EDISON

Immunovia

Outlook

IMMray PanCan-d approaches the market

Healthcare equipment & services

Immunovia is preparing to market its IMMray PanCan-d for self-pay patients at high risk of pancreatic cancer (PC) in Q418, after preparatory activities were pushed back slightly from mid-2017 to 2018. To achieve reimbursement, a prospective trial in this population is being run and if positive, the test could be reimbursed in 2020. Immunovia is pursuing other groups ie patients with new-onset T2 diabetes aged 50+ and those with early gastric symptoms. Our revised valuation is SEK3.6bn as we now include early gastric symptoms. Autoimmune diseases represent upside.

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	27.2	(61.8)	(3.65)	0.0	N/A	N/A
12/19e	38.1	(73.4)	(4.34)	0.0	N/A	N/A

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

First self-pay sales in sight in high-risk patients

Immunovia plans to market its lead indication the IMMray PanCan-d test in late 2018 in the private self-pay market following a slight delay to its pre-marketing activities from mid-2017 to this year. The company is also running the PANFAM-1 study, a three-year prospective clinical trial in 1,000 high-risk patients to achieve reimbursement. At SEK5,000/test and two tests per year, we estimate the total market opportunity is c SEK2bn in the EU/US, based on c 200k potential patients.

PC in diabetes is a much larger opportunity

In December 2017, Immunovia started the prospective PANDIA-1 study in new-onset type 2 diabetes (T2D) patients aged 50+ as part of a consortium. It is also continuing with the retrospective study using the biobank of Lund University Diabetes Centre (LUDC) which comprises samples from over 17,000 patients. Applied to the c 3.4m patients diagnosed with diabetes every year in the EU and the US, the opportunity is worth SEK34bn/year based two tests per year for three years at SEK5,000/test.

Trial in patients with early gastric symptoms starts

The prospective PANSYM-1 study started with a pilot study collecting samples from 360 patients with early gastric symptoms. The results of this study are expected this year and the trial will be expanded if they are positive. The company's own primary research estimates a potential market of 1m tests in the US/EU, which is a SEK5bn opportunity at SEK5,000/test. Separately, the company's platform has shown it can differentiate Lupus from other autoimmune diseases with 96% accuracy, representing future upside.

Valuation: updated to SEK3.6bn or SEK208/share

Our updated valuation is SEK208/share vs SEK155.2/share previously. The main change is the addition of the early symptoms population with 5% penetration and SEK250m peak sales. We add end-2017 net cash of SEK192.4m and roll the model forward in time. Due to increased costs and pushed out revenues we now have a funding gap of SEK150m in 2019. Peak sales are SEK2.7bn in the EU/US.

22 March 2018

Price	**SEK99.5**
Market cap	**SEK1,721m**
	USD$0.12/SEK
Net cash (SEKm) at 31 December 2017	192.4
Shares in issue	17.3m
Free float	66.52%
Code	IMMUNOV
Primary exchange	NASDAQ FN Stockholm
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	6.8	(8.1)	(12.0)
Rel (local)	4.7	(5.9)	(18.1)
52-week high/low	SEK116.25		SEK76.5

Business description

Immunovia is a Swedish company specialised 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 2018.

Next events

Decision on uplisting to Nasdaq Stockholm's main market	Q118
Interim PANSYM-1 data	2018
First IMMray PanCan-d sales	Q418
Final PANFAM-1 data	2019

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Edison profile page

Investment summary

Company description: A versatile diagnostics platform

Immunovia AB is a technology platform and product development company headquartered in Lund's Medicon Village in Sweden. The company was founded in 2007 based on research from Lund University and the Centre for Translational Cancer Research (CREATE Health) in Lund. Its proprietary technology platform IMMray utilises antibody microarrays to detect biomarkers of early disease to allow rapid treatment. The system is complemented with proprietary antibody libraries, antibody production and purification as well as software and clinical algorithms. The IMMray system has the potential to allow for monitoring of cancer treatment, predicting disease progression and assessing response to therapy. The company's main product is IMMray PanCan-d, a blood-based test for early detection of pancreatic cancer. Immunovia floated on First North market in 2015. During 2017 the company submitted an application to list on Nasdaq Stockholm's main market with a decision expected in Q118.

Valuation: rNPV of SEK3.6bn or SEK208/share

Our updated valuation is SEK3.6bn or SEK208/share vs SEK2.6bn or SEK155.2/share previously, based on a risk-adjusted NPV analysis using a 12.5% discount rate. The main change to our valuation is the addition of the early gastric symptoms group. We assume a price of SEK5,000 per test, in line with the pricing of other indications and peak sales of c SEK2.7bn in the EU and US. 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.

Financials: FY17 results released

Immunovia reported FY17 financial results on 15 February 2018. While R&D remains the main cost driver, Immunovia has also ramped up its marketing activities. Total operating expenses (including depreciation and amortisation) increased to SEK69.7m in FY17 from SEK39.4m in FY16, above our estimate of SEK46m. This increase was mainly driven by marketing activities and a new laboratory in the US. The number of full time employees increased to 34 at the end of 2017 vs 21 at end 2016. From 2017 to 2020 we expect Immunovia to fund the prospective PANFAM-1 clinical trial in individuals at high risk of pancreatic cancer at an estimated cost of SEK40m over three years; the PANDIA-1 study in newly diagnosed T2D patients over 50 years of age at an estimated cost of SEK90m for three years; and the PANSYM-1 study in patients with early vague gastric symptoms which we estimate will cost c SEK30m over three years. Due to the increased clinical trial activity and marketing expenses associated with the launch of IMMray PanCan-d, we are raising our total expense forecasts to SEK87.6m in 2018 and SEK101.5m in 2019 vs the previous SEK68.3m and SEK75.3m, respectively). Immunovia's end of 2017 cash position was SEK192.4m. We project a cash shortfall in FY19e that we cover with SEK150m debt for illustrative purposes.

Sensitivities: Commercial execution is key

The key sensitivity is commercialisation. Immunovia plans to start the first self-pay sales in the high-risk population later this year. It needs to complete a number of activities to achieve this, including obtaining the CE mark in Europe, Clinical Laboratory Improvement Amendments (CLIA) accreditation in the US, ISO certifications and manufacturing scale up. Any delay in meeting these milestones would push back first revenues. Successful commercialisation will require reimbursement and managing price sensitive healthcare authorities in each country. For example, although FDA approval is not needed for reimbursement in the US, the strategy of marketing the product as a laboratory developed test (LDT) validated by a CLIA-accredited laboratory may limit its ability to distribute its test beyond the CLIA-certified lab and may mean a slow ramp-up in revenues

and a lower probability of reimbursement. FDA approval, which requires additional resources, would increase the chances of getting reimbursement. As an example, Exact Sciences's Cologuard was only reimbursed after FDA approval. True acceptance will likely only come after full reimbursement and inclusion in various cancer screening guidelines.

IMMray technology for the early diagnosis of cancer

Immunovia's proprietary IMMray technology platform is based on the analysis of antibody microarrays. Through its in-house antibody production and purification facility the company generates a slide of 14 antibody arrays. Using the company's bioinformatics platform the tests are processed and provide a snapshot of the patient's disease status. This information can be used to assess the patient's responsiveness to therapy, diagnostics, disease follow up and monitoring.

The company's first product is IMMray PanCan-d, a blood-based test for the early detection of pancreatic cancer. Pancreatic cancer is classified according to progression, with stages I and II being localised and amenable to surgical resection, while stages III and IV have spread to lymph nodes and other internal organs.

Exhibit 1: Pancreatic cancer is split into stages

Stages	Comments
Stage 0	Also called carcinoma in situ. Abnormal cells are found in the pancreas and may become cancer.
Stage I	Cancer has formed and is only in the pancreas. Stage IA: tumour is 2cm or smaller. Stage IB: tumour is larger than 2cm.
Stage II	Cancer may have spread to nearby tissue and organs, and may have spread to lymph nodes near the pancreas. Stage IIA: it has spread to nearby tissue and organs but has not spread to lymph nodes. Stage IIB: it has spread to nearby lymph nodes and may have spread to nearby tissue and organs.
Stage III	The tumour has spread to the major blood vessels near the pancreas and may have spread to nearby lymph nodes.
Stage IV	Cancer has spread to distant organs such as the liver, lung and the peritoneal cavity.

Source: Edison Investment Research

Typically, symptoms do not appear until the disease has spread and it is too late for full resection. As a result, less than 5% of patients are alive five years after diagnosis. Early detection at stage I or II, when the tumour can be removed with surgery, could improve five-year survival rates to c 50%. Pancreatic cancer is one of the most lethal cancers with 53,000 new cases in the US in 2016 and an estimated 41,780 deaths, according to SEER. In the EU-27, there were 78,654 new cases and 77,958 deaths in 2012 according to EUCAN.

In addition to patients at high risk of pancreatic cancer, the company is targeting new-onset diabetic patients over 50 years of age. This population group has up to eight times higher risk of developing pancreatic cancer. Between 1% and 2% of patients with T2D develop pancreatic cancer. The test could be a first filter to diagnose early-stage PC that would be confirmed later.

Immunovia is also targeting patients with early gastric symptoms. Primary research conducted by the company's academic collaborator, the University College of London (UCL) suggests that patients with early gastric symptoms undergo up to 18 visits to the doctor and a six- to nine-month delay until pancreatic cancer is diagnosed.

The company also has ongoing projects in other indications such as systemic lupus erythematosus (SLE), prostate and breast cancer. To support clinical development and commercialisation, Immunovia works with key opinion leaders and top cancer research centres and consortia.

First sales on sight this year in the high-risk setting

Immunovia expects first sales of IMMray PanCan-d in the hereditary and familial risk patient group in late 2018. The company's initial plan is to target the private sector, mainly individuals through

patient organisations and pancreatologists at healthcare institutions that will pay for the tests from their own budget. In order to achieve this goal, Immunovia is working on several fronts:

- Obtain ISO 13485 and ISO 17025 certifications
- Obtain the CE mark following the 98/97/EC directive of In Vitro Diagnostic Medical Devices in Europe
- Receive the CLIA/CPA accreditation in the US
- Scale up manufacturing and ensure the reproducibility of laboratory processes

These preparatory activities were initially expected to be completed in mid-2017, but will now be conducted during 2018 and are critical to start commercialisation later in the year.

PANFAM-1 prospective trial to pave the way for reimbursement

Although sales are possible without reimbursement, we believe that securing reimbursement is central to the investment case, to maximise the potential of the test and achieve our peak sales forecast. Therefore, Immunovia is running a prospective clinical trial (PANFAM-1) in high-risk individuals (those with a family history of pancreatic cancer, hereditary pancreatitis, chronic pancreatitis or rare genetic diseases such as Peutz-Jeghers syndrome or Lynch Syndrome) that started in December 2016. The study will run for three years and recruit 1,000 patients. This trial intends to show the clinical utility of the test by discriminating between people who have pancreatic cancer and those who do not, even at early stages. There will be a readout after an undisclosed number of events with final results expected in 2019, although these timelines depend on the enrolment of patients and centres that join the study. The study is being conducted in top research centres in the US and Europe.

Immunovia aims to have PanCan-d included in surveillance programmes in familial pancreatic cancer and we estimate that US and EU sales could represent a total SEK2bn opportunity. The company will market the test to pancreatologists with its own salesforce.

An extensive dataset of retrospective studies

Immunovia has conducted a number of retrospective trials where the main end point was the area under the receiver operating characteristic (ROC) curve (AUROCC or AUC, see Exhibit 3). This is an accuracy measure that relates to the ability of the test to discriminate among alternative states of health; in this case among pancreatic cancer and healthy individuals, other conditions of the pancreas or PC stages. On the back of these data the company has developed a signature of 35 biomarkers that discriminates pancreatic cancer from healthy samples and other pancreatic diseases.

The company's largest study to date has been the Scandinavian study (n=1,355); IMMray PanCan-d was able to differentiate between stage I and II pancreatic cancer and healthy subjects at a rate of 96%, with 98% for stages I to IV and healthy subjects. The rate was 96% in the US validation study (see Exhibit 2). Rates are lower when discriminating between pancreatic cancer and other pancreatic diseases: 85% in one study, 70% in another (Exhibit 2).

Exhibit 2: Retrospective studies

Study	Number of samples	Data
Ingvarsson J et al. Proteomics 2008 8(11):2211-9	44	AUC=1 PC vs healthy individuals
Wingren et al. Cancer Res. 2012 15;72(10):2481-90	103	AUC=0.95 PC vs healthy individuals
		AUC=0.86 PC vs pancreatitis
		AUC=0.99 PC vs autoimmune pancreatitis
		AUC=0.85 PC vs combined healthy, pancreatitis and immune pancreatitis
Sandström et al. Proteomics Clin. Appl. 2012, 6, 486–496.	113	AUC=1 acute pancreatitis vs healthy controls
		AUC=0.96 chronic pancreatitis vs healthy controls
		AUC=0.98 autoimmune pancreatitis vs healthy controls
Gerdtsson et al. Int Journal of Proteomics 2015;2015:587250	338	PC vs healthy controls: average AUC 0.98, sensitivity 99%, specificity 80%. Average PPV of 96% and NPV of 95%
		PC vs other pancreatic disease: average AUC 0.7, 62% sensitivity, 80% specificity, 73% PPV, 71% NPV
Gerdtsson et al. Chinese study.	213	AUC value of 0.80 for early stage disease (stage I/II) and 0.96 for late stage disease (stage three/four) vs normal controls, respectively
South Scandinavian study	1,355	AUC value of 0.96 for stage I and II PC vs normal controls
		AUC value of 0.98 for all PC vs normal controls
North American validation study	429	AUC=0.96 for PC stage I and II vs normal controls

Source: Edison Investment Research, Immunovia. Note: PC = pancreatic cancer. AUC = area under the ROC Curve. PPV = positive predictive value. NPV = negative predictive value.

Sensitivity, specificity and the clinical value of a diagnostic test

It is important to reduce false positives as much as possible for a critical condition like pancreatic cancer. A good diagnostic test for pancreatic cancer needs to show that a positive result is actually a positive. Therefore, a high specificity and high positive predictive value (PPV) will ultimately determine the value of the test for this condition and influence reimbursement decisions. Ideally, the test needs to demonstrate a high specificity (true negatives) with high PPV (true positives according to the prevalence of the disease in a given population). In other words, the test needs to properly detect those patients with the disease and keep the false negatives to a minimum to reduce the need for expensive secondary testing with ultrasound, magnetic resonance imaging (MRI) or computerised tomography (CT) scan.

Exhibit 3: Measures of diagnostic accuracy

Concept	Definition
Sensitivity	The ability of a test to correctly classify an individual with the disease
Specificity	The ability of a test to correctly classify an individual without the disease
Positive predictive value (PPV)	The probability that the disease is present when the test is positive eg a PPV of 15% means that among those who had a positive screening test, the probability of disease is 15%
Negative predictive value (NPV)	The probability that the disease is not present when the test is negative eg a NPV of 15% means that among those who had a negative screening test, the probability of being disease-free is 15%
Area under the ROC curve (AUC)	Estimate the discriminative power of a test. The closer to 1, the better the accuracy

Source: Edison Investment Research

Since the incidence of pancreatic cancer is low (c 13 cases per 100,000 people), screening in the general population is not feasible. A test with 99% specificity and 99% sensitivity in a population with low incidence of a disease (like the 0.013% of pancreatic cancer) used to screen 100,000 individuals would detect nearly all patients with the disease, but would classify 1,000 healthy individuals as having the disease. This would result in a PPV of just 1.3%, which is too low to justify screening the general population. That is why it is important to focus on particular subgroups with increased incidence of pancreatic cancer. In the high-risk population, it is estimated that the incidence is around 2.2%, which is a PPV of c 60%, assuming the test has 99% sensitivity and specificity rates.

Exhibit 4: Competitors and current tests for PC

Company	Product	Status	Description	Data	Cost per test ($)
Interpace	PancraGen TM	Market	Assesses the risk of cancer in precursor lesions. No direct competitor. Retrospective data. Reimbursed, but small sales due to invasiveness and inconclusive data	Sensitivity: 47%-83% Specificity: 81%-100% PPV: 55%-100% NPV: 50%-97%	Not disclosed
Myriad	Panexia	Market	Identifies patients with higher risk of developing cancer. Not competitive, but complementary to Immunovia	Sensitivity: 99% Specificity: 99%	3,025
Natimab	EZR/ENOA Abs	Clinical development	Blood-based two marker test for prognosis and detection of pancreas cancer	Sensitivity: 100% Specificity: 92.3% AUC: 0.96	NA
VolitionRx	NuQ	Clinical development	Blood test based on the NuQ nucleosome technology	Sensitivity: 84% Specificity: 92%	40-80
Trovagene	Trovera KRAS ctDNA	Pre-clinical	Liquid biopsy. Measures ctDNA KRAS mutations	Sensitivity: 30%-50% Specificity: 90%	NA
Current tests					
Various	EUS	Market	Endoscopy ultrasound	Sensitivity: 89% Specificity: 96%	500
Various	CA-19-9	Market	Blood marker for follow up	Sensitivity: 79% Specificity: 82%	20-40

Source: Edison Investment Research, Immunovia

PANDIA-1 trial: diabetes is the next big market

In December 2017 Immunovia joined a consortium formed of the Lund and Uppsala Universities, Lund University Diabetes Centre, Region Skåne, Region Uppsala and more recently, the Danish Centre for Strategic Research into Type 2 Diabetes. The consortium will give Immunovia access to 9,500 new T2D patients over 50 years of age and run the prospective PANDIA-1 trial. The consortium has received a grant of SEK7.6m from SWElife, the Swedish government's strategic innovation programme. According to Immunovia first data will be available in 2020 and full results in 2021.

In parallel Immunovia is conducting a retrospective study to compare samples from diabetes patients that developed pancreatic cancer with those who did not using the biobank of Lund University Diabetes Centre (LUDC). The LUDC has samples from all newly diagnosed patients in the Skåne region of Sweden, which is approximately over 17,000 patients.

Furthermore, Immunovia has signed a memorandum of understanding (MoU) with the US National Cancer Institute to validate biomarkers to improve early diagnosis of pancreatic cancer in patients over 50 years old with new onset diabetes. These patients have eight times more risk to develop pancreatic cancer.

While there is a link between pancreatic cancer and diabetes, it is unclear whether diabetes is a symptom or a cause of pancreatic cancer. Around 50% of patients with pancreatic cancer have T2D and they are often diagnosed shortly after of before their pancreatic cancer diagnosis. On the other hand, diabetes involves changes in cell metabolism, inflammation and other changes that may have cancer-promoting effects, which could increase the risk of cancer in certain cases. The prevalence of pancreatic cancer in T2D patients is around 1% to 2.2%, according to different studies. The Rochester study conducted in 2,127 diabetic subjects shows 1% of those over 50 years old being diagnosed with pancreatic cancer three years after diagnosis. A meta-analysis of 88 studies demonstrates a strong association between pancreatic cancer and recently diagnosed diabetes and highlights the risk of pancreatic cancer even long after the diagnosis of diabetes, suggesting that selective screening of patients recently diagnosed with diabetes for pancreatic cancer should be considered. Furthermore, since 2015 the UK's NICE recommends a CT scan or ultrasound to assess for pancreatic cancer in people aged 60 and over with weight loss and new-onset diabetes.

IMMray PanCan-d could be a first filter to diagnose early-stage pancreatic cancer that would be later confirmed.

With c 3.4 millon new patients per year and two tests per patient per year for three years, at a price of SEK5,000/test, this represents an annual opportunity of SEK34bn.

Evaluate IMMray's potential in early gastric symptoms

Immunovia's collaborator Professor Stephen Pereira and his team at the Institute for Liver and Digestive Health of the University College London (UCL) have started collecting samples from patients with early vague gastric symptoms. Up to 360 blood samples from this patient population will be used in a study that aims to assess the utility of IMMray PanCan-d in this population. This study will present interim data in 2018 and now forms the initial part of the prospective PANSYM-1 study.

An American study published in 2015 found that c 31% of pancreatic cancer patients are initially misdiagnosed. The most common misdiagnosis was gallbladder disease, followed by gastroesophageal reflux disease and peptic ulcer disease. Importantly, there was an average three-month time difference from the first visit to a physician to the actual cancer diagnosis in patients who were initially misdiagnosed with respect to those that were correctly diagnosed. Patients who were initially misdiagnosed had a 1.4-fold greater risk of having stage III or IV disease at the time of the pancreatic cancer diagnosis. There was a trend toward shorter survival among those who were initially misdiagnosed (median overall survival of 9.6 vs 10.3 months).

The UCL's primary research suggests that patients that present to their doctor with early symptoms such as abdominal pain (in 39% of cases), jaundice (36%), change in bowel habit (30%), or dyspepsia (21%) undergo up to 18 visits and six- to nine-months until pancreatic cancer is diagnosed. Hence, identifying patients with pancreatic cancer and initial vague symptoms could lead to improved diagnosis and earlier treatment.

The fact that there are not noticeable symptoms or that they are vague (weight loss, abdominal pain, jaundice) make pancreatic cancer difficult to detect at early stages and therefore difficult to treat and deadly.

We now include this indication in our valuation and estimate a potential opportunity of SEK5bn based on the company's estimate of 1m tests per year at SEK5,000/test. We forecast that the company achieves 5% of this market in 2028.

IMMray in autoimmune diseases provides upside

Immunovia has generated data from its IMMray biomarker microarray in autoimmune diseases. In particular, data from a retrospective trial in 315 blood samples designed to assess IMMray SLE biomarker signature showed that IMMray can differentiate samples with SLE from other diseases such as rheumatoid arthritis (RA), vasculitis and Sjögren's syndrome (SS) with 96% accuracy. The data are relevant as up to half of SLE cases are usually misdiagnosed, according to Immunovia.

Further data show the potential of the IMMray signatures in the differential diagnosis of autoimmune diseases. IMMray differentiated rheumatoid arthritis from a mix of systemic lupus erythematosus (SLE), Sjögren syndrome and systemic vasculitis (SV), with 89% accuracy. It differentiated RA from SS, and SV, with accuracies of 83% and 95%, respectively.

The company is collaborating with Linköping University to discover biomarkers to explore IMMray's potential in autoimmune diseases. Immunovia plans to do additional tests in SLE and RA.

Sensitivities

As previously discussed, the key sensitivity is market penetration. To secure payers' acceptance the test needs to demonstrate high specificity with high PPV. This would avoid expensive secondary testing. Initial self-pay sales may gain some traction in the US where this market is more developed, but more widespread acceptance will come after positive data from the prospective study, regulatory approval and full reimbursement is granted. The company plans to obtain the CE mark in Europe and market its product as an LDT under the CLIA waiver programme in the US among other activities needed to start commercialisation. The timeline for this is 2018 (vs the previous target of mid-2017); if these activities are completed as planned, launch could be possible in late 2018. We believe that true acceptance will come after a full reimbursement and inclusion in various cancer screening guidelines. This may involve the need for FDA approval which may require additional trials to be conducted that are not currently included in our forecasts.

Expansion to other population groups such as autoimmune diseases and other cancer indications could provide upside.

Valuation: DCF of SEK3.6bn or SEK208/share

Our updated valuation is SEK3.6bn or SEK208/share (SEK202.5/share fully diluted) vs SEK2.6bn or SEK155.2/share previously (SEK150.5/share fully diluted), based on a risk-adjusted NPV analysis with a 12.5% discount rate. The main change to our valuation is the addition of the early gastric symptoms group. We assume a price of SEK5,000 per test and total peak sales of c SEK2.7bn in the EU and the US in 2028 after the PANFAM-1, PANDIA-1 and PANSYM-1 trials have readout and the company obtains reimbursement. We maintain a 35% penetration rate in the c 200,000 population of patients at increased risk of pancreatic cancer, 5% in the 3.4 million newly diagnosed diabetic patients and 5% in patients with early gastric symptoms. This represents a combined opportunity of SEK41bn per year at 8.2m tests. We also roll the model forward, include net cash of SEK192.4m (down from SEK215.3m previously) and our increased expenses forecast for the period 2018-21.

We maintain two valuation scenarios:

- **Scenario 1 (SEK208/share):** This is our base case valuation in which we assume the test is reimbursed for the diabetes group and achieves a market share of 5%. With a potential population of 3.4 million new patients per year at two tests per year the group equates to 6.8m tests and represents a total market opportunity of SEK34bn at SEK5,000/test. Peak sales in 2028 are c SEK1.7bn. We also include the early symptoms population with a potential 1m tests at SEK5,000/test and small 5% market share in Europe and the US reflecting a new and untested market. Peak sales are SEK250m in 2028 on 50,000 tests. Finally, the high-risk pancreatic cancer group represents 200,000 potential patients and we project peak sales in 2025 of SEK707m at SEK5,000 per test and 35% market share in Europe and the US, used twice a year.
- **Scenario 2 (SEK104/share):** if the test is not reimbursed for diabetic patients, we project a 1% market share. Peak sales in this case would be SEK340m in 2028. The assumptions for the early symptoms and high-risk pancreatic cancer groups remain unchanged.

Exhibit 5: Valuation summary

	Scenario 1		Scenario 2	
	US$m	SEKm	US$m	SEKm
Peak sales in T2D patients (US and EU in 2028)	208	1,700	42	340
Peak sales in at-risk patients (US and EU in 2025)	87	707	87	707
Peak sales in early symptoms group (US and EU in 2028)	31	250	31	250
PV of explicit FCF forecast (2018-2028)	160	1,308	69	561
Terminal value (2.5% TGR)	837	6,830	417	3,396
PV of terminal value	258	2,103	129	1,046
Total NPV	**418**	**3,411**	**198**	**1,607**
Add net cash (FY17	24	192	24	192
Implied equity value	**441**	**3,604**	**221**	**1,800**
Number of shares (m)	17.3	17.3	17.3	17.3
Per basic share	**$25/share**	**SEK208/share**	**$13/share**	**SEK104/share**

Source: Edison Investment Research. Note: Exchange rate US$0.12/SEK. Numbers are rounded.

Financials

We now project first sales in late 2018, hence we have adjusted our forecast to SEK2.7m from SEK9.4m to reflect the late launch of IMMray PanCan-d. Additionally, we forecast similar levels of revenues in the form of capitalised R&D work in FY18 (c SEK24.5m) that will decrease from 2019 onwards as clinical trials begin to complete. We forecast increased sales from 2020 onwards as the company obtains approval and reimbursement for IMMray PanCan-d in the high-risk indication and from 2021 in the other two indications. We model increasing total operating costs of SEK87.6m in FY18e (vs SEK68.3m before) as a result of a further SEK10m rise in R&D for the new PANSYM-1 study and marketing activities. We 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 6: Forecast adjustment

Concept (SEKm)	2017e	2017 actual	2018e previous	2018e new
Total revenues	27.8	24.2	43.6	27.2
Opex (incl. depreciation & amortisation)	46	69.7	68.3	87.5
Operating profit/(loss)	(18.2)	(45.5)	(31.3)	(62.3)
Net profit/(loss)	(17.5)	(45.2)	(30.8)	(61.8)
Cash flow from operations	(19.7)	(46.5)	(33.7)	(62.3)

Source: Company accounts. Edison Investment Research

Immunovia's end of 2017 cash position was SEK192.4m, which we estimate should be sufficient to fund operations for the next 18 months. We expect Immunovia to end 2018 with a cash balance of SEK100m. Due to increased clinical activity and commercial activities we project a cash shortfall in 2019 that we cover with SEK150m debt for illustrative purposes. We expect Immunovia to achieve positive operating cash flow in 2021.

Exhibit 7: 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	27,222	38,123
Cost of Sales	0	0	0	(1,889)	(10,142)
Gross Profit	17,007	24,503	24,249	25,333	27,981
Operating expenses	(17,377)	(24,115)	(39,113)	(53,333)	(53,333)
Personnel	(6,749)	(14,815)	(29,138)	(32,052)	(45,000)
EBITDA	(7,136)	(14,429)	(44,256)	(60,052)	(70,354)
Operating Profit (before amort. and except.)	(7,424)	(14,978)	(45,520)	(62,252)	(73,670)
Intangible Amortisation	0	0	0	0	1
Exceptionals/Other	0	0	0	0	0
Operating Profit	(7,424)	(14,978)	(45,520)	(62,252)	(73,669)
Net Interest	40	255	288	481	264
Exceptionals/Other	0	0	0	0	0
Profit Before Tax (norm)	(7,384)	(14,723)	(45,232)	(61,771)	(73,406)
Profit Before Tax (IFRS)	(7,384)	(14,723)	(45,232)	(61,771)	(73,405)
Tax	0	0	0	0	0
Discontinued operations	0	0	0	0	0
Profit After Tax (norm)	(7,384)	(14,723)	(45,232)	(61,771)	(73,406)
Profit After Tax (IFRS)	(7,384)	(14,723)	(45,232)	(61,771)	(73,405)
Average Number of Shares Outstanding (m)	11.42	14.99	16.93	16.93	16.93
EPS - normalised (ore)	(65)	(98)	(267)	(365)	(434)
EPS - normalised (ore)	(65)	(98)	(267)	(365)	(434)
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	66,326	83,339
Intangible Assets	13,885	19,483	36,791	59,115	76,128
Tangible Assets	671	3,002	7,211	7,211	7,211
Other	0	0	2,759	0	0
Current Assets	76,959	260,925	204,009	106,506	167,549
Stocks	0	0	0	378	1,521
Debtors	814	1,830	11,584	540	3,559
Cash	75,767	259,095	192,425	105,589	162,469
Other	378	0	0	0	0
Current Liabilities	(7,713)	(6,778)	(13,975)	(567)	(2,028)
Creditors	(1,252)	0	0	(567)	(2,028)
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)	0	0
Long Term Liabilities	0	0	0	0	(150,000)
Long term borrowings	0	0	0	0	(150,000)
Deferred revenues	0	0	0	0	0
Other long term liabilities	0	0	0	0	0
Net Assets	83,802	276,632	236,795	172,265	98,860
CASH FLOW					
Operating Cash Flow	-2,844	(11,868)	(46,525)	(62,313)	(72,789)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	-8,636	(30,809)	(31,187)	(24,524)	(20,330)
Acquisitions/disposals	0	0	0	0	0
Financing	55,441	207,233	4,923	0	0
Dividends	0	0	0	0	0
Other	0	18,772	8,880	0	0
Net Cash Flow	43,961	183,328	(63,909)	(86,836)	(93,119)
Opening net debt/(cash)	(31,804)	(75,767)	(259,095)	(192,425)	(105,589)
HP finance leases initiated	0	0	0	0	0
Exchange rate movements	0	0	0	0	0
Other	1	0	(2,761)	0	0
Closing net debt/(cash)	(75,767)	(259,095)	(192,425)	(105,589)	(12,469)

Source: Company accounts, Edison Investment research

Contact details	Revenue by geography
Immunovia Medicon Village SE-223 81 Lund Sweden +46 46 275 60 00 www.immunovia.com	N/A

Management team

CEO: Mats Grahn	CSO: Rolf Ehrnström
Mr Grahn has been the CEO of Immunovia since 2012. Mr Grahn holds an MSc in engineering physics from Lund University, Sweden. Mr Grahn has more than two decades of experience in the healthcare industry, where he has held different positions, including: VP of product management and VP of marketing at GE Healthcare; CVP marketing at Dako A/S; VP marketing Amersham Biosciences; VP laboratory separations at Pharmacia Biotech; and VP at Prevas Bioinformatics.	Mr Ehrnström holds an MSc in biochemistry & biotechnology engineering from the Royal Institute of Technology, Stockholm, Sweden. He has held leadership positions at medtech and diagnostic companies, including: CSO at Dako-Agilent, CVP of R&D at Dako A/S, VP of R&D at Gyros AB, science director Amersham Biosciences, senior scientific advisor Amersham Pharmacia Biotech, senior programme manager MicroArrays Amersham-Pharmacia Biotech and director R&D molecular biology Pharmacia Biotech.
CTO: Christer Wingren	**CFO: Hans Liljenborg**
Dr Wingren is a lecturer at Lund University's CREATE centre. Dr Wingren holds a BSc in chemistry and a PhD in biochemistry from Lund University. He conducted his postdoctoral training in structural biology at the laboratory of Professor Ian Wilson at the Scripps Research Institute, La Jolla, US. His research focus is the development of recombinant antibody microarrays for high-throughput disease proteomics, with a particular focus on oncoproteomics and autoimmunity. Dr Wingren joined Immunovia in 2007.	Mr Liljenborg has a BSc in business and mathematics from Lund University. He has held different roles in finance management at biomedical companies. He was finance director at Physio Control and Jolife AB. Mr Liljenborg was finance manager at Vivoline Medical AB. He has also been CFO at QuickCool AB and finance manager at Pharma Visions Systems AB.

Principal shareholders	(%)
Carl Borrebaeck	9.87
Vincent Saldell	5.77
Sara Andersson Ek	5.13
Per Mats Ohlin	5.13
Christer Wingren	5.13
Handelsbanken Svenska Småbolag	4.02

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