EDISON

Immunicum

Very busy second half

Q2 results and clinical trial progress

Pharma & biotech

Immunicum's second-quarter financial results have been superseded by significant product development and financing news. The agreement of the Phase Ib/II US protocol for ilixadencel with the FDA was an important milestone, but the negotiations on an agreement with a leading global pharmaceutical company for checkpoint inhibitor (CPI) access would be a significant endorsement. The recently proposed c SEK351m combined stock issues will be used to accelerate the manufacturing and potentially the development of ilixadencel, resulting in a cash runway until the end of 2021.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/17	0.0	(80.3)	(3.1)	0.0	N/A	N/A
12/18e	0.0	(83.8)	(1.7)	0.0	N/A	N/A
12/19e	0.0	(273.4)	(3.0)	0.0	N/A	N/A
12/20e	0.0	(70.6)	(0.8)	0.0	N/A	N/A

Note: *PBT and EPS are as reported.

Fund-raising trumps other recent news

Net cash at end June was SEK149.1m (SEK129m at end 2017), but the recently proposed rights issues are expected to generate c SEK351m gross, which Immunicum has suggested will give it cash runway until the end of 2021. We had assumed that ilixadencel would be partnered in 2019 based on the clinical results to be announced in H119, but the fund-raising now gives Immunicum the option to retain more value for shareholders by licensing a Phase III-ready asset at the end of 2020, rather than a Phase II-ready asset at the end of 2019.

Spotlight on the CPI collaboration and clinical supply

The agreement of a clinical trial protocol with the FDA is an important milestone in any company's history, but more so for companies in the oncology space that are exploring the use of combinations of agents. However, a potential CPI clinical collaboration and supply agreement for the Phase II part of the ILIAD study will have a number of significant benefits, which include the endorsement of ilixadencel as an active oncology agent, as well as potentially faster trial recruitment. The performance of ilixadencel in three disease indications should also help Immunicum and its partners prioritise indications in subsequent studies.

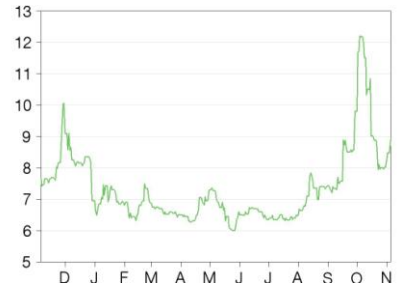
Valuation: Multiple changes

We have made some initial adjustments to our model to reflect Q2 results and the impact on cash, investment and share count of the proposed directed and rights issues. In addition, as the publication of the Phase Ib/II study in hepatocellular carcinoma (HCC) is under review, so we have increased the probability of success from 7.5% to 17.4% and applied that probability across all of Immunicum's Phase II studies. In total, our valuation moves to SEK1.52bn or SEK16.4 per share from SEK1.13bn or SEK22.10 per share, the latter incorporating the dilution from the higher share count.

6 November 2018

Price	**SEK8.9**
Market cap	**SEK454m**
	$/SEK9.1; €/SEK10.6
Net cash (SEKm) at end-Q2 (before proposed c SEK351m rights issues)	149.1
Shares in issue	51m
Free float	86.1%
Code	IMMU
Primary exchange	NASDAQ Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(26.9)	34.2	11.0
Rel (local)	(22.3)	41.1	17.6
52-week high/low	SEK12.3		SEK6.0

Business description

Immunicum is a clinical-stage immunoncology company based in Gothenburg, Sweden. The company is developing an allogeneic off-the-shelf dendritic cell immune activator or immune primer for use in combination with tyrosine kinase inhibitors and checkpoint inhibitors in potentially any solid tumour indications.

Next events

Interim Q3 results	7 November 2018
Multi-indication Phase Ib/II (ILIAD) study start	H218
RCC Phase II (MERECA) top-line data	Q319
Multi-indication Phase Ib/II (ILIAD) interim data	2019

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Edison profile page

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Potential CPI agreement should have multiple benefits

Immunicum's recent news is that the supply of CPI in the Phase I/II ILIAD multi-indication study is being negotiated with a leading global pharmaceutical company to be provided to Immunicum at no cost. When signed, this will be the most significant announcement since the summer for the following reasons:

- A collaboration and supply agreement between a big global pharmaceutical company and Immunicum implies at least some validation of ilixadencel's therapeutic potential, in our view, otherwise a valuable CPI would be sold rather than supplied free of charge to Immunicum.
- The number of collaborations where pharmaceutical companies supply a CPI for a combination clinical study has slowed more recently after the failure of the CPI combination studies with Bavarian Nordic's Prostvac and Incyte's IDO1 inhibitor. This suggests that the CPI supply agreements that are now being negotiated have passed a higher diligence hurdle.
- We estimate that the collaboration and clinical supply agreement for a CPI and the on-label US reimbursement of CPIs remove c SEK10m in clinical supply costs (at list prices) which we had included in our initiation model or about one-third of the cost of the ILIAD study.
- Depending on the CPI to be supplied, the Phase II portion of the ILIAD study could be expanded to Europe resulting in potentially faster trial results.

We now assume that the Phase Ib portion of the multi-indication ILIAD study (see below) will be conducted in the US where CPIs are the approved standard of care and is reimbursed. This means Immunicum does not need to buy CPI clinical trial supply for either the Phase Ib or potentially the II parts of the ILIAD study when the supply agreement has been signed and hence we have reduced the clinical trial costs in our model.

The availability of the CPIs across Europe can be described as patchy at best in 2018, so depending on whether the CPI being negotiated is approved in Europe the CPI backbone the ILIAD study could potentially enrol patients at European study sites. This brings the possibility of a faster recruitment in the Phase II portion of the study since European study sites, and therefore more patients, could be available.

Merck &Co's CPI Keytruda overtook Bristol-Myers Squibb's Opdivo (nivolumab) in Q218 sales for the first time since their launches at the end of 2014. Keytruda has become the standard of care in first and later lines of non-small cell lung cancer (NSCLC), hence our assumption of its status as at least a component of the backbone therapy in the US part of the ILIAD study. CPIs from other companies have launched and are playing selective catch-up with Keytruda and Opdivo in an attempt to demonstrate activity in combination studies that would be superior to either Keytruda or Opdivo alone. Nevertheless, Keytruda and Opdivo are being studied in 268 and 242 combination studies respectively, with 52 and 148 being immunoncology combination studies. Other CPIs from Roche, AstraZeneca and others appear to be more selective probably because many immunoncology studies have already failed (in combination with Opdivo, for example).

Fund-raising: Allows potentially faster trial results

In mid-October, Immunicum announced an underwritten fund-raising split between a directed share issue (about SEK178m) and a rights issue (about SEK173m), which management states will extend its cash runway to the end of 2021. The rights issue is contingent on shareholder approval at the 8 November EGM and the rights will trade separately between 26 November and 10 December. The issues propose two new shares for every current five – the outcome will be announced around 13 December.

Meanwhile, we have updated our model to reflect the following changes:

- The total amount expected to be raised.
- The consequent approximate maximum number of new shares to be issued.
- The increased clinical and preclinical spend and supportive investment into manufacturing, which Immunicum has indicated will exhaust its funding at the end of 2021.
- The Q2 financial results published in August 2018.
- Lower clinical expenses as a result of the removal of the CPI costs from the ILIAD study.

Before considering the effect of the proposed rights issues, we updated our model to take account of the end-Q2 net cash position (SEK149.1m), adjusted for current exchange rates and reduced clinical trial spend in 2018 and 2019. The latter reflects our assumption of the removal of the cost of the CPIs from the ILIAD study. In our initiation note, we had modelled a licensing transaction for ilixadencel in Q419, which subsequently reduced R&D and SG&A spend and had the effect of concentrating the cash outflows in our model after 2019. The removal of the costs (SEK10m in 2018 and 2019) of the CPIs from the clinical trial spend has a positive effect on the valuation, but this is more than outweighed by the increased investment provided by the recent fund-raising.

Cash runway to end-2021 suggests accelerated investment

The funding announcement noted that the equity issues will provide a cash runway through to the end of 2021. In terms of our model, this materially alters the pattern of our forecast cash outflows, concentrating much of this investment between the end of 2018 and the (initiation of) out-licensing of ilixadencel at the end of 2019 and resulting in the exhaustion of the pro forma Q418 cash balance by the end of 2021. Incorporating the anticipated maximum fund-raising proceeds of SEK351m gross, we estimate a year-end FY18 net cash balance of SEK423.1m. In our previous model, we had assumed illustrative funding of SEK50m in Q220, which is now obviated by the funding from the forthcoming rights issues.

The recent funding is expected to result in earlier initiations of the clinical trials, for example the Phase II portion of the ILIAD study, and to bring the GMP manufacture of ilixadencel to commercial-grade quality faster than we previously assumed. The fund-raising also puts Immunicum in a stronger position to negotiate the licensing transaction for ilixadencel after the next tranche of clinical trial results are issued in 2019.

Exhibit 1: Changes to financials

	EPS (SEK)			PBT (SEKm)			Reported operating profit (SEKm)		
	Old	New	% chg.	Old	New	% chg.	Old	New	% chg.
2018e	(1.9)	(1.7)	(10.5)	(91.2)	(83.8)	(8.1)	(80.7)	(84.1)	4.2
2019e	(1.5)	(3.0)	100.0	(78.3)	(273.4)	278.0	(82.9)	(260.4)	214.1
2020e	(0.4)	(0.8)	100.0	(21.7)	(70.6)	225.4	(26.3)	(39.1)	48.7

Source: Edison Investment Research. Note: Forecasts assume successful conclusion of proposed rights issues.

Q218 financial results

Foreign exchange rate movements in Q218 resulted in gains of SEK54m (SEK0m in Q217). Updating for current exchange rates in our model results in a 10% increase in our valuation. At the operating level, administrative Q218 costs were SEK6.4m vs SEK5.3m in Q217. R&D costs were the most significant operational expense at SEK12.8m (SEK13.7m in Q217), in large part due to the preparations for the US Phase Ib/II (ILIAD), as well as the ongoing Phase II renal cell carcinoma (MERECA) studies. Administrative costs were SEK6.4m vs SEK5.3m in Q218, which were slightly lower than we had forecast. The operating loss for Q218 was SEK19.3m (vs SEK13.7m). Net cash at end June 2018 was SEK149.1m (SEK62m in Q217 and SEK128.0m at end 2017). Operating cash outflow for Q218 was SEK18.1m vs SEK23.1m in Q217, and included share issue costs of SEK32.5m from the issue that raised SEK167.5m net and completed in early Q118.

Clinical trial progress on multiple fronts

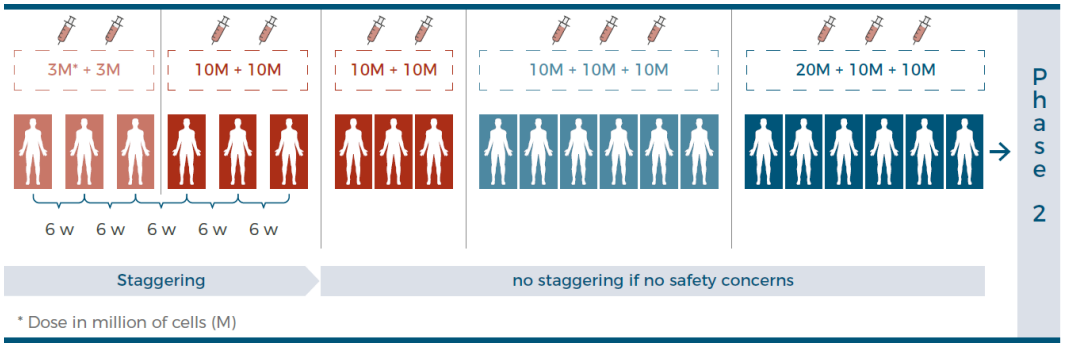
Immunicum's clinical trial programme seems to follow a trend of threes: three clinical studies – renal cell carcinoma (RCC), HCC and the multi-indication ILIAD study. The Phase Ib/II ILIAD study will include patients with three diagnoses: HNSCC, NSCLC and gastric adenocarcinoma. The staggered portion of the ILIAD will dose three patients at each dose.

Phase Ib/II ILIAD study

The multi-indication ILIAD study is the earliest of the three studies and, in our opinion, is the most interesting. The ILIAD protocol was agreed with the FDA over the summer and enrolment is expected to start in H218. The study will be in two parts:

- Phase Ib in 21 patients will be enrolled in a staggered format (Exhibit 2); and
- Phase II in up to 150 patients will include a higher dose of ilixadencel, which would not have been tested in Phase Ib and up to one more administration than would have been tested in Phase Ib.

Exhibit 2: Phase Ib/II multi-indication CPI combination ILIAD study design



Source: Immunicum

Two key points can be derived from the announcement of the FDA's approval of the ILIAD study protocol. First, the CPI that will be dosed in combination with ilixadencel in the Phase I portion (and we assume for the moment at least the NSCLC patients in the Phase II portion) has now been disclosed as Keytruda. Keytruda is Merck & Co's best-selling anti-PD1 monoclonal antibody, which has well-known efficacy and safety in NSCLC, HNSCC and gastric cancer (among others). However, it is not benign and significant dose-limiting toxicities like pneumonitis, colitis and hepatitis have been reported. In contrast, ilixadencel has a benign safety profile that is largely confined to mild-to-moderate adverse events in small numbers of patients such as fever, chills and rash. Unlike the CPIs, no dose-limiting toxicity has been found with ilixadencel, hence the top dose in the Phase II part of the ILIAD study will escalate up to 40m cells over three administrations. The protocol for the Phase Ib part involves a six-week staggered period between the dosing of the first six patients. The staggered part of the ILIAD study almost certainly represents the FDA's usual caution resulting from additive or overlapping toxicity in a number of historical CPI combination studies. Based on ilixadencel's side effect profile to date, we do not expect any significant additive toxicity with CPIs in the Phase Ib/II portions of the ILIAD study. The Phase II NSCLC portion of the ILIAD study is randomised 2:1 ilixadencel plus CPI vs CPI alone.

Although safety and the optimal administration regimen are the main aims of the Phase Ib part of the study, efficacy will also be measured and the expanded 21 patient group to be reported during 2019 will give more weight to any positive indications of efficacy. The expansion of the Phase Ib part of the protocol from nine to 21 patients may have an additional advantage. Very strong efficacy differentiation in one of the three indications (NSCLC, HNSCC and gastric adenocarcinoma) may provide a rationale for prioritising the indications in the subsequent studies.

ILIAD protocol agreed by the FDA

The agreement of a clinical trial protocol with the FDA is a significant milestone in any company's history, but more so for companies in the oncology space that are exploring the use of combinations of agents. The ILIAD study is an open-label, multi-centre, Phase Ib/II study in 21 and up to 150 patients to evaluate ilixadencel when injected intratumourally in combination with the world's best-selling CPI Keytruda (pembrolizumab). The cautious six-week observation between patients (staggered) in the Phase Ib portion of the study could imply recognition of efficacy by the FDA. The performance of ilixadencel in three disease indications should help Immunicum and its partners prioritise indications in subsequent studies.

RCC

Patient enrolment for the Phase II (MERECA) study in 88 newly diagnosed, metastatic RCC patients completed in early January. The patients were treated with ilixadencel in combination with a subsequent nephrectomy (removal of the kidney) and the tyrosine kinase inhibitor (TKI) Sutent (sunitinib) vs nephrectomy and TKI alone. The primary endpoints of the study are the hard clinical endpoints of median overall survival and median survival after 18 months, in addition to other safety and efficacy endpoints. Reporting these hard clinical data in Q319 should enable any prospective partners to make a fully informed business development decision. We assume these data could be combined with those from ILIAD combinations so that ilixadencel's first Phase III RCC study could include a CPI combination arm.

HCC

Ilixadencel has completed a Phase I/II study in 18 HCC patients and was shown to be safe and well tolerated when given as a single treatment, or in combination with Nexavar (sorafenib), and evidence of tumour-specific immune activation was observed in the majority of evaluable patients. The commercial opportunity for ilixadencel in HCC is the lowest (11.4% of the product rNPV) due to the smaller number of patients. This supports Immunicum's strategy of prioritising the future development of the HCC indication after the multi-indication and RCC studies because the global distribution of HCC is not concentrated in Western markets. About 75% of liver cancer occurs in Asia, with China accounting for over 50% of global incidence.[1] Although we have not yet included a licensing transaction for ilixadencel in China in our model, the high healthcare burden in China suggests that we could include royalties on Chinese sales at some point.

The pipeline emerges

As well as the ongoing gastrointestinal stromal tumour (GIST) Phase I/II study in combination with a TKI, Immunicum provided an update on the progress of its preclinical assets IMM-2 (Subcuvax/adenovirus vector) and IMM-3 (CD70, ex vivo CAR-T expansion) at its recent quarterly results announcement. Despite ilixadencel being in Phase I/II in GIST patients, we have not yet included this indication in our valuation, as the number of patients is considerably lower than those with HCC. Neither of Immunicum's preclinical programmes IMM-2 and IMM-3 is included in our valuation, although Immunicum's proven ability to turn a product into a multi-indication platform, as it has done with ilixadencel, suggests that at some point we will include them in our model.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4712629/pdf/nihms732346.pdf

Valuation

We have made adjustments to our model to reflect changes in exchange rates (which are minor) and the Q218 balance sheet, which showed net cash at the end June of SEK149.1m (SEK62m at the end of Q217). As discussed in our financials section, we have reduced clinical trial cost estimates for FY18, reflecting the reimbursement of the CPI in the US. Should the potential CPI supply agreement be signed, it would add more than big pharma endorsement to our investment case for Immunicum as we assume CPI availability as part of a clinical trial protocol would speed the conduct of the study and avoid waiting for the reimbursement of the CPI to be confirmed by the patients' payers.

In addition, as the Phase I/II study in HCC has now been reported, and we have assumed the company finalises the CPI collaboration and clinical supply agreement, our probability of success[2] has increased from 7.5% to 17.4% and applied that probability across all of Immunicum's Phase II studies. This change alone increased our valuation by just over 11% or SEK2.66 per share before other changes are taken into account.

Additional substantive pipeline changes increase our valuation

However, the main change to our valuation lies in incorporating the proposed capital raise, the associated accelerated investment levels and the increased share count.

Exhibit 3: Components of rNPV valuation

Product	rNPV (SEKm)	rNPV per share (SEK)
Ilixadencel – RCC	247.0	2.7
Ilixadencel – HCC	141.9	1.5
Ilixadencel – NSCLC	456.0	4.9
Ilixadencel – HNSCC	226.5	2.5
Ilixadencel – gastric adenocarcinoma	173.8	1.9
Unallocated costs	(278.5)	(3.0)
Net cash at end FY17	128.0	1.4
Estimated net proceeds of 2018 issues*	421.2	4.6
Valuation	**1,515.9**	**16.4**
Share count (92.3m)*		

Source: Edison Investment Research. Note: *Assumes successful completion of proposed (approximately SEK351m gross) rights issues.

For the most advanced indication in RCC, the rNPV valuation decreases by c 11% as a larger proportion of the proposed investment arising from the fund-raising affects its value earlier in the NPV calculation, is unaffected by the saving of the CPI costs in the ILIAD study and not offset by the increase in probability of success. For the other later clinical programmes, the savings from not bearing the cost of the CPIs and the increase in probabilities of success have a positive effect, the magnitude of which is related to how much of the programme Immunicum funds before ilixadencel is licensed. We have also absorbed some of the investment into unallocated costs until 2021, which have risen by 54% between our initiation and our latest model. When the cash raised in the fund-raisings, the cost savings in the clinical programmes and the investment apportioned by product are all included (in Exhibit 3, above), our valuation increases to SEK1.52bn or SEK16.4 per share from SEK1.13bn or SEK22.10 per share. The lower per-share value results from the expected 41% dilution from the new share issues.

[2] https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf

Exhibit 4: Financial summary

SEK'000s	2017	2018e	2019e	2020e	2021e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT					
Revenue	0	0	0	0	0
Operating expenses	(80,847)	(84,003)	(260,427)	(39,075)	(39,573)
Depreciation	(71)	(65)	(1)	0	0
Operating income	218	258	284	312	343
Reported operating profit	(80,700)	(84,068)	(260,428)	(39,076)	(39,574)
Net Interest	362	(20)	6	(13)	6
Profit before tax (reported)	(80,338)	(83,765)	(273,416)	(70,592)	(76,688)
Reported tax	0	0	0	0	0
Profit after tax (reported)	(80,338)	(83,765)	(273,416)	(70,592)	(76,688)
Minority interests	0	0	0	0	0
Net income (reported)	(80,338)	(83,765)	(273,416)	(70,592)	(76,688)
Basic average number of shares outstanding	25,959	49,444	92,258	92,258	92,258
EPS - basic reported (SEK)	(3.09)	(1.69)	(2.96)	(0.77)	(0.83)
BALANCE SHEET					
Non-current assets	105,309	3	2	1	1
Property plant and equipment, net	69	2	1	0	0
Other financial assets	1	1	1	1	1
Other non-current assets	105,239	0	0	0	0
Current assets	140,837	432,508	159,530	89,600	13,126
Cash and cash equivalents	128,883	423,944	150,782	80,660	3,982
Accounts receivable	0	3,675	3,859	4,052	4,254
Marketable securities and short-term investments	0	0	0	0	0
Prepaid expenses	8,454	4,889	4,889	4,889	4,889
Current liabilities	55,740	12,134	12,570	13,233	13,446
Accounts payable	11,714	842	1,278	1,941	2,154
Accrued other liabilities	43,694	10,066	10,066	10,066	10,066
Other current liabilities	331	1,226	1,226	1,226	1,226
Non-current liabilities	850	850	850	850	850
Long-term debt	850	850	850	850	850
Equity	189,557	418,264	(44,803)	87,429	4,644
Retained earnings	(151,447)	(235,212)	(508,628)	(579,220)	(655,908)
Total shareholder's Equity	189,557	418,264	(44,803)	87,429	4,644
CASH FLOW					
Cash flow from operations					
EBIT (operating profit)	(80,700)	(84,068)	(260,428)	(39,076)	(39,574)
Depreciation	71	65	1	0	0
Income tax paid	0	0	0	0	0
Other working capital changes	34,455	(46,092)	252	469	11
Cash interest paid	(274)	(13)	(26)	(26)	0
Cash interest received	0	0	32	13	6
Net cash used in operating activities	(46,447)	(129,784)	(273,162)	(70,122)	(76,677)
Cash flow from investing					
Purchase of fixed assets	0	0	0	0	0
Sale of investments	10,162	0	0	0	0
Net cash used in investing activities	10,162	0	0	0	0
Cash flow from financing					
Change in capital stock	62,269	421,229	0	0	0
Net cash from financing activities	62,269	421,229	0	0	0
Net changes in cash and cash equivalent	25,984	291,445	(273,162)	(70,122)	(76,677)
Cash and cash equivalents - beginning	102,899	128,883	420,328	147,165	77,043
Cash and cash equivalents - end	128,883	420,328	147,165	77,043	366
Net cash	128,033	423,094	149.932	79,810	3,132

Source: Company data, Edison Investment Research. Note: Forecasts incorporate the proposed rights issues, the associated accelerated investment levels and the expected increased share count.

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