IRLAB interim report January - March 2021

Significant events during the first quarter (1 January – 31 March, 2021)

- In January, new preclinical data were presented that indicates that not only can mesdopetam treat, but also prevent, the development of levodopa-induced dyskinesias (LIDs) in Parkinson's. The new results increase the commercial potential of mesdopetam.
- In January, results were also presented from a collaboration with Chalmers University of Technology, AI-company Smartr and IRLAB about the application of deep learning on multidimensional effects of CNS drugs. A summary of the interesting results were presented at the leading congress Society of Neuroscience (SfN) Global Connectome: A Virtual Event.
- At the beginning of March, it was announced that the first European patients had beendosed 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.
- During the quarter, the company signed a new and extended lease agreement the company's premises. The new premises are located in direct connection to the current premises. As a result, the right of use and lease liabilities in the company's balance sheet have increased.

Finansial overview 1 January – 31 March, 2021

(TSEK)	jan-mar 2021	jan-mar 2020	jan-dec 2020
Operating result	-19 967	-19 062	-91 458
Result for the period	-20 041	-19 118	-91 653
Earnings per share before and after dilution attributable to the parent company's shareholders	-0,39	-0,42	-1,92
Number of shares at the end of the period, incl. subscribed but not yet registered shares	51 748 406	48 498 406	51 748 406
Cash and cash equivalents	253 905	221 509	277 009

Equity per share	6,34	6,15	6,72
Average no. Employees	19	19	18
of which are in R&D	18	17	17

CEO’s comments

As IRLAB's drug development projects mature and enter clinical studies in late stage, Phase IIb and Phase III, the commercial aspects of drug development become increasingly central. This places new demands on our organization, and we have during the first quarter therefore obtained new core competencies. At the same time, new preclinical research results have shown a broadened commercial potential for mesdopetam and the ISP research platform has been continuously strengthened with AI-based methodology.

Development for launch

We are preparing the company to pursue ‘development for launch’. This means that in parallel with clinical Phase IIb studies, we also carry out the preparatory activities for the start of Phase III studies and future applications for marketing approvals of new original drugs based on mesdopetam and pirepemat. In addition, commercial aspects in the planning of future Phase III studies to create the best possible conditions for successful drug launch are ongoing. We continue to develop our manufacturing processes of drug substance and tablets (CMC) to meet regulatory requirements and keep projects attractive to potential partners.

Strengthened competence enables growth

During the first quarter, IRLAB has recruited highly experienced personnel specialized within commercialization, regulatory affairs, preclinical research, analytical chemistry, manufacturing chemistry (CMC) and clinical development. This too, is a step in the company's ‘development for launch’ strategy where the new expertise supports the company’s medical and clinical work developing the drug candidates. This will contribute to broaden the clinical work further with the goal to minimize time to launch of approved drugs.

Strengthening the organization is also important for maintaining a high level of activity in our research platform, ISP, and continuously identifynew drug candidates to transition through preclinical development and to Phase I and Phase II.

Phase IIb/III study with mesdopetam

At the end of the third quarter 2020, the FDA gave the go-ahead to start the study with mesdopetam and shortly thereafter, the first patients were recruited. In the study, each patient is treated with mesdopetam for three months. Thus, the first patients completed their treatment period during the first quarter 2021.

In Europe, the application processes in the countries included in the study program have run in parallel. European patients were recruited, and treatment was initiated during the first quarter 2021. Current forecast indicates that we will be able to report results during the first half of 2022, in accordance with what has been previously communicated. During the first quarter we worked to increase the number of clinics participating in the study. This, to prevent possible impact of covid-19 on the study timelines.

External scientists confirm MOA for mesdopetam

A group of independent scientists have confirmed that the dopamine D3 receptor (D3R) is a highly promising drug target with therapeutic potential in levodopa-induced dyskinesia. In the article, mesdopetam is used as an example of a drug candidate that can come to transform the treatment of a number of disorders characterized by aberrant D3R activity.

Wider potential for mesdopetam

New results from our own research show that mesdopetam have a wider potential in neurology than previously known. In addition to treatment of established involuntary and troublesome movements, dyskinesia in Parkinson’s, and psychosis in Parkinson’s (PD-P), new preclinical results indicate potential to also prevent the development of dyskinesias. These exciting and important new results from preclinical studies increases the potential benefit of mesdopetam treatment in Parkinson's disease substantially, since we now see the possibility not only to treat already established dyskinesia, but also to prevent the occurrence of dyskinesia. To prevent the development of disease symptoms has long been a goal in science and increases the commercial potential for mesdopetam.

We see that there is also an opportunity for mesdopetam to be able to treat patients with tardive dyskinesia, a condition characterized by troublesome, involuntary, slow and repeated, movements that affect patients being treated for psychosis. It has been shown in studies that the dopamine D3 receptor is a contributing factor to these difficult symptoms and that D3 receptors, just like in PD-LIDs, are upregulated in the brain. Since mesdopetam

inhibits D3 receptor activity, the substance could therefore have effect also in tardive dyskinesia.

About three million patients globally are diagnosed with this condition and the indication make up a large market. We are working to prepare mesdopetam for studies within this disease area and thus widen the indication areas for mesdopetam.

Mesdopetam is the furthest developed D3R antagonist in the current global pipeline and is 4-5 years ahead of any competitor with this mechanism. This is possible thanks to the ISP research platform and IRLAB's unique strategy for discovery and development of new drug candidates.

Pirepemat

Pirepemat, which was also discovered with the ISP technology, is in development for the treatment of impaired balance and falls in Parkinson's (PD-Falls). The aim is to give patients with Parkinson's improved balance to avoid falls and fall injuries, which are common, and thus provide a possibility to improve quality of life.

IRLAB prepares for a Phase IIb study with pirepemat where the drug candidate will be administered for 12 weeks to evaluate the effect on fall frequency compared with placebo. The study is designed in dialogue with regulatory authorities.

As for mesdopetam, we are exploring the opportunities to additional indications for pirepemat and are therefore developing the substance also for the treatment of dementia in Parkinson's.

Covid-19

The global covid-19 pandemic has not yet had any significant direct effects on IRLAB's operational activities. The organization is still adapted to the prevailing conditions with social distancing and remote work for those who have the possibility to do so.

For the clinical programs, we see signs that the situation is strenuous for the healthcare systems in some countries and regions and that processing times for regulatory authorities are longer. This can come to impact IRLAB's projects. We are monitoring the situation closely and have prepared measures to minimize the impact on our projects and timelines.

Continued development of ISP research platform and the AI-based methodology

We have continued to develop our ISP research platform with AI-based methodology in collaboration with the Department of Mathematical Sciences at Chalmers University of Technology and the specialist artificial intelligence (AI) company Smartr.

Application of AI-methodology on our ISP database gives stable results that supports the use of deep learning as a valuable addition to the machine learning methods we use in our systems biological research platform ISP. The ISP technology is key to the rapid and successful development of our clinical drug candidates mesdopetam and pirepemat. Increasing the precision in our methodology improves the quality further and contributes to an increased competitive advantage for IRLAB and our drug candidates. We see that there may be an independent commercial potential for an AI-based systems biology research platform and are therefore evaluating the possibility to develop ISP into a new business area.

Gothenburg, May 2021

Nicholas Waters, CEO

Financial calendar

AGM 2021	May 6, 2021
Interim report January – June, Q2 2021	August 25, 2021
Interim report January – September, Q3 2021	November 10, 2021
Year-end report January – December, Q4 2021	February 23, 2021

For more information

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About IRLAB

IRLAB is a Swedish research and 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 (The Integrative Screening Process), IRLAB discovers and develops unique drug candidates for central nervous system (CNS) related disorders where large and growing medical need exist. In addition to the clinical candidates, the ISP platform has also generated several CNS programs that are now in preclinical phase. IRLAB is listed on Nasdaq Stockholm Main Market. More information on www.irlab.se.