



Covid-19 delays short term revenue, while the commercial launch of IRRAflow and Hummingbird progresses

- Normal business operations and short-term revenue impacted by covid-19 pandemic and associated restrictions
- In spite of covid-19 challenges, forward progress shown with global commercial product launches
- First European patients treated with IRRAflow after CE Mark recertification
- IRRAflow capital systems also placed in additional EU markets

Stockholm, June 30, 2020 – IRRAS AB, a commercial stage medical technology company with a comprehensive portfolio of innovative products for neurocritical care, today provided an update on the launch of its IRRAflow® and Hummingbird ICP Monitoring product lines during the evolving global covid-19 pandemic.

“Since early March, like many other companies around the world, covid-19 has changed IRRAS’ business significantly, and our expected revenue growth during the first and second quarters of 2020 has been negatively impacted,” said Kleanthis G. Xanthopoulos, Ph.D., Chief Executive Officer of IRRAS.

The *New England Journal of Medicine* recently analyzed data on more than 231,000 patients that were imaged for a potential stroke in the United States from July 2019 to April 2020 and estimated that imaging was down 39% from February to early April of this year. A second study published in *Stroke* showed a similar 40% decrease in stroke admissions between February 2019 and February 2020 in China.

“Patients with intracranial bleeding require emergent treatment, so our current customer base where IRRAflow has been previously evaluated and ordered have continued their use of the system. However, overall stroke volumes have dropped globally, and our IRRAS team’s access to hospitals around the world has understandably been restricted,” added Xanthopoulos. “Hospitals have also reallocated staff and patient beds in the neurosurgical intensive care unit (ICU) to focus on covid-related treatments, which has delayed the approval of new technologies. Because of these challenges, ongoing IRRAflow evaluations and new hospital launches were placed on hold for a period of time.”

In the United States, IRRAflow evaluations, including those at 6 comprehensive stroke centers that were underway during Q1, were paused due to the limitations implemented during the covid-19 pandemic. Each hospital’s covid-19 regulations differ, and the company’s US direct sales team is working closely with the staff and physicians to prepare a strategy to restart the evaluations when possible. Because of the varying local guidelines, the IRRAS team is prioritizing opportunities in regions that have accelerated reopening and have resumed their review of new product requests. At the same time, the company has overcome the restrictions on in-person meetings with an increased use of digital marketing.

“For a growing company like IRRAS, a significant portion of our expected revenue is forecasted to come from new hospital customers, and, in the short-term, the completion of product evaluations and the resulting commercial orders have been delayed,” said Will Martin, President and Chief Commercial Officer of IRRAS. “However, our IRRAS team has remained remotely engaged with our customer base, and, as hospitals return to more normal operations, our team is ready to resume our activities with these targeted customers. Even with the challenges caused by the covid-19 pandemic, we have been able to continue to make progress with the global launch of both IRRAflow and Hummingbird to better position the company for long-term growth.”

The company’s IRRAflow system received its CE Mark recertification in December 2019, and early launch efforts were underway in Europe before the full impact of covid-19 was felt. Now, as certain markets begin to slowly reopen, IRRAS’ commercial activities can also resume.

Recently, the initial European patients were treated with IRRAflow since the product’s CE Mark recertification. To date, two patients have been successfully treated by Dr. António Marques Baptista and the team at Centro Hospitalar de Vila Nova de Gaia / Espinho in Gaia, Portugal. While training support could not be provided in-person due to covid-19 travel and hospital access restrictions, IRRAS personnel was able to support the treatments virtually using the company’s digital training tools.

“These initial patient treatments in Portugal mark an important next step for the European launch of IRRAflow,” added Xanthopoulos. “Our team’s primary focus over the past several months has been to ensure that we are prepared for expansion as things return to normal, and the introduction of our products into new markets is a key part of that strategy.”

In addition to the initial patient treatments in Portugal, progress has also been made with distribution partners in other European markets to prepare for commercial launches during the second half of 2020. Previously, IRRAS announced its intentions to launch IRRAflow in an additional 7 to 10 markets globally during 2020, and, even after covid-19’s impact, the company remains on track to achieve that target. In addition to Portugal, IRRAflow control units have now been placed in Italy, Spain, Poland, Austria, and the United Kingdom, and distributor and customer training is underway using IRRAS’ remote training capabilities.

“We see the potential and versatility of the IRRAflow system for the treatment of neurocritical patients in Poland, said Mariusz Tyszkewicz, Managing Director of Biameditek Sp. z o.o, IRRAS’ distribution partner in Poland. “IRRAflow brings much needed innovation in intracranial fluid management and offers safety and efficacy to physicians. The system fits in very well with our other ICU products, and we are excited to enter into a relationship with IRRAS.” Biameditek is a wholly owned subsidiary of Indutrade AB, a publicly-traded Swedish company.

To support the expanding European launch of its product portfolio, IRRAS has also recently finalized the addition of personnel in key sales and training roles. An International Training Manager has already joined the company in Germany, and a Director of Nordic Sales and a Director of German Sales have signed employment agreements to join the team during the 3rd quarter of 2020 to oversee growth in these strategic markets.

"Expanding the launch of IRRAflow to additional European countries is a critical element of IRRAS' future success," added Martin. "In spite of covid-19's impact, we've taken needed initial steps to launch IRRAflow in these important markets. As situations allow in each individual market, we look forward to helping critically ill patients throughout Europe in coming months."

About IRRAS

IRRAS is a global medical care company focused on delivering innovative medical solutions to improve the lives of critically ill patients. IRRAS designs, develops, and commercializes neurocritical care products that transform patient outcomes and decrease the overall cost of care by addressing complications associated with current treatment methodologies. IRRAS markets and sells its comprehensive, innovative IRRAflow and Hummingbird ICP Monitoring product lines to hospitals worldwide through its direct sales organization in the United States and select European countries as well as an international network of distribution partners.

IRRAS maintains its headquarters in Stockholm, Sweden, with corporate offices in Munich, Germany, and San Diego, California, USA. For more information, please visit www.irras.com.

IRRAS AB (publ) is listed on Nasdaq Stockholm (ticker: IRRAS).

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