

Unleashing a paradigm shift in early detection of pancreatic cancer

Advancing into commercial phase, Immunovia has achieved a strong launch of its first product IMMray PanCan-d which was shortly followed by backing of the largest US patient organization Pancreatic Cancer Action Network (PanCAN) and the US National Pancreas Foundation (NPF). Such support provides real-world commercial third-party validation and should reinforce the capital market's confidence in the test's performance and clinical utility offer.

As anticipated, and addressed in our [latest update](#), there is price elasticity supporting a pricing of USD 995 per test – up from previous company target of USD 600 and in line with conducted pricing analyses and health-economic evaluations. An industry standard discount of up to 30% is expected in the initial stages, decreasing in conjunction with gradual reimbursement unlocking. Broader national health insurance coverage (Medicare) and commercial coverage among 30-50% of US commercial payors is targeted in selected states by end 2022 for familial/hereditary risk group.

Surveillance of familial/hereditary risk patients is currently limited to the population with hereditary background from two or more first-degree relatives, about 350.000 patients in the US (an increase from previous estimate of ~100.000 patients). This translates into an initial addressable market of approx. USD 700m/year given two tests per patient and year in accordance with surveillance guidelines. However, it is likely that the entrance of a simple blood test, such as IMMray PanCan-d, motivates expanding surveillance to include individuals with hereditary predisposition from at least one first-degree relative, still at significant risk of developing disease. This would increase the annual patient population under surveillance in the US to 1.5m, a market expansion of 4x and significant upside to the initial opportunity targeted.

Immunovia is launching and have investigator-driven trials ongoing for the symptomatic and NOD groups. Evidence on clinical utility from these combined with data from ongoing prospective trials will be essential as basis to drive commercial impact. As the commercial roadmap is not as straightforward as for surveillance of the familial/hereditary risk group, it is likely that gradual reimbursement unlocking will start from 2023 onwards – when more substantial evidence on utility should have been gathered. We assume that detailed commercial roll-out and reimbursement plans for these subgroups are being developed precisely as the plan for the familial/hereditary group. We particularly look forward to understanding how the prevalence in the NOD group will be enriched from 0.85% to 2-3% in order for surveillance to qualify for payor coverage. There are established methods available, and we believe that the investigator-driven studies will evaluate these further.

It is worthwhile to yet again emphasize that the opportunities in NOD and symptomatic risk groups have been entirely excluded in the pricing of the share, trading below the value of the initial opportunity in the familial/hereditary risk group. We see significant short-term upside to today's pricing of the company as sales reporting approaches. We maintain the Outperform rating and raise the target price to SEK 320 per share (SEK 300), corresponding to an equity value of SEK 7.2bn non-diluted, derived from a DCF valuation of the opportunity in pancreatic cancer. The value increase is motivated by overall commercial de-risking combined with value expansion achieved through launch, albeit delayed, higher pricing and larger initial US patient population than previously estimated. Surveillance expansion of the familial/hereditary risk group and pipeline program provide further upside potential.



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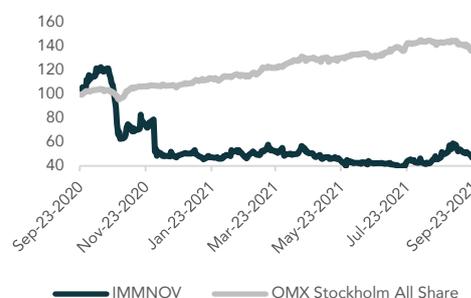
Update Report

Target price: SEK 320
Current price (close 23/09): SEK 115
Implied upside potential: 178%

Immunovia at a glance

Immunovia, a diagnostic company, is developing and commercializing highly accurate blood tests for the early detection of cancer and autoimmune diseases based on Immunovia's proprietary test platform called IMMray™. Tests are based on antibody biomarker microarray analysis using advanced machine-learning and bioinformatics to single-out a set of relevant biomarkers that indicate a certain disease. Thus, forming a unique "disease biomarker signature".

Share price development (index= Sep 23, 2020)



Key Data

As per 2021-09-23

Ticker	IMMNOV
Share price (close)	SEK 115.0
Free float	75.7%
Market cap	SEK 2.6bn
Website	immunovia.com
Average daily volume (13 Aug – 23 Sep)	SEK 12.2m

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Outperform rating and target price SEK 320

Valuation

We maintain the Outperform rating and raise the target price to SEK 320 per share, based on a DCF valuation of the opportunity in pancreatic cancer. The value increase is motivated by the fact that the overall commercial risk-profile of the company has been lowered combined with value expansion due to launch, albeit delayed, higher pricing per test (USD 995) and larger familial/hereditary patient population in the US (~350.000 p.a.) than previously estimated (i.e., USD 600 per test and ~100.000 patients p.a. in the US).

We forecast sales of SEK4.2 bn in 2030

In our financial outlook, we include US+Canada and Immunovia's prioritized EU regions¹. Our forecast is based on the following assumptions concerning IMMray PanCan-d:

- A list price of USD 995 per test. We model a 5-30% discount, on par with industry standard, decreasing over the forecast period in conjunction with gradual reimbursement unlocking. We expect reimbursement to gradually unlock from 2022 in the familial/hereditary risk group and initially from 2023 in the symptomatic and NOD risk group. We expect a slower ramp up of coverage in these latter groups.
- The company has set a long-term goal of 30% market penetration across the defined risk groups, without specifying timing. We believe that this will correspond to the following market penetration rates in respective risk group by 2030:
 - Hereditary risk group: 70% and 60% in the US+Canada and EU, respectively. This represents a very well-defined patient population of ~350.000 patients per year in the US where pancreatic cancer surveillance is already established in the guidelines. In comparison, Oncotype Dx (Exact Sciences) has since launch 2011 exceeded a 70% adoption rate in its breast cancer target population of 140,000 individuals per year, which is comparable to the hereditary pancreatic cancer population.
 - Early symptoms group: 30% in the US+Canada, 20% in European countries.
 - Newly onset diabetes: 5% in the US, 3% in the European countries. This is by far the largest target population.
- We assume a quick organizational build-up to effectively execute an accelerated commercialization strategy of IMMray PanCan-d.
- Gross margin through gradual economies of scale reaching 90% by 2029.
- We expect the company to raise an additional ~SEK 300m to fund the commercialization of PanCan-d and advancement of pipeline programs.

¹ The Nordics, UK, Spain, Italy, Austria, Germany, Switzerland, Belgium, Netherlands, Luxembourg, France.

P&L (SEK m)

P&L SEK m	FY19A	FY20A	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E	FY32E
Net sales	1	1	11	93	225	499	972	1 546	2 163	3 022	3 756	4 168	4 377	4 486
Sales growth (YoY)	n/a	21%	1057%	718%	141%	122%	95%	59%	40%	40%	24%	11%	5%	2%
COGS	0.0	0.0	(2)	(19)	(45)	(100)	(175)	(263)	(368)	(483)	(376)	(417)	(438)	(449)
Gross Profit	0.8	1.0	9	75	180	399	797	1 283	1 795	2 538	3 380	3 752	3 939	4 038
Gross margin	100%	100%	80%	80%	80%	80%	82%	83%	83%	84%	90%	90%	90%	90%
Total operating costs	(160)	(206)	(243)	(323)	(413)	(473)	(543)	(623)	(813)	(940)	(1 080)	(1 210)	(1 290)	(1 350)
Operating costs as % of Net Sales	n/m	n/m	2133%	347%	184%	95%	56%	40%	38%	31%	29%	29%	29%	30%
EBITDA	(159)	(205)	(234)	(249)	(234)	(74)	254	660	982	1 598	2 300	2 542	2 649	2 688
EBITDA-margin	n/m	n/m	n/m	n/m	n/m	n/m	26%	43%	45%	53%	61%	61%	61%	60%
EBIT	(168)	(214)	(244)	(262)	(251)	(94)	232	637	957	1 572	2 274	2 515	2 622	2 660
EBIT-margin	n/m	n/m	n/m	n/m	n/m	n/m	24%	41%	44%	52%	61%	60%	60%	59%
Net income	(168)	(226)	(256)	(262)	(251)	(94)	232	637	806	1 233	1 783	1 972	2 056	2 085
Profit margin	n/m	n/m	n/m	n/m	n/m	n/m	24%	41%	37%	41%	47%	47%	47%	46%
Key metrics: P&L	FY19A	FY20A	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E	FY32E
COGS increase	n/m	n/m	n/m	718%	141%	122%	75%	50%	40%	31%	-22%	11%	5%	3%
EPS (SEK)	(7.4)	(10.0)	(11.3)	(11.6)	(11.1)	(4.1)	10.3	28.1	35.6	54.5	78.8	87.1	90.8	92.1

Source: Vator Securities

The opportunity in pancreatic cancer indicates an equity value of SEK 7.2bn

We use a discount rate (WACC) of 12.9% and a 2.5% terminal growth rate (in line with GDP growth). The risk-free rate is 0%, based on the Swedish government ten-year bond, and the risk premium is 9.2%, based on a size and market risk premium of 1.8% and 7.4% respectively. Lastly, we use an equity beta value of 1.5. We have also included a net present value of the cumulative tax shield. With our estimates and DCF input variables, our DCF model indicates an equity value for Immunovia of approximately SEK 7.2bn, equivalent to SEK 320 per share (based on approximately 22.6 m outstanding shares)

Forecast from 2021 to 2032, with an 85% life cycle adjustment applied to the terminal value in 2032.

DCF valuation (SEK m)

DCF (SEK)	FY19A	FY20A	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E	FY32E
EBIT	(167.7)	(214.4)	(244)	(262)	(251)	(94)	232	637	957	1 572	2 274	2 515	2 622	2 660
Paid tax	0.0	0.0	0	0	0	0	0	0	151	340	491	543	566	575
NOPLAT	(167.7)	(214.4)	(244)	(262)	(251)	(94)	232	637	806	1 233	1 783	1 972	2 056	2 085
Adj. for non-cash items	8.4	9.8	10	14	17	20	22	23	25	26	26	27	27	28
Changes in NWC	(14.9)	(4.4)	(0)	9	13	39	67	93	116	136	123	84	63	29
Capex	36.6	47.5	30	30	30	30	30	30	30	28	29	29	30	31
Free cash flow	(180.9)	(247.7)	(264)	(287)	(277)	(143)	157	537	685	1 094	1 657	1 885	1 990	19 743
Discount factor (formula based)	-	-	1.06	1.20	1.35	1.53	1.73	1.95	2.20	2.48	2.80	3.17	3.58	3.58
Net Present Value - Free Cash Flows	n/a	n/a	(248)	(240)	(205)	(94)	91	275	311	440	591	595	557	5 522

SEK million

Terminal value	19 743
Life cycle adjustment TV	85%
Adjusted Terminal value	16 781
Net Present Terminal Value	4 694
Net Present Value FCF	2 074
NPV of FCF incl. TV	6 768
Tax shield value, NPV	125
Interest bearing net debt	(346)
Equity Value	7 239
Number of shares, non-diluted, million	22.6
SEK/Share	320
Key metrics	
Terminal value/DCF	69%

Source: Vator Securities

There are upsides to our financial outlook and resulting target price, currently based on IMMray PanCan-d:

- Immunovia could very well start unlocking reimbursement earlier on the back of interim analyses from the ongoing prospective studies, which consequently would trigger a quicker adoption in each risk group.
- Expansion of the familial/hereditary risk group to include surveillance of individuals with hereditary predisposition from at least one first-degree relative, still at significant risk of developing disease. This would increase the annual patient population in the US under surveillance to 1.5 million, a market expansion of 4x and as such upside potential to the initial opportunity targeted.
- Advancement of pipeline programs toward development stage should trigger inclusion into financial models and pricing of the share.

The main risk to our forecast and target price is if gradual reimbursement unlocking, and consequently adoption, would develop slower over the forecast period. However, Immunovia is attractively positioned to mitigate the commercial risk and successfully commercialize its pancreatic test.

Key personnel

Patrik Dahlen, Chief Executive Officer. Patrik holds a MSc in Biochemistry from Åbo Akademi University and a PhD in Biochemistry from Turku University. He brings over 30 years of senior level experience as an executive in the life science and diagnostics industry. Patrik contributes with broad international experience in Europe and the US with substantial diagnostic and international industry expertise. As Chief Executive Officer of Dako, Patrik, carried out a major strategic repositioning of the company as a leading supplier of cancer diagnostics. As President of Life Sciences at the American company Perkin Elmer, Patrik was instrumental in building the company's diagnostic business with a niche focus on diagnostic systems for neonatal and prenatal screening. He has led organizations ranging from 10 to 2,000 people based in Finland, Denmark, UK and USA and has considerable public company experience. Additional experience includes CEO, SSI Diagnostic, Denmark, CEO, Immunodiagnostic Systems (IDS), UK; CEO NeuroSearch, Denmark.

Rolf Ehrnström, Chief Scientific Officer. Rolf holds a MSc in biochemistry & biotechnology engineering from Royal Institute of Technology, Stockholm, Sweden. Rolf is the owner of Reomics AB and an independent partner at Ventac Partners. He has long experience of leading research and has been a Corporate Vice President R&D and Chief Scientific Officer at Dako/Agilent and Gyros AB. Rolf has also experience as a Science Director at Amersham Pharmacia Biotech.

Hans Liljenborg, Chief Financial Officer. Hans Liljenborg has a degree as subject teacher in Business Administration and Mathematics from Lund University, Sweden. Hans has long experience as Financial Manager for growing, global medical technology companies and has been Finance Director at Physio Control Inc, Jolife AB and Finance Manager at Vivoline Medical AB, listed on Nasdaq First North in March 2015. He also operates an own accounting firm.

Hans Christian Pedersen, VP of Strategy & Business Development. Hans Christian holds a MSc in Molecular biology from University of Copenhagen, Denmark. He brings over 18 years of industry experience working with drug development, antibody development, breast cancer research, companion diagnostics development, IVD global marketing, scientific affairs, and business development. Hans Christian has an extensive experience in both development and commercialization of diagnostic tests and has been involved in building and launching strategic partnerships with global pharma partners.

Linda Mellby, VP Research & Development. Linda received her PhD in Immunotechnology from Dept. of Immunotechnology within CREATE Health Translational Cancer Center, Lund University, in 2010, and a MSc in Chemistry Engineering in 2004. She has more than 15 years' experience of recombinant antibody microarray technology, the Immunovia platform. She has deep knowledge about platform features, technology development as well as clinical applications within oncoproteomics and autoimmunity. Linda has been one of the key researchers managing the development of the Immunovia antibody microarray platform for disease proteomics, conducting extensive work related to process optimizations, standardizations as well as clinical studies.

Lotta Blomgren, Operations Director. Lotta holds a MSc in Chemical Engineering from Lund University, Sweden. Lotta has more than 30 years' experience within the life science and diagnostics industry, whereof 15 years in leading positions. She contributes with extensive experience from leading manufacturing, quality control and logistics teams, as well as managing transfer of new products from development to commercial scale. Her track record includes strategic reorganizations of international manufacturing networks, managing people and project portfolios, as well as due diligence of potential acquirement of new companies and Contract Manufacturing (CMO).

Annika Andersson, QA/RA Director. Annika is a Biomedical Scientist from Malmö University. She has more than 25 years' experience within the life science and diagnostics industry, with the main focus on regulatory affairs and quality assurance of in vitro diagnostic medical devices. Annika contributes with global experience within regulatory strategies and regulatory submissions of IVDs. Her track record includes leading successful regulatory approval processes of medical devices for IVD CE marking as well as IVD approvals in Canada, China, India, Japan, Korea, Mexico, Russia and 510(k) clearances in USA.

Board of Directors

Carl Borrebaeck, Chairman of the Board. Professor Carl Borrebaeck is a successful serial entrepreneur, having co-founded Immunovia AB, Senzagen AB (SENZA; Nasdaq First North), BioInvent International AB (BINV: Stockholm), Alligator BioScience AB (ATORX; Nasdaq Stockholm) and PainDrainer AB. Prof. Borrebaeck is a 2009 recipient of the AkzoNobel Science Award and was awarded the 2012 Gold Medal from the Royal Academy of Engineering Sciences in recognition of his ground-breaking research regarding biomarkers. He has over 350 publications within life science and cancer research.

In 2017 he was designated as the Biotech builder of the Year for his entrepreneurship. In addition, Prof. Borrebaeck is previously the Vice-President of Lund University, Sweden (responsible for its Innovation systems); and founder and Director of CREATE Health, a Translational Cancer Center; and previously chairman of the Department of Immunotechnology. Carl Borrebaeck is also a founding mentor for NOME (Nordic Mentor Network for Entrepreneurship).

Ann-Christine Sundell, Director of the Board. Ann-Christine Sundell has a MSc in biochemistry and more than 30 years of experience from the medical device industry where she has held various global positions. For 10 years she served as president for Genetic Screening, one of five strategic business areas with over 1,500 employees worldwide within PerkinElmer, one of the world's largest Life Science companies.

Hans Johansson, Director of the Board. Hans Johansson has a MSc in Chemical Engineering and excessive experience and a wide network from his previous positions in Life Science and Diagnostics companies, lately as VP, Head of Companion Diagnostics at ThermoFisher Inc Speciality Diagnostics Group. Hans Johansson was also a former VP of Global Marketing and Commercial Development within the same company but at the ImmunoDiagnostics division and earlier VP, Head of the Laboratory Business Unit at Pharmacia Biotechnology.

Hans Johansson has also been an active entrepreneur as CEO/Board member in the life science sector. Altogether, he has 30 years of experience from global business development and commercialization of biotechnical and diagnostic innovations.

Christofer Sjögren, Director of the Board. Christofer Sjögren has 15 years of experience in the financial industry as equity analysts at companies like Carnegie, Danske Bank (publ) and Deutsche Bank (publ) based in Stockholm. Christofer Sjögren has also been an Investor Relations consultant at Citigate Stockholm (formerly part of Huntsworth plc) and has been Vice President of Trelleborg AB (publ) for seven years as Head of Trelleborg Investor Relations.

Peter Høngaard Andersen, Director of the Board. Dr. Peter Høngaard Andersen has a B.Sc. in Chemistry, a M.Sc. in Biochemistry, is Doctor of Medicine and have excessive experience and a wide network from his previous positions in Life Science and the biotech industry. His extensive drug discovery and development experience from Pharma include 14 years from Novo Nordisk in CNS, neuroendocrinology, women health, type 2 diabetes and 15 years at Lundbeck in CNS drug discovery and early development. Dr. Høngaard Andersen has been involved in the discovery and development of several drugs on the market (e.g., Norditropine Simplex, Victoza, Trintellix/Brintellix, Cipralext).

Dr. Høngaard Andersen has founded or co-founded several biotech companies e.g., Acadia Pharmaceuticals, Zealand Pharma, Glycom, Serendex, Epitherapeutics and Prexton Pharmaceuticals.

Dr. Høngaard Andersen was involved in Innovative Medicines Initiative (IMI) from the beginning in 2003 and was chairing the industry side of IMI from 2009 – 2014.

Mimmi Ekberg, Director of the Board. Mimmi Ekberg has almost 30 years of experience of from the pharmaceutical industry and 25 years within the oncology disease area. She has held different national and Nordic positions with experience of successful launches of specialist products. Mimmi has extensive strategic and operational experience within sales & marketing for different indications in the Oncology area. She has experience as Business Unit Manager from E. Merck, Amgen and currently serves as the Business Unit Manager Oncology Nordic at Celgene, with a special focus on pancreatic cancer. Mimmi is educated as an operating room nurse with various additional educations as Medical Oncology from Lund University, Clinical trials in Oncology Karolinska University hospital, and Executive Master of Business Administration from Stockholm University.

Martin Møller, Director of the Board. Martin Møller has broad and deep experience in the international healthcare industry from more than 20 years at McKinsey & Company, a global management consultancy, where he was a leader in the Pharmaceuticals & Medical Products Practice until 2021. In that role, he advised companies on strategy, transformation, and business development, as well as product development, launch and commercialization. Martin Møller has worked with many segments of the life science industry and across geographies. His experience includes both working with companies in the rapid growth phase and more established companies with global operations. Martin Møller left McKinsey in the summer of 2021. Martin's university degree is in the humanities. He is a citizen of Denmark and the US.

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