EDISON

Immunicum

Company update

Potentially transformational merger

Pharma & biotech

On 18 November, Immunicum announced that it had agreed to acquire biotech company DCprime by issuing 73.9k new shares or 44% of the enlarged capital. Based in the Netherlands, the privately owned biotech is developing a novel class of allogeneic dendritic cell-based cancer vaccines. The most advanced programme is in AML (Phase II) with interim data presented at the ASH conference on 5–8 December. Immunicum held an Investor event on 8 December, while the EGM will be held on 18 December. Our valuation and estimates are under review and we will revise our model once the merger is complete.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/18	0.0	(97.9)	(1.90)	0.0	N/A	N/A
12/19	0.0	(134.0)	(1.49)	0.0	N/A	N/A
12/20e	N/A	N/A	N/A	N/A	N/A	N/A
12/21e	N/A	N/A	N/A	N/A	N/A	N/A

Note: *PBT and EPS are reported.

Complementary assets and business synergies

With both ilixadencel and DCP-001 now under the same roof, Immunicum has two allogeneic dendritic cell-based cancer vaccinations for intradermal and intratumoural administrations and can target both solid tumours and haematological 'liquid' malignancies. The positioning is also different. 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. The newly combined company will maintain its corporate headquarters in Stockholm, Sweden, with additional R&D activities in Leiden, the Netherlands.

Acquisition follows strategy update in September

Following his appointment as CEO in August, Sven Rohmann updated the company's strategy in September. GIST and sarcoma-type cancers were highlighted as proven indications that do not require a partner to reach the market (Immunicum has Phase I data with ilixadencel) and orphan disease opportunities that could shorten ilixadencel's path to the market. The Phase Ib/II ILIAD trial, a multi-indication study with ilixadencel in combination with checkpoint inhibitors (CPIs), is moving towards completion of Phase Ib after no dose-limiting toxicities were seen in the staggered phase. In renal cell carcinoma Immunicum will pursue ilixadencel in a triple combination with PD1 and CTLA4 CPIs.

Valuation: Under review pending merger completion

Since DCprime is a private company with limited information available, we believe it will take time for the share price to reflect the potential of DCP-001. Our valuation is under review (last published on 3 September at SEK2.27bn or SEK24.6/share) and we will evaluate DCP-001's potential when the merged company releases its joint business and development plan during Q121. Immunicum guided that the combined entity has cash reach until 2022, while DCprime's shareholder Van Herk Investments intends to invest up to SEK82.5m in the combined company.

16 December 2020

Price	**SEK7.92**
Market cap	**SEK731m**

Last reported net cash (SEKm) at Q320	197.6
Shares in issue	92.3m
Free float	90%
Code	IMMU
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(5.0)	(25.4)	(24.1)
Rel (local)	(6.6)	(29.3)	(33.1)

52-week high/low	SEK12.12	SEK6.61

Business description

Immunicum is a clinical-stage immunoncology company based in Stockholm, Sweden. It is developing an allogeneic off-the-shelf dendritic cell immune activator or immune primer, ilixadencel, for use in combination with checkpoint inhibitors and other anti-cancer therapies in potentially any solid tumour indications accessible via direct injection.

Next events

EGM	18 December 2020
Multi-indication Phase Ib (ILIAD) next safety data	H121
RCC Phase II (MERECA) next update	Q121

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Edison profile page

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Interim ADVANCE-II data in AML at ASH

Using its platform, DCprime was able to transform proprietary allogeneic leukaemia cells (DCOne line) into dendritic cell (DC) phenotype. Because these DCs are derived from leukemic progenitors, they contain multiple antigens making them highly immunogenic in combination with their inflammatory profile and dendritic cell phenotype. DCP-001 is administered intradermally.

DCprime presented Phase II ADVANCE-II data for its lead asset DCP-001 at the ASH 2020 annual conference (5–8 December). ADVANCE-II is an ongoing, open-label Phase II trial investigating DCP-001 as a potential relapse vaccination in acute myeloid leukaemia (AML) patients who are in their **first complete remission but still have measurable residual disease** (MRD).

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 last few years, several new therapies have been approved, so the treatment paradigm is likely to change. However, having reviewed the emerging treatment options (see below), we find that the survival benefit of the new therapies is limited, especially in elderly patients, so the unmet need in AML is likely to persist.

Given the high relapse rate in AML, the scope of the ADVANCE-II study is to see whether remissions can be lengthened with DCP-001. Interim results included data from the ten patients in the first, lower dose cohort. Five patients in the higher dose cohort have started, but not completed the vaccination schedule. 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 also highlight that DCP-001 induced an immune response to tumour-associated antigens (TAAs) relevant to AML. Top-line efficacy data are expected in Q421 and will include data from the second, higher dose cohort.

AML: Changing treatment paradigm, but still an unmet need

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 nearly 40,000 patients in the EU and 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 which 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 $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. In the Phase III trial, treatment with

gilteritinib resulted in complete remissions (CRs), or CRs with partial haematologic recovery in 21% of patients (95% CI 14.5%–28.8%). Consensus forecasts Xospata sales of $775m in 2026.

Outside 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.

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 $405m in 2026); and
- IDH1/IDH2 inhibitors ivosidenib in July 2018 (Tibsovo, Agios Pharmaceuticals; consensus AML sales forecast of $763m in 2026) and enasidenib in August 2017 (Idhifa, BMS/Celgene; consensus AML sales forecast of $257m 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 three or four years, so the clinical treatment paradigm and guidelines are still in the development stage, which makes it an interesting indication to follow. The ongoing ADVANCE-II trial investigates DCP-001 as a potential relapse vaccination in AML patients who are in their first complete remission but still have MRD. EvaluatePharma calculates the total market value of AML drugs at $910m in 2020, which is forecast to grow to $10.1bn in 2026.

Additional transaction details; EGM on 18 December

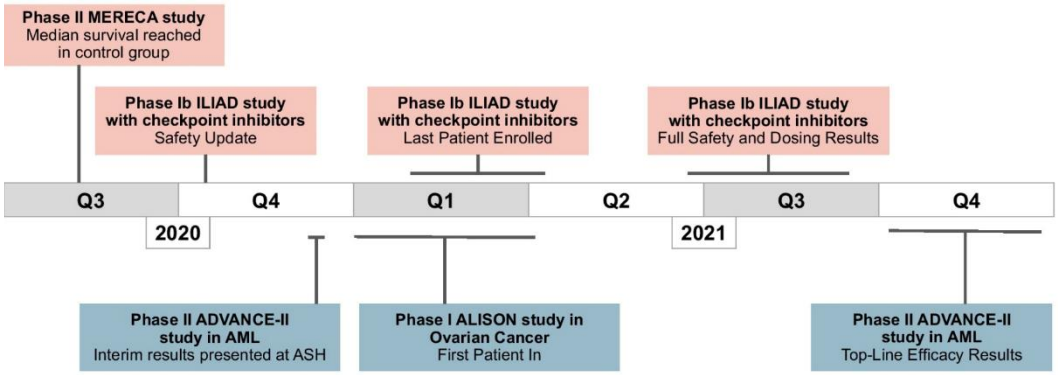
Erik Manting, the current CEO of DCprime, will become chief business officer and deputy CEO of the combined company. Mr Manting, PhD, is a seasoned pharma and biotech executive with several years of research experience in immunology and 15 years' experience in commercial and management roles in banking. We note that as the acquisition was initiated during the ongoing pandemic, it indicates a keen interest by both companies in working together and a smooth transition, in our view.

DCprime's current majority shareholder, Van Herk Investments, will own 43% of the combined company. Van Herk Investments is a European life science investor founded in Rotterdam in 1951 (invested in Zealand Pharma, Ablynx, Crucell and Galapagos among others). Van Herk Investments and Immunicum's largest shareholder Fourth Swedish National Pension Fund (AP4) have expressed their support for the merger. The EGM is scheduled on 18 December 2020. Closure of the transaction is expected to take place at the end of December 2020.

Immunicum indicated that the funds that would be available for the combined company should finance operations into 2022. If the merger is approved, Van Herk Investments intends to invest up to SEK82.5m in the company. Furthermore, Immunicum will ask the EGM to approve a mandate for the board of directors to issue shares up to 20% of the total outstanding amount. Cash reach including these additional funds will depend on R&D activities post-merger.

Following completion of the transaction, the immediate plan for the combined company will be the expansion into haematological malignancies and enriched clinical catalysts in the near term (Exhibit 1).

Exhibit 1: Expected clinical timelines from merged entity



Source: Company presentation

Exhibit 2: Financial summary

SEK'000s	2018	2019	2020e	2021e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT				
Revenue	0	0	N/A	N/A
Operating expenses	(98,029)	(133,213)	N/A	N/A
Depreciation	(5)	N/A	N/A	N/A
Operating income	184	893	N/A	N/A
Reported operating profit	(97,845)	(132,325)	N/A	N/A
Net Interest	(15)	N/A	N/A	N/A
Profit before tax (reported)	(97,860)	(134,016)	N/A	N/A
Reported tax	0	N/A	N/A	N/A
Profit after tax (reported)	(97,860)	(134,016)	N/A	N/A
Minority interests	0	0	N/A	N/A
Net income (reported)	(97,860)	(134,016)	N/A	N/A
Basic average number of shares outstanding	51,387	51,387	N/A	N/A
EPS - basic reported (SEK)	(1.90)	(1.49)	N/A	N/A
BALANCE SHEET		N/A	N/A	N/A
Non-current Assets	10	N/A	N/A	N/A
Property Plant and equipment, net	9	9	N/A	N/A
Other financial assets	1	N/A	N/A	N/A
Other non-current Assets	0	N/A	N/A	N/A
Current Assets	450,362	N/A	N/A	N/A
Cash and cash equivalents	443,798	296,811	N/A	N/A
Accounts receivable	3,307	2,983	N/A	N/A
Marketable securities and short-term investments	0	0	N/A	N/A
Prepaid expenses	3,257	3,783	N/A	N/A
Current Liabilities	43,482	30,199	N/A	N/A
Accounts payable	31,266	12,819	N/A	N/A
Accrued other liabilities	11,378	15,736	N/A	N/A
Other current liabilities	838	1,644	N/A	N/A
Non-current Liabilities	850	850	N/A	N/A
Long term debt	850	850	N/A	N/A
Equity	406,041	N/A	N/A	N/A
CASH FLOW		N/A	N/A	N/A
Cash Flow from Operations			N/A	N/A
EBIT (Operating profit)	(97,845)	(132,325)	N/A	N/A
Depreciation	58	N/A	N/A	N/A
Income Tax paid	0	0	N/A	N/A
Other Working Capital changes	(6,867)	(13,485)	N/A	N/A
Cash interest paid	(14)	N/A	N/A	N/A
Cash interest received	0	N/A	N/A	N/A
Net cash used in Operating activities	(104,668)	(145,808)	N/A	N/A
Cash Flow from Investing		N/A	N/A	N/A
Purchase of fixed assets	0	N/A	N/A	N/A
Sale of Investments		N/A	N/A	N/A
Net cash used in investing activities	0	(251)	N/A	N/A
Cash Flow from Financing			N/A	N/A
Change in Capital Stock	419,584	756	N/A	N/A
Net cash from Financing activities	419,584	756	N/A	N/A
Net Changes in Cash and Cash Equivalent	314,916	(145,303)	N/A	N/A
Cash and Cash Equivalents - Beginning	128,883	443,799	N/A	N/A
Cash and Cash Equivalents - End	443,799	296,812	N/A	N/A
Net cash/(debt)	442,948	295,961	N/A	N/A

Source: Immunicum accounts, Edison Investment Research

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