

# PRESS RELEASE



May 23, 2023, Lund, Sweden

## Immunovia Publishes Interim Report for January-March 2023

### January-March 2023

- Net sales amounted to kSEK 520 (182) divided by sales of tests kSEK 379 (122) and royalties kSEK 141(60).
- Net earnings were MSEK -51.7 (-44.1) and earnings per share before and after dilution were SEK -2.28 (-1.95).
- Cash Flow from operating activities were MSEK -39.7 (-46.1).
- Cash and equivalents at the end of the period amounted to MSEK 68.2 (239.8).
- On January 17, the Company appointed Lara E. Sucheston-Campbell as Head of Clinical and Medical Affairs
- On January 19, the Company announced that a process to re-align the Swedish operations with strategic priorities and the focus on US commercialization of the IMMray™ PanCan-d test had started and on February 8 the Company informed that the consultation process was completed.
- On February 20, the company announced a rights issue of approximately SEK 202.2 million and postponed the publication of the January – March quarterly report until May 23 and the annual general meeting until May 26.
- On February 20, the Company also gave notice for an Extraordinary General Meeting on Thursday 16th March 2023
- On March 1, the Company appointed Karl Stone as chief operating officer to lead R&D and operations.
- On March 16, the Company released a bulletin from the extraordinary general meeting in Immunovia AB, where a resolution by the board of directors on February 20, 2023, to increase the company's share capital by not more than SEK 1,508,772.00, by way of issuance of not more than 30,175,440 new shares with preferential rights for existing shareholders was approved.
- On March 17, the Company published the prospectus relating to the rights issue.

### Significant events after the period

- On April 12, the Company announced the outcome of the rights issue. The Rights Issue was subscribed to approximately 75.1 per cent and Immunovia will thereby receive approximately SEK 151.8 million before issue costs.
- On April 25, the Company gave notice for the Annual General Meeting on Friday 26th May 2023.
- On April 26, the Company announced a discussion on adoption of IMMray™ PanCan-d with key opinion leaders on May 3, 2023.

- On April 29, the Company announced the appointed of Jeff Borcharding as global CEO replacing Philipp Matthieu.
- On May 6, the Company announced that the board member Philipp von Hugo resigned from Immunovia’s board at his own request.

## Key indicators

SEK thousand unless otherwise stated	2023 Jan-March	2022 Jan-March	2022 Full year
Net sales	520	182	1,145
Operating earnings/loss	-49,082	-47,367	-191,150
Earnings before tax	-51,658	-44,112	-168,092
Net earnings	-51,658	-44,112	-168,092
Earnings per share before dilution (SEK)	-2.28	-1.95	-7.43
Earnings per share after dilution (SEK)	-2.28	-1.95	-7.43
Equity ratio (%)	77	86	81
Number of shares at the end of the period	22,631,581	22,631,581	22,631,581

## CEO’s comments

Our mission is simple: We want to save lives by detecting pancreatic cancer earlier. With the IMMray™ PanCan-d test, we can dramatically improve patient survival by identifying pancreatic cancer early when it can still be treated effectively. I am honored and energized to lead Immunovia as the global CEO to achieve our mission. In my first year with Immunovia, as head of U.S. operations, I have seen a very promising and growing response to our test among gastroenterologists as well as very strong interest among individuals concerned about their risk for this deadly disease.

In the first quarter of 2023, we made important progress in the commercialization of the IMMray™ PanCan-d test:

- 39 clinicians ordered the test for the first time this quarter.
- We grew the number of high-risk surveillance centers using IMMray™ PanCan-d to 34.
- We increased the number of adopters-centers that have ordered five or more IMMray tests - to 21.
- We successfully transitioned physicians and patients from free tests to patient-paid tests, with more than half of tests in Q1 paid for by patients.
- We conducted meetings with nine payers this quarter, including several of the largest commercial payers in the U.S., presenting models that illustrate the economic benefits and care gaps that can be addressed by IMMray™ PanCan-d .

- We raised a net of 122 MSEK after issue costs in a rights issue, funding operations into 2024.
- Our burn rate has historically been around 15-20 MSEK per month and we are currently trending towards the lower end of this range.

Going forward, we must overcome three key challenges to achieve our business and financial objectives:

Challenge 1: Demanding requirements from payers, especially the need to demonstrate clinical utility. Payers in the U.S. require extensive clinical evidence supporting the accuracy and clinical utility of diagnostic tests before they are willing to pay for those tests. Clinical utility is the ability of the test to improve patient outcomes when used by a physician. Currently, we have one study showing the accuracy of the IMMray™ PanCan-d test. The PanFam-1 study was intended to provide additional evidence of the accuracy of IMMray™ PanCan-d and provide evidence of clinical utility. Since the recruited study population resulted in a surprisingly low number of pancreas cancer cases, our clinical data package needs to be expanded with additional studies to satisfy most payers.

Challenge 2: Inherent challenge in proving clinical utility in pancreas cancer early detection. Clinical studies of an early detection test in pancreas cancer generally must include a very large number of patients over a period of multiple years. The size and duration of these clinical trials may require a significant investment if not properly planned.

Challenge 3: A tight, risk-averse financial climate. Access to capital has declined dramatically, especially for pre-profit companies like Immunovia. The rights issue we concluded in the first quarter reflects this challenging financial environment. Limited capital requires that we need to operate in a very lean way and with limited commercial and clinical investment.

However, we have a plan to overcome these challenges and seize the opportunities in the market. We will:

Partner with existing clinical research studies to deliver the scale required to demonstrate clinical utility of IMMray™ PanCan-d in a cost effective way. We have identified existing and planned clinical studies that will enable us to demonstrate the accuracy and clinical utility of the IMMray™ PanCan-d test. One approach is to support one of the multi-center research consortia that are conducting large studies in pancreatic cancer surveillance. Collaborating with these ongoing studies is faster and less costly than proprietary clinical trials. We will also partner with researchers who have secured government funding for their studies and are eager to evaluate pancreatic cancer biomarkers like ours. Finally, we are negotiating with institutions that have large biobanks that would allow us to retrospectively study IMMray™ PanCan-d in robust and well-defined patient cohorts. Our clear expectation is that the combination of these approaches enables us to generate more clinical data, faster, and at a much lower cost.

Pursue a two-pronged approach to securing reimbursement. Most commercial payers and Medicare, the U.S.A.'s federal insurance program for seniors over age 65, require extensive evidence of accuracy and clinical utility before agreeing to pay for a test. However, a subset

of payers will pay for the test for a fixed period, while gathering clinical evidence from the use of the test among the payer's members. We are currently discussing pilots with several of these innovative payers and hope to announce one or more programs in 2023 and 2024. For the other payers, we will rely on the clinical program outlined above to secure coverage in 2025 and beyond.

Manage costs in a very disciplined manner and pursue funding as needed. Prior to securing reimbursement, we will limit our spending to the only most crucial R&D, clinical and commercial activities. To fund operations prior to achieving profitability, we will explore a variety of funding sources. For example, we are pursuing collaborative research grants that would enable us to fund a portion of the clinical studies described above.

Drive clinician and patient awareness and adoption of the IMMray™ test in targeted, cost-efficient ways. We have assembled a small and highly talented team of sales representatives. They have proven adept at penetrating high-risk surveillance centers for pancreas cancer. Our sales representatives have also begun growing the market for pancreas cancer surveillance by convincing gastroenterologists of the importance of early detection. In 2023, we will bolster and amplify the efforts of our sales team with targeted public relations and digital marketing to increase consumer demand for our test. Our sales and marketing spending will be targeted, disciplined, and rigorously measured.

We have a strong team to execute this plan. First, our strategic R&D collaboration with Proteo- medix, a Swiss diagnostics company with complementary skills to Immunovia, has exceeded our expectations. Second, our organizational changes in Lund have driven efficiency, reduced costs, and strengthened leadership for our lab and production efforts. Thirdly, we strengthened our U.S. organization by recruiting a VP of Clinical & Scientific Affairs who has dramatically increased our clinical research expertise. We now have a rigorous clinical plan and by securing partnerships with key researchers we are executing this plan. Our reimbursement leader has built an excellent pipeline of opportunities for payer pilots and is providing expert leadership for our payer efforts. Our sales and marketing team are refining our go-to-market approach and building the capability of our sales team.

Going forward in 2023, I would like to share a preview of what you as a shareholder can expect:

- Prior to securing reimbursement for IMMray™ PanCan-d, we will limit our investment in the field sales force, resulting in modest volume in 2023.
- Revenue growth will be modest in 2023 as most of our tests will still be patient paid, and many of these tests will be offered at a discount based on the patient's ability to pay.
- We hope to secure and announce initial reimbursement through "coverage with evidence development" pilots with innovative payers in 2023.
- During the second half of 2023 we expect to announce specific collaboration agreements on clinical studies with leading health care systems and research consortia. At least two of the studies will be retrospective, so we would hope to announce results from those studies in 2024. Others will be prospective and will extend into at least 2025.

As we execute on our plan, we will increase the frequency of our communication to the market. We are energized by the opportunity in front of us. We face challenges, but we will overcome them. In the U.S. alone there are 1.8 million people at increased risk of pancreas cancer who are counting on us. We will not let them down.

*May 23, 2023*

*Jeff Borcharding, CEO and President  
Immunovia AB*

**For more information, please contact:**

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**Conference call**

Immunovia will hold a webcast tele conference at 15:00 CET on May 23 with President and CEO Jeff Borcharding 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://access.creomediamanager.com/registration/058aa458-36d2-4352-9dbf-1894dc75828d?ref=https%3A%2F%2Fcreo-live.creomediamanager.com%2F058aa458-36d2-4352-9dbf-1894dc75828d>

**About Immunovia**

Immunovia 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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