

Immunovia

Exploring new avenues

Immunovia has announced that it needs to optimise the algorithms used in the IMMray PanCan-d test in high-risk patients due to sample collection-related variability, which will delay the first sales of the product for a year from late 2018 to late 2019. Separately, Immunovia has shown the IMMray platform can differentiate between healthy and lung cancer samples with 95% accuracy. On the autoimmune front, IMMray has proven efficacious in detecting patients with rheumatoid arthritis (RA) who tested negative for antibodies against cyclic citrullinated peptides (CCP) with 90% accuracy, allowing a potential increase of up to 30% in detection rate. Both studies will be validated in further trials. Net cash at end H118 was SEK447.2m. Our updated valuation is SEK3.5bn vs SEK3.6bn before.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/16	24.5	(14.7)	(0.98)	0.0	N/A	N/A
12/17	24.2	(45.2)	(2.67)	0.0	N/A	N/A
12/18e	29.9	(74.2)	(4.00)	0.0	N/A	N/A
12/19e	22.6	(88.8)	(4.56)	0.0	N/A	N/A

Note: *Normalised, excluding amortisation of acquired intangibles and exceptionals.

PanCan-d first self-pay sales delayed for a year

In retrospective analysis of 1,000 samples, Immunovia found that different blood-collection procedures introduced variability in the test algorithms. Therefore, additional optimisation work is needed, which the company estimates will cost SEK5m. The interim analysis of the prospective PANFAM-1 clinical trial in high-risk individuals will now be conducted in Q119 (vs Q318 before); however, the company still expects to complete the interventional phase during 2019. We continue to estimate the total market opportunity is SEK2bn in the EU/US, based on 200,000 potential patients.

Emerging opportunities in lung cancer and RA

Immunovia has announced that the IMMray technology was able to detect normal from non-small cell lung cancer (NSCLC) samples with 95% accuracy in a study that involved 100 serum samples (50 healthy and 50 NSCLC). The company and its pharma partner plan to conduct larger, confirmatory studies. Approximately 200,000 new NSCLC cases are diagnosed each year in the US according to [SEER](#). Separately, in a preliminary study IMMray has demonstrated it is able to detect RA patients that tested negative for anti-cyclic citrullinated peptide (anti-CCP) antibodies with 90% accuracy; we think this is important as up to 30% of patients with negative test results for anti-CCP antibodies have RA.

Valuation: DCF SEK3.5bn or SEK177 per share

Our updated valuation is SEK3.5bn or SEK177 per share vs SEK3.6bn or SEK208 per share previously. The main change is the delay in first sales of PanCan-d in high-risk patients, now pushed back to 2020 in our model from late 2018, partially offset by end-H118 net cash of SEK447.2m. Additionally, we update the number of shares after the June 2018 offering that resulted in c 11% dilution. Peak sales are unchanged at SEK2.5bn in the EU and US in 2028.

H118 results and business update

Healthcare equipment & services

6 September 2018

Price **SEK166.60**
Market cap **SEK3248m**

Net cash (SEKm) at 30 June 2018	447.2
Shares in issue	19.5m
Free float	70.94%
Code	IMMUNOV
Primary exchange	NASDAQ Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(1.9)	(3.1)	67.9
Rel (local)	(2.8)	(7.0)	55.1
52-week high/low	SEK265.0	SEK76.5	

Business description

Immunovia is a Swedish company specialising in diagnostics for oncology and autoimmune diseases. Its main product is IMMray PanCan-d, an antibody microarray based on its proprietary IMMray platform. A prospective trial in patients at high risk of pancreatic cancer is ongoing. The company expects to generate initial self-pay sales in late 2019.

Next events

Interim PANFAM-1 data	Q119
First IMMray PanCan-d sales	2019
Final PANFAM-1 data	2019

Analysts

Juan Pedro Serrate	+44 (0)20 3681 2534
Jonas Peciulis	+44 (0)20 3077 5728

healthcare@edisongroup.com

[Edison profile page](#)

**Immunovia is a research client
of Edison Investment
Research Limited**

IMMray opens new avenues for diagnostics

Potential in RA may lead to improved diagnosis rate

According to the European League Against Rheumatism [2010 criteria](#), the rheumatoid factor (RF) and anti-CCP are used to diagnose RA. Sensitivity and specificity for the anti-CCP test range from 53–71% and 95–96% respectively ([Braschi E. et al 2016](#)). In addition to the anti-CCP tests, testing for RF and imaging scans are also used to diagnose RA. Anti-CCP antibodies are thought to be present in 60–70% of patients with RA. They may be present early in the disease process and have not been found consistently in any other autoimmune disease syndrome, hence they are considered particularly specific to RA. It is important to diagnose RA early as early treatment is associated with better outcomes. In particular, anti-TNF alpha products are more effective when taken early in the disease. The annual worldwide incidence of RA is 40 in 100,000 people and prevalence is c 1% of the population ([Sherine E. et al, 2018](#)).

Immunovia's IMMray test accuracy was higher than 90% for all RA patients. Immunovia and its collaborator Linköping University expect to start the design of confirmatory studies in the short term, leading to the development of a commercial assay.

We believe this reinforces the potential of IMMray in autoimmune diseases. In particular, Immunovia announced earlier this year that IMMray was able to differentiate rheumatoid arthritis from a mix of systemic lupus erythematosus, Sjögren syndrome (SS) and systemic vasculitis (SV), with 89% accuracy. It differentiated RA from SS and SV with accuracies of 83% and 95%, respectively.

New opportunity in lung cancer arises

Immunovia's IMMray technology has shown it can differentiate normal samples from NSCLC samples with 95% accuracy. These preliminary data are based on 100 serum samples, 50 healthy and 50 NSCLC in a study conducted with an undisclosed pharma partner. The partners now plan to run larger, confirmatory studies; no specific timelines have been provided. We await additional information on the stage of NSCLC the test can differentiate and additional data on the differentiation with other lung conditions (eg [tuberculosis](#)) in further studies.

Lung cancer affects 214,000 people in the US and 313,000 people in the EU-28 according to [Globocan](#) data from 2012. Around 80–85% of these cases is NSCLC.

Prospective studies advance

Due to the algorithm optimisation process, the observational phase of the PANFAM-1 study has been delayed from Q318 to Q119. This is a three-year prospective clinical trial in 1,000 high-risk patients intended to achieve reimbursement. Immunovia still expects to release final data in 2019. We estimate the total market opportunity is c SEK2bn in the EU/US, based on c 200,000 potential patients.

The prospective PANDIA-1 study in new-onset type 2 diabetes (T2D) patients aged 50 and over as part of a consortium with centres in the Nordic region continues. It is also continuing with the retrospective study using the biobank of Lund University Diabetes Centre with samples from over 17,000 patients. The company expects first data to be available in 2020 and full results in 2021. We believe this continues to be a large opportunity worth SEK34bn a year based on two tests per year for three years at SEK5,000 per test ([see our initiation for more details](#)). There are c 3.4 million patients diagnosed with diabetes every year in the EU and the US.

The prospective PANSYM-1 study continues in the form of a pilot study collecting samples from 360 patients with early gastric symptoms. The company expects to report first data this year and the trial

will be expanded if they are positive. We view this as a potential opportunity of SEK5bn based on the company's estimate of 1m tests per year at SEK5,000 per test.

Financials: H118 results released, forecasts adjusted

As a result of the delay, we now project first sales of PanCan-d in the high-risk population in 2020, vs late 2018 before, hence we have adjusted our FY18 sales forecasts to SEK0.2m from SEK2.7m to reflect the late launch of IMMray PanCan-d. We now forecast increased sales from 2021 onwards as the company obtains approval and reimbursement for IMMray PanCan-d in the high-risk indication and starts marketing in the diabetes and early symptoms indications. We model higher total operating costs of SEK104.6m in FY18 (vs SEK87.6m before) as a result of the additional SEK5m for algorithm optimisation, as guided by the company; and a further SEK13m rise in personnel costs, in line with H118 expenses of SEK21m, mainly associated with R&D and marketing activities. We continue to project the PANFAM-1 study in the at-risk population to consume SEK40m in 2017–19, the PANDIA-1 study in the T2D population to cost SEK90m and run from 2018 to 2020 and the PANSYM-1 study to consume SEK30m from 2018 to 2020.

Exhibit 1: Forecast adjustments

Concept (SEKm)	2018e previous	2018e new	Difference
Sales	2.7	0.2	-93%
Opex (incl. depreciation & amortisation)	87.6	104.6	19%
Operating profit/(loss)	(62.3)	(74.7)	20%
Net profit/(loss)	(61.8)	(74.2)	20%
Cash flow from operations	(62.3)	(61.3)	-2%

Source: Company accounts. Edison Investment Research

After the June 2018 fund-raise, Immunovia's end-H118 cash position was SEK447.2m. We estimate this should be sufficient to fund operations for the next three years, including its ongoing clinical trials and commercial activities, until the company reaches positive operating cash flow in 2021. We expect Immunovia to end 2018 with a cash balance of SEK404.2m.

Valuation: DCF of SEK3.5bn or SEK177/share

Our updated valuation is SEK3.5bn or SEK177 per share vs SEK3.6bn or SEK208 per share previously, based on a risk-adjusted NPV analysis using a 12.5% discount rate. The main change to our valuation is the delay of first sales of IMMray PanCan-d, which we now project to start in 2020. We take a more conservative approach in our model than Immunovia does, as the company still has to conduct a number of pre-marketing activities after the optimisation has been completed, namely receive the ISO 13485 and ISO 17025 certifications, CE mark and production scale-up. This is partially offset by end-June 2018 net cash of SEK447.2m. The decrease in the value per share from SEK208 to SEK177 is associated with the dilution (c 11%) from the share issue in June 2018. We continue to assume a price of SEK5,000 per test, and peak sales of c SEK2.5bn in the EU and US in 2028. As previously, we project a 35% penetration rate in the c 200,000 population of high-risk patients, 5% in the 3.4 million newly diagnosed diabetic patients and 5% in patients with early gastric symptoms.

Additionally, we project an alternative scenario in which the company does not receive reimbursement in the diabetic population, resulting in a 1% market share. In this case, the valuation is c SEK1.7bn and SEK85.6 per share vs SEK1.8bn and SEK103 per share previously. We have included the same assumptions as in the main scenario, ie first sales in high-risk population in 2020, reimbursement in 2022, number of tests and price per test.

Exhibit 2: Financial summary

	SEK '000s	2015	2016	2017	2018e	2019e
Year end 31 December		GAAP	GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS						
Revenue		17,007	24,503	24,249	29,908	22,628
Cost of Sales		0	0	0	0	0
Gross Profit		17,007	24,503	24,249	29,908	22,628
External costs		(17,377)	(24,115)	(39,113)	(58,333)	(53,333)
Personnel		(6,749)	(14,815)	(29,138)	(44,062)	(55,078)
EBITDA		(7,136)	(14,429)	(44,256)	(72,488)	(85,784)
Operating Profit (before amort. and except.)		(7,424)	(14,978)	(45,520)	(74,688)	(89,762)
Intangible Amortisation		0	0	0	0	1
Exceptionals/Other		0	0	0	0	0
Operating Profit		(7,424)	(14,978)	(45,520)	(74,688)	(89,761)
Net Interest		40	255	288	481	1,011
Exceptionals/Other		0	0	0	0	0
Profit Before Tax (norm)		(7,384)	(14,723)	(45,232)	(74,207)	(88,752)
Profit Before Tax (IFRS)		(7,384)	(14,723)	(45,232)	(74,207)	(88,751)
Tax		0	0	0	0	0
Discontinued operations		0	0	0	0	0
Profit After Tax (norm)		(7,384)	(14,723)	(45,232)	(74,207)	(88,752)
Profit After Tax (IFRS)		(7,384)	(14,723)	(45,232)	(74,207)	(88,751)
Average Number of Shares Outstanding (m)		11.42	14.99	16.93	18.53	19.48
EPS - normalised (ore)		(65)	(98)	(267)	(400)	(456)
EPS - normalised (ore)		(65)	(98)	(267)	(400)	(456)
Dividend per share (ore)		0.00	0.00	0.00	0.00	0.00
Gross Margin (%)		N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)		N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets		14,556	22,485	46,761	82,567	99,061
Intangible Assets		13,885	19,483	36,791	63,878	82,377
Tangible Assets		671	3,002	7,211	15,684	16,684
Other		0	0	2,759	3,005	0
Current Assets		76,959	260,925	204,009	413,948	282,829
Stocks		0	0	0	0	0
Debtors		814	1,830	11,584	9,720	9,720
Cash		75,767	259,095	192,425	404,228	273,109
Other		378	0	0	0	0
Current Liabilities		(7,713)	(6,778)	(13,975)	(22,868)	0
Creditors		(1,252)	0	0	0	0
Short term borrowings		0	0	0	0	0
Deferred revenues		0	0	0	0	0
Other short term liabilities		(6,461)	(6,778)	(13,975)	(22,868)	0
Long Term Liabilities		0	0	0	0	0
Long term borrowings		0	0	0	0	0
Deferred revenues		0	0	0	0	0
Other long term liabilities		0	0	0	0	0
Net Assets		83,802	276,632	236,795	473,646	381,890
CASH FLOW						
Operating Cash Flow		(2,844)	(11,868)	(46,525)	(61,250)	(107,641)
Net Interest		0	0	0	0	0
Tax		0	0	0	0	0
Capex		-8,636	(30,809)	(31,187)	(37,760)	(23,478)
Acquisitions/disposals		0	0	0	0	0
Financing		55,441	207,233	4,923	309,733	0
Dividends		0	0	0	0	0
Other		0	18,772	8,880	981	0
Net Cash Flow		43,961	183,328	(63,909)	211,705	(131,119)
Opening net debt/(cash)		(31,804)	(75,767)	(259,095)	(192,425)	(404,228)
HP finance leases initiated		0	0	0	0	0
Exchange rate movements		0	0	0	(98)	0
Other		1	0	(2,761)	0	0
Closing net debt/(cash)		(75,767)	(259,095)	(192,425)	(404,228)	(273,109)

Source: Company accounts, Edison Investment Research

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world-renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors, advisers and stakeholders. Edison Advisors leverages our core research platform to provide differentiated services including investor relations and strategic consulting. Edison is authorised and regulated by the [Financial Conduct Authority](#). Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Pty Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. www.edisongroup.com

DISCLAIMER

Copyright 2018 Edison Investment Research Limited. All rights reserved. This report has been commissioned by Immunovia and prepared and issued by Edison for publication globally. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in the Investment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Investment Research Pty Ltd (Corporate Authorised Representative (1252501) of Myonlineadvisers Pty Ltd (AFSL: 427484)) and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is registered as an investment adviser with the Securities and Exchange Commission. Edison US relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. As such, Edison does not offer or provide personalised advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions. The information that we provide or that is derived from our website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. Also, our website and the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. This document is provided for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research. Edison has a restrictive policy relating to personal dealing. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report. Edison or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (ie without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision. To the maximum extent permitted by law, Edison, its affiliates and contractors, and their respective directors, officers and employees will not be liable for any loss or damage arising as a result of reliance being placed on any of the information contained in this report and do not guarantee the returns on investments in the products discussed in this publication. FTSE International Limited ("FTSE") © FTSE 2018. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.