procedures linked to it to ensure that IRLAB has updated and sufficient protection.

Dependence on personnel and key people

IRLAB is dependent on its highly qualified and experienced personnel and leading key employees. There is a risk that personnel losses and possible difficulty in recruiting corresponding experience and competence may have a negative impact on the ability to maintain schedules and quality within research and development. At IRLAB, ensuring adequate competence and resources in order to achieve the

business goals is a focus area. Continuous work is underway to ensure the knowledge of individual employees is not isolated, and to gradually rejuvenate the personnel without losing competence and experience.

Dependence on suppliers

IRLAB has a limited own organization and is highly dependent on collaborations with suppliers in various areas. There is a risk that manufacturers and suppliers do not deliver in accordance with agreements entered into, and changing suppliers can be both costly and time-consuming, and quality, quantity and conditions may differ from those of original suppliers.

IRLAB’s quality processes include thorough evaluation to ensure competence and experience before initiating collaborations, and thereby reduce the risk of problems. During ongoing collaborations, continuous follow-up occurs to ensure that deliveries take place with the expected quality and in accordance with the agreed schedule. The language in agreements is also a focus area where IRLAB collaborates with legal experts.

Risks related to financing

Future financing

The financing of IRLAB’s operations is dependent on the possibility to generate revenue or carry out new issues. There is a risk that revenue will not be generated and that new issues will not be possible to carry out when the need arises, or that they cannot be carried out on terms acceptable to IRLAB.

IRLAB maintains an active and continuous dialogue with advisors and potential investors to ensure the best model for IRLAB.

Currency fluctuations

The company’s accounting and functional currency is Swedish kronor, SEK. Over the next few years, however, a

major part of IRLAB’s operating costs will be denominated primarily in foreign currencies. There is a risk that currency fluctuations will impact future results. IRLAB works actively to analyze the impacts of this risk and to evaluate tools to manage it in the best way.

For a further description of financial risks, see Note 3.

Outlook for 2021

The company intends to expand the Phase IIb/III study with mesdopetam to more countries in Europe and more clinics during 2021.

The company also aims to initiate a Phase IIb study for the pierepemat during the first half of 2021.

With regard the drug candidates IRL942 & IRL1009, the preclinical work will be accelerated according to plan.

The company’s priority is to expand and further utilize the research platform ISP’s unique discovery capability in 2021.

The company does not expect to have any significant income in 2021.

Shares and owners

The largest owners on December 31, 2020 are shown in the table on page 67 and refer to registered shares. No individual owner has more than 10 percent of the capital or votes in the company.

The December new share issue has been registered after the balance sheet date, whereupon Nordnet Pensionsförsäkring AB and Unionen are the ninth and tenth largest owners, respectively. The total registered number of shares increases in conjunction with the new share issue by 3 250 000 A shares.

The development of the share capital is shown in Note 20.

Proposed division

The Board of Directors proposes that no dividend be paid for the financial year 2020.

Consolidated financial statements

Consolidated income statement in summary

Amount in TSEK	Note	2020 Jan-Dec	2019 Jan-Dec
Operating income			
Net revenue		0	26
Other operating income	7	404	422
<i>Total income</i>		<i>404</i>	<i>448</i>
Operating expenses			
Other external costs	8, 9	-65 630	-71 162
Personnel costs	10	-23 968	-22 136
Depreciation of intangible and tangible fixed assets	8	-2 256	-2 931
Other operating costs		-8	-67
<i>Total operating expenses</i>		<i>-91 862</i>	<i>-96 296</i>
Operating result		-91 458	-95 848
Result from financial items			
Financial income		1	0
Financial costs	8, 11	-196	-272
<i>Total financial items</i>		<i>-195</i>	<i>-272</i>
Result after financial items		-91 653	-96 120
Tax on income	12	0	0
Result for the year		-91 653	-96 120
Earnings per share before and after dilution (SEK)		-1.92	-2.37
Average number of shares before and after dilution		47 677 734	40 592 654
Number of shares at year-end		51 748 406	43 109 695

The result for the year is in its entirety attributable to the parent company’s shareholders.

Consolidated statement of comprehensive income in summary

Amount in TSEK	2020 Jan-Dec	2019 Jan-Dec
Result for the year	-91 653	-96 120
Other comprehensive income	0	0
Total result for the year	-91 653	-96 120

Consolidated financial statements

Consolidated
balance sheet

Amount in TSEK	Note	2020-12-31	2019-12-31
ASSETS			
Fixed assets			
Intangible fixed assets			
Research database	13	518	777
Acquired development projects	14	81 492	81 492
		82 011	82 270
Tangible fixed assets			
Improvements to someone else's property	15	95	101
Equipment, tools and installations	16	1 006	932
Utilized assets	17	3 216	4 880
		4 317	5 919
Total fixed assets		86 328	88 189
Current assets			
Short-term receivables			
Other receivables		4 711	7 687
Prepayments and accrued income	19	2 020	1 664
		6 732	9 351
Cash and cash equivalents		277 009	110 527
Total current assets		283 741	119 878
TOTAL ASSETS		370 068	208 067

Amount in TSEK	Note	2020-12-31	2019-12-31
EQUITY AND LIABILITIES			
Equity			
Share capital	20	970	862
Unregistered share capital		65	0
Other contributed capital		685 630	428 097
Retained earnings incl. results for the year		-338 786	-247 133
Total equity		347 880	181 827
Long-term liabilities			
Leasing debt	8	1 270	2 900
Total long-term liabilities		1 270	2 900
Short-term liabilities			
Leasing debt	8	1 657	1 643
Accounts payable		3 683	8 438
Other liabilities		3 773	5 445
Accrued expenses and prepaid income	22	11 805	7 814
Total short-term liabilities		20 918	23 340
TOTAL EQUITY AND LIABILITIES		370 068	208 067

Consolidated financial statements

Consolidated statements of changes in equity in summary

Amount in TSEK	Share capital	Unregistered share capital	Other capital contributed equity	Retained earnings incl. total result for the period	Total equity
Equity January 1, 2019	810	0	362 678	-151 013	212 476
Total result for the year				-96 120	-96 120
Transactions with owners in their capacity as owners:					
Rights issue	52		70 418		70 471
Issue costs			-5 000		-5 000
Equity December 31, 2019	862	0	428 097	-247 133	181 827
Equity January 1, 2020	862	0	428 097	-247 133	181 827
Total result for the year				-91 653	-91 653
Transactions with owners in their capacity as owners:					
Rights issue	108	65	275 322		275 495
Issue costs			-17 789		-17 789
Equity December 31, 2020	970	65	685 630	-338 786	347 880

Consolidated statements of cash flows in summary

Amount in TSEK	Note	2020 Jan-Dec	2019 Jan-Dec
Operating activities			
Operating result		-91 458	-95 848
Adjustment for items not included in the cash flow	23	2 256	2 960
Interest received		1	0
Paid interest		-196	-272
Paid tax		0	0
Cash flow from operating activities before changes in working capital		-89 397	-93 160
Cash flow from changes in working capital			
Change in operating receivables		2 620	-3 778
Change in operating liabilities		-2 437	5 737
Cash flow from operating activities		-89 214	-91 201
Investment activities			
Acquisition of tangible fixed assets		-394	-137
Cash flow from investment activities		-394	-137
Financing activities			
Amortization of financial liabilities	21	-1 616	-1 547
Issue of new shares		275 495	68 970
Issue costs		-17 789	0
Cash flow from financing activities		256 091	67 423
Cash flow for the year		166 482	-23 915
Cash and cash equivalents at the start of the year		110 527	134 442
Cash and cash equivalents at the end of the year	24	277 009	110 527

Financial statement of the parent company

Parent company
income statement
in summary

Amount in TSEK	Note	2020 Jan-Dec	2019 Jan-Dec
Operating income	6		
Net revenue		3 274	2 828
<i>Total income</i>		3 274	2 828
Operating expenses	6		
Other external costs	9	-8 052	-8 673
Personnel costs	10	-7 794	-7 356
<i>Total operating expenses</i>		-15 845	-16 028
Operating result		-12 572	-13 201
Result from financial items			
Result from shares in group companies		-35 000	-25 000
Interest income		1	0
Interest costs	11	-1	0
<i>Total financial items</i>		-35 000	-25 000
Result after financial items		-47 572	-38 201
Appropriations			
Provided group contribution		-150 000	0
<i>Total appropriations</i>		-150 000	0
Result before tax		-197 572	-38 201
Tax on the year's result	12	0	0
Result for the year		-197 572	-38 201

Parent company
statement of
comprehensive income
in summary

Amount in TSEK	2020 Jan-Dec	2019 Jan-Dec
Result for the year	-197 572	-38 201
Other comprehensive income	0	0
Total result for the year	-197 572	-38 201

Financial statement of the parent company

Parent company
balance sheet in summary

Amount in TSEK	Note	2020-12-31	2019-12-31
ASSETS			
Fixed assets			
Financial fixed assets			
Shares in group companies	18	350 320	350 320
Total fixed assets		350 320	350 320
Current assets			
Current receivables			
Receivables in the group		447	278
Other receivables		506	636
Prepaid expenses and accrued expenses	19	280	301
		1 232	1 215
Cash and cash equivalent		239 693	79 166
Total current assets		240 926	80 381
TOTAL ASSETS		591 246	430 701

Amount in TSEK	Note	2020-12-31	2019-12-31
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	20	970	862
Unregistered share capital		65	0
		1 035	862
Unrestricted equity			
Share premium fund		739 740	482 207
Balanced result		-61 318	-23 118
Result for the year		-197 573	-38 201
		480 849	420 888
Total equity		481 884	421 750
Short-term liabilities			
Accounts payable		461	3 416
Liabilities to the group		100 120	212
Other liabilities		194	172
Accrued expenses and prepaid income	22	8 587	5 151
Total liabilities		109 362	8 951
TOTAL EQUITY AND LIABILITIES		591 246	430 701

Financial statement of the parent company

Parent company statements of changes in equity

Amount in TSEK	Share capital	Unregistered share capital	Other capital contributed equity for the period	Retained earnings incl. total result	Total equity
Equity January 1, 2019	810	0	416 789	-23 118	394 481
Total result for the year				-38 201	-38 201
Transactions with owners in their capacity as owners:					
Rights issue	52		70 418		70 470
Issue costs			-5 000		-5 000
Equity December 31, 2019	862	0	428 207	-61 319	421 750
Equity January 1, 2020	862	0	428 207	-61 319	421 750
Total result for the year				-197 572	-197 572
Transactions with owners in their capacity as owners:					
Rights issue	108	65	275 322		275 495
Issue costs			-17 789		-17 789
Equity December 31, 2020	970	65	739 740	-258 891	481 884

Parent company statements of cash flows in summary

Amount in TSEK	Note	2020 Jan-Dec	2019 Jan-Dec
Operating activities			
Operating result		-12 572	-13 201
Interest received		1	0
Paid interest		-1	0
Cash flow from operating activities before changes in working capital		-12 572	-13 201
Cash flow from changes in working capital			
Change in operating receivables		-18	57
Change in operating liabilities		411	2 610
Cash flow from operating activities		-12 179	-10 533
Investment activities			
Cash flow from investment activities		0	0
Financing activities			
Rights issue		275 495	68 970
Issue costs		-17 789	0
Provided shareholder contributions and group contributions		-85 000	-25 000
Cash flow from financing activities		172 706	43 970
Cash flow for the year		160 527	33 437
Cash and cash equivalents at the start of the year		79 166	45 729
Cash and cash equivalents at the end of the year	24	239 693	79 166

Key financial ratios for the group

	2020 Jan-Dec	2019 Jan-Dec	2018 Jan-Dec	2017 Jan-Dec
Operating result, TSEK	-91 458	-95 848	-73 897	-54 218
Result for the period, TSEK	-91 653	-96 120	-74 099	-56 225
Result for the period attributable to Parent Company shareholders, (TSEK)	-91 653	-96 120	-74 099	-56 225
Earnings per share before and after dilution, (SEK)	-1.92	-2.37	-1.94	-1.67
R&D costs, TSEK	75 989	79 381	58 927	45 219
R&D costs as a percentage of operating costs, %	83	82	80	82
Cash and cash equivalents at the end of the period, (TSEK)	277 009	110 527	134 442	74 709
Cash flow from operating activities, (TSEK)	-89 214	-91 201	-70 790	-57 741
Cash flow for the period, TSEK	166 482	-23 915	59 733	48 973
Equity, TSEK	347 880	181 827	212 476	155 000
Equity attributable to Parent Company shareholders, TSEK	347 880	181 827	212 476	155 000
Equity per share, SEK	6.72	4.22	5.25	4.43
Equity ratio, %	94	87	94	95
Average number of employees	18	17	15	12
Average number of employees in R&D	17	16	14	11

Of the above key financial ratios, only the key financial ratio ‘Earnings per share before and after dilution’ is mandatory and defined in accordance with IFRS. Of the other key financial ratios, Profit for the period, ‘Cash and cash equivalents at the end of the period’, ‘Cash flow from operating activities’, ‘Cash flow for the period’ and ‘Equity attributable to the Parent Company’s shareholders’ are drawn from a financial statement defined by IFRS.

The table below derives the calculation of key financial ratios, both for the IFRS mandatory key financial ratio ‘Earnings per share before and after dilution’, but also for the key financial ratios ‘R&D costs’, ‘R&D costs as a percentage of operating costs’, ‘Equity attributable to the Parent Company’s shareholders per share’ and ‘Equity ratio’.

The company’s business is to conduct research and development (R&D), which is why R&D costs as a percentage of operating costs are a significant key financial ratio as a measure of efficiency and the proportion of the company’s costs used in R&D.

The company’s operations are such that it does not have a steady flow of revenue, but rather this comes irregularly in conjunction with the signing of license agreements and achieved milestones. Therefore, the company follows the key financial ratios ‘Equity’ and ‘Equity attributable to the Parent Company’s shareholders per share’ in order to be able to assess the company’s financial position and stability. Together with these key financial ratios, the various measures of cash flows that follow from the Group’s report on cash flow are also followed.

For definitions, see the section Definitions below.

	2020	2019
Result for the period attributable to Parent Company shareholders, (TSEK)	-91 653	-96 120
Average number of shares before and after dilution	47 677 734	40 592 654
Earnings per share before and after dilution, (SEK)	-1,92	-2,37
Operating costs, (TSEK)	91 862	96 296
Administrative costs, (TSEK)	-13 617	-13 983
Depreciation and impairment of fixed assets, TSEK	-2 256	-2 932
R&D costs (TSEK)	75 989	79 381
R&D costs as a percentage of operating costs, (%)	83	82
Equity attributable to Parent Company shareholders, (TSEK)	347 880	181 827
Number of shares per balance sheet date incl. emissions not yet registered *	51 748 406	43 109 695
Equity attributable to Parent Company shareholders per share, (SEK)	6,72	4,22
Equity, TSEK	347 880	181 827
Total assets, TSEK	370 068	208 067
Equity ratio, %	94	87

* As of 31 December 2020, 3 250 000 shares were not yet registered.

Definitions

Key financial ratio	Definition	Reasons for using financial ratios that are not defined in accordance with IFRS
Net revenue	Revenues for goods and services sold in the main business during the current period.	
Operating result	Result before financial items and tax.	Operating result provides a picture of the results that the company's regular operations have generated.
Earnings per share before and after dilution	The result attributable to the Parent Company's shareholders divided by the weighted average number of shares during the period before and after dilution, respectively.	
Average number of shares before and after dilution	Average number of shares outstanding during the period before and after dilution, respectively.	
R&D costs as a percentage of operating costs	R&D costs divided by operating costs, which include other external costs, personnel costs and depreciation.	Management believes that the company's R&D costs in relation to total costs are an important parameter to follow as an indicator of how great a proportion of the total costs are used for the company's main operations.
Cash and cash equivalents	Cash and bank balances.	

Key financial ratio	Definition	Reasons for using financial ratios that are not defined in accordance with IFRS
Cash flow from operating activities	Cash flow before cash flows from investing and financing activities.	
Cash flow for the period	The period's change in cash and cash equivalents excluding the effect of unrealized exchange rate gains and losses.	
Equity per share	Equity attributable to the Parent Company's shareholders divided by the number of shares at the end of the period.	Management follows this number in order to monitor how great a value equity is per share.
Equity ratio	Equity as a percentage of total assets.	Management follows this figure as an indicator of the financial stability of the company.
Average number of employees	The average number of employees is calculated as the sum of hours worked during the period divided by normal working hours for the period.	
Average number of employees in R&D	The average number of employees in the company's research and development departments.	

Notes

Note 1. General information

IRLAB Therapeutics AB (publ) with its registered office in Gothenburg, registered in Sweden with corporate identity number 556931-4692, is the parent company of Integrative Research Laboratories Sweden AB and its subsidiaries IRL626 AB, IRL752 AB and IRL790 AB. These companies are collectively referred to as the Group.

The address is Arvid Wallgrens backe 20, 413 46 Gothenburg. The Group was formed in July 2014 when a controlling influence was obtained over Integrative Research Laboratories Sweden AB. On April 14, 2021, the Board of Directors approved this annual report and consolidated financial statements for publication.

The group’s operations

The group’s operations are conducted in the subsidiary Integrative Research Laboratories Sweden AB, which is a research company that develops new treatment principles for neurological and psychiatric diseases, with a primary effect on the functions of the central nervous system. The company’s main assets are the drug candidates IRL752 and IRL790, both in the clinical phase, for the treatment of axial motor symptoms and dementia in Parkinson’s disease, and dyskinesias and psychosis in Parkinson’s disease, respectively, as well as a unique and proprietary research platform for developing new drug substances.

The parent company’s operations

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

Note 2. Accounting principles

The consolidated financial statements are prepared in accordance with the Swedish Annual Accounts Act, RFR 1 Supplementary Accounting Rules for Groups, Interna-

tional Financial Reporting Standards (IFRS) and interpretations from the IFRS Interpretations Committee (IFRS IC), as adopted by the EU.

The parent company’s annual report has been prepared in accordance with the Swedish Annual Accounts Act and RFR 2 Accounting for Legal Entities. The recommendation means that the parent company applies the same accounting principles as the group, except in cases where the Swedish Annual Accounts Act or applicable tax rules limit the possibilities of applying IFRS. Differences between the parent company’s and the group’s accounting principles are reported under the parent company’s accounting principles below.

Basis for the report

The consolidated financial statements have been prepared in accordance with the acquisition value method. The balance sheet items that are classified as current assets and current liabilities are expected to be recovered and paid within 12 months. All other balance sheet items are expected to be recovered or paid later. The group’s functional accounting currency is Swedish kronor (SEK). The consolidated financial statements are stated in thousands of Swedish kronor (TSEK), unless otherwise stated.

New and changed standards such as applied by the group

No standards to be applied by the group for the first time on 1 January 2020 have had or are expected to have any impact on the consolidated accounts.

New standards and interpretations that have not yet been applied by the group

A number of new standards and interpretations enter into force for financial years beginning after January 1, 2020 and have not been applied in the preparation of this annual report. The new standards and interpretations that have not yet entered into force are not expected to have any impact on the group’s financial reports.

Consolidated financial statements

Subsidiaries are all companies over which the group has a controlling influence. The group controls a company when it is exposed to or has the right to a variable return from its holding in the company, and has the opportunity to influence the return through its influence in the company. Subsidiaries are included in the consolidated financial statements from the date on which the controlling influence is transferred to the group. They are excluded from the consolidated financial statements from the date on which the controlling influence ceases.

The acquisition method is used to report the group’s operational acquisitions. The purchase price for the acquisition of a subsidiary consists of the fair value of transferred assets and liabilities that the group incurs to the previous owners of the acquired company and the shares issued by the group. The purchase price also includes the fair value of all assets or liabilities that are a consequence of an agreement on a contingent purchase price. Identifiable acquired assets and liabilities assumed in an operational acquisition are initially valued at fair value on the acquisition date. Acquisition-related costs are registered as an expense when they arise.

Intra-group transactions, balance sheet items and unrealized gains and losses on transactions between group companies are eliminated. The accounting principles for subsidiaries have been changed, where applicable, to ensure a consistent application of the group’s principles.

Foreign currency translation

Functional and report currency

Items included in the financial reports for the various units in the group are valued in the currency used in the economic environment in which each company is primarily operative (functional currency). In the consolidated financial statements, Swedish kronor (SEK) is used, which is the group’s reporting currency.

Transactions and balance sheet items

Transactions in foreign currency are translated into the functional currency according to the exchange rates that apply on the transaction date, or the day when the items are revalued. Exchange rate gains and exchange rate losses that arise from the payment of such transactions, and from the translation of monetary assets and liabilities in foreign currency at the exchange rate on the balance sheet date, are reported in the income statement.

Exchange rate gains and exchange rate losses relating to loans and cash and cash equivalents are reported in the income statement as financial income or expenses. All other exchange rate gains and exchange rate losses are reported net in the items ‘Other operating income’ or ‘Other operating costs’ in the income statement.

Intangible and tangible fixed assets

Intangible and tangible fixed assets are reported at acquisition value less depreciation. The acquisition value includes expenses that can be directly attributed to the acquisition of the asset. Additional expenses are added to the asset’s carrying amount or are reported as a separate asset, as appropriate, only when it is probable that the future economic benefits associated with the asset will benefit the group and the asset’s acquisition value can be measured reliably. Expenses for repairs and maintenance are reported as costs in the income statement during the period in which they arise.

Depreciation is made on a linear basis as follows:

- Improvements to someone else’s property 20 years
- Inventory, tools and installations 5 years

Development expenditure that add functionality and value are reported as intangible assets when the following criteria are met, which is normally the case when a development project is in Phase III.

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- it is technically and financially possible to complete the asset,
- adequate technical, financial and other resources to complete the development and to use or sell the asset are available,
- there is an intention and prerequisite to sell or use the asset,
- it is likely that the asset will generate revenue or lead to cost savings, and
- the expenditure can be calculated satisfactorily.

Directly attributable expenses, which are capitalized as part of an intangible asset, include expenses for employees and a reasonable share of indirect costs. Other development costs, which do not meet the above criteria, are registered as an expense when they arise. Development costs that were previously registered as an expense are not reported as an asset in the subsequent period.

The group does not currently have a development project in Phase III or in a later Phase, which is why no development expenditure has yet been capitalized. The intangible assets reported in the balance sheet refer to acquired intangible assets consisting of a research database and acquired development projects. Acquired development projects consist of five patent families, after impairment of two, which are not written off but are tested for impairment as they are not yet ready for use.

The assets’ residual values and useful lives are tested at the end of each reporting period and adjusted if necessary. An asset’s carrying amount is immediately written down to its recoverable amount if the carrying amount of the asset exceeds its estimated recoverable amount.

Impairments

Intangible assets that are not ready for use are not depreciated but are tested annually or when there is an indication of devaluation, with regard a possible need for impairment. Assets that are depreciated are assessed with respect to devaluation whenever events or changes in

circumstances indicate that the carrying amount may not be recoverable. An impairment is made with the amount by which the asset’s carrying amount exceeds its recoverable amount. The recoverable amount is the higher of the asset’s fair value, less sales costs, and its value in use. When calculating value in use, the estimated future cash flow is discounted to present value with a discount rate before tax that reflects the current market assessment of the time value of money and the risks associated with the asset.

When assessing the need for impairment, assets are grouped at the lowest levels where there are substantially independent cash flows (cash-generating units). For assets that have previously been impaired, an examination is made on each balance sheet date as to whether reversal should be made.

Financial assets

The group classifies and values its financial assets based on the business model that manages the asset’s contracted cash flows and the nature of the asset. The financial assets are classified in one of the following categories: financial assets that are valued at accrued acquisition value, financial assets that are valued at fair value through other comprehensive income, and financial assets that are valued at fair value through profit or loss.

At present, the group only has financial assets that are not normally sold outside the group, and where the purpose of the holding is to obtain contractual cash flows.

Financial assets valued at accrued value

All financial assets are classified as financial assets that are valued at accrued acquisition value with application of the effective interest method.

When acquiring financial assets, expected credit losses are reported on an ongoing basis during the holding period, normally taking into account credit loss risk within the next 12 months. In the event that the credit risk has increased significantly, a provision is made for the credit losses that are expected to occur during the entire term of the asset.

IRLAB applies the simplified method for calculating credit losses, which is based on historical data regarding payment patterns and solvency of the counterparty. On the basis of historical data, the expected credit losses are considered to be extremely limited.

Cash and cash equivalents

Cash and cash equivalents include, in both the balance sheet and in the report on cash flows, cash, bank balances and other short-term investments maturing within three months from the date of acquisition.

Equity

Share capital

Ordinary shares are classified as share capital.

Issue costs

Transaction costs that can be directly attributed to the issue of new ordinary shares or options are reported, net after tax, in equity as a deduction from the issue proceeds.

Financial liabilities

Financial liabilities valued at accrued acquisition value

The group only has financial liabilities that are classified and valued at accrued acquisition value, with the application of the effective interest method. Reporting initially occurs at fair value, net after transaction costs.

Provisions

Legal and informal obligations are reported as provisions that are attributable to the financial year or previous financial years and which on the balance sheet date are certain or likely to occur, but uncertain as to the amount or time when they shall be honored.

Income tax

Reporting of income tax includes current tax and deferred tax. The tax is reported in the income statement, except in cases where it relates to items that are reported directly in equity. In such cases, the tax is also reported in equity. Deferred tax is reported according to the balance sheet method for all significant temporary differences. A temporary difference exists when the book value of an asset or liability differs from the tax value.

Deferred tax is calculated with the application of the tax rate that has been decided on or announced on the balance sheet date, and that is expected to apply when the tax claim in question is realized or the tax liability is settled.

Deferred tax assets are reported to the extent that it is probable that future tax surpluses will exist, against which the temporary differences can be utilized.

Revenue from agreements with customers

Revenue from agreements with customers is reported when the performance commitment has been fulfilled and control of a product or service has been transferred to the customer. This assessment shall be viewed from the customer’s perspective, taking into account indications such as transfer of ownership and risks, customer acceptance, physical access, and the right to invoice. Assessment must also be made if the control is transferred at a particular time or over time.

Services

The group has, at present, limited revenue. The agreement that generated revenue during the year was intended for customized solutions that were binding on the customer, and where the commitments for both parties were clearly defined during the term of the contract. Revenues for the services are reported over time. A transaction price in relation to the services is represented by payments based on the degree of completion. A contract asset arises in cases where services have been performed and there is an unconditional right to payment, but invoicing has not yet taken place.

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Reporting of public grants

Public grants are reported at fair value as soon as there is reasonable assurance that the conditions associated with the grant will be met and thereby that the grant will be received.

Grants received to cover costs are reported under the heading ‘other income’ in the same period as the costs arise.

Leasing agreements

When signing new leasing agreements, a usufruct asset and a leasing liability are reported in the balance sheet. The acquisition value consists of the discounted remaining leasing fees for non-cancellable leasing periods. Possible extension periods are included if the group is reasonably certain that these will be used. When discounting, the group’s marginal borrowing rate is used.

The leasing agreement may change during the leasing period, whereby a revaluation of the leasing debt and the usufruct asset takes place. Leasing fees are divided between amortization of the leasing debt and payment of interest.

The company applies the relief rules in relation to leasing agreements where the underlying asset has a low value, as well as short-term leasing agreements. These leasing agreements are reported as an expense during the period in which the use takes place.

Remuneration to employees

Liabilities for salaries and remuneration and paid absence, which are expected to be settled within 12 months after the end of the financial year, are reported as current liabilities to the amount that is expected to be paid when the debts are settled, without regard to discounting. The cost is reported in line with the duties being performed by the employees.

The group has both defined benefit and defined contribution pension plans. In defined contribution plans, the company pays fixed contributions to an independent pen-

sion institution. Once the fee is paid, the company has no additional obligations. Defined benefit plans are available in the form of ITP1 and ITP2 from the insurer Alecta. Alecta cannot provide a distribution of the group’s total plan assets and pension commitments, which is why these pension plans are also reported as defined contribution plans.

The cost of pensions is reported during the period when the employees performed the duties to which the remuneration relates.

Cash flow analysis

The cash flow analysis is prepared according to the indirect method, which means that the operating result is adjusted for transactions that did not result in incoming or outgoing payments during the period, as well as for any revenue and costs attributable to the investment or financing operations’ cash flows. Cash and cash equivalents include cash and immediately available balances with banks.

Parent company’s accounting principles

The parent company applies the same accounting principles as the group, except in the respects set out below. The parent company’s accounting principles are unchanged compared with the previous year.

Shares in subsidiaries

Shares in subsidiaries are reported at acquisition value after deductions for any impairments. The acquisition value includes acquisition-related costs and any additional purchase considerations. When there is an indication that shares in subsidiaries have decreased in value, a calculation of the recoverable amount is made. If the recoverable amount is lower than the carrying amount, an impairment is reported. Impairments are reported in the item ‘Result from shares in group companies’.

Financial instruments

The parent company does not apply IFRS 9 except with regard the rules for assessing and calculating the need

for impairment of financial assets. In the parent company, financial fixed assets are valued at acquisition value less any impairment, and financial current assets at the lower of acquisition value and fair value less sales costs.

Leasing agreements

The parent company uses the exemption relating to the application of IFRS 16 Leasing Agreements, which means that all leasing is reported as an expense on a linear basis over the leasing period.

Note 3. Financial risk management and capital risk

FINANCIAL RISK MANAGEMENT

Through its operations, the group is exposed to various financial risks, such as market risk (extensive currency risk and interest rate risk in cash flow), credit risk and liquidity risk. The group’s overall risk management policy, which has been established by the Board of Directors, is to strive for minimal adverse effects on financial results and position.

Market risk

Currency risk

The group operates both nationally and internationally,

which means exposure to fluctuations in various currencies, and especially with regard to GBP, USD and EUR. Currency risk arises through future business transactions, as well as reported assets and liabilities. The scope of the company’s operations currently means that the net exposure in foreign currencies is limited. The group’s foreign exchange policy means that amounts received in foreign currency shall immediately be exchanged for Swedish kronor.

If the Swedish krona had weakened or strengthened by 10%, with all other variables constant, the recalculated result after tax as of December 31, 2020 would have been TSEK 159 (TSEK 248) higher or lower, largely as a result of gains and losses when recalculating current receivables and liabilities. The corresponding impact on the parent company would have been TSEK 0 (TSEK 15).

Interest rate risk in the cash flow

Interest rate risk is the risk that the value of financial instruments varies due to changes in market interest rates. The group currently only has interest-bearing financial assets in the form of bank balances and interest-bearing liabilities in the form of leasing liabilities.

Calculated on the basis of financial interest-bearing assets and liabilities that have a variable interest rate as of December 31, 2020, a single percentage point change

Financial liabilities as of
December 31, 2020 due for payment:

	Within 3 months	Between 3 months and 1 year	Between 1 year and 2 years	Between 2 years and 5 years	Later than 5 years
Leasing debt	438	1 313	1 313	0	0
Accounts payable	3 683	0	0	0	0
Other liabilities and accrued expenses	7 089	0	0	0	0
Total	11 210	1 313	1313	0	0

Notes

in the market interest rate would affect the group’s result after tax by TSEK 2 740 (TSEK 1 060). The corresponding effect on the parent company would have been TSEK 2 397 (TSEK 792).

Credit risk

Credit risk is the risk that a party to a transaction with a financial instrument will not be able to fulfill its obligation. The maximum exposure to credit risks relating to financial assets as of December 31, 2020 amounted to TSEK 280 776 (TSEK 117 419). The corresponding figure for the parent company was TSEK 240 365 (TSEK 79 871). Cash and cash equivalents are only placed in a cash account or similar, and the group only uses credit institutions with a high credit rating to minimize credit risk.

Liquidity risk

Caution in managing liquidity risk means holding sufficient cash or cash equivalent, or alternatively agreed credit facilities to be able to close market positions. In preparing this financial report, the Board of Directors estimates that there is sufficient capital to complete the planned implementation of the Phase IIb study for pirepemat and the Phase IIb/III study for mesdopetam, which means that the capital requirement is secured for at least 12 months from the balance sheet date. The maturity structure for the group’s financial liabilities is shown below.

Capital risk management

The group’s goal regarding capital structure, defined as equity, is to secure the company’s ability to continue its operations in order to generate returns for shareholders and benefits to other stakeholders, and that the capital structure is optimal with regard to the cost of capital. Dividends to shareholders, redemption of shares, issue of new shares or sale of assets are examples of measures that the company can use to adjust the capital structure.

The group’s debt to equity ratio	2020-12-31	2019-12-31
Total interest-bearing liabilities	2 927	4 543
Deduct: interest-bearing assets	277 009	10 527
Net debt	-274 082	-105 984
Total equity	347 880	181 827
Net debt to equity ratio	-78,8%	-58,3%

Net debt: Interest-bearing liabilities less interest-bearing assets (incl. cash and cash equivalents).
Net debt to equity ratio: Net debt in relation to equity.

Note 4. Important estimates and assessments for accounting purposes

The most important assumptions about the future, and other important sources of uncertainty in estimates as of the balance sheet date, which entails a significant risk of material adjustments in the reported values of assets and liabilities during the coming financial year, are described below. The greatest uncertainty is found in the intangible fixed assets. Intangible fixed assets are held by the subsidiary and the subsidiaries, and were acquired by the group through operational acquisitions. Intangible fixed assets are tested annually for impairment.

Impairment tests are based on a review of the recoverable amount that is estimated on the basis of the value in use of the assets. Company management makes calculations of future cash flows according to internal business plans and forecasts. This review also uses estimates of, among other things, the discount rate and future growth rates beyond established budgets and forecasts. Impairment of intangible assets has been made in the amount of TSEK 0 (TSEK 740). Reported values for intangible assets amount to TSEK 82 011 (TSEK 82 270) at the end of the year, of which acquired development costs amount to TSEK 81 492 (TSEK 81 492) and the research platform amounts to TSEK 519 (TSEK 777). Changes in the assumptions made by the company management during the impairment test could have a significant impact on the company’s results and financial position.

As of December 31, 2020, deficit deductions in the group amount to TSEK 466 711 (TSEK 353 828). For the parent company, deductible deficiencies amount to TSEK 245 102 (TSEK 61 266). Before the group shows positive results, the assessment is made that only value deficit deductions to such an extent that the deferred tax asset meets the deferred tax liability that arose from the acquisition of the intangible assets.

Note 5. Segment information

Operating segments are reported in a manner consistent with the internal reporting submitted to the chief operating decision maker. The chief operating decision maker is the function responsible for allocating resources and assessing the operating segments’ results. In the group, this function has been identified as the management team, which consists of eight people, including the CEO. The management team has determined that the group as a whole constitutes a segment based on the information that is processed and which, in consultation with the Board of Directors, is used as a basis for allocating resources and evaluating results.
All fixed assets are located in Sweden.
The group did not have any net revenue during the year.

Note 6. Purchases and sales within the group

TSEK 3 274 (TSEK 2 825) of the parent company’s net revenue is made up of invoicing to group companies. The parent company’s procurement of services from group companies in 2020 amount to TSEK 486 (TSEK 892).

Note 7. Other operating income

The group	2020	2019
Public grants: Planning grants, EU	300	346
Insurance payment	0	74
Exchange rate gains	104	2
Total	404	422

Note 8. Leasing agreements

The group has leasing agreements, primarily in the form of contracts for the use of office premises. When discounting future leasing payments, the group’s marginal borrowing rate has been used, which currently amounts to 5%.
The following amounts have been reported in the income statement.

The group	2020	2019
Amounts reported in the result		
Depreciation of usufruct assets	-1 664	-1 664
Interest expenses for leasing liabilities	-193	-271
Costs attributable to leasing agreements of low value	0	-77
Costs attributable to variable fees that are not included	-130	-127

The total cash flow for leasing agreements amounted to TSEK -1 818 (TSEK -1 818).

Notes

Note 9.
Remuneration to auditors

	The group		The parent company	
	2020	2019	2020	2019
Fees and cost reimbursements				
Öhrlings PricewaterhouseCoopers AB				
Auditing activities	290	280	290	280
Auditing activities in addition to the auditing assignment	102	75	102	75
Tax advice	5	1	5	1
Other assignments	298	0	298	1
Total	695	357	695	357

Audit assignments refer to the review of the annual report and accounting, as well as the Board of Directors’ and the CEO’s administration, other tasks that are the responsibility of the company’s auditors to perform, and advice or other assistance that is the brought about by observations of such tasks.

Auditing activities in addition to the audit assignment primarily consist of a review of interim reports.

Tax advice includes advice on income taxation and VAT.

Note 10.
Employees and personnel costs

The average number of employees	2020		2019	
	Number of employees	Of which are men	Number of employees	Of which are men
The Parent Company				
Sweden	2	2	2	2
Subsidiary				
Sweden	16	6	15	5
The group total	18	8	17	7

Gender distribution of senior executives	2020		2019	
	Women	Men	Women	Men
The Parent Company				
The Board of Directors	3	3	3	6
CEO and other company management	0	2	0	2
Subsidiary				
The Board of Directors	3	3	3	6
CEO and other company management	3	3	3	3

Salaries and other remuneration (TSEK)	The group		The parent company	
	2020	2019	2020	2019
Salaries and other remuneration				
Chair of the Board	450	350	450	350
Other board members	1 235	1 635	1 235	1 635
CEO	2 008	1 597	2 008	1 597
Other employees	12 567	10 823	1 235	977
	16 260	14 405	4 928	4 559
Pensions				
The Board of Directors	0	0	0	0
CEO	602	477	602	477
Other employees	2 444	2 050	344	272
	3 046	2 527	946	749
Social security costs	3 839	4 082	1 612	1 550
	23 145	21 014	7 486	6 858

Notes

Note 10.
Employees and
personnel costs

Remuneration to the Board of Directors, the CEO and senior executives

Remuneration to board members elected by the general meeting is decided by the Annual General Meeting. The CEO’s remuneration is decided by the Board of Directors. In relation to the previous year, the number of board members has decreased to 6 (9). Remuneration levels for board and committee work have increased in relation to the previous year.

Senior executives refer to the people who, together with the CEO, form the company’s management. The management team consists of eight people, including the CEO. Remuneration to senior executives consists of a basic salary, pension benefit, other benefits, and conditions upon termination.

Remuneration to the Board of Directors, the CEO and senior executives of the group is shown in the tables below.

2020 (SEK) Name	Position	Salary and benefits/ board fee	Variable remune- ration	Pension costs	Other remune- ration	Total
Gunnar Olsson	Chair of the Board	450 000	0	0	0	450 000
Carola Lemne	Vice-chair of the Board	230 000	0	0	0	230 000
Lars Adlersson	Board member	250 000	0	0	0	250 000
Eva Lindgren	Board member	250 000	0	0	0	250 000
Rein Piir	Board member	275 000	0	0	0	275 000
Lena Torlegård	Board member	230 000	0	0	0	230 000
Total Board of Directors		1 685 000	0	0	0	1 685 000
Nicholas Waters	CEO	1 878 486	130 000	748 433	0	2 756 919
Other senior executives, 7 people		5 619 029	241 490	2 325 261	926 606	9 112 386
Total CEO and senior executives		7 497 515	371 490	3 073 694	926 606	11 869 305

2019 (SEK) Name	Position	Salary and bene- fits/board fee	Pension costs	Other re- muneration	Total
Anders Vedin	Chair of the Board	350 000	0	0	350 000
Carola Lemne	Vice-chair of the Board	175 000	0	0	175 000
Lars Adlersson	Board member	225 000	0	0	225 000
Eva Lindgren	Board member	225 000	0	0	225 000
Gunnar Olsson	Board member	205 000	0	0	205 000
Hans-Olov Olsson	Board member	175 000	0	0	175 000
Rein Piir	Board member	250 000	0	0	250 000
Lena Torlegård	Board member	205 000	0	0	205 000
John D Wakely	Board member	175 000	0	0	175 000
Total Board of Directors		1 985 000	0	0	1 985 000
Nicholas Waters	CEO	1 596 995	592 720	0	2 189 715
Other senior executives, 7 people		4 884 701	1 861 419	915 289	7 661 409
Total CEO and senior executives		6 481 696	2 454 139	915 289	9 851 124

The notice period for the CEO is twelve months, regardless of which party gives the notice, however, the CEO has a notice period of eighteen months in certain situations. The notice period for CSO, Director of Biology & Biostatistics and Director of Computational Chemistry & Biology/CIO is six months, regardless of which party gives the notice. For other senior executives who are employed, the notice period that applies is that according to the applicable collective agreement, which currently means 1-3 months. The consulting agreement regarding Cecilia Tivert Stenberg runs until further notice with a mutual notice period of three months. Remuneration according to this agreement is reported under “Other remuneration”. No employee is entitled to severance pay.

The group only has pension obligations that are managed as defined contribution plans. In defined contribution plans, the company pays fixed fees to insurance companies. Retirement age is 65 years. For the CEO, Nicholas Waters, the company shall pay a fixed premium corresponding to 30% of his regular salary, and for the CFO, the corresponding 28% of his regular salary applies. The pension costs reported above include separate income tax.

Anders Vedin and John D Wakely resigned from the Board of Directors at the May 7, 2020 Annual General Meeting. Carola Lemne was elected to the Board of Directors at the April 25,2019 Annual General Meeting.

Notes

Note 11.
Financial expenses/
interest expenses
and similar income
statement items

	The group		The parent company	
	2020	2019	2020	2019
Interest costs group companies	0	0	0	0
Interest costs leasing debt	-193	-271	0	0
Interest costs other	-2	-1	-1	0
Total	-196	-272	-1	0

Note 12.
Income tax

	The group		The parent company	
	2020	2019	2020	2019
Current tax	0	0	0	0
Deferred tax	0	0	0	0
Total	0	0	0	0
<i>Theoretical tax</i>				
Reported result before tax	-91 653	-96 120	-197 572	-38 201
Tax according to current tax rate, 21.4% (21.4%)	19 614	20 570	42 281	8 175
<i>Reconciliation of reported tax</i>				
Effect foreign tax rate	-9	-16	-7 496	-5 356
Effect of deficit deductions not valued	-53 831	-21 624	-38 592	-3 889
Effect of utilized previously not valued deficit deductions	30 420	0	0	0
Effect of costs reported over equity	3 807	1 070	3 807	1 070
Total	0	0	0	0

Tax-related deficit deductions in the group as of December 31, 2020 amount to TSEK 466 711 (TSEK 357 328). For the parent company, tax-related deficit deductions as of December 31, 2020 amount to TSEK 245 102 (TSEK 64 766). All deficit deductions run without a time limit. Of the tax-related deficit deductions, TSEK 77 325 (TSEK 78 092) has been valued in the group, and TSEK 0 (TSEK 0) has been valued in the parent company.

The group	Deferred tax assets		Deferred tax liabilities	
	2020	2019	2020	2019
Opening reported value	15 976	16 025	-15 976	-16 025
Changed tax rate	0	0	0	0
Change via the income statement for the year	-47	-49	47	49
Reported value	15 929	15 976	-15 929	-15 976

Temporary differences are found in the following items:

	The group	
	2020	2019
Intangible fixed assets	-15 963	-16 112
Utilized assets	34	25
Tax-related deficit deductions	15 929	16 087
Reported value	0	0

Note 13.
Research database

	The group	
	2020	2019
Opening acquisition value	1 036	1 036
Closing accumulated acquisition values	1 036	1 036
Opening depreciations	-259	0
Depreciations for the year	-259	-259
Closing accumulated depreciations	-218	-259
Reported value	518	777

Notes

Note 14.
Acquired development projects

	2020	The group 2019
Opening acquisition value	81 492	82 233
Depreciations and impairments for the year	0	-740
Closing accumulated acquisition values	81 492	81 492
Reported value	81 492	81 492

Note 15.
Improvements to someone else’s property

	2020	The group 2019
Opening acquisition value	116	116
Closing accumulated acquisition values	116	116
Opening depreciations	-15	-9
Translation difference for the year	-6	-6
Closing accumulated depreciations	-21	-15
Reported value	95	101

Note 16.
Equipment, tools and installations

	2020	The group 2019
Opening acquisition value	2 547	2 524
Purchases	394	135
Sales and disposals	0	-112
Closing accumulated acquisition values	2 941	2 547
Opening depreciations	-1 609	-1 433
Depreciations for the year	-327	-262
Sales and disposals	0	85
Closing accumulated depreciations	-1 936	-1 609
Reported value	1 006	938

Note 17.
Utilized assets

	2020	The group 2019
Opening acquisition value, IFRS 16	6 544	6 544
Closing accumulated acquisition values	6 544	6 544
Opening depreciations	-1 664	0
Depreciations for the year	-1 644	-1 664
Closing accumulated depreciations	-3 328	-1 664
Reported value	3 216	4 880

Notes

Note 18.
Shares in group companies

Company	Corporate identity number	Site	Number	Capital share	Reported value 2020	2019
Integrative Research Laboratories Sweden AB	556922-0444	Göteborg	150 995	100%	350 320	350 320
IRL 626 AB	559041-8389	Göteborg	50 000	100%	–	–
IRL 752 AB	559041-8371	Göteborg	50 000	100%	–	–
IRL 790 AB	559041-8405	Göteborg	50 000	100%	–	–
					350 320	350 320
The parent company				2020	2019	
Opening acquisition value				350 320	350 320	
Shareholder contribution				35 000	25 000	
Impairment of shares in subsidiaries				–35 000	–25 000	
Reported value				350 320	350 320	

Note 19.
Prepayments and accrued income

	The group		The parent company	
	2020	2019	2020	2019
Prepaid insurance	531	125	242	0
Prepaid rents	523	67	0	0
Other prepayments and accrued income	966	1 472	38	301
Reported value	2 020	1 664	280	301

Note 20.
Equity

Number of shares	2020	The group 2019
Registered number of shares	48 498 406	43 109 695
	48 498 406	43 109 695
Average number of shares before and after dilution	47 677 734	40 592 654
	47 677 734	40 592 654

The registered number of shares consists of 48 418 630 (43 029 919) Series A shares and 79 776 (71 551) Series B shares. Both A and B shares have one vote each. The nominal value for all shares amounts to SEK 0.02 per share. Only A shares are admitted to trading on Nasdaq Stockholm.

After the balance sheet date, the new issue decided in December has been registered, where-upon Nordnet AB and Unionen are the ninth and tenth largest owners, respectively. The total registered number of shares increases in conjunction with the new issue by 3 250 000 A shares.

Year	Event	Issued amount (SEK)	Total share capital (SEK)	Change (SEK)	Total number of shares	Change shares	Nominal value (SEK)
2013	New formation	25 000 000	50 000	50 000	100 000	100 000	0.50
2015	New issue	24 106 969	84 473	34 473	168 946	68 946	0.50
2015	New issue	14 772 000	104 169	19 696	208 338	39 392	0.50
2015	New issue	8 407 125	115 379	11 210	230 757	22 419	0.50
2015	Share division		115 379		2 307 570	2 076 813	0.05
2015	Non-cash issue	54 515 644	181 358	65 980	3 627 162	1 319 592	0.05
2016	New issue	41 350 000	231 358	50 000	4 627 162	1 000 000	0.05
2016	New issue	15 350 195	249 919	18 561	4 998 388	371 226	0.05
2016	New issue	726 243	253 497	3 578	5 069 939	71 551	0.05
2016	Fund issue	0	506 994	253 497	5 069 939	0	
2017	New issue	115 800 000	699 994	193 000	6 999 939	1 930 000	0.10
2018	New issue	138 600 000	809 994	110 000	8 099 939	1 100 000	0.10
2019	Share division (Split) 5:1	0	809 994	0	40 499 695	32 399 756	0.02
2019	New issue	70 470 000	862 194	52 200	43 109 695	2 610 000	0.02
2020	New issue	145 495 197	969 968	107 774	48 498 406	5 388 711	0.02
2020	New issue	130 000 000	1 034 968	65 000	51 748 406	3 250 000	0.02
At the end of the period		784 593 373	1 034 968		51 748 406		0.02

The issued amount above is the total issued amount including a premium but before issue costs. The most recent issue in 2020 was not registered as of the balance sheet date.

Notes

Note 20.
Equity

Incentive program

In April 2016, a decision was made on a share and subscription warrant program for key personnel, both employees and board members. A total of 71 551 Series B ordinary shares (357 755 after split) and 39 355 subscription warrants (196 775 after split) were subscribed for in the program. The subscription price for the shares and the subscrip- tion warrants corresponded to the market value. Proceeds from the issue of the shares was paid by the group as a benefit to the key personnel.

During the month of July 2019, a conversion of B shares into A shares was called for by holders of B shares. 277 979

B shares were converted into A shares. The remaining 79 776 B shares are not sub- ject to conversion as the holders may only convert B shares on one occasion, and all holders have now exercised this and carried out a conversion.

Subscription warrant program

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

Proposal for appropriation of the company’s profit (SEK)	
At the disposal of the Annual General Meeting are:	
premium fund	739 739 970
accumulated loss	–61 318 237
result for the year	–197 572 480
	480 849 253
The Board of Directors proposes that: is carried forward	480 849 253
	480 849 253

Note 21.
Leasing debt

	The group	
	2020	2019
Opening reported value	4 543	6 090
Amortization during the year, affecting cash flow	–1 616	–1 547
Reported value	2 927	4 543
Of which is long-term	1 270	2 900
Of which is short-term	1 657	1 643

Note 22.
Accrued expenses and prepaid income

	The group		The parent company	
	2020	2019	2020	2019
Personnel-related costs	4 715	3 855	1 717	1 346
Other accrued expenses	7 090	3 959	6 870	3 805
Reported value	11 805	7 814	8 587	5 151

Note 23.
Items that do not affect cash flow

	The group	
	2020	2019
Depreciations	2 256	2 932
Disposal loss of equipment	0	28
Total	2 256	2 960

Notes

Note 24.
Cash and cash equivalents

	The group		The parent company	
	2020	2019	2020	2019
Cash	4	3	1	0
Bank balances	277 005	110 524	239 692	79 166
Total cash and cash equivalents	277 009	110 527	239 693	79 166

Note 25.
Transactions with related parties

Remuneration to the Board of Directors and senior executives is reported in Note 10. All transactions with related parties have taken place on market terms.

As of the balance sheet date, the parent company has a receivable from group companies amounting to TSEK 447 and a liability to group companies of TSEK 100 120.

Information on sales to and purchases from group companies is provided in Note 6.

Note 26.
Financial instruments by category

	The group		The parent company	
	2020	2019	2020	2019
Financial assets valued at accrued acquisition value				
Other receivables	81	6 892	0	913
Cash and cash equivalents	277 009	110 527	239 693	79 166
	277 090	117 419	239 693	80 080
Financial liabilities valued at accrued acquisition value				
Leasing debt	2 927	4 543	0	0
Accounts payable	3 683	8 438	461	3 416
Other liabilities and accrued expenses	7 089	3 959	106 990	4 017
	13 699	16 940	107 452	7 433

Financial assets valued at accrued acquisition value

The group’s operations currently give rise to very few accounts receivable, and even historically, accounts receivable have not amounted to any material amounts. There have historically been no losses regarding accounts receivable. As of the balance sheet date, accounts receivable amounted to TSEK 0 (TSEK 0).

Cash and cash equivalents consist of a small cash register and bank balances.

The group applies the simplified method for calculating expected credit losses. The method means that expected losses during the entire term of the receivables are used as a basis for loss risk provisions.

The group currently has very limited accounts receivable, which is why no loss risk reserve has been calculated.

The parent company has receivables from subsidiaries, for which it is not deemed that there is a material risk of loss.

As of the balance sheet date, no receivables have been identified where there is a need for impairment. All receivables are in SEK.

The fair value of the financial assets is deemed to correspond in all material respects to its carrying amounts.

Financial liabilities valued at accrued acquisition value

The group’s only has loan liabilities in the form of leasing debts for rental agreements, where security is the right to use the premises.

The maturity structure relating to financial liabilities is shown in Note 3.

The fair value of the group’s financial liabilities is deemed to correspond in all material respects to its carrying amount.

In January, new preclinical data were presented indicating that mesdopetam can not only treat but also prevent the development of levodopa-induced dyskinesias (LIDs) in Parkinson’s. The new results increase the commercial potential of mesdopetam.

In January, results were presented from a collaboration with Chalmers University of Technology, the AI company Smartr and IRLAB on the application of deep learning to multidimensional effects of CNS drugs. A summary of the interesting results was presented at the leading conference Society of Neuroscience (SfN) Global Connectome: A Virtual Event.

Note 27.
Significant events after the end of the financial year

Notes

Note 27.
Significant events after the end of the financial year

At the beginning of March, it was announced that the first European patients had been dosed in the Phase IIb/III clinical trial with mesdopetam. Regulatory authorities across Europe have approved the study and Poland is the first European country where patients have been dosed with mesdopetam. The study is currently underway on two continents, both in the US and in Europe.

At the end of March, it was announced that independent scientists have confirmed that the dopamine D3 receptor (D3R) is a highly promising drug target with therapeutic potential in levodopa-induced dyskinesia, especially when the receptor’s unique signaling properties are taken into account. IRLAB’s mesdopetam is currently the most advanced D3R antagonist compound in the global neurology pipeline. It is used in the scientific article to exemplify a compound that could have an impact on the management of anumber of disorders marked by aberrant D3R activity. The article was published in the scientific journal Biomedicines in March 2021.

The Board of Directors and the CEO certify that the consolidated financial statements have been prepared in accordance with International Financial Reporting Standards as adopted by the EU and give a true and fair view of the Group’s financial position and results.

The financial statements for the parent company have been prepared in accordance with generally accepted accounting principles and give a true and fair view of the parent company’s financial position and results.

Gothenburg 14 April 2021

GUNNAR OLSSON
Chair of the Board

REIN PIIR
Board member

CAROLA LEMNE
Vice Chair

LARS ADLERSSON
Board member

EVA LINDGREN
Board member

LENA TORLEGÅRD
Board member

NICHOLAS WATERS
CEO

Our audit report was submitted on 14 April 2021
Öhrlings PricewaterhouseCoopers AB

Johan Rippe
Authorized Public Accountant
Partner in charge

Martin Oscarsson
Authorized Public Accountant

Auditor’s report

Report on the annual accounts and consolidated accounts

Opinions

We have audited the annual accounts and consolidated accounts of IRLAB Therapeutics AB for the year 2020. The annual accounts and consolidated accounts of the company are included on pages 72-118 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company and the group as of 31 December 2020 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2020 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the income statement and report on financial position for the group.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company’s audit committee in accordance with the Audit Regulation (537/2014) Article 11.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor’s Responsibilities section. We are independent of the parent com-

pany and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Our audit approach

Audit scope

We designed our audit by determining materiality and assessing the risks of material misstatement in the consolidated financial statements. In particular, we considered where management made subjective judgements; for example, in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits, we also addressed the risk of management override of internal controls, including among other matters consideration of whether there was evidence of bias that represented a risk of material misstatement due to fraud.

We tailored the scope of our audit in order to perform sufficient work to enable us to provide an opinion on the financial statements as a whole, taking into account the structure of the Group, the accounting processes and controls, and the industry in which the group operates.

Materiality

The scope of our audit was influenced by our application of materiality. An audit is designed to obtain reasonable assurance whether the financial statements are free from material misstatement. Misstatements may arise due to fraud or error. They are considered material if individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the consolidated financial statements.

Based on our professional judgement, we determined certain quantitative thresholds for materiality, including the overall group materiality for the consolidated financial statements as a whole as set out in the table below. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures and to evaluate the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

Key audit matter	How our audit addressed the key audit matter
<p><i>Valuation of acquired development projects</i></p> <p>The Group’s assets include intangible fixed assets regarding acquired development projects of 81.5 million kronor, which comprise a significant part of the Group’s total assets.</p> <p>The acquired development projects comprise the development projects which were acquired as a part of the transaction when IRLAB Therapeutics AB became the parent company of the Group in 2014.</p> <p>Intangible fixed assets which are not yet finalized are not amortized, instead they are subject to annual impairment testing. The value of the development projects is based on management’s subjective assessment about future cash flows and estimation of discount rate etc. which makes the valuation inherently uncertain as it can be affected by future events.</p> <p>Based on the impairment test performed, management has not identified any impairment requirements.</p> <p>A description of the significant estimates and assumptions made in the impairment test is disclosed in note 4.</p>	<p>Our audit of management’s impairment test of acquired development projects has included review of the Company’s documentation where we have assessed if the impairment test has been prepared in accordance with applicable accounting principles and by using generally acceptable valuation models.</p> <p>We have discussed the methods, estimates and assumptions with management of which the impairment test is based on. We have reviewed and assessed the reasonableness of assumptions about future cash flows, discount rate and other significant assumptions which management has presented for us. Where applicable we have also reconciled data with supporting documentation and performed sensitivity analyzes.</p> <p>Finally, we have evaluated if the disclosures provided sufficiently describes how the impairment test was performed and which estimates and assumptions it has been based on.</p>

Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-70. The other information also comprises the remuneration report which we have received before the date of the auditor’s report. The Board of Directors and

Key audit matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts

Auditor’s report

and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Director’s and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company’s and the group’s ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director’s responsibilities and tasks in general, among other things oversee the company’s financial reporting process.

Auditor’s responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor’s report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts. A further description of our responsibility for the audit of the annual accounts and consolidated accounts is available on Revisorsinspektionen’s website:

www.revisorsinspektionen.se/revisornsansvar

This description is part of the auditor’s report.

Report on other legal and regulatory requirements

Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Director’s and the Managing Director of IRLAB Therapeutics AB for the year 2020 and the proposed appropriations of the company’s profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Director’s and the Managing Director be discharged from liability for the financial year.

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities

under those standards are further described in the Auditor’s Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Director’s and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company’s profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company’s and the group’s type of operations, size and risks place on the size of the parent company’s and the group’ equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company’s organization and the administration of the company’s affairs. This includes among other things continuous assessment of the company’s and the group’s financial situation and ensuring that the company’s organization is designed so that the accounting, management of assets and the company’s financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors’ guidelines and instructions and among other matters take measures that are necessary to fulfill the company’s accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor’s responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company’s profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company’s profit or loss are not in accordance with the Companies Act.

A further description of our responsibility for the audit of the administration is available on Revisorsinspektionen’s website: www.revisorsinspektionen.se/revisornsansvar

This description is part of the auditor’s report.

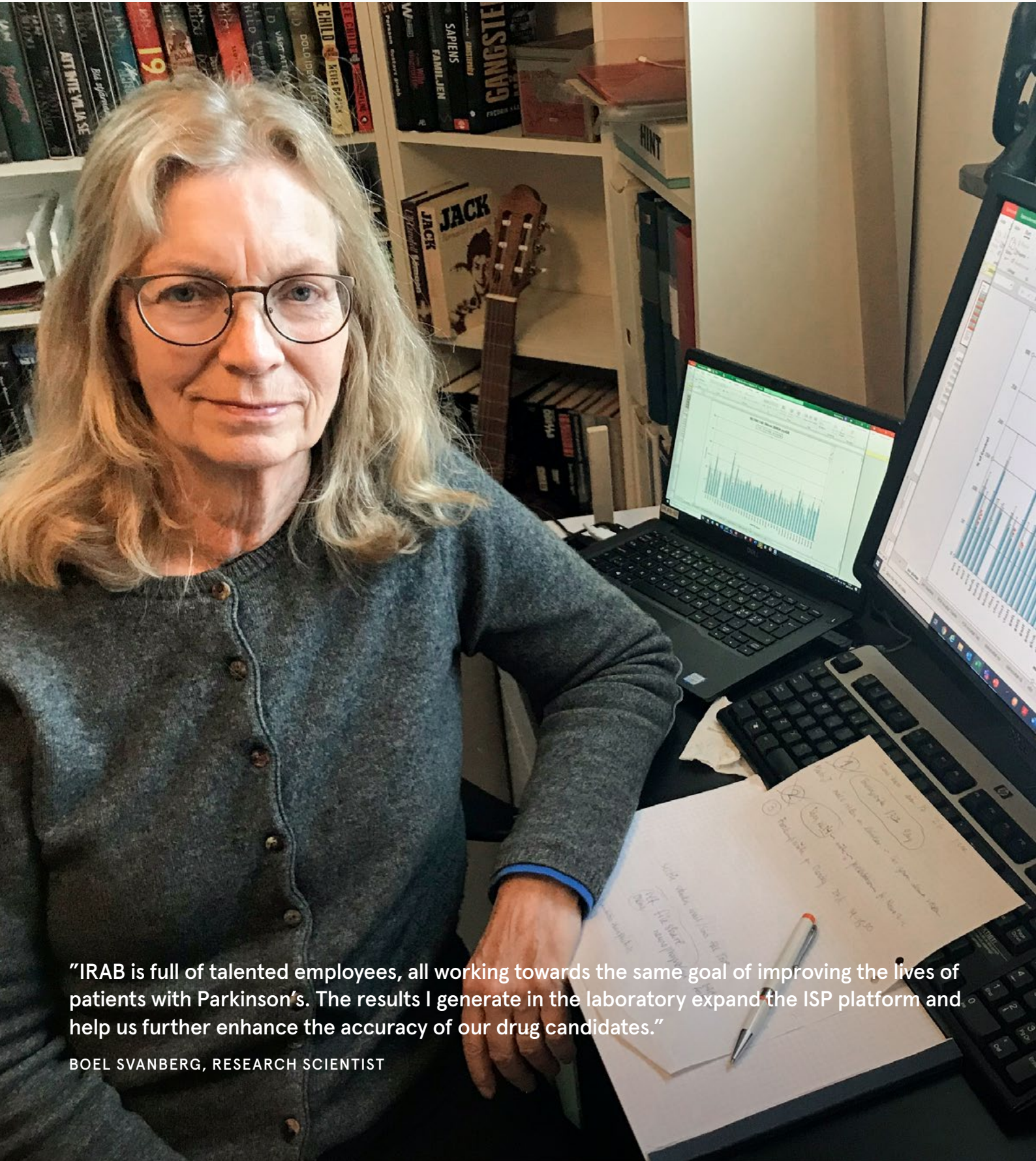
Öhrlings PricewaterhouseCoopers AB, 113 97 Stockholm, was appointed auditor of IRLAB Therapeutics AB by the general meeting of the shareholders on the 7 May 2020 and has been the company’s auditor since the 9 December 2016.

IRLAB Therapeutics AB has been a public interest entity since 30 September 2020 when the shares of IRLAB Therapeutics AB began trading on a regulated market.

Gothenburg 14 April 2021

Öhrlings PricewaterhouseCoopers AB

Johan Rippe	Martin Oscarsson
Authorized Public Accountant	Authorized Public Accountant
Partner in charge	



“IRAB is full of talented employees, all working towards the same goal of improving the lives of patients with Parkinson’s. The results I generate in the laboratory expand the ISP platform and help us further enhance the accuracy of our drug candidates.”

BOEL SVANBERG, RESEARCH SCIENTIST

Corporate governance report

IRLAB Therapeutics AB (publ) is a Swedish public limited company with its registered office in Gothenburg, Sweden. The company’s A shares have been listed on Nasdaq Stockholm Main Market since September 30, 2020. The company follows Nasdaq Stockholm’s regulatory framework for issuers and has applied the Swedish Corporate Governance Code (“the Code”) since January 1, 2017. The Code can be found on the Swedish Corporate Governance Board’s website, www.bolagsstyrning.se.

The corporate governance report refers to the financial year 2020, and has been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Corporate Governance Code. The report is reviewed by the company’s auditor.

Deviations from the Code

Clas Sonesson was a member of the Nomination Committee during 2020. Sonesson is part of the company’s management team, is one of the company’s founders, and represents a group of founders, who are owners, on the Nomination Committee. It is therefore reasonable that he, on behalf of the founders, is given the opportunity to exercise influence in the Nomination Committee.

IRLAB’s fundamental principles for corporate governance

IRLAB’s corporate governance is based on the Swedish model for corporate governance as defined by the Swedish Companies Act, the Swedish Annual Accounts Act, the Swedish Corporate Governance Code and practice. The purpose is to create a clear division of roles and responsibilities between the owners, the board and the executive management, where the bodies exercise their responsibility, influence, and control in relation to each other.

Shareholders

The shareholders’ influence is exercised primarily through the right to vote at the Annual General Meeting and appoint members to the company’s Nomination Committee. All shareholders also have the right to propose new

board members to the Nomination Committee. However, this must be done well in advance of the General Meeting so that the Nomination Committee has the opportunity to make relevant evaluations of the proposed candidates. Prior to the Annual General Meeting on May 6, 2020, owners were invited to submit proposals no later than the end of January 2020. For information on the stock and the owners, please refer to IRLAB’s annual report.

Annual General Meeting

The Annual General Meeting is the company’s highest decision-making body and shall be held in Gothenburg or Stockholm. The shareholders’ influence is exercised at the Annual General Meeting, which decides on key issues. The Annual General Meeting shall, among other things, decide on approving the company’s income statement and balance sheet, appropriation of the company’s profit or loss, discharge of liability for the board members and the CEO, appointment of Board of Directors, Chair of the Board and auditor, and decide on remuneration to the Board of Directors and auditor. The Annual General Meeting also decides on issues of shares, convertibles, options and other financial instruments, as well as authorization for the Board of Directors to make decisions on such issues.

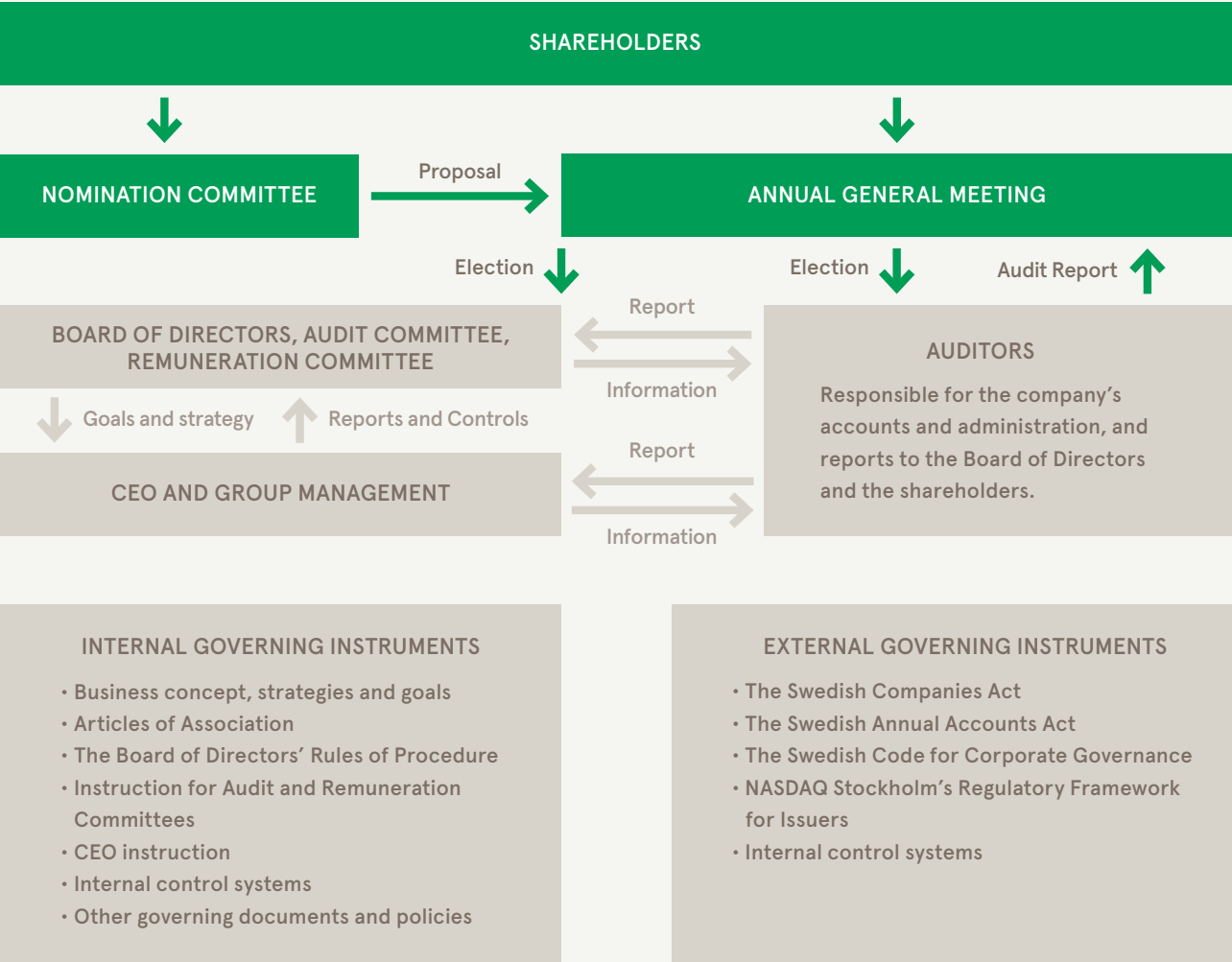
The Annual General Meeting shall also decide on the instructions for the appointment and work of the Nomination Committee, as well as the principles for remuneration and terms of employment for the CEO and other senior executives. In addition to the Annual General Meeting, Extraordinary General Meetings may be held.

Notice of both an Annual General Meeting and an Extraordinary General Meeting shall be given by advertising in *Post- och Inrikes Tidningar* and by making the notice available on the company’s website. The fact that notice has been given shall be simultaneously published in *Dagens Industri*.

Annual General Meeting 2020

IRLAB’s Annual General Meeting 2020 was held on May 7 in

Corporate governance report



Gothenburg. At the general meeting, the following resolutions were passed:

- Resolution that the general meeting should be held in open format in such a way that webcasting of the general meeting shall be permitted in the form of recording of audio and video.
- Resolution on the adoption of the income statement and balance sheet for both the parent company and the group.
- Resolution to dispose of the company's results by transfer to a new account.
- Resolution to grant discharge from liability to the Board of Directors and CEO for the financial year 2020.
- Resolution authorizing the Board of Directors to issue a maximum of 6 500 000 Series A shares.
- Resolution on the re-election of Lars Adlersson, Eva Lindgren, Gunnar Olsson, Rein Piir, Lena Torlegård and Carola Lemne as board members. Resolution on the election of Gunnar Olsson as Chair of the Board and Carola Lemne as Vice-chair.
- Resolution on the re-election of Öhrlings PricewaterhouseCoopers AB as auditor, with a note that Johan Rippe has been appointed principal auditor.
- Resolution on fees to the Board of Directors and auditors.
- Resolution on instructions to the Nomination Committee.
- Resolution on guidelines for remuneration to senior executives.

The minutes from the 2020 Annual General Meeting, instructions for the Nomination Committee's work, guidelines for salaries and remuneration to senior executives, and other information, are available on the company's website.

Annual General Meeting 2021

IRLAB's Annual General Meeting 2021 will be held on May 6, 2021. The Annual General Meeting will be held digitally

with a possibility for shareholders to vote by post. For the right to participate and more information, please refer to the notice on the company's website. The minutes from the Annual General Meeting will be available on the company's website.

Nomination committee

The Nomination Committee's work is governed by the instructions decided at the General Meeting and, in addition to the Chair of the Board, consists of representatives for the three largest owners or groups of owners, according to Euroclear Sweden AB, as of August 31 the year prior to the General Meeting. The instructions for the Nomination Committee's work have been available in both the minutes from the Annual General Meeting of May 7, 2020, and separately on the company's website. The composition of the Nomination Committee was announced, together with contact details to enable shareholders to contact the Nomination Committee, on October 30, 2020, after which the information has also been available on the company's website.

The Nomination Committee's task is to evaluate the existing Board of Directors, and to evaluate submitted proposals for new board members, in order to ensure that the Board has appropriate competence, experience and background. The Nomination Committee's proposals for the Board of Directors, and who shall be the Chair of the Board, shall be submitted to the owners no later than in conjunction with the publication of the notice of the Annual General Meeting. In addition to proposals for the Board and the Chair of the Board, the Nomination Committee shall submit proposals for the following:

- Chair of the general meeting
- The number of board members and deputies
- Remuneration to the members of the board and to members of any committees
- The number of auditors and deputy auditors
- Auditor
- Fee to auditor

Corporate governance report

NOMINATION COMMITTEE FOR THE 2020 ANNUAL GENERAL MEETING

Board member	Appointed by
1) Daniel Johnsson	Group of owners who represent approximately 23 percent of the shares and votes
2) Bo Rydlinger	Group of owners who represent approximately 19 percent of the shares and votes
3) Clas Sonesson	Group of owners, consisting of the company’s founders, who represent approx. 11 percent of the shares and votes
4) Gunnar Olsson	Chair of the Board

The Nomination Committee shall also, if they deem it necessary, submit proposals for amendments to the instructions to the Nomination Committee.

The Nomination Committee’s work prior to the AGM 2020

The Nomination Committee has had five meetings in addition to a number of telephone calls. The evaluation of the incumbent Board of Directors’ work, competence, experience and composition has been based on the following information:

- The Chair of the Board’s report on the Board of Directors’ work
- An anonymous survey-based evaluation of the Board of Directors’ work from board members, conducted by an external independent party
- Interviews with individual board members
- The Chair of the Board’s, CEO’s and the executive management’s reports on the company’s operations, goals and strategy.

Auditor

The external auditor is elected by the Annual General Meeting for a period of one year at a time. The auditors review the annual report and accounts, as well as the Board of Directors’ and the CEO’s administration, in accordance with an audit plan that is established together with the Board of Directors or the Audit Committee. In conjunction with the audit, the auditors shall report their observations to the group management, as well as the Board of Directors or the Audit Committee. At least once a year, the auditors shall report their observations directly to the Board of Directors without the presence of the executive management. The auditors also participate in the Annual General Meeting, where they go through their audit and their recommendations in the auditor’s report.

The company’s auditor

Since the Extraordinary General Meeting on November 30, 2016, the company’s auditor has been the registered auditing company Öhrlings PricewaterhouseCoopers AB (“PwC”), which was also re-elected at the Annual General Meeting on May 7, 2020. PwC has announced that they have appointed the authorized public accountant Johan Rippe as the auditor in charge, and that the annual report shall also be signed by the authorized public accountant Martin Oscarsson.

The auditor has audited the annual report and the consolidated accounts for the financial year 2020-01-01 to 2020-12-31, and also reviewed the quarterly report for the second quarter. The auditor has also stated that this corporate governance report has been prepared, and that certain information herein is consistent with the annual report and consolidated accounts.

The auditor’s review is reported primarily through the audit report but also through specific opinions on the corporate governance report, the reviewed quarterly report, and compliance with guidelines for remuneration to senior executives. These are presented to the Annual General Meeting.

Prior to the 2021 Annual General Meeting, the Nomination Committee has consisted of the Chair of the Board and representatives for the three largest owners or groups of owners, according to Euroclear Sweden AB on August 31, 2020, which represent just over 50 percent of the number of shares and votes in the company. The three largest owners or owner-groupings have been evaluated based on the ownership statistics obtained from Euroclear Sweden AB, sorted by voting power (grouped by ownership as owner-groupings were reported to the company before August 31, 2020). In the event that there are nominee-registered shareholdings in these ownership statistics, these have only been taken into account if the nominee has stated the identity of the underlying shareholders to Euroclear Sweden AB, or if the company, without taking any own measures, receives other information showing shareholders’ identities.



Corporate governance report

The auditor has also provided more detailed reports on both the audit’s planning and the observations made to the Audit Committee and the Board of Directors. In the parts concerning the review of the executive management’s administration, the reporting has been to the Board of Directors without the executive management being present.

The fees invoiced by the auditor for the last two financial years are reported in Note 9 in the 2020 annual report.

The Board of Directors

The Board of Directors’ responsibilities and work

The Board of Directors is the company’s highest decision-making body after the Annual General Meeting, and is responsible for the company’s administration and organization in accordance with the Swedish Companies Act.

The Board of Directors’ responsibilities and tasks are regulated in the Swedish Companies Act, the Articles of Association, the Swedish Corporate Governance Code, and the Board of Directors’ written Rules of Procedure. This means that the Board of Directors is responsible for

determining goals and strategies, for making decisions on particularly important issues, following preparation by the executive management, for ensuring and monitoring procedures and systems for risk management, and for evaluating operational management.

The Board of Directors is also responsible for ensuring that the annual report, consolidated accounts and interim reports are prepared in a timely manner. In addition, it is the Board’s task to appoint and dismiss the CEO.

The Board of Directors’ composition and independence

In accordance with the Articles of Association, the Board of Directors shall consist of a minimum of three and a maximum of ten members, with a maximum of ten deputies. In accordance with the Swedish Corporate Governance Code, the company shall not appoint any deputies.

Since the Annual General Meeting on May 7, 2020, IRLAB’s Board of Directors has consisted of six members without deputies; Chair of the Board Gunnar Olsson, Lars Adlersson, Carola Lemne, Eva Lindgren, Rein Piir and Lena

Torlegård. Information about the board members, with information on year of birth, year of election to the Board, training, experience, ongoing assignments and shareholdings in the company as of March 31, 2021, can be found on pages 134 - 135. Other assignments in the group are not specified.

The Board of Directors has established an Audit Committee and a Remuneration Committee, which prepare and make decisions on specific issues.

Chair of the Board

The Chair of the Board is proposed by the Nomination Committee and elected by the Annual General Meeting. In addition to the regular responsibilities as a board member, the Chair of the Board shall lead the Board’s work, convene board meetings, compile agendas and ensure that adequate follow-up takes place, and that the Board’s work is carried out in the most organized and efficient manner possible. The Chair of the Board shall also keep himself informed on an ongoing basis about the company’s operations through regular contact with the CEO and other

executive management, also in addition to board meetings and committee work.

The Chair of the Board shall also ensure that both incumbent and new board members receive sufficient information to be able to familiarize themselves with IRLAB’s operations, and that they have the prerequisites to continuously update and deepen their knowledge in issues concerning IRLAB and its operations.

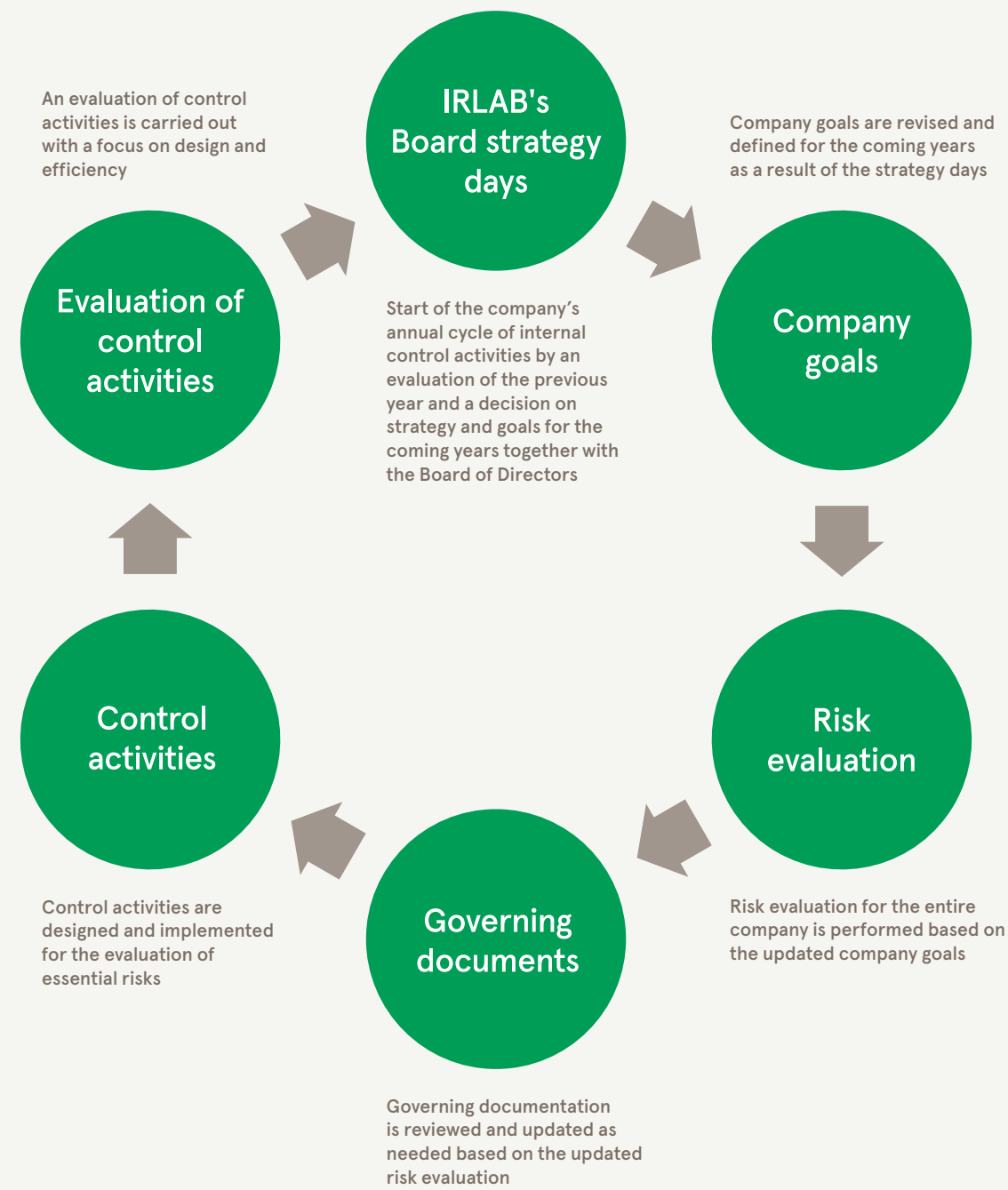
Committee work

The Board of Directors has established two formal committees, the Audit Committee and the Remuneration Committee, in accordance with a decision at the annual general Meeting on May 16, 2018. The Remuneration Committee has the task of preparing questions on remuneration and terms of employment for the group’s management. The Audit Committee tasks include maintaining and improving the efficiency of contact with the group’s auditors, supervising the procedures for accounting and financial reporting, and the internal audit of the group. The Board of Directors has adopted rules for the work of both committees.

Name	Board function	Elected	Independent in relation to the company and the executive management	Independent in relation to large owners	Board fees ¹	Fee remuneration committee ¹	Fee audit committee ¹	Attendance board meetings ²	Attendance committee meetings ³
Lars Adlersson	Board member	2017	Yes	Yes	200 000	–	50 000 (member)	15	5
Carola Lemne	Vice-chair	2019	Yes	Yes	200 000	30 000 (member)	–	14	6
Eva Lindgren	Board member	2016	Yes	Yes	200 000	–	50 000 (member)	15	5
Gunnar Olsson	Chair	2017	Yes	Yes	400 000	50 000 (chair)	–	16	6
Rein Piir	Board member	2016	Yes	Yes	200 000	–	75 000 (chair)	15	5
Lena Torlegård	Board member	2018	Yes	Yes	200 000	30 000 (member)	–	15	6

¹ Fees refer to remuneration decided by the Annual General Meeting excluding social security contributions for the period from the Annual General Meeting 2020 to the Annual General Meeting 2021.
² The board held five meetings before the Annual General Meeting and eleven meetings after the Annual General Meeting 2020. Regarding meetings before the Annual General Meeting, the outgoing board members attended as follows: Anders Vedin – 5, Hans-Olov Olsson – 4 and John Wakely – 2.
³ The Audit Committee held five meetings, and the Remuneration Committee held 1 meeting in 2019.

Annual cycle for internal control at IRLAB



Corporate governance report

In addition to the work of the formal committees, special working groups were formed during the year, where the board members' special competence was utilized with regard to, for example, financing, IR and clinical development.

The Board of Directors' Rules of Procedure

At the Statutory Board Meeting, following the general meeting, the Board of Directors adopts Rules of Procedure which, among other things, regulate the division of work and responsibilities between the Board, the Chair of the Board, and the company's CEO. According to the Rules of Procedure decided after the Annual General Meeting on May 7, 2020, the Board of Directors shall hold five to ten meetings per year, where the regular meetings are held in the following months: May, August, November, January and March.

The Board of Directors' work and important events during 2020

The Board of Directors convenes in part on dates determined during the year, and in part when it is deemed necessary depending on the provision of information or when specific decisions are to be made. In addition to the board members, the company's CEO participates in the board meetings as rapporteur, and the company's CFO as rapporteur in matters that fall within his area of responsibility.

During 2020, the Board of Directors held sixteen meetings, relatively evenly spread over the year.

During the year, the Board of Directors' work was dominated by strategic issues, contact with the international capital market, financing matters, and business development, including licensing matters. In addition, the Board has been involved in strategic issues regarding the company's research portfolio and business development, and has continuously received reports on the company's operations.

The Board of Directors continuously evaluates its work internally, and allows an independent external party carry

out a survey-based evaluation annually. Based on the results of the survey, the Board's working methods are discussed and adjusted.

CEO and executive management

The CEO is subordinate to the Board of Directors and is primarily responsible for day-to-day operations and day-to-day administration. The CEO has obligations according to law, furthermore, the division of work between the Board and the CEO is regulated primarily in the instructions for the CEO, which the Board of Directors decided on at its Statutory Board Meeting.

In summary, the instruction means that the CEO is responsible for the following points:

- Lead the business according to the Board of Directors' guidelines
- Ensure that the company's accounting is discharged in accordance with law
- Ensure that taxes and fees are paid on time
- Ensure that the company follows the budget, and to implement plans so that established goals are achieved
- Ensure that the company follows its information and insider policy

The CEO shall prepare and participate in board meetings in accordance with good order and the special instructions specified by the Chair of the Board. The Board of Directors shall prepare an agenda for board meetings, and the CEO shall present the matters to the Board of Directors so that the Board can make well-informed decisions. The CEO shall also continuously keep the Board informed of the business's development, financial position, liquidity and credit status, as well as all important business events.

The CEO shall also lead the work of the executive management. In 2020, the executive management, in addition to the CEO, consisted of the Chief Scientific Officer (CSO), Chief Medical Officer (CMO), Director of Biology

Corporate governance report

and Biostatistics, Director of Computational Chemistry and Biology (CIO), Finance and Human Resource Manager, Chief Financial Officer (CFO) and Director of Clinical Operations. The executive management accordingly consists of eight people. For more information about the senior executives in IRLAB, when they took up their positions, as well as year of birth, education, experience, shareholding in the company and ongoing assignments, please see pages 131–133.

Remuneration to board members and senior executives

Fees to board members and members of board committees are decided by the Annual General Meeting. The Annual General Meeting on May 7, 2020 resolved that a fee of SEK 1 685 000 be paid to the Board of Directors, of which SEK 400 000 should be paid to the Chair of the Board and SEK 200 000 to each of the other board members, and that a fee shall be paid to the Board’s Audit Committee, of which SEK 75 000 should be paid to the Chair of the Committee and SEK 50 000 to each of the other committee members, and that a fee shall be paid to the Board’s Remuneration Committee, of which SEK 50 000 should be paid to the Chair of the Committee and SEK 30 000 to each of the other committee members.

The company is a party to a collective agreement, and as such follows applicable agreements and rules. The CEO and the company’s management team constitute the company’s senior executives. These shall be offered market compensation, which shall take into account the individual’s areas of responsibility and experience. The remuneration shall, in accordance with the guidelines established at the Annual General Meeting on May 7, 2020, consist of a fixed salary, pension, and other benefits.

Internal control and risk management

The Board of Directors’ responsibility for internal control is regulated by the Swedish Companies Act, the Swedish

Annual Accounts Act, and the Swedish Corporate Governance Code. The board shall ensure that the company has good internal control and formalized procedures which ensure that established principles for financial reporting and internal control are complied with, and that there are appropriate systems for follow-up and control of the company’s operations, and the risks associated with the company and its operations.

The procedures for internal control which regard financial reporting have been designed in order to ensure reliable overall financial reporting and external reporting in accordance with IFRS, applicable laws and regulations, and other requirements to be applied by companies listed on Nasdaq Stockholm’s main list.

During 2020, the company has developed its systems for internal control and has created a system that not only includes risk assessment and control procedures for financial reporting, but for the entire operation.

Control environment

Good internal control is based on a functioning control environment. At IRLAB, the control environment consists of, among other things, an organizational structure, instructions, policies, guidelines, reporting, and defined areas of responsibility.

The Board of Directors has the overall responsibility for internal control with regard financial reporting. The board’s instructions to the CEO and an established reporting instruction have determined how the financial reporting to the Board is to be formulated. The board has also delegated the responsibility for maintaining an effective control environment to the CEO, even though the Board of Directors remains ultimately responsible. Established systems and procedures have been created to provide management with the necessary reports in order to be able to assess risks on an ongoing basis and meet the requirements for correct financial reporting.

The Board of Directors has, based on an assessed good control environment, deemed that there are no special

circumstances in the business or other circumstances that justify the establishment of a function for internal audit.

Risk assessment

IRLAB’s risk assessment aims to identify and evaluate the most significant risks that affect internal control with regard both the company’s operations and financial reporting throughout the group.

The identified most significant risks with regard financial reporting are managed through control structures based on deviation reporting from the established goals or from established standards.

Control activities

The design of control activities within IRLAB is based on clear roles in the organization that enable an effective division of responsibilities for specific control activities that include, among other things, authorization controls in IT systems, business systems and certification procedures. The continuous analysis made of the financial reporting is very important to ensure that the financial reporting does not contain any significant inaccuracies.

Information and communication

Internal information and communication involve ensuring that the company’s employees who are able to influence the financial information, or manage identified risks, are updated with regard to changes to policies, guidelines, laws or regulations. The executive management handles, if necessary, these issues at management group meetings, and other employees are regularly informed about such changes that affect their ability to make decisions, or that affect the impact of their decisions on financial reporting. During the year, a system was set up to ensure that all employees have been issued with the relevant documents.

The external information aims to keep the market up to date on the company’s operational development, and ensure that IRLAB meets the requirements for correct

information provision to the market. This is also governed by the company’s established information policy.

Follow-up, evaluation and reporting

The Board of Directors receives continuous operational and financial reporting from the executive management, and can follow the operational and financial development of the company. The group’s financial position, capital requirements, investments and cost base are discussed at each board meeting. Reconciliations against budgets and outcomes from previous years are made on an ongoing basis, and major deviations are also reported to the Board of Directors at each board meeting.

Internal control is evaluated regularly and new procedures are continuously set up to further increase internal control of the company’s financial reporting, and to manage the risks identified.

The external auditors, the company’s finance function, and the Audit Committee have ongoing contact throughout the financial year in order to identify any risks at an early stage and handle issues that may affect the financial reporting. The auditors also report regularly to the Board of Directors, primarily through meetings with the Audit Committee.

Diversity initiatives

IRLAB’s organization promotes an inclusive corporate culture at all levels. The company, which conducts research and development activities, usually needs very specific competencies and education, and the main principle is that everyone with relevant competencies and education shall have the same opportunity during recruitment, and to development at work. By investing in diversity and supporting employees with different genders, ages, ethnic backgrounds, religions and personalities, IRLAB is provided with better prerequisites to operate a better business, where many years of experience are combined with new ideas and perspectives to best help patients in need of effective treatments.

Board of directors



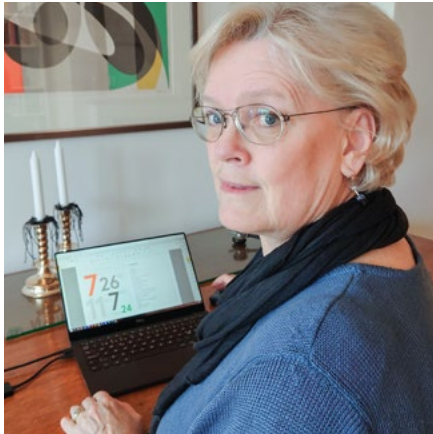
Gunnar Olsson, born 1953

Chair of the Board (elected 2020). Board member of IRLAB and IRLAB Sweden since 2017. First elected 2017. Independent in relation to the company, the executive management and the company’s major shareholders.

Education and background: 25 years’ experience in senior positions within Astra Zeneca, including in the management team for the Cardiovascular and Gastro-intestinal therapy areas within Global R&D, of which 10 years was as head of the same unit. Gunnar Olsson has participated in the development and launch of seven global blockbusters/ mega-brands.

Ongoing assignments: Chair of the Board of Athera Biotechnologies AB. Board member of Olsson Solutions AB, Gesynta Pharma AB and Hjärt-Lungfonden.

Holding: 2 000 Class A shares.



Carola Lemne, born 1958

Board member and Vice-chair. Board member of IRLAB since 2018. Independent in relation to the company, the executive management and the company’s major shareholders.

Education and background: Former CEO of the Confederation of Swedish Enterprise and Danderyds Sjukhus AB, and former group CEO of Praktikertjänst AB, Head of Clinical Research and Head of Global Strategic Drug Development and Regulatory Strategy at Pharmacia Corp. Carola Lemne has held board positions in Getinge, Apoteket, MEDA, Investor and AFA Insurance, and has also been a board member of the Swedish Foundation for Strategic Research, the State Delegation for Clinical Research, Stockholm University, the Swedish Institute for Business Research, and the Swedish Corporate Governance Board, as well as Chair of the Swedish Education Council for Clinical Trials at Uppsala University.

Ongoing assignments: Chair of the Board of Ung Företagsamhet Sverige, Internationella Engelska Skolan i Sverige Holdings II AB, and Art Clinic Holding AB. Board member of Arjo AB and Calgo Enterprise AB. Principal and board member of King Gustav V’s anniversary fund.

Holding: 9 000 Class A shares.



Eva Lindgren, born 1950

Board member of IRLAB since 2016 and of IRLAB Sweden since 2015. First elected 2016. Independent in relation to the company, the executive management and the company’s major shareholders.

Education and background: 40 years’ broad experience in the pharmaceutical industry through various positions in AstraZeneca, including international marketing, business negotiations, project and corporate management issues, drug development (among other things, responsible for bringing two projects to market at blockbuster level) and in recent years represented and coordinated AstraZeneca’s involvement in a Public-Private Partnership, IMI, between the European Commission and the pharmaceutical industry.

Ongoing assignments: Board member of Aktiebolaget Kulturtuben, Kulturlådan Aktiebolag, Aktiebolaget Kulturpåsen, Aktiebolaget Gypius, Toleranzia AB and RolfAllan design AB.

Holding: 73 510 Class A shares, 5 661 Class B shares and 5 009 subscription warrants, corresponding to 25 045 Class A shares, personally and via companies/related parties.



Rein Piir, born 1958

Board member of IRLAB since 2016 and of IRLAB Sweden since 2015. First elected 2016. Independent in relation to the company, the executive management and the company’s major shareholders.

Education and background: Many years of experience in advising stock market companies, including as Head of Analysis at Carnegie Investment Bank AB and Strategist at Alecta. Other experience includes CFO/Head of Investor Relations at listed Medivir Aktiebolag and auditor at PricewaterhouseCoopers AB. He is Vice President Investor Relations in listed Camurus AB and Alligator Bioscience AB.

Ongoing assignments: Chair of the Board of Piir & Partner AB. Board member of L. E. Svensson Snickeri Aktiebolag.

Holding: 36 333 Class A shares, 5 567 Class B shares and 5 009 subscription warrants, corresponding to 25 045 Class A shares, personally and via companies/related parties.



Lars Adlersson, born 1964

Board member of IRLAB and IRLAB Sweden since 2017. First elected 2017. Independent in relation to the company, the executive management and the company’s major shareholders.

Education and background: Master of Business Administration from Uppsala University and has also completed strategy and management training at Duke University, London Business School and IFL Executive Education. 30 years’ experience from the life science industry, including as CEO of Medivir, Managing Director of GlaxoSmithKline, Austria and Sweden, and Senior Analyst at Handelsbanken Capital Markets. Lars Adlersson is currently a Partner and Senior Advisor at Adlersson Heath AB.

Ongoing assignments: Chair of the Board of SwedenBIO Service AB, Adlersson Heath AB and Bostadsrättsföreningen Östbra.

Holding: 3 000 Class A shares.



Lena Torlegård, born 1963

First elected 2018. Independent in relation to the company, the executive management and the company’s major shareholders.

Education and background: Master of Business Administration from the Stockholm School of Economics. Lena Torlegård has been an advisor in financial and corporate communications to a large number of companies, including in the life sciences sector.

Ongoing assignments: Board member of Codesign Sweden AB, Nanologica AB (publ), Annexin Pharmaceuticals AB (publ), Synartro AB and Lena Torlegård AB.

Holding: 7 312 Class A shares.

Ongoing assignments refer to assignments registered with the Swedish Companies Registration Office as of April 12, 2021 and do not include assignments within the IRLAB group. Shareholdings refer to holdings registered in the Euroclear Sweden AB share register as of March 31, 2021, adjusted for changes known by the company up to April 12, 2021.

Management

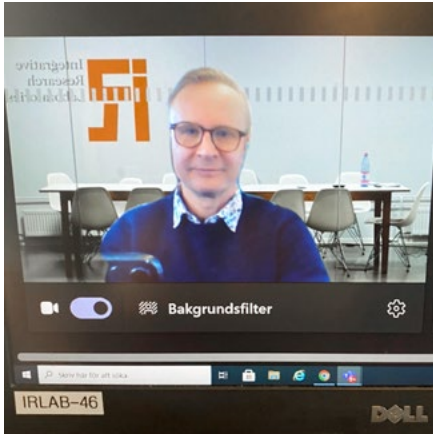


Clas Sonesson, born 1961

Chief Scientific Officer (CSO) of IRLAB since 2016 and of IRLAB Sweden since 2013.

Education and background: Worked as a pharmaceutical chemist and doctoral student in the Nobel Laureate Arvid Carlsson’s research group at the Department of Pharmacology at the University of Gothenburg 1989-2000. In 1998, he co-founded A Carlsson Research AB, which was sold to NeuroSearch Sweden A/S in 2006, and in conjunction with that changed company to NeuroSearch Sweden AB. In A Carlsson Research AB/NeuroSearch Sweden AB, he was a board member from 1998-2002, Head of Medicinal Chemistry 2000-2002, Director of Chemistry & IP 2002-2009, Head of Discovery 2009-2011 and Vice President Chemistry & IP 2011-2012. During the years at A Carlsson Research AB/NeuroSearch Sweden AB, he was also responsible for CMC in a number of development projects. In 2013, he was a co-founder of IRLAB Sweden.

Holding: 748 589 Class A shares and 8 946 Series B shares.



Joakim Tedroff, born 1961

Chief Medical Officer (CMO) of IRLAB since 2016 and of IRLAB Sweden since 2013.

Education and background: Co-founded A Carlsson Research AB in 1998, which was sold to NeuroSearch A/S in 2006, and in conjunction with that changed company to NeuroSearch Sweden AB. In A Carlsson Research/NeuroSearch Sweden AB, Joakim Tedroff was Vice President Clinical Science. In 2013, he was a co-founder of IRLAB Sweden. Joakim Tedroff is a practicing neurologist specializing in neuro-degenerative diseases, and an Associate Professor at Karolinska Institutet. He has more than 15 years’ experience in the pharmaceutical industry. As a consultant, he has performed services for a number of pharmaceutical companies in the field of neurology, including for Allergan, Orion, Pfizer, Teva, Novartis and Lundbeck, and for venture capital companies in various life science projects.

Ongoing assignments: Board member: Tedroff NeuroCare AB. Deputy board member: Palette Film AB.

Holding: 681 339 Class A shares, 8 946 Class B shares, and 8 049 subscription warrants, corresponding to 40 245 Class A shares, in person and via companies/related parties.

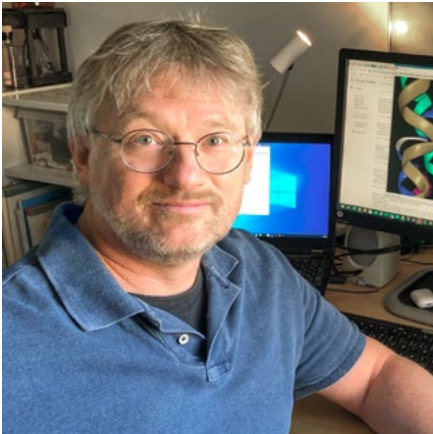


Susanna Holm Waters, born 1966

Director of Biology & Biostatistics of IRLAB Therapeutics since 2016 and of IRLAB Sweden since 2013.

Education and background: Worked in the Nobel laureate Arvid Carlsson’s research group at the Department of Pharmacology at the University of Gothenburg 1993-2000. In 1998, she co-founded A Carlsson Research AB. In A Carlsson Research/NeuroSearch Sweden AB she was Director of Computational Biology & Biostatistics 2000-2006, Director of Molecular Biology & Pharmacokinetics 2007-2010 and Director of Biology 2011-2012. In 2013, Susanna Holm Waters co-founded IRLAB Sweden. She also works clinically, as a doctor at Sahlgrenska University Hospital 2015-2019.

Holding: 1 340 904 Class A shares and 17 892 Class B shares, of which 604 704 Class A shares and 8 946 Class B shares are owned directly and the others via related parties.



Peder Svensson, born 1962

Director of Computational Chemistry & Biology and Chief Information Officer (CIO) of IRLAB since 2016 and of IRLAB Sweden since 2013.

Education and background: Over 25 years’ experience in research and research management in the pharmaceutical industry. He started at A Carlsson Research AB in 2000, the company later changed to NeuroSearch Sweden AB. In A Carlsson Research AB/NeuroSearch Sweden AB he was Head of Computational Chemistry & Chief Information Officer 2000-2011 and Director of Computational Chemistry & Biology, IT 2011-2012. In 2013, he co-founded IRLAB Sweden.

Holding: 252 979 Class A shares and 8 946 Class B shares in person and via companies/related parties.



Cecilia Tivert Stenberg, born 1957

Head of Finance and Human Resources Manager (HRM) of IRLAB since 2016 and of IRLAB Sweden since 2013.

Education and background: Has been CFO and Human Resources Manager at Spectrogon AB and A Carlsson Research/NeuroSearch Sweden AB. In 2013, she co-founded IRLAB Sweden.

Ongoing assignments: Board member: Terzett Konsult AB and Tivert Konsult AB. Deputy board member: Bohini AB.

Holding: 356 264 Class A shares, 8 946 Class B shares, and 8 049 subscription warrants, corresponding to 40 245 Class A shares, in person and via companies/related parties.



Viktor Siewertz, born 1971

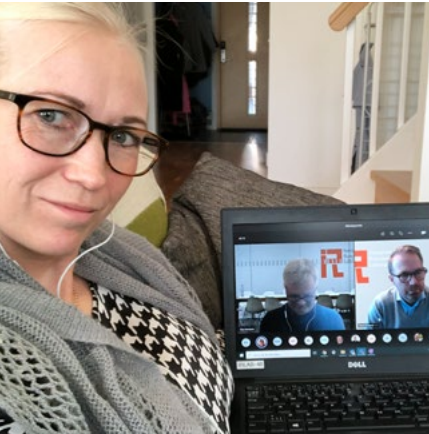
Chief Finance Officer (CFO) of IRLAB since 2017 and prior to that Chief Operating Officer (COO) since 2016.

Education and background: Worked as an accountant, financial advisor and in his own business as support to senior managements in small and medium-sized companies, and has experience in strategy, financing, raising capital and company transfers, including within the framework of the company he owns, which is part of Investigium AB.

Ongoing assignments: Board member: A.J. Dahlberg Slakteri Aktiebolag, Vestigium AB, Investigium AB, FTT Holding AB, Slavestigium AB and Ignavia AB. Deputy board member: HyrMax Rental AB, Moorgate Investment AB, Töreboda Vind AB, FTT Sweden AB, DB Mat AB, ContentMap Holding AB, Gris & Kalv i Sjöbo AB and Traxmitech AB.

Holding: 223 465 Class A shares in person and via companies/related parties.

Management



Maria Jalmelid, born 1979

Chief of Clinical Operations of IRLAB Therapeutics and IRLAB Sweden since 2018.

Education and background: Master’s degree in Medical Biology from Linköping University, specializing in clinical trials. Maria Jalmelid has 15 years’ experience from the pharmaceutical industry and clinical trials in various phases, mainly from AstraZeneca but also from academic research projects.

Ongoing assignments: Deputy board member: CodeMint AB.

Holding: 2 752 Class A shares.

Ongoing assignments refer to assignments registered with the Swedish Companies Registration Office as of April 12, 2021 and do not include assignments within the IRLAB group. Shareholdings refer to holdings registered in the Euroclear Sweden AB share register as of March 31, 2021, adjusted for changes known by the company up to April 12, 2021.



Nicholas Waters, born 1962

CEO of IRLAB since 2016 and of IRLAB Sweden since 2013.

Education and background: Worked in the Nobel laureate Arvid Carlsson’s research group at the Department of Pharmacology at the University of Gothenburg 1987-2000. He defended his dissertation in 1995. In 1996, he was a brain trust fellow. In 1998, he co-founded A Carlsson Research AB (CR), and then worked as Head of Research in the company until 2006 when he was appointed CEO. He worked as CEO of CR and Neurosearch Sweden AB 2006-2012. He was a board member of A Carlsson Research AB 1998-2002, and at NeuroSearch Sweden AB he was a board member 2006-2012. During 2010-2012, he was also Executive Vice President Research at NeuroSearch A/S. During the years 2007-2010, he was a board member of SwedenBIO. In 2013, he co-founded IRLAB Sweden.

Holding: 1 340 904 Class A shares and 17 892 Class B shares, of which 736 200 Class A shares and 8 946 Class B shares are owned directly and the others via related parties.

Gothenburg 14 April 2021

GUNNAR OLSSON
Chair of the Board

EVA LINDGREN
Board member

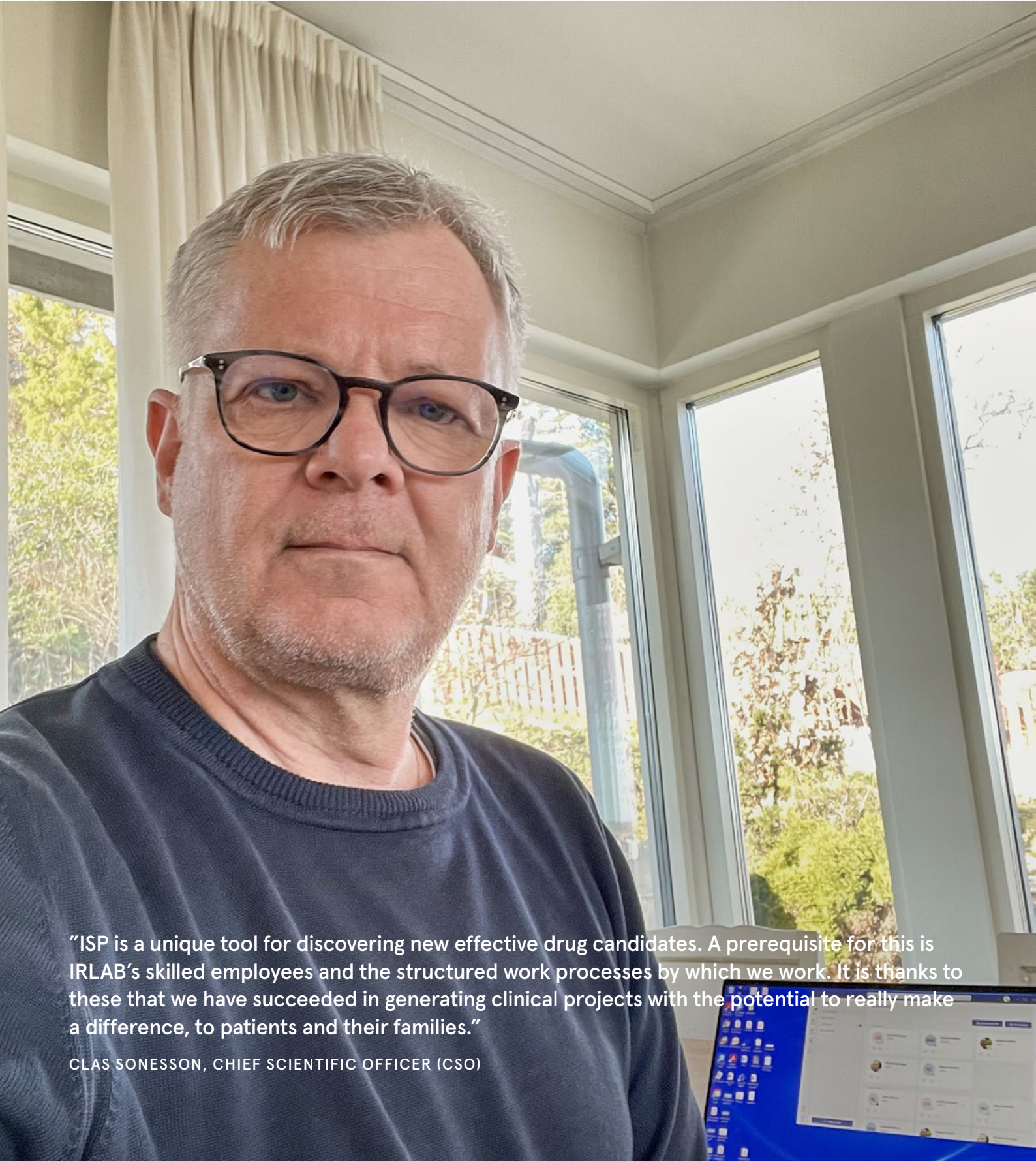
LARS ADLERSSON
Board member

CAROLA LEMNE
Vice Chair

REIN PIIR
Board member

LENA TORLEGÅRD
Board member

NICHOLAS WATERS
CEO



“ISP is a unique tool for discovering new effective drug candidates. A prerequisite for this is IRLAB’s skilled employees and the structured work processes by which we work. It is thanks to these that we have succeeded in generating clinical projects with the potential to really make a difference, to patients and their families.”

CLAS SONESSON, CHIEF SCIENTIFIC OFFICER (CSO)

Auditor’s report on the Corporate Governance Statement

To the general meeting of the shareholders in IRLAB Therapeutics AB (publ.), corporate identity number 556931-4692.

Engagement and responsibility

It is the board of directors who is responsible for the corporate governance statement for the year 2020 on pages 123-139 and that it has been prepared in accordance with the Annual Accounts Act.

The scope of the audit

Our examination has been conducted in accordance with FAR’s auditing standard RevR 16 The auditor’s examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

Opinions

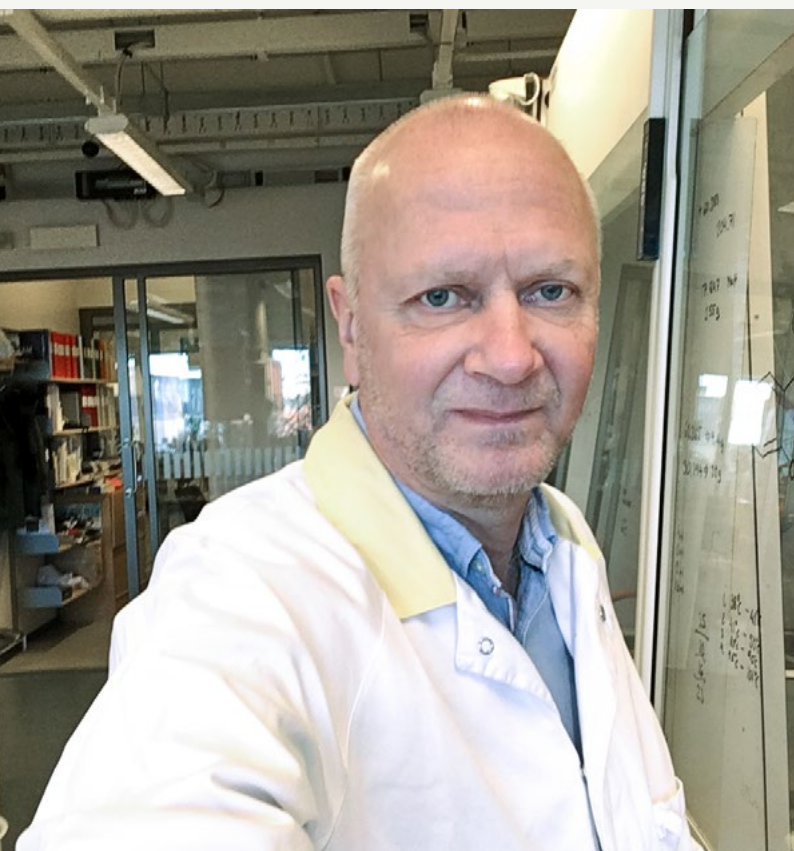
A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Gothenburg April 14, 2021

Öhrlings PricewaterhouseCoopers AB

Johan Rippe
Authorized Public Accountant
Partner in charge

Martin Oscarsson
Authorized Public Accountant



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

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



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

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

CONTACT INFORMATION

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