

# Interim Report 2019

January-September



# Q3 report 2019

## Important milestone passed with MERECA topline results

### Significant events during July -September

- » Net sales for the period amounted to KSEK - (-).
- » Result for the quarter amounted to -29,643 (-23,520) KSEK
- » Earnings and diluted earnings per share totaled SEK -0.3 (-0.5)
- » Immunicum announced the topline data from the exploratory Phase II MERECA clinical trial. Five patients had complete responses and the topline data on survival benefit in all patients showed that a higher percentage of ilixadencel patients were alive as per data cut-off in July 2019.

### Significant events after end of period

- » Immunicum AB Announced Advancement to Next Dosage Group Level in Phase Ib/II ILIAD Combination Trial
- » Immunicum Announced the Nomination Committee for the AGM 2020
- » Immunicum AB Announced Positive Preclinical Data on Ilixadencel in Combination with CTLA-4 Immune Checkpoint Inhibitor
- » The European Patent Office decided to grant the new Immunicum patent "Improved allogeneic dendritic cells for use in cancer treatment".

## Financial summary

KSEK unless otherwise stated	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Full year
	2019	2018	2019	2018	2018
Operating profit/loss	-29,643	-23,520	-91,993	-71,637	-97,846
Net profit/loss	-29,643	-23,520	-92,004	-71,645	-97,860
Earnings per share, before and after dilution (SEK)	-0.3	-0.5	-1.0	-1.4	-1.9
Cash	334,088	133,273	334,088	133,273	443,798
Shareholders equity	314,793	117,912	314,793	117,912	406,041
Number of employees	12	11	11	11	12

# CEO comment

## Third quarter

» **We have concluded** a very successful third quarter with the announcement of positive topline results from the phase II MERECA study with ilixadencel, our allogeneic, off-the-shelf, cell-based therapy. Ilixadencel demonstrated initial signs of efficacy and has maintained a positive safety and tolerability profile. Based on these results we can begin advancing ilixadencel towards late-stage clinical development.



### **Achieving Complete Tumor Responses**

During the third quarter we shared the positive topline results from the Phase II MERECA study. The achievement of complete and durable responses in patients with advanced-stage kidney cancer while maintaining a positive tolerability and safety profile is what practicing physicians and the pharmaceutical industry is looking for in potential new therapies. The findings from this study are in line with other successful and recently published immuno-oncology studies in metastatic Renal Cell Carcinoma (RCC) patients. These results support the continued clinical development of ilixadencel, and we have initiated the preparations for a pivotal study.

The development plans will now be discussed with regulatory authorities to define next step for a pivotal study. In addition, we will continue to have discussions with potential partners in order to provide them with a more comprehensive understanding of the MERECA results.

I would like to extend a special thank you to the team for its hard work and dedication to concluding the complete analysis of topline data from the MERECA study in a timely fashion. Given the vast amount of data from the MERECA study, we have, and will continue to, invest a great deal of time informing and explaining the results from the study through our website and answering questions from analysts, the media and shareholders to facilitate the interpretation of the results. At this time, I would also like to take the opportunity to thank Peter Suenart, our Chief Medical Officer, for his leadership of the study and his commitment to the company. For personal reasons he will be transitioning away from Immunicum but will continue to support the company on a part-time basis. In parallel, we are actively searching for a candidate that can fill his position full-time.

### **The ILIAD Study is Progressing According to Plan**

At the start of the fourth quarter we shared the first update from the Phase Ib/II ILIAD clinical trial examining the safety and tolerability of ilixadencel in combination with the checkpoint inhibitor, Keytruda® (pembrolizumab). We were able to report a favorable safety profile with no serious adverse events in the first three patients. Based on these data, the study will progress to the next dose level as planned.

One of the key objectives in the study is to investigate if ilixadencel can increase the efficacy of checkpoint inhibitors in indications where CPI monotherapy has limited efficacy. ILIAD will test this combination in three types of cancer, with the objective of providing evidence that ilixadencel is an effective immune primer in a broad range of solid tumors. Furthermore, the design of the ILIAD study gives us multiple opportunities to generate valuable data.

### **Expanding the Potential of Ilixadencel**

As ilixadencel progresses through clinical development, we will continue to conduct preclinical studies to identify new opportunities for our lead candidate where it may provide therapeutic benefit to patients without adding toxicity when combined with standard cancer treatments.

The recently announced preclinical study examining ilixadencel in combination with the immune checkpoint inhibitor, CTLA-4 is a good example. In this study, animals treated with ilixadencel and anti-CTLA-4 showed a stronger anti-tumor response compared to a control group treated with PD-1 and CTLA-4, a well-known combination of checkpoint inhibitors.

### **Our Efforts are Being Recognized**

During this quarter, we had the opportunity to present Immunicum at several international conferences including the European Biotech Investor Day in New York, the China

BioMed Innovation and Investment Conference and the Sachs Biotech Forum in Basel. Through these efforts we continue to increase the awareness of Immunicum and ilixadencel within the investor and pharma industry communities.

In addition, we are proud to have been included on the Albright Foundation list of the most gender equal publicly listed companies for the second year in a row. Moreover, Immunicum has been shortlisted as a finalist by the Network for Life Science Executive Leaders, LSX, in the 2019 European Lifestars Awards within the European Post-IPO Equity Raise category, recognizing the most successful follow-on equity raise of the year. The winner of that award will be announced on November 19th.

### **Looking Ahead**

We expect to be able to share the first six-month follow-up on overall survival for the patients in the MERECA study in January 2020. We are also expecting to provide additional updates on the ILIAD study during the second quarter of 2020, as the trial advances to the non-staggered phase.

Given the promising clinical results achieved this year, we are well-positioned to advance the clinical development of ilixadencel and provide hope to patients battling difficult-to-treat solid tumors. As we continue to gain experience from combining ilixadencel with both tyrosine kinase inhibitors and checkpoint inhibitors, we are able to discuss with regulatory authorities and opinion leaders the best alternative for proceeding to a pivotal study.

We remain focused on advancing our projects according to plan and preparing ilixadencel for late-stage clinical development and, in the future, for the market. Our goal is to deliver on our milestones, to generate value for our shareholders and to offer better treatment options to cancer patients.

**CARLOS DE SOUSA**  
CEO

# Introduction to Immunicum

» **Immunicum is a biopharmaceutical company that develops immune therapies against a range of solid tumors. Immunicum's approach allows for an off-the-shelf product based on a type of immune cells called dendritic cells that are designed to induce a personalized anti-tumor immune response.**

The Company's lead product, ilixadencel, has been developed to be able to take advantage of each patient's unique profile of tumor-specific antigens by injecting ilixadencel directly into the tumor. This approach thereby eliminates the need to characterize, select and produce each patient's tumor-specific antigens before treatment.

Ilixadencel is currently being evaluated in kidney cancer, liver cancer, gastrointestinal stromal tumors, head and neck cancer, non-small cell lung cancer and gastric cancer; with kidney cancer being the furthest advanced indication with a Phase II study. Immunicum is a Swedish company listed at Nasdaq Stockholm Small Cap.

## Ilixadencel – an immune primer

### There are four major expected advantages with ilixadencel:

- I. Intratumorally injected ilixadencel uniquely covers all major aspects of tumor specific immune priming:
  - » recruitment of immune cells including NK cells and dendritic cells into the tumor,
  - » induction of local tumor cell death leading to increased release of tumor-specific antigens and
  - » maturation of antigen-loaded dendritic cells for subsequent migration to tumor-draining lymph nodes where the dendritic cells activate/prime tumor-specific T cells
- II. ilixadencel is applicable for all injectable solid tumors

- III. Off-the-shelf cell-based therapies are applicable to all patients and batches can be stockpiled and thereby be available for immediate use
- IV. The concept uses the patient's own tumor as the antigen source in vivo, which aims to ensure that the full set of immunogenic neoantigens are used for activation of a tumor-specific immune response.

### Combination with other immune therapies

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 tyrosine kinase inhibitors. This is for the patient to have a stronger immune response with a more effective and safe anti-tumor treatment.

# Product portfolio

Product & Indication	Combination	Preclinical	Phase I	Phase II	Phase III
<b>Ilixadencel:</b> an off-the-shelf cancer immune primer					
Kidney cancer	Kinase inhibitors	MERECA	Top-line results Q3 2019		
Liver cancer	Kinase inhibitors		Results Q3 2017		
Gastrointestinal stromal tumors (GIST)	Kinase inhibitors		Results Q2 2019		
Head and neck cancer	Checkpoint inhibitors	ILIAD			
Non-small cell lung cancer	Checkpoint inhibitors	ILIAD			
Gastric cancer	Checkpoint inhibitors	ILIAD			
<b>IMM-2:</b> allogeneic dendritic cells with adenovirus coding for tumor antigens					
<b>IMM-3:</b> optimized CAR-T expansion protocol for improved anti-cancer activity					

## Studies 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 at standard doses in the selected indications. The Phase Ib part of the study is ongoing in the US. During this part ilixadencel will be combined with Keytruda® (pembrolizumab). The first patient was treated in February 2019.

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 are enrolled with the aim to assess safety and define the optimal dose and schedule of ilixadencel administration in combination with Keytruda® (pembrolizumab). Ilixadencel showed a favorable safety profile with no serious adverse events in combination with Keytruda® in the first three patients that were dosed with two intratumoral injections of 3 million cells.

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.

### Collaboration and supply agreement with Merck KGaA and Pfizer for ILIAD

In November 2018, Immunicum announced a collaboration with Merck KGaA and Pfizer for the evaluation of ilixadencel in combination with the 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.

## Studies in renal cancer

### Phase II - MERECA

In August 2019, Immunicum completed an exploratory, international, randomized, controlled and open-label Phase II clinical trial (MERECA) in which a total of 88 newly diagnosed, intermediate and high risk metastatic renal cancer patients were enrolled. Fifty-six patients received treatment with ilixadencel followed by nephrectomy (the removal of the tumor affected kidney) and standard treatment with the tyrosine kinase inhibitor Sutent® (sunitinib). Thirty patients included in the control group underwent only nephrectomy and standard treatment with Sutent®.

The primary objectives of the study were to evaluate median overall survival (OS) and 18-month survival rates. Secondary objectives included evaluation of safety and tolerability, tumor response and immunological profiling including T cell infiltration.

#### The topline results showed the following data:

##### Overall Survival (OS)

As of July 2019, 57% (32 out of 56 patients) in the ilixadencel treatment group were alive compared with 43% (13 out of 30 patients) in the control group. The median Overall Survival final value cannot yet be calculated in either group as the data is not mature enough.

Based on Kaplan-Meier probabilities, the 18-month OS rate is 63% in the ilixadencel combination group and 66% in the sunitinib monotherapy group.

Follow up on survival data will be collected and updated continuously at 6-month intervals, with the first update expected in January 2020. Based on this ongoing follow-up, Immunicum will communicate the median OS values once the data becomes more mature.

##### Tumor Response

The Objective Response Rate (ORR) is the proportion of patients with Complete Responses (CR) or Partial Responses (PR), measured by CT scan within the 18-month follow-up. The ORR was similar in the two groups with 44% (20 out of 45 patients) in the ilixadencel combination group and 48% (12 out of 25 patients) in the sunitinib monotherapy group. However, the number of Complete Responders was higher in the ilixadencel combination group with 11% (5 out of 45 patients) compared to 4% (1 out of 25 patients) in the sunitinib monotherapy group.

#### Furthermore, the ilixadencel combination group showed:

- » a longer median Duration of Response (7.1 months versus 2.9 months in the sunitinib monotherapy group) within the 18-months follow-up;
- » a higher percentage of responses ongoing at the 18-months follow-up, 60% (12 out of 20 patients) versus 33% (4 out of 12 patients) in the sunitinib monotherapy group;
- » a higher percentage of Responders alive at last patient contact, 85% (17 out of 20 patients) versus 58% (7 out of 12 patients) in the sunitinib monotherapy group.

All Complete Responders in the ilixadencel combination group were still alive at last patient contact (5 out of 5 CRs), while the Complete Responder in the sunitinib monotherapy group had died at the latest point of follow-up.

##### Tumor Infiltration

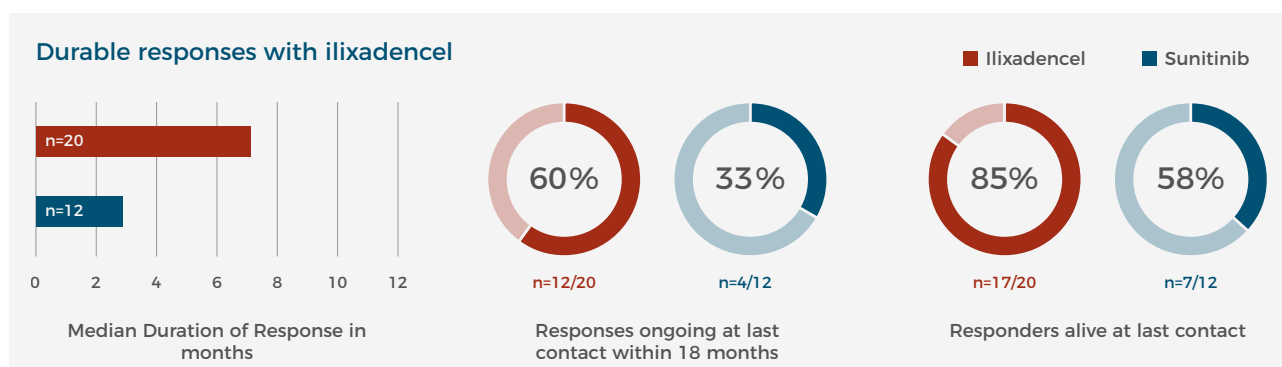
Tumor tissue from the surgically removed kidney tumors was available from post-ilixadencel treatment patients and non-treatment control patients. The analysis was performed on a tissue section from each tumor placed on a slide and immuno-stained with anti-CD8 antibodies. Tumor infiltration of CD8+ T cells was then assessed on the entire slide by a new methodology including a customized and validated computer algorithm software to quantify the CD8-stained area as a percentage of the total tumor area.

This analysis showed a median stained area of 1.08% in the ilixadencel group as compared to 0.84% in the untreated control group, at time of kidney surgery. The high variability of CD8-stained area in the tumors within the treatment groups, between different samples taken from the same tumor and also within Complete Responders, indicate that the intratumor infiltration of CD8+ T cells by itself, without considering CD8+ T cell specificity and functionality, does not explain the systemic therapeutic impact of ilixadencel when combined with sunitinib.

##### Safety and Tolerability

The overall safety and tolerability data was similar in both treatment groups, meaning that the addition of ilixadencel to sunitinib did not add toxicity. This confirms ilixadencel's favorable safety profile from previous studies and supports that ilixadencel is well-suited for combination therapies.

These results indicate that ilixadencel provided a systemic therapeutic benefit while maintaining a positive safety and



tolerability profile. Overall the data supports the continued clinical development of ilixadencel as an immune primer in RCC and other solid tumors.

### Completed Phase I/II trial

In 2014 Immunicum presented the results from a Phase I/II study in twelve patients with newly diagnosed metastatic renal cell carcinoma (mRCC). No treatment-related serious adverse events have been noted. The immunology data show clear signs of tumor-specific immune activation and strong infiltration of CD8+ T cells in the treated tumor, but also in a distant metastasis, which indicates that the activated immune system is also able to identify and target cancer cells in other parts of the body after injection of ilixadencel. The median overall survival time for the patient group as a whole was 48 months compared to the expected median survival time of 14 - 16 months for standard treatment with Sutent® (sunitinib).

### Studies in Gastrointestinal cancer (GIST)

#### Completed Phase I/II

Immunicum completed a Phase I/II clinical trial with ilixadencel concerning the treatment of patients with GIST in June 2019. Six patients were enrolled and treated with ilixadencel in combination with Sutent® (sunitinib), Stivarga® (regorafenib) or similar tyrosine kinase inhibitor (targeted therapy). Ilixadencel met the primary endpoint of safety, with no life-threatening treatment-related adverse events and no signs of autoimmunity. The secondary endpoint of efficacy was primarily evaluated based on tumor growth. The most positive outcome was seen in two patients where tumor growth halted and partially regressed for three and six months, respectively. These partial responses indicate that ilixadencel had a therapeutic impact by overcoming resistance to TKIs in these two patients with metastatic disease whose disease previously progressed on second- and/or third-line TKI treatment.

### Studies in liver cancer

#### Completed Phase I/II

In September 2017, Immunicum announced the topline results from the completed Phase I/II clinical trial of ilixadencel in 18 advanced liver cancer patients (Hepatocellular carcinoma; HCC). 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. 11 out of 15 evaluable patients exhibited an increase in, tumor-specific CD8 T-cell in peripheral blood. Overall survival ranged from 1.6 - 21.4 months in the total group of 17 HCC patients.

### Preclinical studies

#### Ilixadencel

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 in the immunology field 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 in activating the immune system. 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 CTLA-4 showed a stronger anti-tumor response as compared to animals treated with anti-PD-1 and anti-CTLA-4, a well-known combination of checkpoint inhibitors (CPIs).

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

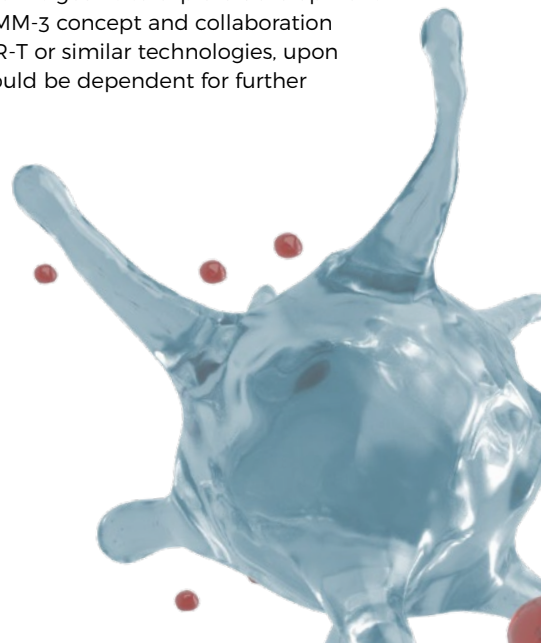
#### IMM-2 platform

IMM-2 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 cells. These cells are then injected subcutaneously (under the skin) as opposed to ilixadencel's intratumoral injection. The objective is to examine the possibilities of using the vector for the production of relevant tumor antigens to be used in the IMM-2 immune priming and activating cells.

The European Patent Office recently decided to grant a new Immunicum patent. 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

Immunicum's IMM-3 platform 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 IMM-3 concept as an optimal method for the *ex-vivo* expansion of CAR-T cells for the treatment of 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.





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

According to Radiant Insights, the market for immune therapies is expected to grow at an annual growth rate of 23.9 percent, and amount to USD 75.8 billion by 2022.

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.

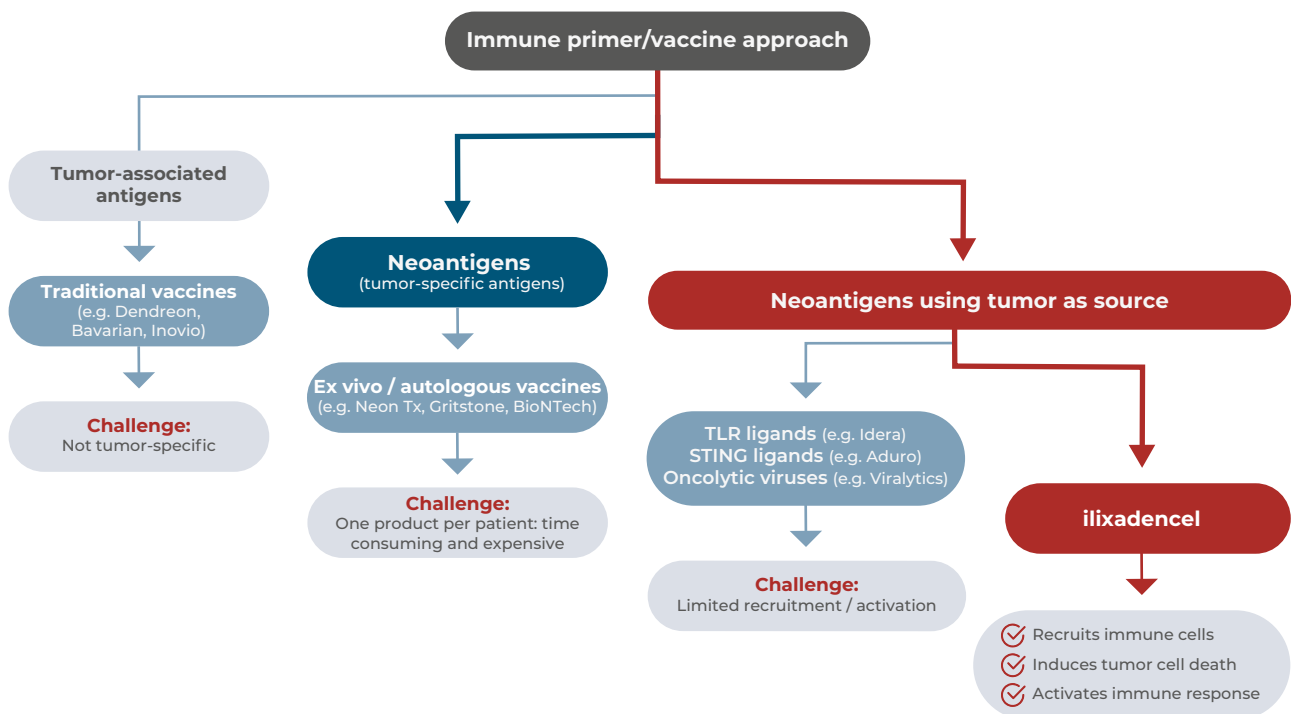
Within immuno-oncology there are two categories of drugs that are designed to attack the cancer in two different ways:

- » Immune stimulation (priming)
- » Anti-immunosuppression

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

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®. These therapies are checkpoint inhibitors that block an immune pathway on T cells that the tumor can exploit to suppress the immune system.

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*. 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. The strength with Immunicum's immune primer ilixadencel is that it engages the entire immune system activation process needed instead of addressing parts like the above-mentioned methods.



# Financial information

## Revenue

No revenue was reported for the quarter or the nine-month period (-). Other operating income amounted to KSEK 226 (7) for the quarter and to KSEK 445 (146) for the nine-month period and consisted of exchange rate gains.

## Operating expenses

Total operating expenses for the quarter amounted to KSEK 29,869 (23,527) and for the nine-month period to KSEK 92,438 (71,783).

### Research and development costs

Research and development costs for the quarter amounted to KSEK 23,722 (17,204) and for the nine-month period to KSEK 72,699 (52,259). The cost increase is explained by the increased development costs related to the process development activities to strengthen the manufacturing process of ilixadencel as well as activities in ongoing clinical and preclinical studies.

### Administrative costs

During the third quarter, administrative expenses amounted to KSEK 5,889 (6,105) and to KSEK 19,286 (18,453) for the nine-month period. The costs are attributable to the organization and to the company's continued high level of business activity.

## Financial Results

Operating profit for the quarter was KSEK -29,643 (-23,520) and for the nine-month period KSEK -91,993 (-71,637). The result for the quarter amounted to KSEK -29,643 (-23,520) and to KSEK -92,004 (-71,645) for the period. Earnings per share before and after dilution amounted to SEK -0.3 (-0.5) for the quarter and to SEK -1.0 (-1.4) for the nine-month period.

## Tax

No tax was reported for the quarter or the nine-month period (-).

## Cash flow, investments and financial position

Cash flow from operating activities for the quarter amounted to KSEK -29,217 (-16,698) and for the nine-month period to KSEK -110,494 (-100,850). The continued negative cash flow is according to plan and is explained by the company's increased clinical activities as well as process development for manufacturing of ilixadencel. Cash flow for the nine-month period from operating activities is also affected by paid accounts payable.

During both the quarter and the nine-month period, cash flow from investing activities amounted to KSEK 250 (0).

Cash flow from financing activities for the quarter amounted to KSEK 0 (0). Cash flow from financing activities for the nine-month period amounted to KSEK 756 (105,239) which is related to warrant premiums from the incentive program that was initiated in May.

The company's cash and cash equivalents on September 30, 2019 amounted to KSEK 334,088 (133,273).

Total equity as of September 30, 2019 amounted to KSEK 314,793 (117,912), which corresponds to SEK 3.4 (2.3) per share. The company's equity ratio at the end of the nine-month period was 93 % (85 %).

## Other

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

# 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 co-workers 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 new 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](http://www.immunicum.com).

Full utilization of granted options corresponding to 2,178,089 shares will result in a dilution for shareholders of 2.3 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 30 September 2019, the Company had 12 (11) direct employees, of whom 7 (6) were women and 5 (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 number of shares in the Company as of 30 September 2019 amounted to 92,257,531 (50 958 531) 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 2019-09-30

Owners	IMMU	Capital/Votes
Fourth Swedish National Pension Fund	7,000,000	7.59 %
Avanza Pension	6,923,978	7.51 %
Nordnet Pension Insurance	5,750,057	6.23 %
Gladiator	3,631,071	3.94 %
Loggen Invest AB	3,240,000	3.51 %
Holger Blomstrand Byggnads AB	2,975,386	3.23 %
Second Swedish National Pension Fund	1,150,000	1.25 %
Alfred Berg Funds	966,020	1.05 %
BNP Paribas Sec Serv Luxembourg	957,450	1.04 %
Göran Källebo	931,863	1.01 %
Fred Persson	882,330	0.96 %
Elivågor AB	875,000	0.95 %
Other	56,974,376	61.76 %
<b>Total</b>	<b>92,257,531</b>	<b>100.0 %</b>

Stockholm November 6, 2019

**Immunicum AB (publ)**

*Carlos de Sousa*

**CHIEF EXECUTIVE OFFICER**

# Review report

## Immunicum AB, corporate identity number 556629-1786

### Introduction

We have reviewed the condensed interim report for Immunicum AB as at September 30, 2019 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 with regards to the exceptions from and additions to IFRS which are listed in RFR 2 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

### Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 Review of Interim Financial Statements Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for

financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 with regards to the exceptions from and additions to IFRS which are listed in RFR 2 and the Swedish Annual Accounts Act.

Stockholm, November 6, 2019  
Ernst & Young AB

Anna Svanberg  
Authorized Public Accountant

## Income statement

Amounts in KSEK	2019	2018	2019	2018	2018
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Other operating income	226	7	445	146	184
	<b>226</b>	<b>7</b>	<b>445</b>	<b>146</b>	<b>184</b>
<b>OPERATING EXPENSES</b>					
Sales, general and administration expenses	-5,889	-6,105	-19,286	-18,453	-25,614
Research and development expenses	-23,722	-17,204	-72,699	-52,259	-70,930
Other operating expenses	-258	-218	-453	-1,070	-1,485
<b>Operating profit/loss</b>	<b>-29,643</b>	<b>-23,520</b>	<b>-91,993</b>	<b>-71,637</b>	<b>-97,846</b>
<b>RESULT FROM FINANCIAL ITEMS</b>					
Interest income and similar items	-	-	-	-	-
Interest expense and similar items	-	-1	-11	-8	-14
<b>Profit/loss after financial items</b>	<b>-29,643</b>	<b>-23,520</b>	<b>-92,004</b>	<b>-71,645</b>	<b>-97,860</b>
<b>TOTAL PROFIT/LOSS BEFORE TAXES</b>	<b>-29,643</b>	<b>-23,520</b>	<b>-92,004</b>	<b>-71,645</b>	<b>-97,860</b>
Income tax expense	-	-	-	-	-
<b>PROFIT/LOSS FOR THE PERIOD</b>	<b>-29,643</b>	<b>-23,520</b>	<b>-92,004</b>	<b>-71,645</b>	<b>-97,860</b>
Earnings/loss per share before and after dilution (SEK)	-0,3	-0,5	-1,0	-1,4	-1,9

## Statement of comprehensive income

Amounts in KSEK	2019	2018	2019	2018	2018
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Result for the period	-29,643	-23,520	-92,004	-71,645	-97,860
Other comprehensive income	-	-	-	-	-
<b>Total comprehensive result for the period</b>	<b>-29,643</b>	<b>-23,520</b>	<b>-92,004</b>	<b>-71,645</b>	<b>-97,860</b>

## Balance sheet

Amounts in KSEK	30 Sept 2019	30 Sept 2018	Dec 2018
<b>ASSETS</b>			
<b>Fixed assets</b>			
<i>Tangible assets</i>			
Equipment	-	23	9
<b>Total tangible assets</b>	<b>-</b>	<b>23</b>	<b>9</b>
<i>Financial assets</i>			
Other securities held as fixed assets	1	1	1
Other long term receivables	250	-	-
<b>Total financial assets</b>	<b>251</b>	<b>1</b>	<b>1</b>
<b>Total fixed assets</b>	<b>251</b>	<b>24</b>	<b>10</b>
<b>Current assets</b>			
<i>Inventories</i>			
	-	-	1,469
<i>Current receivables</i>			
Tax credits and related receivables	525	404	465
Other receivables	1,937	1,688	2,842
Prepaid expenses and accrued income	2,072	2,977	1,788
<b>Total current receivables</b>	<b>4,535</b>	<b>5,069</b>	<b>5,095</b>
<i>Cash and bank balances</i>	334,088	133,273	443,798
<b>Total current assets</b>	<b>338,624</b>	<b>138,342</b>	<b>450,363</b>
<b>TOTAL ASSETS</b>	<b>338,875</b>	<b>138,367</b>	<b>450,373</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>SHAREHOLDERS' EQUITY</b>			
<i>Restricted equity</i>			
Share capital	4,613	2,548	3,594
New share issue in progress	-	-	1,019
<b>Total restricted equity</b>	<b>4,613</b>	<b>2,548</b>	<b>4,613</b>
<i>Unrestricted equity</i>			
Share premium reserve	731,828	418,793	731,073
Retained earnings	-329,645	-231,785	-231,785
Profit/loss for the period	-92,004	-71,645	-97,860
<b>Total unrestricted equity</b>	<b>310,180</b>	<b>115,364</b>	<b>401,428</b>
<b>Total shareholders' equity</b>	<b>314,793</b>	<b>117,912</b>	<b>406,041</b>
<b>LIABILITIES</b>			
<b>LONG-TERM LIABILITIES</b>			
Other long-term liabilities	850	850	850
<b>Total long-term liabilities</b>	<b>850</b>	<b>850</b>	<b>850</b>
<b>CURRENT LIABILITIES</b>			
Accounts payable	10,099	5,234	31,266
Other liabilities	1,384	1,291	838
Accrued expenses and deferred income	11,749	13,081	11,378
<b>Total current liabilities</b>	<b>23,232</b>	<b>19,605</b>	<b>43,482</b>
<b>Total liabilities</b>	<b>24,082</b>	<b>20,455</b>	<b>44,332</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>	<b>338,875</b>	<b>138,367</b>	<b>450,373</b>

## Cash flow Statement

Amounts in KSEK	2019	2018	2019	2018	2018
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
<b>Operating activities</b>					
Operating profit/loss before financial items	-29,643	-23,520	-91,993	-71,637	-97,846
Adjustment for items not included in cash flow	-150	14	-270	44	58
Interest expense paid	-	-1	-11	-7	-14
Increase/decrease in other current receivables	2,609	1,984	2,030	6,884	5,389
Increase/decrease in accounts payable	-6,169	1,745	-21,168	-6,481	19,552
Increase/decrease in other current liabilities	4,135	3,079	917	-29,653	-31,807
<b>Cash flow from operating activities</b>	<b>-29,217</b>	<b>-16,698</b>	<b>-110,494</b>	<b>-100,850</b>	<b>-104,670</b>
<b>Investeringsverksamheten</b>					
Investment in financial assets	-250	-	-250	-	-
<b>Kassaflöde från investeringsverksamheten</b>	<b>-250</b>	<b>-</b>	<b>-250</b>	<b>-</b>	<b>-</b>
<b>Financing activities</b>					
New share issues	-	-	-	105,239	456,281
Premiums for warrants	-	-	756	-	-
Costs attributable to the new share issues	-	-	-	-	-36,697
<b>Cash flow from financing activities</b>	<b>-</b>	<b>-</b>	<b>756</b>	<b>105,239</b>	<b>419,583</b>
<b>Cash and cash equivalents at the beginning of the period</b>					
	<b>363,406</b>	<b>149,971</b>	<b>443,798</b>	<b>128,883</b>	<b>128,883</b>
Cash flow for the period	-29,468	-16,698	-109,989	4,390	314,914
Foreign exchange difference in cash and cash equivalents	150	-	279	-	-
<b>Cash and cash equivalents at the end of the period</b>	<b>334,088</b>	<b>133,273</b>	<b>334,088</b>	<b>133,273</b>	<b>443,798</b>

## Report on changes in shareholders' equity

Amounts in KSEK	Share capital	Share premium reserve	Retained earnings incl. profit/loss for the period	Total
<b>Opening shareholders' equity 01/01/2019</b>	4,613	731,073	-329,645	406,041
Premiums for warrants		756		756
Profit/loss for the period			-92,004	-92,004
<b>Shareholders' equity 30/09/2019</b>	<b>4,613</b>	<b>731,828</b>	<b>-421,648</b>	<b>314,793</b>
<b>Opening shareholders' equity 01/01/2018</b>	2,548	418,793	-231,785	189,556
Profit/loss for the period			-71,645	-71,645
<b>Shareholders' equity 30/09/2018</b>	<b>2,548</b>	<b>418,793</b>	<b>-303,429</b>	<b>117,912</b>
<b>Opening shareholders' equity 01/01/2018</b>	2,548	418,793	-231,785	189,556
Share issue	2,065	348,977		351,042
Expenses for new share issue		-36,697		-36,697
Profit/loss for the period			-97,860	-97,860
<b>Shareholders' equity 31/12/2018</b>	<b>4,613</b>	<b>731,073</b>	<b>-329,645</b>	<b>406,041</b>

# 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 2019 was approved for publication on November 6, 2019.

## 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 2018. Disclosures in accordance with IAS 34.16A are provided both in Notes as well as elsewhere in the interim report.

### IFRS 16 Leases

From January 2019 the new standard IFRS 16 applies. The standard causes changes to the lessee but does not entail any material change for the lessor. The amendment compared with the current IAS 17 Leases is that all contracts in which the company is the lessee are to be handled in the same way as Financial leases have been handled in accordance with IAS 17.

The company applies the simplification rule in RFR 2 and will continue to report leasing costs linearly over the lease term.

### 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 250 (566)

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

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 2018 which can be downloaded from the Company's website: [www.immunicum.com](http://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 Immunicum's results.

## Note 6 - Information on Transactions With Closely Related Parties

Margareth Jorvid, Head of Regulatory Affairs and Quality System, and member of Immunicum's management team has during the quarter invoiced Immunicum KSEK 403 in consultancy fees through the company Methra in Uppsala AB.

## Note 7 - Financial instruments

Immunicum's financial assets and liabilities comprise of cash and cash equivalents, other current assets, accrued expenses and accounts payable.

The fair value of all financial instruments is materially equal to their carrying amounts.

## Note 8 - Significant events after end of period

Immunicum Announced Advancement to Next Dosage Group Level in Phase Ib/II ILIAD Combination Trial. Immunicum Announced the Nomination Committee for the AGM 2020. Immunicum Announced Positive Preclinical Data on Ilixadencel in Combination with CTLA-4 Immune Checkpoint Inhibitor. The European Patent Office decided to grant the new Immunicum patent "Improved allogeneic dendritic cells for use in cancer treatment".



## 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.

	Jul- Sept 2019	Jul- Sept 2018	Jan- Sept 2019	Jan- Sept 2018	Jan-Dec 2018
Total registered shares at the beginning of period	92,257,531	50,958,431	71,874,119	25,958,541	25,958,541
Total registered shares at the end of period	92,257,531	50,958,431	92,257,531	50,958,431	71,874,119
Share capital at the end of period, SEK	4,612,877	2,547,927	4,612,877	2,547,927	3,593,706
Equity at the end of period, SEK thousand	314,793	117,912	314,793	117,912	406,041
Earnings per share before and after dilution, SEK	-0.3	-0.5	-1.0	-1.4	-1.9
Research and development costs, SEK thousand	23,722	17,204	72,699	52,259	70,930
Research & development costs/operating expenses %	79 %	73 %	79 %	73 %	72 %

## 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 and development costs divided by total 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

	Jul- Sept 2019	Jul- Sept 2018	Jan- Sept 2019	Jan- Sept 2018	Jan-Dec 2018
<b>Equity ratio at the end of the period %</b>					
Total shareholders' equity at the end of the period (KSEK)	314,793	117,912	314,793	117,912	406,041
Total assets at the end of the period (KSEK)	338,875	138,367	338,875	138,367	450,373
Equity ratio at the end of the period %	93 %	85 %	93 %	85 %	90 %
<b>Research &amp; development costs/operating expenses %</b>					
Research & development costs	23,722	17,204	72,699	52,259	70,930
Administrative costs	5,889	6,105	19,286	18,453	25,614
Other operating expenses	258	218	453	1,070	1,485
Total operating expenses	29,869	23,527	92,438	71,782	98,029
Research & development costs/operating expenses %	79 %	73 %	79 %	73 %	72 %

## 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

**Year-End report 2019: 18 February 2020**

**Annual general meeting 2020: 28 April 2020**

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The information was submitted for publication, through the agency of the contact persons set out above, on November 6, 2019, at 8:00 CET.



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