

2022

NEW YEAR LETTER



Dear Immunovia Shareholders,

2021 has been an eventful year with several positive milestones, taking the company into the US market for early diagnosis of cancer. In this letter, I would like to highlight a few of these milestones before going into 2022 events.

In February, we announced that our PanFAM-1 prospective study gathered over 3000 familial/hereditary pancreatic cancer risk samples. According to the American Cancer Society, as many as 10% of pancreatic cancers are caused by familial and hereditary risk factors. PanFAM-1 is the largest prospective study to date, focusing on early diagnosis of high-risk individuals with familial/hereditary pancreatic cancer. Designed to support the road to reimbursement for our blood test, IMMray™ PanCan-d, the study has enrolled samples from 23 clinical sites in USA and Europe.

In March, we reported positive results of the blinded clinical validation of IMMray™ PanCan-d blood test in USA, which paved the way for the CLIA certification of our US lab in Massachusetts. We also reported improved test performance of IMMray™ PanCan-d in detecting early-stage pancreatic cancer in high-risk symptomatic patients with non-specific but concerning symptoms.

In April, we updated our assessment of the total market size for familial/hereditary pancreatic cancer risk group with two First Degree Relatives (FDR) in the US, which showed that 315,000 – 350,000 individuals have a familial/ hereditary risk for pancreatic cancer. The total potential annual market size, assuming testing twice a year, range from 630,000 – 700,000 tests, following current recommendations and guidelines. Updated guidelines from US Preventive Services Task Force (USPSTF), National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), and the International Cancer of the Pancreas Screening (CAPS) Consortium recommended to follow-up on individuals with a family history of pancreatic cancer, individuals with one FDR with a confirmed germline mutation. The addition of these individuals would increase the market to over 3 million high risk individuals. This suggestion is not yet in any guidelines, but NCCN and ASCO already propose systematic germline testing for all individuals diagnosed with PDAC and for their first-degree relatives if a mutation is identified.

In June, we received our CLIA Certificate of Registration and on August 3 we finally received the approval from the Massachusetts Department of Public Health to begin testing patients for pancreatic cancer with the IMMray™ PanCan-d test, after a delay at the regulating authority due

to Covid-19. As a result, Immunovia, Inc. could finally begin selling the IMMray™ PanCan-d test for early detection of pancreatic cancer through our laboratory in Marlborough, Massachusetts.

In August we also reported a further improved test accuracy, for individuals with CA19-9 levels greater than 2.5 U/ml, reaching an overall sensitivity of 89% in stages I and II and 92% in all stages with a specificity of 99%, meaning very few false positives!

We have had a fruitful collaboration with the largest patient organization for pancreatic cancer in the US, Pancreatic Cancer Action Network (PanCAN), since 2012 and in September they informed their constituents of our blood test, the first-ever blood test for early diagnosis of pancreatic cancer. Interested individuals can contact PanCAN Patient Services, which provides free information and answers questions about the IMMray™ PanCan-d test.

In October, our medical director Thomas King, MD, PhD was awarded the Presidential Poster Award at the American College of Gastroenterology (ACG) for our pivotal blinded validation results and was also invited as a keynote speaker to the National Cancer Institute (NCI) Pancreatic Cancer Detection Consortium (PCDC).

In November, we celebrated World Pancreatic Cancer Day by a grand opening of Immunovia, Inc., that exclusively offers the first available blood test for early detection of pancreatic cancer. State Senator Jamie Eldridge provided an official citation from the State Senate of Massachusetts to Immunovia, Inc. in recognition of the “momentous occasion of your grand opening”, and by highlighting how important it is to have an early detection test for pancreatic cancer available. The Mayor of Marlborough, Mayor Arthur Vigeant, cut the ribbon for the new laboratory.

We also announced that we strengthen our management by hiring a new CFO, Karin Almqvist Liwendahl, and a new IR responsible, Tobias Bülow to our organization in Lund.

Outlook for 2022

We are now entering a very exciting 2022, leaving 2021 where we reported on several successful clinical studies, which all demonstrated the accuracy of the IMMray™ PanCan-d test. In 2022 we also expect several major events important for Immunovia’s commercial success, which we are looking forward to sharing with you.

To mention but a few, Immunovia is becoming more and more focused on USA, where we have our largest market for our IMMray™ PanCan-d test. The addressable annual market in the US is estimated to be over b\$ 4. We have therefore taken several decisions to assure that we can approach this important market in a more efficient way to achieve our communicated market penetration going forward. Since December, we are actively searching for a commercially experienced CEO for our US organization, where we also are constantly staffing up with experts within sales and marketing, reimbursement, development etc. This represents the first important step for an increased presence in the US.

In parallel, we are also hiring a new CEO for our Swedish organization with HQ in Lund. Both positions, with a strong commercial focus and with experience from the cancer test market world-wide, will significantly strengthen our company when we now are transforming from a development company to a commercial diagnostic company. Together with our cutting-edge

R&D unit in Lund our product pipeline will feed into already proven, well-oiled clinical and commercial processes.

We have a strong focus as the pancreatic cancer company and we consequently have several studies ongoing, and we will soon announce their outcome. The Pancreatitis Study for the symptomatic risk group, is close to completion in collaboration with the University of Pittsburgh School of Medicine. Additional collaborations focused on individuals at risk because of pancreatic imaging abnormalities are in the final planning stages with initial results expected in 2022.

In Summary - 2021 was a highly successful year for Immunovia. As the first company in the world, we have brought a test for early detection of pancreatic cancer to market. However, 2022 will be an even more exiting year as we move towards reimbursement for our IMMray™ PanCan-d test, leading to potentially higher sales figures going forward. Our communicated long-term market penetration goal of 30% of the 4b USD market remains unchanged.

I wish You all a Happy New Year and a prosperous 2022!

Carl Borrebaeck

Chairman