EDISON

Immunicum

Primed for value appreciation

Company outlook

Pharma & biotech

Following the transformational merger with DCprime in December 2020, Immunicum now aims to become a global leader in off-the-shelf, allogeneic cell therapies, using its expertise in dendritic cell (DC) biology. It has two advanced clinical-stage pipeline products, addressing both solid tumours and haematological malignancies. Ilixadencel is being developed as an immune primer in combination with anti-cancer therapies, while DCP-001 is aimed at reducing the risk of cancer relapse after standard of care. Given the changes to the R&D pipeline and updated strategy, we have revised our forecasts and valuation and present a new investment thesis. Our valuation is SEK1.95bn or SEK9.76 per share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/19	0.0	(47.8)	(0.65)	0.0	N/A	N/A
12/20	0.0	(89.2)	(1.17)	0.0	N/A	N/A
12/21e	0.0	(137.8)	(0.75)	0.0	N/A	N/A
12/22e	0.0	(136.3)	(0.68)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles and exceptional items.

Complementary assets enhance the pipeline

Ilixadencel is an intratumoural immune primer based on activated allogeneic DCs derived from healthy donors, which is being developed for use in conjunction with other established cancer therapies that either directly target or amplify the immune response against solid tumours. DCP-001 is an intradermal vaccine against cancer relapse that DCprime derived from a proprietary cell line. DCP-001 aims to boost the immune system's ability to control residual disease during cancer remission in solid and blood-borne cancers. So, these assets are complementary from the company's R&D strategy perspective, but the strategic positioning is different as the therapies are not in direct competition.

Enriched newsflow

The merger enhanced expected R&D newsflow and in the near term there are two significant catalysts. ADVANCE-II is an ongoing, open-label Phase II trial investigating DCP-001 as a potential relapse vaccination in AML patients who are in their complete remission but still have measurable residual disease (MRD). Top-line efficacy data from the Phase II ADVANCE-II trial in AML are expected in Q421. The Phase Ib/II ILIAD study is the first trial where Immunicum is combining ilixadencel with checkpoint inhibitors, therefore safety and tolerability data will be of particular interest as they could define the scope in which ilixadencel is used. At the interim safety updates, no dose-limiting toxicities were observed, while full data for the Phase Ib part of the ILIAD trial are expected in Q421.

Valuation: SEK1.95bn or SEK9.76 per share

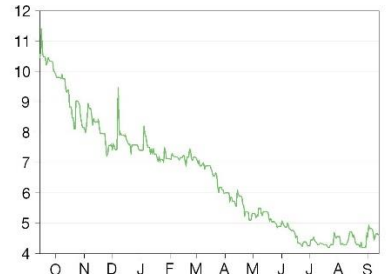
We value Immunicum at SEK1.95bn or SEK9.76 per share (rNPV using a 12.5% discount rate and SEK212m cash at end-Q221). Our model includes the two lead assets in the four prioritised indications (DCP-001 in AML and OC; ilixadencel in RCC and GIST), but there is potential to expand into many more. The latest share issue should fund operations until end of 2022, so the near-term R&D catalysts are reachable before that.

14 September 2021

Price	**SEK4.60**
Market cap	**SEK917m**

Net cash (SEKm) at end-Q221	212
Shares in issue	199.4m
Free float	37%
Code	IMMU
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(2.3)	(3.4)	(52.6)
Rel (local)	0.5	(8.2)	(65.5)

52-week high/low	SEK11.40 SEK4.20

Business description

Immunicum is an allogeneic cell-therapy company based in Stockholm, Sweden. It is developing two 'off-the-shelf' dendritic cell-based vaccines: ilixadencel, for use in combination with checkpoint inhibitors and other anti-cancer therapies for various solid tumours; and DCP-001, a relapse vaccination aimed at preventing or delaying tumour recurrence.

Next events

Full Phase Ib ILIAD data for ilixadencel in combination with CPIs	Q421
Phase II ADVANCE-II data for DCP-001 in AML	Q421

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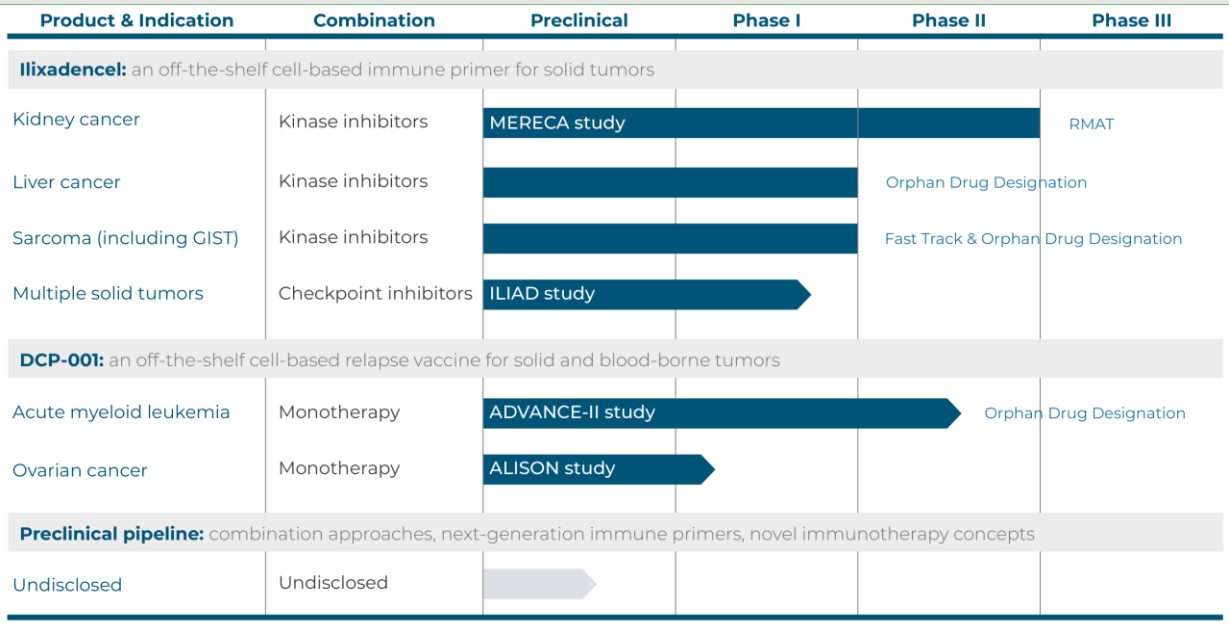
Edison profile page

Transformational merger enhances R&D pipeline

Immunicum is a cell therapy company listed on Nasdaq Stockholm and based in Stockholm, Sweden, with R&D activities in Leiden, the Netherlands. It was formed in 2002 based on research originally carried out at Sahlgrenska University Hospital in Gothenburg, Sweden, but by the end of 2020 the company had finalised a transformational merger with DCprime, a Dutch biotech developing complementary technology. The combined entity now aims to become a global leader in off-the-shelf, allogeneic cell-therapies, building on its expertise in DC biology.

In its current form, Immunicum has two Phase II assets in development for cancer: ilixadencel and DCP-001. **Ilixadencel** is an intratumoural immune primer based on activated allogeneic DCs derived from healthy donors and is being developed for use in conjunction with other established cancer therapies that either directly target or amplify the immune response against solid tumours. **DCP-001** is an intradermal vaccine against cancer relapse that DCprime derived from a proprietary cell line. DCP-001 aims to boost the immune system's ability to control residual disease during cancer remission, preventing or delaying recurrence in solid and blood-borne cancers. Exhibit 1 details all indications for which these two assets have been investigated so far.

Exhibit 1: R&D pipeline



Source: Immunicum

Immunicum now has two off-the-shelf, cell-based immunoncology assets which, from the perspective of the company's strategy, are complementary. However, the positioning is different (relapse versus treatment), so the therapies will not compete with each other. The R&D strategy aims to accumulate proof-of-concept clinical data in larger cancer indications before seeking an out-licensing deal that would support late-stage development. In smaller indications, Immunicum could continue the development until registration. Specifically, to date:

- **Ilixadencel** has been tested in a range of solid tumours, most recently in the Phase II MERECA study in renal cell carcinoma (RCC). Currently, it is being evaluated in the Phase I/II ILIAD study, where for the first time ilixadencel is combined with immune checkpoint inhibitors in multiple solid tumour indications. Full data from the Phase Ib part are expected Q421.
- **DCP-001** is being tested in a Phase II study, ADVANCE-II, in AML with encouraging first interim data presented in December 2020 (ASH conference). Additional interim data from this study

are expected in Q421. In addition, Immunicum has initiated a Phase I ALISON study of DCP-001 in ovarian cancer, which will be its first evaluation in a solid tumour indication.

DCP-001 and ilixadencel address key challenges in cancer therapy

A quick reminder about immunity and cancer

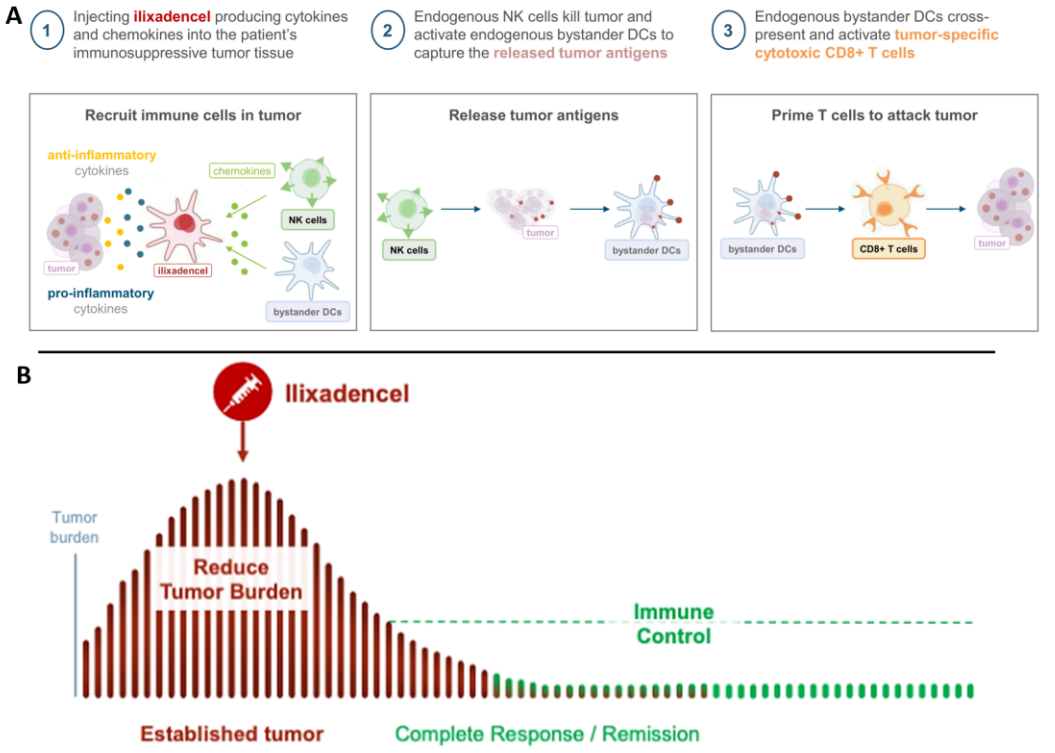
There are two immune system types: innate and acquired. Innate immunity is inborn, non-specific and provides the ability to defend against infections; acquired (adaptive) immunity is specific to a pathogen and responsible for long-lasting immunity. The latter is subdivided into an antibody-based immune response (humoral) and a cellular response involving T-cells. T-cells can sense and kill infections or tissue that become abnormal and cause the risk of a tumour developing.

There are several subsets of T-cells, but the two major ones are CD4+ (also called 'helper') and CD8+ ('killer'), indicating which CD glycoprotein they express. CD4+ T-cells are involved in the coordination of other immune cells that participate in the immune response. CD8+ T-cells can directly attack and kill other cells which, for example, have been infected with viruses or become malignant. Another important class of immune cells is DCs, which aid in 'directing' T-cells. In a malignant process, as cancer cells die, they can release tumour-associated antigens (also called neoantigens), which DCs can pick up, process and present to the T-cells, which will direct them to specifically target cancerous cells.

Ilixadencel and DCP-001

Ilixadencel is an immune primer made up of pro-inflammatory activated allogeneic DCs and intended for intratumoural administration. These are derived from healthy donors and activated ex vivo using a potent cocktail (COMBIG), which induces DCs to produce chemokines (CCL4/5 and CXCL10) that aid in the recruitment of other immune cells and cytokines (IL-1β & TNF-α). When injected into the tumour, ilixadencel DCs causes local recruitment and activation of the patient's immature DCs, natural killer cells and T-cells. Maturation of recruited bystander DCs within the tumour microenvironment (driven by ilixadencel) results in uptake of tumour-associated antigens. Cross-presentation of these by DCs to CD8+ 'killer' cells makes the latter cytotoxic and capable of targeting cancer cells displaying the same tumour-associated antigens. Recognition of the ilixadencel DCs by the immune system as foreign (to the patient or host) also helps this inflammatory process, cancer cell death and tumour-associated antigen release (Karlsson-Parra et al, 2018). **The positioning of ilixadencel is to stimulate the cancer immunity cycle at the height of tumour burden and mount an anti-cancer immune response** that can be sustained throughout subsequent treatment course(s), be it surgical resection, radiotherapy, chemotherapy or immunotherapy. If the cancer immunity cycle is efficiently initiated, then both the primary tumour and metastases can be targeted (abscopal effect).

Exhibit 2: Mechanism of action and therapeutic principle for ilixadencel

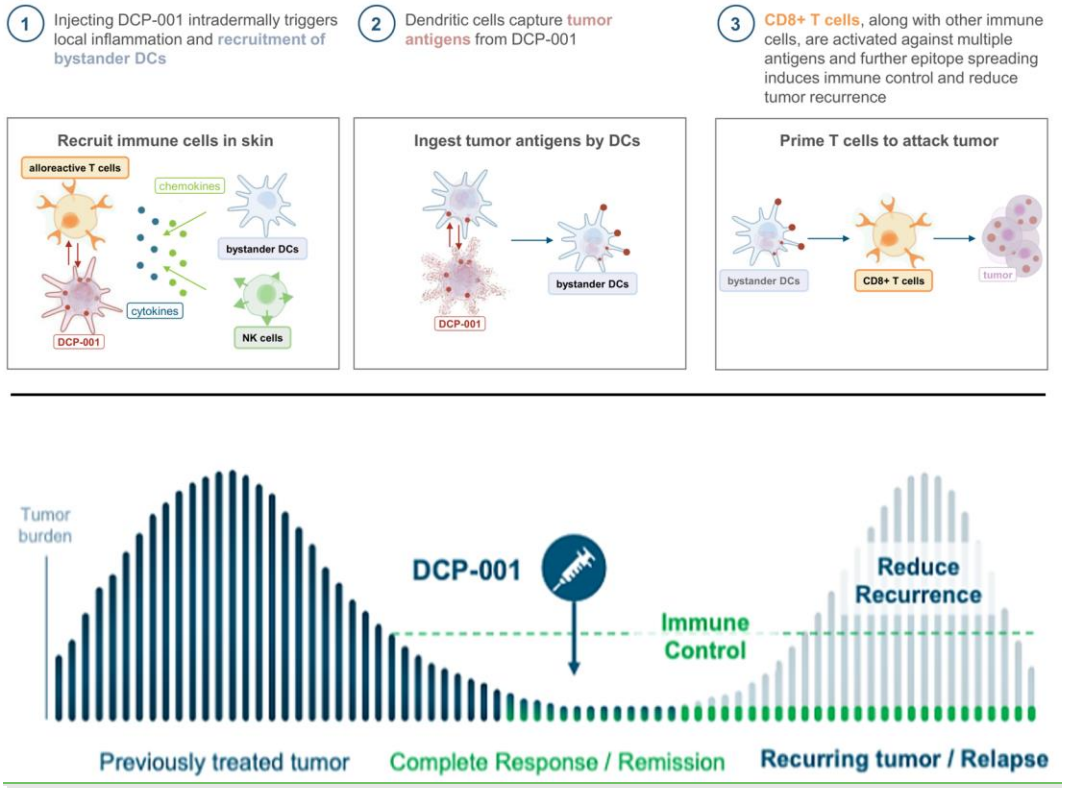


Source: Immunicum

Conversely, DCP-001 is given during tumour remission (intradermally). DCP-001 cells are derived from the proprietary DCOne platform and consist of a leukaemia cell line, which has been shifted into a DC phenotype with a cocktail of cytokines (GM-CSF, IL-4 and TNF-α) and subsequently matured (PGE2, TNF-α and IL-1β). As a result, the leukemic DCOne cells endogenously expresses multiple common tumour-associated antigens and they are highly immunogenic. Once injected, these cells are phagocytosed (ingested) by the hosts DCs, which in turn cross-present the antigens from the original leukaemia cell line, stimulating a tumour-specific T-cell response.

DCOne cells express multiple common tumour-associated antigens such as WT-1, RHAMM, PRAME and MUC-1, which are also expressed by other blood-borne and solid tumours. This suggests that in addition to leukaemias, DCP-001 could have an anti-tumour effect in other cancers that express these antigens. Ovarian cancer (now in Phase I) was the first solid tumour indication investigated in preclinical models beyond leukaemia (now in Phase II) (Nagasawa et al, SITC 2020), but there is potential to expand into other types as well. **The treatment setting for DCP-001 is to administer it during cancer remission with the aim of priming the immune system and boosting its ability to control residual disease, thereby preventing or delaying recurrence.**

Exhibit 3: Mechanism of action and therapeutic principle for DCP-001



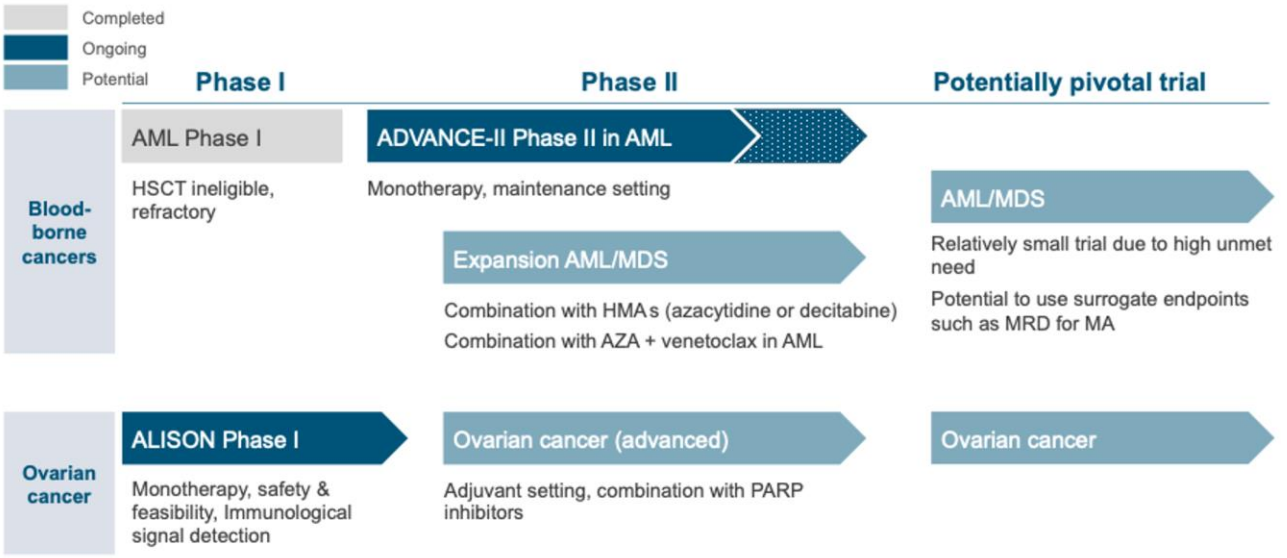
Source: Immunicum

DCP-001: A new spearhead to the pipeline

Through the merger, Immunicum has gained DCP-001, a Phase II asset which has diversified its pipeline offering beyond ilixadencel. DCP-001 is administered during cancer remission with the aim of priming the immune system, thereby preventing or delaying recurrence in solid and blood-borne cancers. As such, Immunicum is primarily developing DCP-001 for use as maintenance therapy in cancers where patients are at high risk of tumour recurrence, initially looking at both acute myeloid leukaemia (AML) and ovarian cancer. Immunicum has also highlighted the potential to move DCP-001 into earlier treatment lines, if used in combination with standard-of-care regimens.

With the merger, Immunicum has also gained the platform technology, DCOne. It could have broader utility to strengthen other T-cell therapies, such as CAR-Ts, either therapeutically to help deepen and prolong clinical responses, or to improve their manufacturing process.

Exhibit 4: Clinical development strategy for DCP-001



Source: Immunicum

AML: ADVANCE-II data could enable pivotal DCP-001 trials

ADVANCE-II is an ongoing, open-label Phase II trial investigating DCP-001 as a potential relapse vaccination in AML patients who are in their complete remission but still have MRD. The goal of this study is to investigate the effect DCP-001 has on the MRD status and whether remissions can be lengthened. Interim results presented at ASH 2020 (5–8 December) included data from the 10 patients in the first lower-dose cohort. Five patients in the higher-dose cohort had started, but not completed the vaccination schedule. Results presented at ASH last year showed that:

- out of these 10 patients, two patients converted to MRD negative following vaccination, and five patients have remained in complete remission despite being MRD positive. Conversely, three patients relapsed prior to completing the vaccination schedule, highlighting that timing and patient status could play a critical factor. Immunogenicity data from the study presented at EHA 2021 (9–17 June) also highlight that DCP-001 induced an immune response to tumour-associated antigens relevant to AML, such as PRAME and WT-1. Additional top-line efficacy data from the Phase II ADVANCE-II trial in AML are **expected in Q421**, which we anticipate Immunicum will aim to present at ASH 2021 (11–14 December).

AML: Changing treatment paradigm, but still an unmet need

For decades, AML treatment relied largely on intensive chemotherapy and allogeneic hematopoietic stem cell transplantation (HSCT), which is unsuccessful in 60–80% of patients due to the persistence of MRD (van de Loosdrecht et al, 2018). Over the past few years, several new therapies have been approved, so the treatment paradigm is likely to change. However, having reviewed the emerging treatment options, we believe the survival benefit of the new therapies is limited, especially in elderly patients, so the unmet need in AML is likely to persist.

AML normally originates in the bone marrow (where new blood cells are made), but often quickly moves into the blood, resulting in uncontrolled growth and accumulation of malignant white blood cells, which fail to function normally and interfere with the production of normal blood cells. AML is the most common type of acute leukaemia in adults and affects around 40,000 patients in Europe and the US (new cases per year). Less than one-third of all AML patients survive for five years, while for 65+ year-olds this rate drops to 10–15%.

Until recently, the standard-of-care treatment for AML was primarily based on chemotherapy (cytarabine with anthracycline or mitoxantrone), followed by a stem cell transplant where

appropriate. The goal of treatment is to reduce the blasts in the bone marrow to below 5% and return the blood cell counts to normal levels. A bone marrow transplant is generally recognised as the only curative treatment option but is not always appropriate.

Rydapt (midostaurin, Novartis) was the first novel targeted therapy approved in April 2017 and specifically targets FLT3 for the treatment of adults with newly diagnosed FLT3-ITD AML in combination with standard-of-care chemotherapy. In the Phase III trial, overall survival was increased from approximately two years to just over six years. Consensus forecasts Rydapt sales of c $240m in 2026 (source: EvaluatePharma). In November 2018, the FDA approved gilteritinib (Xospata, Astellas) as monotherapy for adults with FLT3-positive AML in a relapsed or refractory setting. Consensus forecasts Xospata sales of c $790m in 2026.

Outside of the FLT3-targeted therapy space, Venetoclax (BCL-2 inhibitor, Venclexta, AbbVie/Roche) has generated significant interest. In November 2018, the FDA granted accelerated approval for use in combination with azacitidine or decitabine or low-dose cytarabine for the treatment of 75+ year-old patients with newly diagnosed AML. Venetoclax has been demonstrated to have efficacy similar to standard-of-care chemotherapy regimens, but with a much better safety tolerability profile. Consensus forecasts Venetoclax sales of c $1.4bn in 2026 for AML. Other novel drugs that the FDA approved over the last few years include:

- Glasdegib in November 2018 (a hedgehog pathway inhibitor, Daurismo, Pfizer; consensus sales forecast of $667m in 2026); and
- IDH1/IDH2 inhibitors ivosidenib in July 2018 (Tibsovo, Agios Pharmaceuticals; consensus AML sales forecast of $400m in 2026) and enasidenib in August 2017 (Idhifa, BMS/Celgene; consensus AML sales forecast of $269m in 2026).

Despite these advances, novel drugs rarely extend survival by more than a few months, so survival rates remain poor and the unmet need in AML remains high. Most of these novel drugs were approved over the last few years, so the clinical treatment paradigm and guidelines are still in the development stage which makes it an interesting indication to follow.

Aiming for maintenance therapy in AML

The ongoing ADVANCE-II trial investigates DCP-001 as a potential relapse vaccination in AML patients who are in their complete remission but still have MRD. Until recently, standard of care for most patients with AML achieving a complete response was observation without maintenance therapy with some exceptions despite efforts to find effective treatment options in this setting. However, in September 2020 the FDA approved of Onureg (oral azacitidine) after the QUAZAR AML-001 clinical study (n=472) demonstrated that Onureg improved overall survival in maintenance setting. This is the biggest advance in AML maintenance at the moment and may change the treatment paradigm (Reville and Kadia, 2021). Consensus now forecasts $713m in sales by 2026 in AML (EvaluatePharma).

Clinical trials evaluating maintenance cytotoxic chemotherapy in AML in the past have consistently failed to show a benefit in overall survival. Many other treatments, such as targeted therapies, are still being tested in this setting (Sederstrom, 2020). So, like induction and consolidation (primary AML chemotherapy), maintenance setting is also changing. Immunicum will make final decision about positioning and more precise late-stage R&D plans once the ADVANCE-II data are released. EvaluatePharma calculates the total market value of AML drugs at c $1.6bn in 2021, which is forecast to grow to c $7.4bn by 2026.

Ovarian cancer: ALISON recruitment underway

The Phase I ALISON study is evaluating DCP-001 for first-line maintenance therapy in high-grade serous ovarian cancer, the most prevalent histology type, representing c 70% of all new cases. The single-centre, open-label study will recruit c 17 patients who have completed (neo)adjuvant

chemotherapy and surgery. Patients will receive four bi-weekly vaccinations with 25 million cells per DCP-001 vaccination and two additional booster vaccinations with 10 million cells per vaccination. Patient follow-ups will be conducted for 24 months. The primary endpoint of the study is change from baseline of DCP-001 vaccine antigen-specific T-cells in peripheral blood after treatment. Key secondary endpoints include safety and tolerability as well as recurrence-free survival (RFS) and overall survival (OS) during the follow-up period. If successful, this will be the first validation that the DCP-001 platform also has potential utility beyond AML and may have an effect in solid tumours. In June 2021, Immunicum recruited the first patient into the ALISON trial and **initial data are expected around mid-2022**.

The National Cancer Institute estimates that 21,410 new cases of ovarian cancer were diagnosed in 2020 and c 13,770 women will die from the disease. In key European markets, c 33,400 women were diagnosed in 2020 (GLOBOCAN). Ovarian cancer is characterised by having minimal, non-specific or no symptoms at all, therefore most cases are diagnosed at an advanced stage. Prognosis in ovarian cancer is closely related to the stage at diagnosis, thus the overall prognosis for these patients remains poor (OS across all stages is 46%).

The treatment involves aggressive debulking surgery followed by chemotherapy and novel cancer-targeted therapies. The surgery is considered curative only for a small percentage of patients (certain histology type-tumours in stage I), so most will receive some form of chemotherapy after the surgery (neoadjuvant chemotherapy is also being used).

Despite optimal surgery and appropriate first-line chemotherapy, most patients will relapse and therefore maintenance therapy is considered following standard-of-care, platinum-based chemotherapy. In this so-called first-line maintenance setting, two approved PARP inhibitors have become standard of care and are forecast to generate c $4bn in sales by 2026 in this setting alone (EvaluatePharma).

- **Lynparza** (olaparib, AstraZeneca) – approved for use in combination with Avastin by the FDA in May 2020 for first-line maintenance therapy for advanced ovarian cancer based on Phase III PAOLA-1 data.
- **Zejula** – (niraparib, GlaxoSmithKline) – approved by the FDA in April 2020 for use as first-line maintenance therapy in advanced ovarian cancer irrespective of HRD status, based on Phase III PRIMA data.

TP53 mutations in high-grade serous ovarian cancer, the target population in the ALISON study, are highly prevalent and can be considered characteristic in c 96% of tumours, but also homologous recombination deficiencies (HRD), which occur in c 50%, including mutations to BRCA, which occurs in c 20% (The Cancer Genome Atlas Research Network, 2011). Although HRD+ patients were the original target population for PARP inhibitors, these have been shown to be efficacious irrespective of HRD status have been broadly adopted for first-line maintenance. As such, we anticipate that these PARPs could provide an efficacy benchmark or control for subsequent trials, but Immunicum has also highlighted that combination regimens with PARPs remain a possibility.

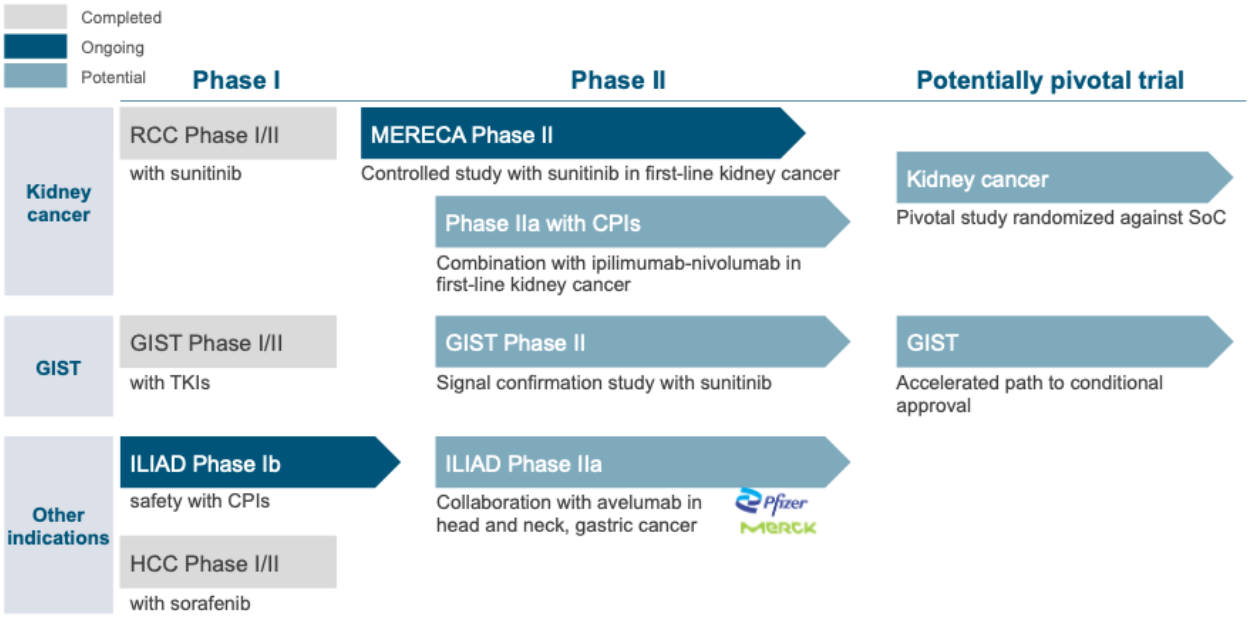
Ilixadencel: Combination with CPIs is safe

The management team is currently reviewing the development strategy for ilixadencel, and we expect some key decisions to be made and communicated in the coming months. Following completion of the Phase II MERECA trial, which tested ilixadencel in combination with standard-of-care chemotherapy versus chemotherapy alone, the currently ongoing Phase Ib ILIAD trial is testing the combination of ilixadencel with CPIs. Against the backdrop of the changing treatment for kidney cancer, we believe that safety data from the ILIAD trial will pave the way for designing the

next efficacy trial with ilixadencel. ILIAD will also open a pathway for targeting other major cancer indications.

Immunicum has identified another indication, gastrointestinal stromal tumours (GIST), as a suitable target for ilixadencel. The strategy here is somewhat different. GIST is a rare cancer, so the advantages include regulatory support and shorter development timelines (eg an accelerated approval pathway), a smaller trial (less dependency on finding a partner), which translates into a faster route to market. The Phase I/II trial in GIST is complete. Immunicum plans a Phase II efficacy study and to initiate discussions with the FDA for accelerated approval.

Exhibit 5: Clinical development strategy for ilixadencel



Source: Immunicum

Landmark Phase II MERECA data

Before the merger, the Phase II MERECA trial for ilixadencel was the most advanced clinical trial in Immunicum's R&D pipeline. The latest update from the MERECA study in February 2021 provides promising efficacy signals and establishes part-clinical proof of concept for ilixadencel.

Exhibit 6: Summary of Phase II MERECA data

	ilixadencel + sunitinib	sunitinib
Median OS	**35.6 months**	**25.3 months**
- Proportion alive (36 months)	41% (23/56)	30% (9/30)
Confirmed ORR	**42% (19/45)**	**24% (6/25)**
- Complete response	6.7% (3/45)	0% (0/25)
- Partial response	36% (16/45)	24% (6/25)

Source: Immunicum; Note: These endpoints are exploratory and not powered to detect predefined efficacy measures, as such p-values were not provided to indicate the statistical significance of these data.

As a reminder, MERECA is an open-label study in RCC evaluating safety and efficacy of intratumourally administered ilixadencel pre-nephrectomy, followed by sunitinib post-nephrectomy. This is compared to surgery and sunitinib post-nephrectomy. However, since the MERECA study started enrolment, the treatment landscape in first-line RCC has evolved beyond sunitinib significantly (Exhibit 7). Checkpoint inhibitors have broadly become adopted as standard of care in this setting, given the substantial survival benefits that have been demonstrated across several Phase III studies (Exhibit 7). Consensus forecasts that ongoing uptake of PD-(L)1 agents in RCC will grow into a >$6bn opportunity in 2026 (EvaluatePharma).

In spite of this, ilixadencel has been granted a regenerative medicine advanced therapy (RMAT) designation by the FDA and advanced therapy medicinal product (ATMP) certification by the EMA, based on the MERECA data and Immunicum is in discussions with the regulators to determine the next development steps for ilixadencel in RCC. It has not yet presented a preliminary design and we understand that all options are on the table, including out-licensing certain rights.

Exhibit 7: PD-(L)1 inhibitors in first-line RCC

Checkpoint inhibitor	Consensus forecast*	Combination	Trial/indication	Notes
Opdivo (nivolumab) **PD-1 antibody**	2020 – $1.8bn 2026 – $3.1bn	Yervoy (ipilimumab) **CTLA-4 antibody**	CheckMate-214 first-line RCC	**Approved by FDA in April 2018**. Compared the control arm of sunitinib monotherapy; the combination provided significant improvements in OS (HR 0.63, p < 0.0001), PFS (11.6 vs 8.4 months; HR 0.82, p = 0.03) and ORR (41.6% vs 26.5%; p < 0.0001) irrespective of PD-L1 expression.
		Cabometyx (cabozantinib) **VEGFR1/2/3 TKI****	CheckMate-9ER first-line RCC	**Approved by FDA in Jan 2021**. Compared the control arm of sunitinib monotherapy; the combination provided significant improvements in OS (HR 0.60, p = 0.001), PFS (16.6 vs 8.3 months; HR 0.51, p < 0.0001) and ORR (55.7% vs 27.1%; p < 0.0001) irrespective of PD-L1 expression.
Keytruda (pembrolizumab) **PD-1 antibody**	2020 – $661m 2026 – $945m	Inlyta (axitinib) **VEGFR1/2/3 TKI****	KEYNOTE-426 first-line RCC	**Approved by FDA in April 2019**. Compared the control arm of sunitinib monotherapy; the combination provided significant improvements in OS (HR 0.53, p < 0.0001), PFS (15.1 vs 11.1 months; HR 0.69, p < 0.0001) and ORR (59% vs 36%; p < 0.0001) irrespective of PD-L1 expression.
Bavencio (avelumab) **PD-L1 antibody**	2020 – $86m 2026 – $665m	Inlyta (axitinib) **VEGFR1/2/3 TKI****	JAVELIN renal 101 first-line RCC	**Approved by FDA in May 2019**. Compared the control arm of sunitinib monotherapy; the combination provided significant improvements in OS (HR 0.80, p = 0.04), PFS (13.8 vs 8.4 months; HR 0.69, p < 0.0001) and ORR (51.4% vs. 25.7%; p <0.0001) irrespective of PD-L1 expression
Tecentriq (atezolizumab) **PD-L1 antibody**	2020 – N/A 2026 – $821m	Avastin (bevacizumab) **VEGFA antibody**	IMmotion151 first-line RCC	Not under regulatory review. Compared to sunitinib monotherapy, the combination showed improvements in mPFS (11.2 vs 7.7 months; HR 0.74; p = 0.02) in PD-L1 +ve patients, which constituted 40% of the intent-to-treat ITT population; mPFS across ITT population was 11.2 vs 8.4 months (HR 0.83; p = 0.02). However, no significant OS benefit was observed.
		Cabometyx (cabozantinib) **VEGFR1/2/3 TKI****	CONTACT-03 second/third-line RCC (PD-(L)1 refactory)	Recruitment ongoing into the Phase III study, with first patient enrolled during Q320 and primary completion expected in December 2022.

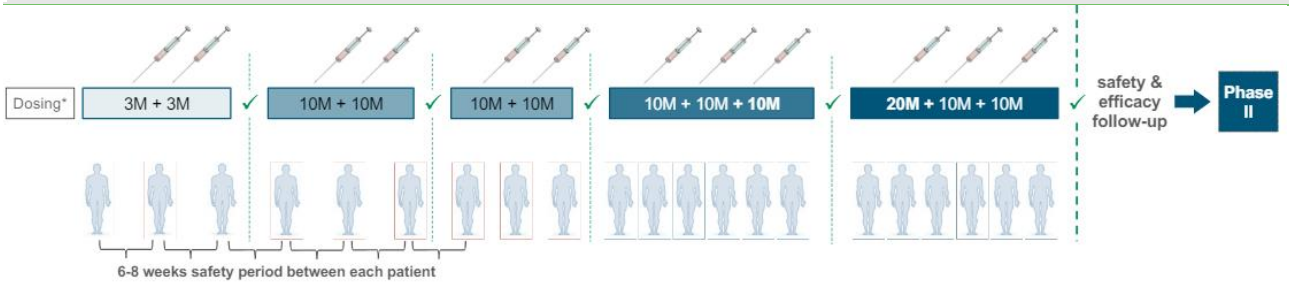
Source: ClinicalTrials.gov, *EvaluatePharma. Note: **Also active against several other receptor tyrosine kinases.

ILIAD: Safety profile good; additional data expected in Q421

The Phase Ib/II ILIAD study is the first trial where Immunicum is combining ilixadencel with Merck KGaA's anti-PD-1 checkpoint inhibitor, Keytruda (pembrolizumab, anti-PD-1), therefore the safety and tolerability data will be of particular interest as they could define the scope in which ilixadencel could be used. Enrolment into the dose escalation part of the trial (Phase Ib) completed in December 2020, with 21 patients enrolled. Immunicum has not provided a breakdown of which tumour types have been enrolled, but the trial can recruit patients with either advanced head and neck cancer (HNSCC), gastric adenocarcinoma (GA) or non-small cell lung cancer (NSCLC). **At the last safety update in July 2021, no dose-limiting toxicities were observed.** Longer-term, follow up safety data and the first assessment of responses to treatment from the Phase Ib portion of the ILIAD study are **expected in Q421**.

Subject to data from the Phase Ib portion of ILIAD being positive, enrolment into the Phase II portion of the study can initiate and enrol up to 150 patients with either HNSCC or GA. During the Phase II portion of the study, ilixadencel will be investigated in combination with Pfizer/Merck's anti-PD-L1 checkpoint inhibitor, Bavencio (avelumab), according to the agreement announced in November 2018. Although the involvement of Merck and Pfizer appears to be limited to supply, we believe it provides a degree of external validation of the technology and rationale behind ilixadencel, as we assume the partners conducted due diligence before committing to supply avelumab.

Exhibit 8: Design of Phase Ib/II ILIAD study



Source: Immunicum

GIST is a rare disease opportunity

The FDA has granted both Fast Track Designation and Orphan Drug Designation to ilixadencel for its potential use in GIST. These were granted based on the results from the Phase I/II open-label, single-arm trial, which evaluated the safety and efficacy of ilixadencel in unresectable or metastatic GIST patients with tumour progression during ongoing second or later lines of treatment with TKI therapy. Patients were treated with two intratumoural doses of ilixadencel in combination with ongoing TKI treatment. Ilixadencel was administered in combination with sunitinib, regorafenib or similar TKI. Immunicum had initially planned to conduct a larger study, but due to the rarity of the disease, enrolment was stopped at six patients. The released top-line results include:

- the primary safety endpoint was met with no life-threatening, treatment-related adverse events; and
- the secondary endpoint exploring initial efficacy was based on tumour growth. In two out of six patients, tumour growth was stopped and partially regressed for three and six months respectively.

GIST is a relatively rare cancer and accounts for less than 1% of all gastrointestinal (GI) tumours, and is therefore a small indication compared to others in Immunicum's R&D pipeline. When diagnosed with GIST, most patients appear to have localised disease so surgery is the mainstay of curative treatment, but 40% of resected tumours recur and spread (Schvartsman et al, 2017). TKIs became standard-of-care chemotherapy, but GIST remains one of the most chemotherapy-resistant solid malignancies. Imatinib is the TKI of choice for first-line treatment, but 50% of patients develop resistance within two years. Other TKIs, sunitinib or regorafenib, were shown to have a benefit in subsequent lines of therapy, but median survival at this stage is typically several months (Feng and Morris, 2014).

The findings in this study showed that two out of six patients had partial regression (patients who received ilixadencel in conjunction with the second or third line of standard TKIs). This could be an indication that ilixadencel helped to overcome resistance to TKIs in these patients but, since the patient sample was small, efficacy claims would need to be investigated in a larger population. As with other trials Immunicum has carried out, the benefit of this study is the fact that ilixadencel will gather data in multiple tumours and more evidence of mechanism of action can be accumulated (eg specific tumour immune response, tumour infiltration).

Sensitivities

Immunicum is subject to typical biotech risks, including the unpredictable outcome of trials, regulatory decisions, the success of competitors, financing and commercial risks. Our model assumes that both DCP-001 and ilixadencel will be out-licensed and therefore our valuation is sensitive to the timing of potential licensing and actual deal terms, although typically the timing of licensing deals is difficult to forecast.

Immunicum has not yet established clinical proof of concept for DCP-001, albeit initial data from ADVANCE-II are promising. Therefore, near-term R&D sensitivities are largely tied to top-line data from the ongoing Phase II in AML expected in Q421. Although Immunicum has established clinical proof of concept for ilixadencel with the Phase II MERECA data, the treatment landscape in RCC has evolved beyond the combinations explored in the study. Therefore, Immunicum will now likely need to replicate proof-of-concept studies for ilixadencel to become attractive to potential partners. This will largely hinge on safety and tolerability data from the Phase Ib ILIAD study expected in Q421.

With the recent capital raise complete, we believe Immunicum has a cash runway for the near term based on its current plans. Further funding will depend on its ambitions to broaden clinical its programmes for the two assets and partner interest, which could alleviate the need for dilutive financing

Valuation

We value Immunicum at SEK1.95n or SEK9.76 per share, based on a risk-adjusted NPV analysis using a 12.5% discount rate, including cash of SEK212m at end-Q221. Following the merger, we have extensively revised our valuation in line with the updated strategy. We include four indications in our valuation model, as discussed in detail above. However, we note that Immunicum has been accumulating data in several other cancers, including hepatocellular cancer (Phase I) and the ongoing ILIAD trial in multiple solid tumours. So, when it comes to the next set of trials, the company will have options. We believe, the late-stage R&D strategy will be finalised after evaluation of the totality of the data, which is when we will review our valuation model.

We use a bottom-up approach to calculate the market sizes and average industry data for the basis of our other assumptions (eg probability of success, eligible patient population and pricing – see Exhibits 9, 10 and 11). We have allocated R&D spend to each of the projects as clinical trial costs to obtain the true rNPV value. We then assume a full out-licensing deal in 2024, with the partner taking over Phase III development and commercialisation. We also separately value other opportunities for Immunicum's DCOne technology (please see page 4 for details) to reflect its broader potential. For that we allocated a portion of benchmarked licensing income and discounted those milestones to present, as described below. The success probabilities in our model are based on historical averages and the amount of data in each indication.

Exhibit 9: Immunicum valuation

Product	Launch	Peak sales* ($m)	NPV (SEKm)	Probability	rNPV (SEKm)	rNPV/share (SEK/share)
DCP-001 – AML	2027	$680m	2,187	15.0%	338	1.69
DCP-001 – ovarian cancer	2031	$760m	1,322	15.0%	342	1.71
Ilixadencel – RCC	2026	$1,000m	2,760	20.0%	560	2.81
Ilixadencel – GIST	2026	$300m	960	15.0%	164	0.82
DCOne other opportunities			1,163	10.0%	331	1.66
Net cash, last reported			212	100.0%	212	1.06
Valuation			**8,604**		**1,947**	**9.76**

Source: Edison Investment Research. Note: *Peak sales rounded to the nearest $10m.

Exhibit 10: Assumptions for valuation

Asset/indication	Comments
Target populations in target geographies*	Note: our principle to calculate target populations is to extrapolate US prevalence data to the selected top 15 western European countries (see notes). This is due to similarity of the population profile, yet very fragmented market in Europe, where reporting of data can vary. **DCP-001**: ■ AML: c 31k patients per year (MRD+ after first-line treatment), 30% peak penetration due to novel indication. ■ Ovarian cancer: c 33k patients per year (high-grade serous OC in first-line maintenance), 30% peak penetration due to novel indication. **Ilixadencel**: ■ RCC: c 140k patients per year, 10% peak penetration due to fragmented market. ■ GIST: c 5k patients per year, 80% peak penetration due to niche market. **DCOne other opportunities valuation** ■ 17% of the deal value is attributed to this technology. Milestones are then spread over a period of 10 years, risk adjusted and discounted to present.
Pricing	■ Pricing: $90k per patient per year in the US, 50% discount in Europe. Peak sales reached in six years. Price is comparable to that of Provenge (dendritic cell vaccine, Dendreon) price tag and higher than Imlygic (oncolytic virus, Amgen), which was guided at launch. Provenge was ultimately not successful as a drug due to complicated logistics and survival benefit similar to chemotherapy. Imlygic was approved on durable response rate endpoint and showed no survival benefit, so a modest clinical effect.
Trial timelines and R&D cost	■ We model a full out-licensing. Partner takes over late-stage development after 2024. Launch dates are in Exhibit 9. R&D spend is assumed around $5m per Phase II trial per year (equates to a total cost of c $15–20m per Phase II trial). After out-licensing, all R&D spend stops and partner takes over the development.
Licensing deal assumptions	■ We assume a deal in 2024 and use the median values of benchmark deals in Exhibit 11. Upfront payment of $250m, $1.4bn in total milestones (one-third allocated to R&D-related payments; the rest are commercial milestones). Tiered 12–15% royalty rates used. Deal values are split proportionally (using peak sales) and allocated to all four projects to get true rNPV per share value.
IP	■ **DCP-001**. The existing patent portfolio provides protection until 2035 and the fact that DCP-001 is a cell therapy means the entry barrier for any generic versions will be high. Our NPV models run well into the 2030s. ■ **Ilixadencel**. The existing patent portfolio provides protection until 2031 and the fact that ilixadencel is a cell therapy means the entry barrier for any generic versions will be high. Our NPV models run well into the 2030s.

Source: Edison Investment Research. Note: *Target countries used in the model are the United States and top 15 European countries (EU4 + the UK, Ireland, Netherlands, Belgium, Luxembourg, Denmark, Finland, Norway, Sweden, Austria and Switzerland).

The partnering strategy is a key element in our rNPV valuation of Immunicum. We note that partnering deals can vary widely from co-development and co-commercialisation to full out-licensing globally or for specific territories. Immunicum's strategy will depend on the strength of the data. The timing of any deal is uncertain, but in our model we assume a global out-licensing deal in 2024.

Theoretically, both DCP-001 and ilixadencel could be evaluated in many different cancer types, so we have used historical licensing deal details for assets for which the deal terms stipulated many potential indications. Based on deals that have occurred since 2015 for Phase III-ready immunoncology assets (Exhibit 11), we assume an upfront payment of c $250m and milestones totalling up to c $1.4bn. We allocate one-third of the milestones to R&D-related payments such as completion of the Phase III trial and NDA approval; the rest are commercial milestones. We assume tiered royalty rates of 12–15% on sales. The deal values are split proportionally (using peak sales) and allocated to all four projects to get a true rNPV per share value.

Furthermore, we also value the DCOne technology separately and allocate 20% of the deal value described above to this technology. Milestones are then spread over a period of 10 years, risk-adjusted and discounted to present. This results in DCOne technology value corresponding to c 17% of the total valuation.

Also worth mentioning is the Vaccibody deal with Genentech/Roche. Vaccibody is a Norwegian biotech, which recently listed on the Oslo Stock Exchange's Merkur Market on 7 October 2020, only a few days after it had signed a licensing and collaboration agreement with Genentech/Roche for $715m, with an impressive $200m upfront. Vaccibody is developing a cancer vaccine technology (which was still in Phase I at that time) using tumour-specific antigens, which is highly personalised for each patient, but the treatment process involves complicated logistics. The approach is different from DCP-001 and ilixadencel in the sense that Immunicum's therapies are off-the-shelf with much more simple logistics and convenience. However, Immunicum's approach is somewhat similar in ilixadencel's case, as it is also expected to prime the anti-cancer immune response with neoantigens using a tumour as a source, which results in a highly specialised response.

Exhibit 11: Phase II oncology deals used as a benchmark

Date	Licensor	Licensee	Product	Pharmacological class/target	Upfront ($m)	Milestones ($m)
04/09/2020	AbbVie	I-Mab	lemzoparlimab (TJC4)	anti-CD47 mAb	200	1,740
27/05/2020	Gilead	Arcus Biosciences	zimberelimab (AB122) domvanalimab (AB154)	anti-PD-1 mAb anti-TIGIT mAb*	175	1,225
05/02/2019	GSK	Merck KGaA	bintrafusp alfa (M7824)	TGF-βxPD-L1 bsAb	354	4,012
05/07/2017	Celgene	BeiGene	tislelizumab (BGB-A317)	anti-PD-1 mAb	263	980
10/02/2017	Seattle Genetics	Immunomedics	sacituzumab govitecan (Trodelvy)	TROP2 ADC	250	1,700
15/10/2015	BMS	Five Prime	Cabiralizumab (FPA008)	CSF-1R mAb	350	1,390
24/04/2015	AstraZeneca	Innate	Monalizumab (IPH2201)	anti-NKG2A mAb	250	1,025
Median					c 250	c 1,390

Source: Edison Investment Research, EvaluatePharma. Note: *Gilead/Arcus deal includes options for additional assets not listed.

Financials

The merger of Immunicum and DCprime completed on 21 December 2020. For accounting purposes, the transaction was deemed a reverse acquisition. For this reason, the accounts before the merger include only the financial results of DCprime (until 21 December 2021) and are combined thereafter. This means that the financial results for FY20 include DCprime for the entire financial year and Immunicum's results for the last 10 days of 2020. The reported results for FY21 and our estimates include the consolidated group. Following the merger, Immunicum has SEK532m booked as intangible assets as at end-Q121.

Immunicum reports no income, while the H121 operating spend was SEK72.1m (comparison with the previous period is not relevant). It had cash of SEK211m at the end of H121. In June 2021, Immunicum carried out a direct share issue raising SEK141m gross. Van Herk, the majority owner of DCprime and the largest shareholder of Immunicum after the merger (43%), supported the share issue subscription pro rata.

Immunicum does not provide guidance, but we model operating spending of SEK134m and SEK133m in 2021 and 2022. This implies that existing funds are sufficient until the end of 2022. According to Edison principles, instead of share issues for our financial forecasts we use illustrative long-term debt, which currently stands at SEK125m in 2023 (assumes stable R&D costs).

Exhibit 12: Financial summary

Accounts: IFRS, year-end: December, SEK000s	2019	2020	2021e	2022e
PROFIT & LOSS				
Total revenues	0	0	0	0
Cost of sales	0	0	0	0
Gross profit	0	0	0	0
SG&A (expenses)	(11,734)	(37,193)	(41,376)	(42,617)
R&D costs	(48,980)	(47,883)	(92,256)	(90,000)
Other income/(expense)	16,689	(64)	(1,000)	(500)
Exceptionals and adjustments	0	0	0	0
Reported EBITDA	(44,025)	(85,140)	(134,632)	(133,117)
Depreciation and amortisation	(831)	(887)	0	0
Reported Operating Profit/(loss)	(44,856)	(86,027)	(134,632)	(133,117)
Finance income/(expense)	(2,915)	(3,220)	(3,151)	(3,220)
Other income/(expense)	0	(1)	0	0
Exceptionals and adjustments	0	0	0	0
Reported PBT	(47,771)	(89,248)	(137,783)	(136,337)
Income tax expense	0	0	0	0
Reported net income	(47,771)	(89,248)	(137,783)	(136,337)
Basic average number of shares, m	73.9	76.2	182.8	199.4
Basic EPS (SEK)	(0.65)	(1.17)	(0.75)	(0.68)
Diluted EPS (SEK)	(0.65)	(1.17)	(0.75)	(0.68)
BALANCE SHEET				
Property, plant and equipment	4,328	2,909	2,909	2,909
Intangible assets	0	424,091	424,091	424,091
Other non-current assets	442	678	678	678
Total non-current assets	4,770	536,028	536,028	536,028
Cash and equivalents	14,032	167,643	146,660	10,323
Trade and other receivables	0	0	0	0
Other current assets	18,695	20,230	20,230	20,230
Total current assets	33,150	192,633	171,650	35,313
Non-current loans and borrowings*	31,062	18,982	33,861	33,861
Total non-current liabilities	32,292	19,285	34,164	34,164
Trade and other payables	1,898	10,365	8,824	8,824
Other current liabilities	8,537	22,158	11,357	11,357
Total current liabilities	11,306	48,282	21,061	21,061
Equity attributable to company	(5,677)	661,094	652,453	516,116
CASH FLOW				
Operating Profit/(loss)	(44,856)	(86,027)	(134,632)	(133,117)
Depreciation and amortisation	831	887	0	0
Other adjustments	0	0	0	0
Movements in working capital	(14,186)	27,731	(12,342)	0
Interest paid/received	(166)	(103)	(3,151)	(3,220)
Income taxes paid	0	0	0	0
Cash from operations (CFO)	(57,569)	(56,626)	(150,125)	(136,337)
Capex	(809)	(464)	0	0
Acquisitions & disposals net	0	0	0	0
Other investing activities	0	0	0	0
Cash used in investing activities (CFIA)	(809)	157,298	0	0
Net proceeds from issue of shares	0	0	129,142	0
Movements in debt*	(760)	(725)	0	0
Other financing activities	67,818	51,629	0	0
Cash flow from financing activities	67,058	50,904	129,142	0
Increase/(decrease) in cash and equivalents	9,627	153,611	(20,983)	(136,337)
Cash and equivalents at beginning of period	4,405	14,032	167,643	146,660
Cash and equivalents at end of period	14,032	167,643	146,660	10,323
Net (debt)/cash	(17,030)	133,782	112,799	(23,538)

Source: Immunicum accounts, Edison Investment Research. Notes: *Of this amount, SEK10.2m in 2022 is long-term debt used instead of equity issue, according to Edison's principle.

Contact details	Revenue by geography
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Management team

Chief executive officer: Erik Manting	Chief scientific officer: Alex Karlsson-Parra
Erik Manting holds an MSc in Medical Biology and a PhD in Molecular Microbiology. For a number of years, he worked as a post-doctoral researcher in the field of immunology before making a career switch to banking in 2001. He spent the next 15 years in different commercial and management roles and his last five years in banking as executive director of corporate finance at Kempen & Co. He was CEO of DCprime until the merger with Immunicum in December 2020 and became Immunicum's CEO in March 2021.	Adjunct Professor Karlsson-Parra has over 20 years' experience working in the field of transplantation immunology and is former chairman of the Swedish Expert Group for Clinical Immunology. He was awarded the Athena Prize, Swedish healthcare's most prestigious award for clinical research, in 2014. He was formerly associate professor and chief physician at the Department of Clinical Immunology at Sahlgrenska University Hospital, Gothenburg.
Chief medical officer: Jeroen Rovers	
Jeroen Rovers trained as a pharmaceutical physician at the European Center of Pharmaceutical Medicine in Basel. Over the past 20 years, he has worked in different academic institutes and companies, such as Wyeth and Organon and most recently at Kiadis Pharma where he held the role of chief medical officer (CMO). Most of the products he worked on are related to oncology, haematology and transplantation. Dr Rovers joined DCprime as CMO at the end of 2018.	

Principal shareholders (30 June 2021)	(%)
Adrianus Van Herk	43.8
Fourth Swedish National Pension Fund	9.7
Avanza Pension	4.8
Nordnet Pension Insurance	3.3
Loggen Invest	1.6
Holger Blomstrand Byggnads	1.5

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