

# PRESS RELEASE



August 24, 2022, Lund, Sweden

## Immunovia Publishes Interim Report Jan-June 2022

### April-June 2022

- Net sales amounted to kSEK 103 (38) divided between sales of tests kSEK 45 and royalties kSEK 58
- Net earnings amounted to MSEK -33 (-49) and earnings per share before and after dilution were SEK -1.49 (-2.18)
- Cash flow from operating activities amounted to MSEK -41 (-34)
- Cash and cash equivalents at the end of the period amounted to MSEK 197 (382)
- In April Immunovia submitted the application for CPT PLA Code for the IMMray™ PanCan-d test
- The Annual General Meeting on April 7<sup>th</sup> elected Eric Krafft and Philipp von Hugo as new board members. Ann-Christine Sundell, Mimmi Ekberg and Christofer Sjögren had declined re-election. The other board members were re-elected.
- On May 16, Natalie Carfora was appointed as Head of Market Access, Immunovia, Inc.
- In May Immunovia, Inc. achieved Clinical Laboratory Licensure from Rhode Island Dept of Health from IMMray™ PanCan-d test
- In May Immunovia, Inc. achieved Clinical Laboratory Permits from Pennsylvania and Maryland Departments of health for IMMray™ PanCan-d test
- On June 2, Philipp Mathieu was appointed Chief Executive Officer and President since January 2022
- In June partly inconclusive results from the Pan-FAM-1 study were announced
- In June Immunovia announced that the PanDIA-1 study for early detection of pancreatic cancer in newly onset diabetes moved into the next phase

### Significant events after the period

- In June Immunovia, Inc. had CPT PLA code for the IMMray™ PanCan-d test approved
- In August Immunovia, Inc. issued Clinical and Public Health Laboratory License from California Dept of Public Health for IMMray™ PanCan-d test

**Key indicators**

SEK thousand unless otherwise stated	2022 April-June	2021 April-June	2022 Jan-June	2021 Jan-June	2021 Full year
Net sales	103	38	285	161	844
Operating earnings/loss	-50,787	-46,731	-98,154	-75,813	-166,628
Earnings before tax	-33,726	-49,261	-77,838	-72,707	-155,966
Net earnings	-33,726	-49,261	-77,838	-72,496	-155,966
Earnings per share before dilution (SEK)	-1.49	-2.18	-3.44	-3.21	-6.89
Earnings per share after dilution (SEK)	-1.49	-2.18	-3.44	-3.21	-6.89
Equity ratio (%)	84	87	84	87	88
Number of shares at the end of the period	22,631,581	22,631,581	22,631,581	22,631,581	22,631,581

**CEO's comments**

During Q2 Immunovia built on our front-runner position in early detection of pancreatic cancer to ensure the execution of a successful commercial US launch by significantly strengthening our US team through the addition of new highly experienced hires. We have also broadened market access to IMMray™ PanCan-d for patients in additional US states and obtained a unique CPT PLA code for our test on the way to reimbursement.

During the second quarter, Immunovia continued to execute on the previously communicated strategic priorities for 2022.

Immunovia is currently in the scale-up phase of its US commercial organisation to facilitate a successful launch of IMMray™ PanCan-d. Our US team was significantly strengthened through Jeff Borcharding, previously Chief Marketing Officer at Myriad Genetics, joining in April to lead our US business and the US commercialization efforts, as well as the hire of Natalie Carfora as Head of Market Access US. Having Jeff and Natalie on board with their combined industrial experience, I feel that we have a solid platform enabling us to grow our brand and diagnostic business in the US market.

In the pursuit of additional clinical validation of IMMray™ PanCan-d we announced PanFAM-1 results and provided an update on PanDIA-1. During PanFAM-1, IMMray™ PanCan-d met its primary endpoint of test specificity comparable to imaging in the study. The study, however, was partly inconclusive since sensitivity could not be evaluated due to the low number of PDACs among study participants. We certainly had aimed for more tangible results of the study, but have gained important learnings from PanFAM-1, which together with our ongoing discussions with payers will inform the way forward in establishing further clinical validation in this risk group.

We also provided an update on PanDIA-1, one of the largest studies for the early detection of pancreatic cancer in newly onset type 2 diabetics. The study aims to give another substantial risk group for pancreatic cancer access to early detection. The prevalence of diabetes is dramatically increasing worldwide, and newly diagnosed diabetics have up to 8 times higher risk of getting pancreatic cancer. PanDIA-1 is now moving into a decisive next phase and during the second half of 2022 we will initiate the analysis of samples from the included patients.

To continue our mission making IMMray™ PanCan-d broadly available on the US market, we initiated a physician experience program in the US, which is now almost fully enrolled at selected pancreatic cancer high-risk-surveillance centers. The program commenced in May and has enrolled more than 20 established surveillance centers. It aims to drive familiarity and adoption amongst physicians who together with other key opinion leaders is expected to play a critical role as advocates for our test with payers.

In April we submitted a CPT PLA Code application for the IMMray™ PanCan-d test to the American Medical Association, which was approved at the beginning of July. The physician experience program, continued collaborations with key opinion leaders and having attained the PLA code, are all important steps in executing our US reimbursement plan.

During the quarter Immunovia has firmly continued the journey to penetrate the US market and generate significant growth. We have a clear path forward and an industry leading team in place focused on our mission to enable broad access to early detection. Improving pancreatic cancer survival rates is hugely motivating and continuously driving us forward.

*August 24, 2022*

*Philipp Mathieu, CEO and President*

*Immunovia AB*

**For more information, please contact:**

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*The information in this report is information that Immunovia AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 08:30 am CET on August 24, 2022.*

**Conference call**

Immunovia will hold a webcast tele conference at 13:00 pm CET on August 24 with President and CEO Philipp Mathieu and CFO Karin Almqvist Liwendahl.

To take part of the presentation, please dial one of the numbers or watch via the web link below.

Sweden: +46 8 5051 0031

United Kingdom: +44 207 107 06 13

United States: +1 631 570 56 13

Link to the webcast:

<https://link.edgepilot.com/s/9134565d/n4saifQXgEG99MipSw3ORw?u=http://creo-live.creomediamanager.com/6074dc43-43a2-4f11-9bff-9647548664fd>

### **About Immunovia**

Immunovia AB is a diagnostic company with the vision to revolutionize blood-based diagnostics and increase survival rates for patients with cancer.

Our first product, IMMray™ PanCan-d is the only blood test currently available for early detection of pancreatic cancer. The test has unmatched clinical performance. Commercialization of IMMray™ PanCan-d started in August 2021 in the USA and IMMray™ PanCan-d is offered as a laboratory developed test (LDT) exclusively through Immunovia, Inc. For more information see: [www.immunoviainc.com](http://www.immunoviainc.com).

Immunovia collaborates and engages with healthcare providers, leading experts and patient advocacy groups globally to make this test available to all high-risk pancreatic cancer groups.

The USA, the first market in which IMMray™ PanCan-d is commercially available, is the world's largest market for the detection of pancreatic cancer with an estimated value of more than USD 4 billion annually.

Immunovia's shares (IMMNOV) are listed on Nasdaq Stockholm. For more information, please visit [www.immunovia.com](http://www.immunovia.com).

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