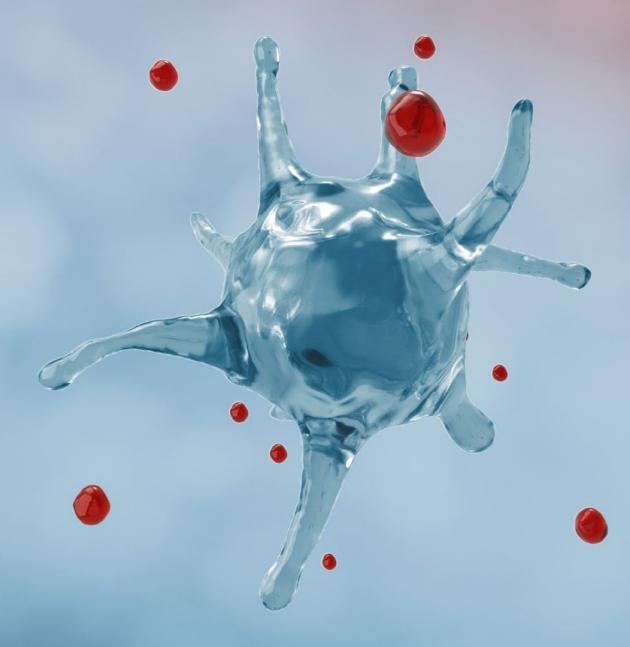


# Interim report January - June





## Interim Report Q2 2020

## April – June in Summary

- » Net sales for the period amounted to KSEK (-).
- » Result for the period amounted to KSEK -26,412 (-33,220).
- » Earnings and diluted earnings per share totaled SEK -0.29 (-0.36).
- » Immunicum received Regenerative Medicine Advanced Therapy (RMAT) Designation from the FDA for Ilixadencel in kidney cancer.
- » Immunicum appointed Peter Hein as interim Chief Financial Officer.
- » Immunicum announced advancement to a nonstaggered inclusion phase in the Phase Ib/II ILIAD combination trial.
- » Immunicum announced publication of Phase I/II clinical trial results of ilixadencel in Gastrointestinal Stromal Tumors (GIST) in Cancer Immunology, Immunotherapy.

### Covid-19

» To date, Immunicum has not experienced any major impact to its operations as a result of the COVID-19 pandemic but it is a risk that the recruitment of patients to the ongoing ILIAD trial will be delayed since it's currently not possible to include additional sites in the study. For further information, go to the risk section on page 17.

## Significant Events after End of Period

» Immunicum announced an update on survival data from the Phase II MERECA trial of ilixadencel in kidney cancer. August 2020 data showed that the median Overall Survival (OS) was reached at 25 months in the control group treated with sunitinib, while the final median OS in the ilixadencel treatment group has not yet been reached.

## Financial information in summary

Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Full year
2020	2019	2020	2019	2019
-25,152	-33,211	-59,021	-62,349	-132,324
-26,412	-33,220	-58,124	-62,360	-134,016
-0.29	-0.36	-0.63	-0.68	-1.46
232,176	363,406	232,176	363,406	296,811
214,646	344,437	214,646	344,437	272,781
11	11	11	11	11
	<b>2020</b> -25,152 -26,412 -0.29 232,176 214,646	2020         2019           -25,152         -33,211           -26,412         -33,220           -0.29         -0.36           232,176         363,406           214,646         344,437	2020         2019         2020           -25,152         -33,211         -59,021           -26,412         -33,220         -58,124           -0.29         -0.36         -0.63           232,176         363,406         232,176           214,646         344,437         214,646	2020201920202019-25,152-33,211-59,021-62,349-26,412-33,220-58,124-62,360-0.29-0.36-0.63-0.68232,176363,406232,176363,406214,646344,437214,646344,437

# **CEO comment**

## Second quarter

» **Our efforts during** the second quarter of 2020 have been focused on key regulatory interactions, the continuation of the ongoing Phase Ib/II ILIAD combination trial, as well as strategic preparations to advance our off-the-shelf immune primer, ilixadencel.

First and foremost, receiving the Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA) for ilixadencel in kidney cancer was an important milestone for the Company. The FDA's decision was based on the previously communicated results from the Phase II MERECA clinical trial that evaluated the safety and efficacy of ilixadencel in combination with Sutent<sup>®</sup> (sunitinib) in patients with newly diagnosed metastatic renal cell carcinoma (mRCC). As such, receiving the RMAT designation recognizes both the potential of our novel therapeutic approach as well as the clear need for viable therapies to address this difficult-to treat disease.

Furthermore, one of the most important benefits of the designation is that we gain access to an increased number of interactions with the FDA and meetings earlier in the process, which can speed up drug development and review. In addition the RMAT status allows us to ensure at an earlier stage that ilixadencel meets the FDA's standard, which reduces the risks in the development program. In doing so, the RMAT also strengthens the chances of final market approval. Importantly, the FDA has confirmed that the RMAT designation is not limited to the combination of ilixadencel with sunitinib, but supports the development of ilixadencel in kidney cancer more broadly.

We recently announced an update on survival from the MERECA trial. The new set of data confirmed that the final median Overall Survival (OS) for the sunitinib control group had been reached at 25.3 months. Meanwhile, the median OS has not yet been reached in the ilixadencel treatment group, indicating a survival benefit in the study's co-primary endpoint. In addition, all five Complete Responders (CRs) in the ilixadencel treatment group were still alive in this follow-up, while the one CR in the control group died during the first follow-up period. The next follow-up on survival data will be announced during the first quarter of 2021. With each round of followup, we have the opportunity to gain additional insight on the potential efficacy of ilixadencel in combination with standard-of-care in patients with metastatic tumors, which enables us to better determine the next set of priorities and objectives for our lead candidate.

During the first half of the year we also provided an update on the ongoing Phase Ib/II ILIAD combination trial evaluating ilixadencel in combination with the checkpoint inhibitor (CPI), Keytruda<sup>®</sup> (pembrolizumab). Based on the confirmation from the Dose Escalation Committee, there were no dose-limiting toxicities, therefore the study can move into the nonstaggered inclusion phase. The Phase Ib portion of the trial includes 21 patients and the non-staggered phase will enable the remaining 15 patients to proceed more rapidly as there will no longer be a need for a safety evaluation period between every individual patient enrolled. However, our ability to further accelerate enrollment with additional clinical centers may be impacted by the Covid-19 pandemic. Based on this, we expect the next safety update by the end of this year and the completion of the Phase Ib including longer follow-up for potential signs of efficacy towards the second half of 2021.

In June 2020, the scientific journal *Cancer Immunology, Immunotherapy* published the final data analysis from the clinical study of ilixadencel in patients with Gastrointestinal Stromal Tumors (GIST) providing further validation of ilixadencel. GIST is a rare and difficult-to-treat disease



and the trial showed that ilixadencel in combination with different tyrosine kinase inhibitors (TKIs) had a favorable safety profile and provided initial signals of clinical benefit, with two out of six patients showing tumor shrinkage despite previous tumor progression on the same TKI.

During the second quarter of this year, we welcomed Peter Hein to the team as Interim CFO. Peter's background in life science and finance has facilitated a smooth transition for the Company and we look forward to continuing to work with him. As the Phase II MERECA data continue to mature and bring insight into the potential longterm survival benefits of ilixadencel in combination with Sutent<sup>®</sup>, our advancements in terms of regulatory feedback and RMAT designation can now also be presented to industry leaders.

Financially we stand on solid ground. Our cash position on June 30 was SEK 232 million and with our current financial commitments, this is sufficient to finance the Company until the end of 2021.

In summary, we have reached significant milestones in 2020 that build long-term value for the Company and our shareholders. Immunicum remains well-positioned to continue validating and advancing ilixadencel with the ultimate goal of benefiting patients with difficult-totreat solid tumors.

ALEX KARLSSON-PARRA Interim CEO

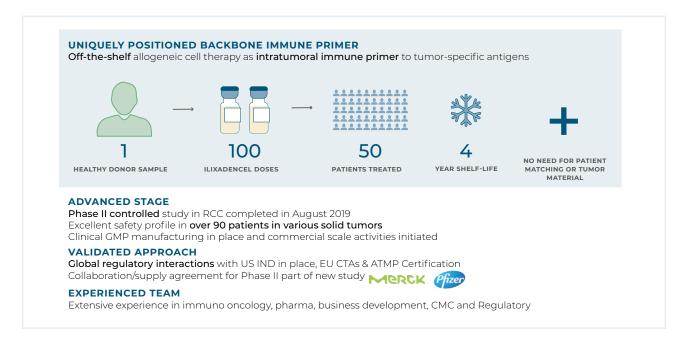
## Introduction to Immunicum

» Immunicum is a biopharmaceutical company that develops immune therapies against a range of solid tumors. The Company is establishing a unique immunooncology approach through the development of allogeneic, off-the-shelf cellbased therapies. Our goal is to improve survival outcomes and quality of life by priming the patient's own immune system to fight cancer. Founded and based in Sweden, Immunicum is publicly traded on Nasdaq Stockholm Small Cap.

#### Ilixadencel - an immune primer

The Company's lead product ilixadencel, consisting of pro-inflammatory allogeneic dendritic cells, has the potential to become a backbone component of modern cancer combination treatments in a variety of solid tumor indications.

Ilixadencel has been developed to be able to take advantage of each patient's unique profile of tumorspecific antigens by injecting ilixadencel directly into the tumor. This approach thereby eliminates the need to characterize, select and produce each patient ´s tumorspecific antigens before treatment. Immunicum has evaluated ilixadencel in several clinical trials including the recently completed exploratory Phase II study MERECA in RCC. The company is currently conducting a multi-indication Phase Ib/II study (ILIAD) in combination with checkpoint inhibitors; in non-small cell lung cancer, head and neck cancer and gastric cancer, among others. The important information that Immunicum have and will receive from these studies, together with continuously ongoing analysis of the cancer treatment landscape, will continue to shape the development plan for ilixadencel.



#### Business and strategy

## Position ilixadencel as the first choice of cancer immune primers

Immunicum's strategy is to position ilixadencel as the first choice of cancer immune primers that are to be combined with treatments that fight immune suppression, e.g. checkpoint inhibitors and certain tyrosine kinase inhibitors. This enables the patient to have a stronger immune response with a more effective and durable anti-tumor treatment.

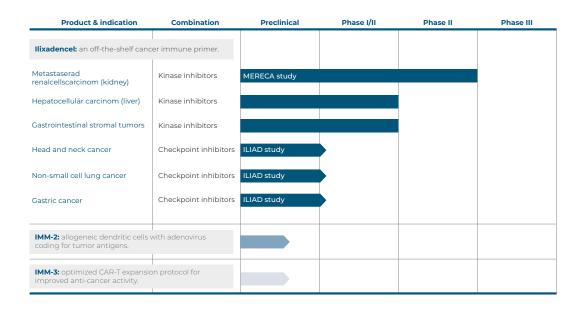
The Company develops these immune therapies primarily by conducting a number of clinical trials to establish the

product candidate's therapeutic potential and safety and demonstrate synergy in combination with other drugs.

#### Build value based on clinical validation

The focus is to generate attractive clinical and pre-clinical data on its programs, to build value and to provide the broadest range of corporate development opportunities to further develop, co-develop or partner with major pharmaceutical and/or biotech companies to ultimately deliver the product candidates to the market as efficiently as possible to provide better cancer therapy and build long term shareholder value.

## **Product portfolio**



## Ongoing study

#### Study in Head and neck cancer (HNSCC), non-small cell lung cancer (NSCLC) and gastric cancer (GA) Phase Ib/II ILIAD

The ILIAD study is a multi-indication, open-label, randomized multicenter, Phase Ib/II trial that evaluates the safety and efficacy of intratumorally administered ilixadencel in combination with a checkpoint inhibitor (anti-PD-1/L1) at standard doses in the selected indications. The Phase Ib part of the study is ongoing in the US and includes patients who are candidates for pembrolizumab therapy in its approved label by the FDA, which includes, among others, the tumor types head and neck squamous cell carcinoma, non-small cell lung cancer and gastric and gastrooesophageal junction adenocarcinoma. The first patient was treated in February 2019. During this part ilixadencel will be combined with the anti-PD-1 antibody Keytruda® (pembrolizumab).

#### The purpose of the multi-indication trial is three-fold:

- » to demonstrate clinical safety of the combination: by showing that ilixadencel can be safely combined with a checkpoint inhibitor.
- » to demonstrate the proof of mechanism: by showing that ilixadencel generates a systemic tumor-specific immune response.
- » to demonstrate improved clinical efficacy: by showing improved benefit of the combo in terms of clinical activity compared to checkpoint inhibitor alone in solid tumor patients.

In the Phase Ib part of the trial, 21 patients will be enrolled with the aim to assess safety and define the optimal dose and schedule of ilixadencel administration in combination with Keytruda<sup>®</sup> (pembrolizumab). In terms of dosing, three patients have received two intratumoral doses of 3 million cells, and another three patients received doses of 10 million cells. The Dose Escalation Committee (DEC) confirmed there were no dose limiting toxicities, therefore the study has received green light to move into the nonstaggered dosing phase where another three patients will receive two doses of 10 million cells, six patients three doses of 10 million cells and the last six patients will receive one dose of 20 million cells followed by two doses of 10 million cells. The Phase II part of the ILIAD trial will then continue with the selected dose regimen from the Phase Ib.

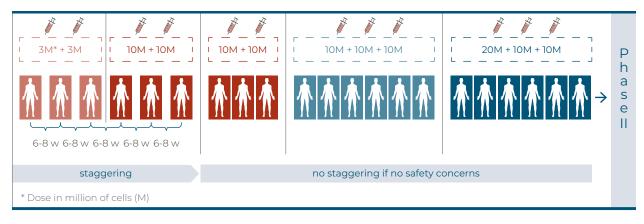
The Phase II part of the trial will group patients by indication (HNSCC, NSCLC and GA) into three studies advancing in parallel. The aim of the Phase II study is to demonstrate a favorable impact of ilixadencel used in combination with checkpoint inhibitor therapy. Each indication group will include enough patients to observe statistically significant clinical activity for the combination group against predetermined efficacy criteria.

The design of the Phase Ib component is shown on the next page.

## Collaboration and supply agreement with Merck KGaA and Pfizer

Immunicum has a collaboration with Merck KGaA and Pfizer for the evaluation of ilixadencel in combination with the anti-PD-L1 checkpoint inhibitor avelumab (Bavencio®) in the Phase II portion of ILIAD.

The safety and efficacy of ilixadencel in combination with avelumab will be evaluated in patients with head and neck cancer and gastric cancer. Immunicum will be fully responsible for the study and retains all commercial rights to ilixadencel.



## **Completed studies**

#### Study in kidney cancer (RCC)

MERECA is a Phase II clinical trial in newly diagnosed, intermediate and poor risk metastatic renal cell carcinoma (RCC) patients were enrolled. Based on a 2-to-1 randomization, patients received either two intratumoral doses of ilixadencel before nephrectomy (kidney removal) and subsequent treatment with sunitinib or sunitinib therapy alone post-nephrectomy. The primary objectives were to evaluate median OS and 18-month survival rates. Secondary objectives include evaluation of safety and tolerability, tumor response and immunological profiling including T cell infiltration. Survival as of August 2020 (30-months) was 43 % (24 of 56) in the ilixadencel treatment group compared with 33 % (10 of 30) of patients in the control group treated with sunitinib monotherapy. The confirmed overall response rate for the ilixadencel treatment group was 42.2 % (19/45) versus 24.0 % (6/25) for the sunitinib control group. The overall safety and tolerability data was similar in both treatment groups, meaning that the addition of ilixadencel to sunitinib did not add toxicity. The next survival update from the study will be communicated during the first quarter 2021.

The results from the MERECA study reinforces the Company's view that ilixadencel has the potential to become part of the treatment paradigm in the future. Immunicum is currently assessing how to continue the clinical development of ilixadencel in RCC and other solid tumors in the most optimal way to offer patients better treatment options.

#### Overview of Immunicum's studies in kidney cancer

INDICATION	KIDNEY CAN	CER/RENAL CELL CARCINOMA
PHASE	I/II	II
NUMBER OF PATIENTS	12	88
		(of which 30 in the control group)
LOCATION	Uppsala University Hospital	Europe (23 sites), The US (5 sites)
NUMBER OF ILIXADENCEL DOSES	2 (5, 10 and 20 million immune cells per dose)	2 (10 million immune cells per dose)
COMBINATION TREATMENT	None, but half of the patients received add-on treatment with either sunitinib or pazopanib afterwards	In sequence: first ilixadencel before nephrectomy, then sunitinib after nephrectomy
TOP-LINE RESULTS	H1 2014 (Completed)	Q3 2019
SUMMARIZED DATA	» Median survival for the whole patient group of 48 months (as of May 2017) which compares favourable with historical controls.	The confirmed ORR for the ilixadencel treatment group was 42.2 % (19/45) versus 24.0 % (6/25) for the sunitinib control group. Higher number of complete responders in the ilixadencel combination group compared to the sunitinib monotherapy group. No difference in survival in the 18-months survival rate, median Overall Survival (OS) was reached at 25 months in the control group treated with sunitinib, while the final median OS value in the ilixadencel treatment group has not yet been reached At the most recent survival follow-up of August 2020, 43 % in the ilixadencel treatment group was still alive, compared to 33 % of patients in the control group treated with sunitinib monotherapy.

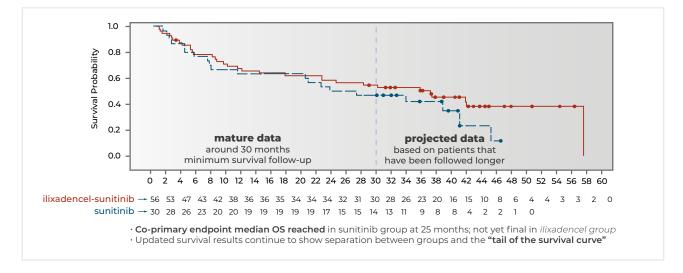
#### Tumor response

llixadencel+sunitinib	Sunitinib
<b>44 %</b> (n=20/45)	<b>48 %</b> (n=12/25)
l1 %* (n=5/45)	4 % (n=1/25)
33 % (n=15/45)	44 % (n=11/25)
<b>42 %</b> (n=19/45)	<b>24</b> % (n=6/25)
7 % (n=3/45)	0 % (n=0/25)
36 % (n=16/45)	24 % (n=6/25)
	<b>44 %</b> (n=20/45) 11 %* (n=5/45) 33 % (n=15/45) <b>42 %</b> (n=19/45) 7 % (n=3/45)

\* Two pts with CR had CR as best response at last available CT scan (at 10 mo and 18 mo respectively)

ORR: objective response rate, proportion of patients with Complete Responses (CR) or Partial Responses (PR)

#### Phase II MERECA: Kaplan-Meier survival probability



#### Studies in gastrointestinal cancer (GIST)

Immunicum completed a Phase I/II clinical trial with ilixadencel in combination with different standard of care TKIs in GIST patients in June 2019. A total of six patients were enrolled. Ilixadencel met the primary endpoint of safety, with no life-threatening treatment-related adverse events and no signs of autoimmunity. Two patients had stable disease (by RECIST 1.1) as best response; one of these patients (on third line regorafenib) progressed at 9 months and the other (a patient on second line sunitinib) showed continued stable disease at end of study (12 months).

Taken together, these data indicate that ilixadencel had a therapeutic impact by overcoming resistance to TKIs in GIST patients with metastatic disease whose disease previously progressed on the same TKI treatment.

#### Overview of Immunicum's study in gastrointestinal cancer and liver cancer

INDICATION	GASTROINTESTINAL STROMAL TUMORS	LIVER CANCER/ HEPATOCELLULAR CARCINOMA
PHASE	1/11	I/II
NUMBER OF PATIENTS	6	18
		(10 first-line, 7 second-line; 1 bile duct cancer)
LOCATION	Karolinska University Hospital, Stockholm	Sahlgrenska University Hospital, Gothenburg
NUMBER OF ILIXADENCEL DOSES	2 (10 million immune cells per dose)	3 (10 and 20 million immune cells per dose)
COMBINATION TREATMENT	Sunitinib, regorafenib or similar TKI	First 12 patients: no combination. Last 6 patients: sorafenib concomitantly
TOP-LINE RESULTS	<b>Q2 2019</b> (Completed)	<b>Q3 2017</b> (Completed)
SUMMARIZED DATA	Ilixadencel met the primary endpoint of safety, with no life-threatening treatment-related adverse events and no signs of autoimmunity. In two patients tumor growth halted and partially regressed for three and six months, respectively.	<ul> <li>Only 1 out of 18 patients experienced grade 3 treatment-related adverse event, as compared to approx. 1 in 3 patients described in literature for standard of care sorafenib or regorafenib</li> <li>11 out of 15 evaluable patients exhibit an increase in, tumor-specific CD8 T-cell in peripheral blood. In the subgroup consisting of 7 patients who received ilixadencel as monotherapy after progression on sorafenib the median OS was 10.9 months which promising compared to historical data</li> </ul>

#### Studies in liver cancer (HCC)

In 2017, Immunicum announced results from an open-label, Phase I/II trial in which 18 patients with advanced liver cancer were enrolled. The primary objective was to investigate safety and tolerability for ilixadencel in HCC as a second line therapy for patients not responding to previous treatments, or first line therapy administered with or without sorafenib.

The data confirm previously communicated positive safety and tolerability of ilixadencel when administered both alone and in combination with current first-line standard of care, sorafenib.

Overall, one patient had a partial response (with ilixadencel as monotherapy) and five had stable disease as overall best response. In the largest subgroup of HCC patients receiving ilixadencel monotherapy as second line treatment after progression on first-line sorafenib (7 patients), the median OS was 10.9 months. The complete results provide further insight on ilixadencel's mode of action, signs of clinical activity and important information that will guide the next stage of clinical development.

## **Preclinical studies**

#### llixadencel

Immunicum has performed preclinical studies in a mouse tumor model where cancer cells (CT26 colon carcinoma) are injected subcutaneously followed by treatment with checkpoint inhibitors (anti-PD1) and immune enhancers (anti-4-1BB/CD137). These two classes block the tumor's defenses against the activated immune system, or expand and further potentiate the activated immune system and are therefore highly complementary to ilixadencel's mechanism of action. Ilixadencel showed synergy in reducing tumor growth and increasing survival in combination with both classes, further positioning our strategy for ilixadencel as a key component in future combination therapies for solid tumors.

In addition, recently conducted preclinical studies in the same animal model show that animals that were treated with the combination of ilixadencel and the checkpoint inhibitor anti-CTLA-4 showed a stronger anti-tumor response as compared to animals treated with both anti-PD-1 and anti-CTLA-4, a well-established combination of checkpoint inhibitors in the clinical setting. Moreover, in a separate study comparing anti-CTLA-4 monotherapy with anti-CTLA-4 in combination with ilixadencel, 70 % (7/10) of the mice treated with ilixadencel/anti-CTLA-4 completely eradicated the tumor as compared with 0 % (0/10) in the group treated with anti-CTLA-4 as monotherapy. Importantly, all seven mice in the ilixadencel/anti-CTLA-4 group that eradicated the primary tumor also resisted a subsequent tumor re-challenge, indicating the formation of an adaptive tumor-specific immune memory.

Immunicum intends to conduct additional preclinical studies with ilixadencel to investigate further combinations.

#### IMM-2 platform

IMM-2 (formerly SUBCUVAX®/Adenovirus) shares the same technology basis as used for production of ilixadencel to benefit from the unique priming and activating technology. The major difference between IMM-2 and ilixadencel is that IMM-2 is transfected with an adenoviral vector to deliver tumor antigens directly to the immune priming cells.

The adenovirus vector was acquired in 2014 with the purpose of being included in the IMM-2 concept. Preclinical studies with the adenovirus vector for the development of IMM-2 are in progress in cooperation with Professor Magnus Essand at Uppsala University. In the end of 2019, the European Patent Office granted a new Immunicum patent "Improved allogeneic dendritic cells for use in cancer treatment". The patent is based on a method in which the allogeneic dendritic cells (ilixadencel) are infected with an adenovirus carrying genes encoding tumor antigen, including mutation-derived neoantigen and tumor-associated virus antigen (oncoviral antigen).

The method enables subcutaneous administration of this ilixadencel based immune primer instead of intratumoral administration.

#### IMM-3 platform

The Company's IMM-3 platform (formerly CD70) is positioned as a strategy that can be used to improve existing and new adoptive immunotherapeutics. Adoptive immunotherapy utilizes the patient's own T cells, which are isolated and usually genetically manipulated to specifically recognize cancer cells; such cells are termed CAR-T cells.

The primary goal is to establish the IMMU-3-concept as a method for the ex-vivo expansion of CAR-T cells with superior survival capacity and cytotoxic efficacy as well as superior proliferative response during tumor cell killing in immunosuppressive environments, including solid tumors.

Immunicum's goal is to explore development opportunities for the IMM-3 concept and collaboration opportunities with CAR-T or similar technologies, upon which the platform would be dependent for further development.

#### Patents

llixadencel, IMM-2 and IMM-3 as well as the manufacturing process are protected by granted patents and patent applications in a total of eight patent families in several countries in Europe, Asia and the US.

## The immuno-oncology market and Immunicum's positioning and focus areas

#### Immuno-oncology

According to Market Insight Report, the market for immune therapies is expected to grow at an annual growth rate of 13 percent, and amount to USD 150 billion by 2025. Furthermore, Allied Market Research estimates that the global immuno-oncology market for checkpoint inhibitors will exceed USD 56 billion in 2025. The growth is expected to be driven by an increased incidence of various types of cancer, a focus on targeted therapies with fewer side effects, and expedited processes for drug approval. Among the factors that hinder growth, mainly the high cost of new cancer therapies has been identified.

Immunotherapeutic drugs have the potential to change the therapeutic landscape in the treatment of cancer. Immuno-oncology, Immunicum's focus area, is a relatively new and rapidly growing part of the market and there is considerable room for new players to take market shares and high potential for products that are based on new technology and potentially offer minor or no side effects.

Within immuno-oncology there are two categories of drugs that are designed to attack the cancer in two different ways:

- » Immune activation (priming): Step 1-3 in the cancer immunity cycle.
- » Anti-immunosuppression: Step 7 in the cancer immunity cycle.

Immunicum's objective is to position ilixadencel as the backbone drug in combination treatments for activating the immune system (immune primers).

#### Anti-immunosuppression

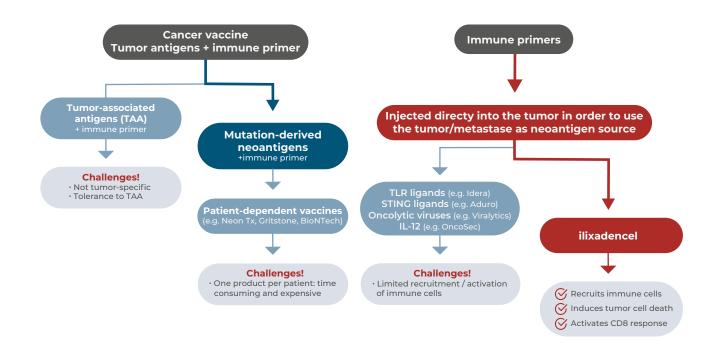
Anti-immunosuppression is the more developed field within immuno-oncology where the majority of all large pharmaceutical companies currently operate. Pioneers in this field are Bristol-Myers Squibb's Opdivo® and MSD's Keytruda®, which were initially approved for malignant melanoma but have now become applicable to several other indications including lung cancer, head and neck cancer, renal cancer and lung cancer. These therapies are checkpoint inhibitors that block an immune pathway on T cells that the tumor can exploit to suppress the immune system.

#### **Immune primers**

In immune activation, there are various approaches and Immunicum operates within the class of immune primers that is used for intratumoral administration and utilizes the patient's own tumor as the neoantigen source in situ, so that the activated immune response is specifically against the patient's tumor. This part of the immune primer landscape is where both Immunicum's ilixadencel and immune enhancers such as Toll Like Receptors (TLR)- and STING- ligands as well as oncolytic viruses operate. Although other immune primers are considered competitors of ilixadencel, it is Immunicum's assessment that they fall short of a key aspect; they are, unlike ilixadencel, only capable of addressing some elements of the crucial immune priming process.

#### The market for Immunicum's current indications

Immunicum is developing ilixadencel in indications in which limited treatment options are available.

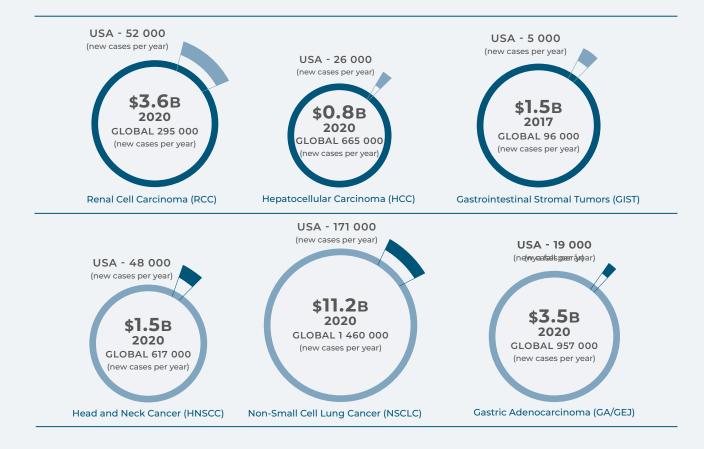


Chemotherapies, targeted therapies and the introduction of checkpoint inhibitors as combination therapies in both earlier and advanced treatment settings of these indications will continue to change the market trends and sizes. Immunicum will develop and further position ilixadencel in combination with checkpoint inhibitors and other targeted therapies in different treatment settings, which will be favorable from both regulatory and market perspectives. Given the limited efficacy of checkpoint inhibitors as monotherapy, and the incremental efficacy targeted therapies are assumed to add based on its growth inhibiting mechanism, Immunicum anticipates immunotherapy combinations to capture a significant part of the market for these indications. Ilixadencel may act as an optimal treatment combination to a number of targeted therapies and immunotherapies based on its safety and priming positioning in the cancer immunity cycle complementary to these therapies.

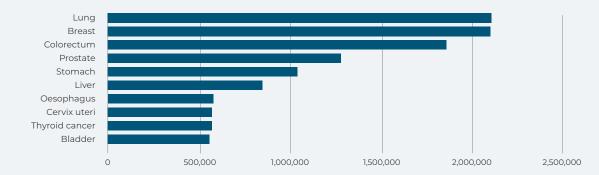
Below is an overview of the indications for which ilixadencel is currently in clinical development, with their current patient populations (incidence) and forecasted market size for the major markets (including US and Europe), based on data from GLOBOCAN, GlobalData and Peristence Market Research.

#### Broader market potential

In addition to the current and new indications outlined below, ilixadencel could potentially be used to treat all injectable, immunogenic solid tumors or injectable metastases of solid tumors. Hence, it is the Company's assessment that a large number of additional indications constitute future potential target markets for Immunicum. Such indications include among others breast cancer, colorectal cancer, cervical cancer, pancreatic cancer and melanoma. Below is an overview of the 10 most common cancer indications globally.



#### Most common cancer indications globally (new cases per year)



Source: GLOBOCAN 2018, Global Cancer Observatory, International Agency for Research on Cancer 2019.

# **Financial information**

#### Revenue

No revenue was reported for the quarter or the first half year - (-). Other operating income amounted to KSEK 1,124 (76) for the quarter and to KSEK 1,214 (219) for the first half year and consisted of exchange rate gains on accounts payable.

### **Operating expenses**

Total operating expenses for the quarter amounted to KSEK 26,276 (33,287) and for the first half year amounted to KSEK 60,235 (62,568). The operating expenses are primarily due to clinical trials and development of products for the clinical trials, and process development for the product ilixadencel. The lower costs during the qarter and the first half 2020 compared with last year is mainly because of the lower costs for the MERECA study which ended in 2019 and for the ILIAD study which yet is not fully recruited.

#### Research and development costs

Research and development costs for the quarter amounted to KSEK 17,690 (25,803) and for the first half year amounted to KSEK 41,146 (48,990). The cost is mainly explained by the increased development costs related to the process development activities to strengthen the manufacturing process of ilixadencel and by activities in ongoing clinical and preclinical studies. The lower costs during the quarter and for the first half year compared to last year is primarily due to the fact that the MERECA study has finished in 2019 and the recruitment of patients to the ILIAD study is ongoing.

#### Administrative costs

Administrative expenses for the quarter amounted to KSEK 8,272 (7,292) and for the first half 2020 amounted to KSEK 17,849 (13,384). The increased costs in the quarter and the first half of 2020 versus last year are mainly attributable to business development, strategy work, support to management during period of CEO recruitment and to the company's intensified level of business activity in general.

### **Financial Results**

Operating profit for the quarter was KSEK -25,152 (-33,211) and for the first half to KSEK -59,021 (-62,349). The result for the quarter amounted to KSEK 26,412 (-33,220) and for the first half year to KSEK -58,124 (-62,360). Earnings per share before and after dilution amounted to SEK -0.29 (-0.36) for the quarter and to SEK -0.63 (-0.68) for the first half year.

#### Tax

No tax was reported for the quarter or the first half year - (-).

# Cash flow, investments and financial position

Cash flow from operating activities for the quarter amounted to KSEK -29,970 (-30,838) and for the first half year to -65,522 (-81,277). The continued negative cash flow is according to development plan and is mainly explained by the company's clinical activities as well as process development for manufacturing of ilixadencel. The less negative cashflow during the quarter and the first half year 2020 compared to 2019 is due to lower cost for R & D.

During the quarter cash flow from investing activities amounted to KSEK 0 (0). Cash flow from financing activities for the quarter amounted to KSEK -11 (756).

The company's cash and cash equivalents on June 30, 2020 amounted to KSEK 232,176 (363,406).

Total equity as of June 30, 2020 amounted to KSEK 214,646 (344,437), which corresponds to SEK 2.33 (3.73) per share. The company's equity ratio at the end of the quarter was 89 % (93 %).

### Other

All operations are conducted in one company and there is therefore no group.

#### Significant events after end of period

Immunicum announced an update on survival data from the Phase II MERECA trial of ilixadencel in kidney cancer.

# **Other information**

#### **Incentive Program**

The purpose of share-based incentive programs is to promote the company's long-term interests by motivating and rewarding the company's senior management and other coworkers in line with the interest of the shareholders. There is currently one outstanding incentive program in the Company. In accordance with a decision by the Shareholder's General Meeting in April 2019, a share-based incentive program; "LTI 2019/2022" was introduced. For further information about this program, see the minutes of the Annual General Meeting 2019 published on the company's website, www.immunicum.com.

In conjunction with that a couple of key employees left their employments, Immunicum has excersized its right to repurchase 538,168 subscription options from the employees that left the company. Of those, 368,812 subscription options have been cancelled and 169,356 have been acquired by an employee according to decisions approved at the general meeting in April 2020.

Full utilization of granted options corresponding to 1,809,277 shares will result in a dilution for shareholders of 1,9 percent.

#### **Employees and Organization**

Immunicum has chosen to conduct its business operations with a minimal number of employees on staff supplemented by consultants, in order to maintain flexibility and cost effectiveness. As of June 30, 2020, the Company had 11 (11) direct employees, of whom 8 (6) were women and 3 (5) men.

#### The Immunicum Share

The share is traded on NASDAQ Stockholm main market under the ticker symbol IMMU, with the ISIN code SE0005003654.

The Board and the CEO confirm that the interim report provides a true and fair overview of the company's

Stockholm August 27, 2020 Immunicum AB (publ)

Michael Oredsson, CHAIRMAN OF THE BOARD Sven Andreasson
BOARD MEMBER

Steven Glazer BOARD MEMBER Christine Lind
BOARD MEMBER

Helén Tuvesson BOARD MEMBER The number of shares in the Company as of June 30, 2020 amounted to 92,257,531 (92,257,531) and the share capital in the company amounted to SEK 4,612,876.55. All shares have equal voting right and share of Immunicum's assets and profit.

#### Shareholders 2020-06-30

Owners	IMMU	Capital/Votes
Avanza Pension	8,307,921	9.01%
Fjärde AP-fonden	7,000,000	7.59%
Nordnet Pensionsförsäkring	5,659,669	6.13%
Martin Lindström	3,158,043	3.42%
Holger Blomstrand Byggnads AB	2,975,386	3.23%
Alfred Berg Fonder	958,208	1.04%
BNP Paribas Sec Serv Luxembourg	957,450	1.04%
Göran Källebo	931,863	1.01%
Elivågor AB	875,000	0.95%
Ivar Nordqvist	843,630	0.91%
SEB Fonder	656,767	0.71%
Ålandsbanken I Ägares Ställe	654,575	0.71%
Alex Karlsson-Parra	621,736	0.67%
Swedbank Försäkring	619,214	0.67%
Hans Edvin Ståhlgren	600,000	0.65%
Other	57,438,069	62.26%
Total	92,257,531	100.00%

#### Review

This report has not been reviewed by the company's auditor.

operations, position and earnings and describes the material risks and uncertainty factors faced by the company.

Charlotte Edenius BOARD MEMBER

Magnus Persson BOARD MEMBER

Alex Karlsson-Parra

### Income statement

	2020	2019	2020	2019	2019	
Amounts in KSEK	Apr-Jun	Apr-Jun Jan-Jun		Jan-Jun	Jan-Dec	
Other operating income	1,124	76	1,214	219	893	
	1,124	76	1,214	219	893	
OPERATING EXPENSES						
Sales, general and administration expenses	-8,272	-7,292	-17,849	-13,384	-28,498	
Research and development expenses	-17,690	-25,803	-41,146	-48,990	-103,144	
Other operating expenses	-313	-191	-1,240	-194	-1,576	
Operating profit/loss	-25,152	-33,211	-59,021	-62,349	-132,324	
RESULT FROM FINANCIAL ITEMS						
Net financial items	-1,260	-9	897	-11	-1,692	
Profit/loss after financial items	-26,412	-33,220	-58,124	-62,360	-134,016	
TOTAL PROFIT/LOSS BEFORE TAXES	-26,412	-33,220	-58,124	-62,360	-134,016	
Income tax expense	-	-	-			
PROFIT/LOSS FOR THE PERIOD	-26,412	-33,220	-58,124	-62,360	-134,016	
Earnings/loss per share before and after dilution (SEK)	-0.29	-0.36	-0.63	-0.68	-1.46	

## Statement of comprehensive income

Amounts in KSEK	2020 Apr-Jun	2019 Apr-Jun	2020 Jan-Jun	2019 Jan-Jun	2019 Jan-Dec
Result for the period	-26,412	-33,220	-58,124	-62,360	-134,016
Other comprehensive income	-	-	-	-	_
Total comprehensive result for the period	-26,412	-33,220	-58,124	-62,360	-134,016

## **Balance sheet**

ASSETS			
Financial assets			
Other securities held as fixed assets	1	1	1
Total financial assets	252	1	252
Total fixed assets	252	1	252
CURRENT ASSETS			
Current receivables			
Other receivables	2,178	3,043	2,983
Prepaid expenses and accrued income	7,524	4,101	3,783
Total current receivables	9,702	7,144	6,766
Cash and bank balances	232,176	363,406	296,811
Total current assets	241,879	370,550	303,577
TOTAL ASSETS	242,131	370,551	303,829
SHAREHOLDERS' EQUITY Restricted equity			
Share capital	4,613	4,613	4,613
Total restricted equity	4,613	4,613	4,613
Unrestricted equity			
Share premium reserve			
	731,818	731,828	731,828
Retained earnings	731,818 -463,661	731,828 -329,645	731,828 -329,645
Retained earnings Profit/loss for the period			
-	-463,661	-329,645	-329,645
Profit/loss for the period	-463,661 -58,124	-329,645 -62,360	-329,645 -134,016
Profit/loss for the period Total unrestricted equity	-463,661 -58,124 <b>210,033</b>	-329,645 -62,360 <b>339,824</b>	-329,645 -134,016 <b>268,168</b>
Profit/loss for the period Total unrestricted equity Total shareholders' equity	-463,661 -58,124 <b>210,033</b>	-329,645 -62,360 <b>339,824</b>	-329,645 -134,016 <b>268,168</b>
Profit/loss for the period Total unrestricted equity Total shareholders' equity LIABILITIES	-463,661 -58,124 <b>210,033</b>	-329,645 -62,360 <b>339,824</b>	-329,645 -134,016 <b>268,168</b>
Profit/loss for the period Total unrestricted equity Total shareholders' equity LIABILITIES LONG-TERM LIABILITIES	-463,661 -58,124 <b>210,033</b> <b>214,646</b>	-329,645 -62,360 <b>339,824</b> <b>344,437</b>	-329,645 -134,016 <b>268,168</b> <b>272,781</b>
Profit/loss for the period Total unrestricted equity Total shareholders' equity LIABILITIES LONG-TERM LIABILITIES Other long-term liabilities	-463,661 -58,124 <b>210,033</b> <b>214,646</b> 850	-329,645 -62,360 <b>339,824</b> <b>344,437</b> 850	-329,645 -134,016 <b>268,168</b> <b>272,781</b> 850
Profit/loss for the period Total unrestricted equity Total shareholders' equity LIABILITIES LONG-TERM LIABILITIES Other long-term liabilities Total long-term liabilities CURRENT LIABILITIES	-463,661 -58,124 <b>210,033</b> <b>214,646</b> 850	-329,645 -62,360 <b>339,824</b> <b>344,437</b> 850	-329,645 -134,016 <b>268,168</b> <b>272,781</b> 850
Profit/loss for the period Total unrestricted equity Total shareholders' equity LIABILITIES LONG-TERM LIABILITIES Other long-term liabilities Total long-term liabilities	-463,661 -58,124 <b>210,033</b> <b>214,646</b> 850 <b>850</b>	-329,645 -62,360 <b>339,824</b> <b>344,437</b> 850 <b>850</b>	-329,645 -134,016 268,168 272,781 850 850
Profit/loss for the period Total unrestricted equity Total shareholders' equity LIABILITIES LONG-TERM LIABILITIES Other long-term liabilities Total long-term liabilities CURRENT LIABILITIES Accounts payable	-463,661 -58,124 210,033 214,646 850 850 20,558	-329,645 -62,360 <b>339,824</b> <b>344,437</b> 850 <b>850</b> 16,267	-329,645 -134,016 <b>268,168</b> <b>272,781</b> 850 850
Profit/loss for the period Total unrestricted equity Total shareholders' equity LIABILITIES LONG-TERM LIABILITIES Other long-term liabilities Total long-term liabilities CURRENT LIABILITIES Accounts payable Other liabilities	-463,661 -58,124 210,033 214,646 850 850 20,558 1,385	-329,645 -62,360 <b>339,824</b> <b>344,437</b> 850 850 16,267 1,369	-329,645 -134,016 <b>268,168</b> <b>272,781</b> 850 <b>850</b> 12,819 1,644
Profit/loss for the period Total unrestricted equity Total shareholders' equity LIABILITIES LONG-TERM LIABILITIES Other long-term liabilities Total long-term liabilities CURRENT LIABILITIES Accounts payable Other liabilities Accrued expenses and deferred income	-463,661 -58,124 <b>210,033</b> <b>214,646</b> 850 850 20,558 1,385 4,692	-329,645 -62,360 <b>339,824</b> <b>344,437</b> 850 850 16,267 1,369 7,628	-329,645 -134,016 <b>268,168</b> <b>272,781</b> 850 <b>850</b> 12,819 1,644 15,736

## Report on changes in shareholders' equity

Amounts in KSEK	Share capital	Share premium reserve	Retained earnings incl. profit/loss for the period	Total
Opening shareholders' equity 01/01/2020	4,613	731,828	-463,661	272,780
Premiums for warrants		-11		-11
Profit/loss for the period			-57,624	-57,624
Shareholders' equity 30/06/2020	4,613	731,818	-521,285	215,146
Opening shareholders' equity 01/01/2019	4,613	731,073	-329,645	406,041
Premiums for warrants		756		756
Profit/loss for the period			-62,360	-62,360
Shareholders' equity 30/06/2019	4,613	731,829	-392,005	344,437
Opening shareholders' equity 01/01/2019	4,613	731,073	-329,645	406,041
Profit/loss for the period			-134,016	-134,016
Comprehensive result for the period			-134,016	-134,016
Transactions with owners				
Premiums for warrants		756		756
Total transaction with owners		756		756
Shareholders' equity 31/12/2019	4,613	731,828	-463,661	272,781

## **Cash flow Statement**

	2020	2019	2020	2019	2019
Amounts in KSEK	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Operating activities					
Operating profit/loss before financial items	-25,152	-33,211	-59,021	-62,349	-132,324
Adjustment for items not included in cash flow	., .	-129		-120	9
Interest income received	-	-	-	-	10
Interest expense paid	-2	-9	-2	-11	-17
Increase/decrease in other current receivables	-4,453	-1,955	-2,936	-579	-202
Increase/decrease in accounts payable	8,401	5,898	7,739	-14,999	-18,447
Increase/decrease in other current liabilities	-8,765	-1,433	-11,303	-3,219	5,164
Cash flow from operating activities	-29,970	-30,838	-65,522	-81,277	-145,808
Investment activities					
Investment in financial assets	-	-	-	-	-251
Cash flow from investing activities	-	-	-	-	-251
Financing activities					
Premiums for warrants	-11	756	-11	756	756
Cash flow from financing activities	-11	756	-11	756	756
Cash and cash equivalents at the					
beginning of the period	263,416	393,359	296,811	443,798	443,798
Cash flow for the period	-29,981	-30,082	-65,533	-80,521	-145,303
Foreign echange difference in cash and cash equivalents	-1,258	129	899	129	-1,684
Cash and cash equivalents at the end of the period	232,176	363,406	232,176	363,406	296,811

## Notes

#### Note 1 - General information

This report covers the Swedish company Immunicum AB (publ), Swedish corporate identity no. 556629-1786. The company is a Swedish public limited company registered in Gothenburg and with its registered office in Stockholm. The interim report for the second quarter 2020 was approved for publication on August 27, 2020.

#### Note 2 - Accounting Policies

The Company prepares its interim reports in accordance with IAS 34 with regard to the exceptions from and additions to IFRS which are listed in RFR2 and the Swedish Annual Accounts Act. The Company is not a part of any group of companies, which is why a full IFRS reporting will not be applicable. Immunicum's business currently consists of research and development for production of pharmaceuticals. The company is of the opinion that this business, in its entirety, constitutes a single operating segment. The accounting principles and calculation methods remain unchanged from those applied in the Annual Report for financial year 1 Jan-31 December 2019. Disclosures in accordance with IAS 34.16A are provided both in Notes as well as elsewhere in the interim report.

#### Other

None of the IFRS or IFRIC interpretations that have yet to come into legal effect are expected to have any significant impact on Immunicum.

#### Note 3 - Pledged assets

Pledged assets total KSEK 251 (251).

## Note 4 - Prospects, Significant Risks and Uncertainty Factors

#### COVID-19 pandemic impact on operations

The COVID-19 pandemic is evolving rapidly and is having a significant impact on the global healthcare system. Many hospitals, regions and countries are updating their guidelines and Immunicum is following the developments closely ready to take necessary steps to fully comply with the new guidance as required. Immunicum has also taken necessary actions to ensure the well-being, safety and security of the Company's employees.

At reporting date, the ongoing ILIAD study continues as planned in the US. However, there is a risk that the pace of recruitment of patients to the study will be impacted in the context of COVID-19. Similarly, this may affect the collection of follow-up survival data like for the MERECA study and/or result in a delay or gap in the clinical study data collection and/or processing by the CRO. Immunicum's team is working closely with the CROs involved to make sure timelines and quality are secured and mitigation steps are in place. Sufficient stock of ilixadencel, to complete the Phase 1b part of the ILIAD study, have been shipped to storage depots and the company does not currently foresee delays in the shipment of product to site(s) as a consequence of the COVID-19 pandemic. At reporting date, regulatory authority interactions are considered unlikely to be affected. There is a general risk associated with the impact the COVID-19 pandemic will have on the capital markets. If extended in time it could adversely affect the Company's access to the capital markets, which could have a negative impact on the Company's business.

Immunicum is a research and development Company that still is in its early stages. The Company has not generated any revenues historically and is not expected to do so in the short term. The Company's candidates for cancer immune primers and technology platforms are dependent on research and development and may be delayed and/ or incur greater costs. The Company is dependent upon its ability to enter into licensing agreements and joint collaboration agreements, as well as dependent on a large number of approvals and remuneration systems and the related laws, regulations, decisions and practices (which may change). In addition, the Company is also dependent upon intellectual property rights. The risk that is determined to have particular importance for future development of Immunicum is access to financial funds. For a more detailed description of the material risk factors, please refer to Annual Report 2019 which can be downloaded from the Company's website: www.immunicum.com.

#### Note 5 - Estimates and judgements

This report includes forward looking statements. Actual outcomes may deviate from what has been stated. Internal factors such as successful management of research projects, and intellectual property rights may affect future results. There are also external conditions, e.g. the economic climate, political changes and competing research projects that may affect Immunicums results.

## Note 6 - Information on transactions with closely Related Parties

Margareth Jorvid, Head of Regulatory Affairs & Quality System and member of Immunicum's management team, has during the first half 2020 invoiced Immunicum KSEK 848 in consultancy fees through the company Methra in Uppsala AB. Peter Suenaert, CMO and member of Immunicum's management team, has during the first half 2020 invoiced Immunicum KSEK 956 in consultancy fees through the company Sparklin BV.

#### Note 7 - Financial instruments

Immunicums financial assets and liabilities comprise of cash and cash equivalents, pledged assets, other current assets, accrued expenses and accounts payable. The fair value of all financial instruments is materially equal to their carrying amounts.

### Key performance measurement

The company presents in this report certain key performance measures, including two measures that is not defined under IFRS, namely expenses relating to research and development / operating expenses % and equity ratio. These financial performance measures should not be viewed in isolation or be considered to replace the performance indicators that have been prepared in accordance with IFRS. In addition, such performance measure as the company has defined it should not be compared with other performance measures with similar names used by other companies. This is because the above-mentioned performance measure is not always defined in the same manner, and other companies may calculate the differently to Immunicum.

	Apr-Jun 2020	Apr-Jun 2019	Jan-Jun 2020	Jan-Jun 2019	Jan-Dec 2019
Total registered shares at the beginning of period	92,257,531	92,257,531	92,257,531	71,874,119	71,874,119
Total registered shares at the end of period	92,257,531	92,257,531	92,257,531	92,257,531	92,257,531
Share capital at the end of period, SEK	4,612,877	4,612,877	4,612,877	4,612,877	4,612,877
Equity at the end of period, SEK thousand	214,646	344,437	214,646	344,437	272,781
Earnings per share before and after dilution, SEK	-0.29	-0.36	-0.63	-0.68	-1.46
Research and development costs, SEK thousand	-17,690	-25,803	-41,146	-48,990	-103,144
Research & development costs/operating expenses %	67%	78 %	68 %	78%	77 %

#### Definitions and reconciliation of alternative performance measurements

Alternative performance measurements	Definition	Justification
Equity ratio	Total shareholders' equity divided by total assets	The Company believes that this key ratio provides investors with useful information of the Company's capital structure.
Research & development costs/operating expenses %	Research & development costs/operating expenses %	The company believes that the research and development / operating expenses ratio is an important complement because it allows for a better evaluation of the company's economic trends and the proportion of its costs that are attributable to the company's core business.

#### Derivation

	Apr-Jun 2020	Apr-Jun 2019	Jan-Jun 2020	Jan-Jun 2019	Jan-Dec 2019
Equity ratio at the end of the period %					
Total shareholders' equity at the end of the period (KSEK)	214,646	344,437	214,646	344,437	272,781
Total assets at the end of the period (KSEK)	242,131	370,551	242,131	370,551	303,829
Equity ratio at the end of the period %	89%	93 %	89 %	93 %	90 %
Research & development costs/operating expenses %					
Research & development costs	-17,690	-25,803	-41,146	-48,990	-103,144
Administrative costs	-8,272	-7,292	-17,849	-13,384	-28,498
Other operating expenses	-313	-191	-1,240	-194	-1,576
Total operating expenses	-26,276	-33,287	-60,235	-62,568	-133,217
Research & development costs/operating expenses %	67%	78 %	68 %	78%	77 %

#### Note 8 - Significant events after end of period

Immunicum announced an update on survival data from the Phase II MERECA trial of ilixadencel in kidney cancer.

## **Governing text**

The report has been translated from Swedish. The Swedish text shall govern for all purposes and prevail in the event of any discrepancy between the versions.

## **Financial Calendar**

Interim report Q3 2020:	5 November 2020
Year-End report 2020:	18 February 2021

# For further information, please contact:

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The information was submitted for publication, through the agency of the contact persons set out above, on August 27, 2020, at 8:00 CET.



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