



# Year-end Report January- December 2018

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## SUMMARY

### FINANCIALS FOR THE QUARTER, OCTOBER-DECEMBER

- Quarterly net sales MSEK 11.1 (13.6)
- Quarterly result MSEK -22.1 (-32.1)
- Cash flow from operating activities MSEK -21.0 (-45.4)
- Result per share SEK -0.5 (-0.7)

### OCTOBER-DECEMBER IN BRIEF

- The first patient in the global Phase III program, POLAR, for PledOx<sup>®</sup> was included in the US
- PledPharma prepares for listing on the Nasdaq Stockholm main market during 2019
- Aladote<sup>®</sup> Phase Ib/IIa study results has been accepted for a poster presentation during the “58th Annual Meeting of the Society of Toxicology” in March, 2019
- Pledpharma has submitted an Orphan Drug Designation (ODD) application to the US Food and Drug Administration (FDA) for the drug candidate Aladote<sup>®</sup>
- The Nomination Committee for the 2019 AGM was appointed and includes members from the four largest shareholders who wished to participate
- The Japanese and Asian investigator meetings for the POLAR studies were held in Tokyo and Seoul

### SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

- A milestone payment of 600 MJPY (c.49 MSEK) was triggered due to the inclusion of the first patient in Japan to the global Phase III program for PledOx<sup>®</sup>
- Patients have been included in the POLAR-program in Europe
- The PledOx<sup>®</sup> phase III program design was presented at the Gastrointestinal (GI) Cancers Symposium, in San Francisco.
- Results from Aladote<sup>®</sup>'s study has been selected for oral presentation at The International Liver Congress, April 2019
- PledPharma invites investors, financial analysts and media to a Capital Markets Day on March 26, 2019.

### FINANCIALS FOR THE PERIOD, JANUARY-DECEMBER

- Net sales for the period MSEK 28.2 (13.9)
- Loss for the period MSEK -85.0 (-87.9)
- Cash position MSEK 229.2 (309.5)
- Cash flow from operating activities MSEK -81.0 (-86.6)
- Result per share SEK -1.7 (-1.8)

### JANUARY-DECEMBER IN BRIEF

#### **PledOx<sup>®</sup>**

- A delayed delivery of the study drug for the PledOx<sup>®</sup> phase III program was announced in February, which was remediated and subsequently delivered in September
- PledOx<sup>®</sup> shows favorable safety and tolerability profile in the SUNCIST Phase I study in Japanese and Caucasian healthy volunteers
- The European Medicines Agency (EMA) approved PledPharma's waiver application for the paediatric investigation plan (PIP) regarding PledOx<sup>®</sup>
- PledOx<sup>®</sup> and Aladote<sup>®</sup> receives an European approval of the composition of matter patent
- The Japanese Medical Agency (PMDA) supports the expansion of the Phase III program for PledOx<sup>®</sup> to include Japanese patients

#### **Aladote<sup>®</sup>**

- Aladote's<sup>®</sup> proof of principle study has been completed with positive results announced in September
- Multiple scientific presentations of Aladote's<sup>®</sup> clinical results have been submitted and accepted
- The Scientific Advisory Board for Aladote<sup>®</sup> was appointed and held its first meeting with focus on the design of the next study

## FINANCIAL SUMMARY

|                                      | 2018    | 2017    | 2018    | 2017    |
|--------------------------------------|---------|---------|---------|---------|
|                                      | Oct-Dec | Oct-Dec | Jan-Dec | Jan-Dec |
| Result after tax, SEKk               | -22,138 | -32,127 | -85,003 | -87,935 |
| Cash flow, SEKk                      | -20,392 | -44,812 | -79,655 | -84,468 |
| Cash, SEKk                           | 229,876 | 309,531 | 229,876 | 309,531 |
| Equity ratio %                       | 91%     | 96%     | 91%     | 96%     |
| Result per share, SEK                | -0.5    | -0.7    | -1.7    | -1.8    |
| Result per share after dilution, SEK | -0.5    | -0.7    | -1.7    | -1.8    |
| Average number of employees          | 8       | 7       | 8       | 5       |

## COMMENTS FROM THE CEO

### **Patients have been included in all regions in the global phase III program for PledOx®**

The largest milestone in PledPharma's history occurred during the last quarter of 2018, with the inclusion of the first patient in the PledOx® phase III program POLAR in November. We are now well on our way to a potential market registration of PledOx® and thus a step closer to providing preventive treatment against nerve damage for the hundreds of thousands of patients undergoing chemotherapy for their colorectal cancer. With no approved treatment against this condition, the execution of the trial is of highest priority for us. Following a successful safety and tolerability Phase I study in Japanese healthy volunteers, the Japanese Medicines Agency (PMDA) supported the expansion of PledOx® Phase III program to include Japanese patients. In January, our Asian partner Solasia Pharma announced the inclusion of the first patient in the Phase III study POLAR-A which triggered the first development milestone payment of c.SEK 49 million from our partner.

With patients included in all regions of the POLAR program (USA, Europe, Asia) it is very satisfying that we are able to maintain our long-term plan to deliver top line data in the fourth quarter of 2020.

### **Planning of next Aladote® study after positive proof of principle study outcome**

We announced positive results from Aladote's® phase Ib/IIa-proof of principle study, in July, its primary objective - to document the drug's safety and tolerability - was achieved. In addition, secondary objectives was also met, as exploratory biomarkers indicate reduced liver injury in paracetamol-intoxicated patients treated with Aladote®.

Since Aladote® is a first in class drug, we applied for orphan drug designation to the FDA in December 2018. An approval may provide favourable conditions from a cost and time to market approval perspective.

A design proposal for the next study has been developed with our scientific advisory board, and will form the basis of our upcoming regulatory interactions.

### **Strengthened competence in the organization**

We have strengthened our expertise in CMC and manufacturing by employing Anders

Sveno as Head of CMC and Supply Chain in April. Furthermore we have also strengthened our competence in clinical development through the recruitment of Helene Depui Ekdal, with 25 years of experience in drug development. Ms Depui Ekdal started as the Clinical Development Director in January 2019.

### **Strong start to the new year and a planned listing on the main market**

The new year has begun with a strong scientific interest for both PledOx® and Aladote® which have been and will be presented at several international scientific conferences.

Furthermore, another step in our ambition is to list our company shares on Nasdaq Stockholm's main market. We see an uplisting as a natural step that reflects the maturity of our business from a capital markets perspective, which can contribute to increased interest from a broader investor base.

With the first patients included in the US, EU and Japan in the PledOx® Phase III program, our first development milestone payment from our partner, next development phase for Aladote®, the scientific interest in our products, the globally robust IP portfolio for PledOx® and Aladote® and a transformed and strengthened organization I am very excited for our continued work in 2019.



**Nicklas Westerholm, CEO**  
Pledpharma AB  
Stockholm

## PLEDPHARMA IN BRIEF

**PledPharma** is an innovative, unique and integrated pharmaceutical drug development company, focusing on improving treatments for diseases with substantial unmet medical need.

The company's most advanced project **PledOx**<sup>®</sup> is being developed to reduce nerve damage associated with chemotherapy. A global phase III program is ongoing.

The drug candidate **Aladote**<sup>®</sup> is being developed to reduce the risk of acute liver injury associated with acetaminophen poisoning. A proof of principle study has been

successfully completed and will serve as the basis for the continued development.

PledPharma (STO:PLED) is listed on Nasdaq First North.

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## PROJECT UPDATES

### PLEDOX<sup>®</sup>



#### PLEDOX<sup>®</sup> IN BRIEF

PledOx<sup>®</sup> is a “first in class” drug candidate that mimics the body’s own enzymatic defence against mitochondrial dysfunction. It is being developed to provide patients, that are treated for adjuvant or metastatic colorectal cancer, prevention against the nerve damage that occurs in conjunction with chemotherapy treatment. This is known as chemotherapy induced peripheral neuropathy (CIPN) and can result in debilitating adverse reaction and may occur at any time after the initiation of chemotherapy. In many patients, the symptoms are resolved after discontinuing the chemotherapy, but up to 20-30% of the patients have sustained chronic symptoms such as numbness, tingling and pain in hands and feet. Patients with CIPN may have difficulties with fine motor skill, such as buttoning buttons, challenges using a computer key board and become hypersensitive to cold. The sensory loss in the feet’s may increase the risk of falls. There is currently no approved drug to prevent or treat CIPN. The manifestation of CIPN can occur anytime during the chemotherapy treatment and does often get more worse the longer patients stay on treatment.

The results from the Phase IIb study PLIANT, where patients with metastatic colorectal cancer were treated with the chemotherapy combination FOLFOX and PledOx<sup>®</sup> (calmangafodipir), indicates that the patients who received PledOx<sup>®</sup> had a lower risk than the placebo group to suffer from nerve damage during the chemotherapy (Glimelius et al., 2018). No apparent negative effect on the efficacy of the cancer treatment was observed.

#### EVENTS DURING THE QUARTER

During the quarter the first patient in the POLAR program was included in the US.

We expect to complete recruitment within 10-12 months from study start. Top-line results are expected in the fourth quarter of 2020.

The phase III program for PledOx<sup>®</sup> consists of two double-blind, randomised, placebo-controlled

studies, POLAR-M and POLAR-A. POLAR-M includes 420 patients undergoing chemotherapy treatment for metastatic colorectal cancer and is planned to be conducted in Europe, Asia and the United States. The study compares PledOx<sup>®</sup> at doses of 2 µmol/kg and 5 µmol/kg, with placebo. POLAR-A includes 280 patients undergoing adjuvant chemotherapy treatment for colorectal cancer and planned to be conducted in Europe and Asia. The study compares PledOx<sup>®</sup> at a dose of 5 µmol/kg with placebo. These studies have been designed based on interactions with the European Medicines Agency (EMA), the US FDA, the Japanese HealthCare Agency (PMDA) and PledPharma’s scientific advisory board. The aim is to show that PledOx<sup>®</sup> reduces sensory nerve damage that the chemotherapy treatment gives rise to by measuring patient reported symptoms of peripheral nerve damage.

#### SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

In January, the first Asian patients were included in the phase III program, POLAR. This triggered a payment of our first development milestone of 600M JPY (c. 49M SEK) from our partner Solasia Pharma which will have a positive impact on our cash flow in the first quarter of 2019.

The POLAR-M trial have been approved by the health authorities in all European countries based on the amended clinical trial applications with data from the newly produced study drug. Final approvals in Europe for POLAR-A is expected in February.

Patients have been included in all regions (the US, Europe and Asia) of the POLAR program. The design of POLAR program was presented at the Gastrointestinal (GI) Cancers Symposium, in San Francisco.

### ALADOTE<sup>®</sup>



#### ALADOTE<sup>®</sup> IN BRIEF

Aladote<sup>®</sup> is a “first-in-class” drug candidate with the potential to prevent the development of acute liver injury caused by paracetamol (acetaminophen) overdose. Paracetamol overdose is one of the most common forms of drug poisoning. When excessive amounts of paracetamol are broken down into the liver, the harmful metabolite NAPQI is formed, which can cause acute liver failure. The current treatment for paracetamol poisoning (N-acetylcysteine) is effective if the patient seeks medical care within 8 hours of ingestion.

However, there is currently no effective treatment for patients who arrive post 8 hours after overdose.

A proof of principle study in patients with paracetamol poisoning has successfully been completed at the Royal Infirmary of Edinburgh. The Aladote<sup>®</sup> study in patients with paracetamol overdose at risk of liver damage has successfully met its primary endpoint of safety and tolerability. Secondary endpoints included exploratory biomarkers for prediction of liver injury, the results indicate a positive signal of reduced paracetamol-induced liver injury in patients treated with Aladote<sup>®</sup>.

## EVENTS DURING THE QUARTER

Aladote's<sup>®</sup> phase Ib/IIa study results (proof of principle) has been accepted for presentation at the 58<sup>th</sup> Annual Meeting of the Society of Toxicology, March 2019.

The company has submitted an application with the US Food and Drug Administration (FDA) for an Orphan Drug Designation (ODD) for the drug candidate Aladote<sup>®</sup>.

A design proposal for the next study has been developed together with our scientific advisory board, and will form the basis of our upcoming regulatory interactions.

## SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

The abstract on the positive results from the Aladote's<sup>®</sup> Phase Ib/IIa proof of principle-study has been selected for an oral presentation at the global conference EASL ILC 2019. EASL ILC, also known as The International Liver Congress, is one of the largest scientific conferences in the field of Hepatology (liver diseases) globally. The conference takes place in Vienna, Austria April 10-14.

## FINANCIAL INFORMATION

FOURTH QUARTER  
OCTOBER – DECEMBER 2018

### REVENUE, AND RESULTS

#### Revenues

Revenue amounted to SEKK 11,098 (13,608) during the quarter and was primarily attributed to reimbursements from Solasia Pharma K.K. for the Asian expansion of the POLAR studies.

#### Expenses

Operating expenses amounted to SEKK 34,134 (45,777) for the quarter. Of these, project costs amounted to SEKK 24,248 (37,022) for the quarter. Project costs related to PledPharma amounted to SEKK 14,207.

Employee costs amounted to SEKK 6,188 (3,643) for the quarter. The increase is due to the recruitment of new employees during 2018, aimed at preparing the company for the continued execution of the phase III trials. Also remuneration for the Board of Directors which is paid as salary according to new rules are included. Cost increases have been mitigated largely by reduction of consultancy expenses. Other operating costs amounted to SEKK 1,107 (1,128) for the quarter. Depreciation amounted to SEKK 0 (0) for the quarter.

#### Results

Operating result amounted to SEKK -23,036 (-32,169) for the quarter. Financial and related items amounted to SEKK 899 (41). Results are related to revaluation of company's FX-accounts at the end of the quarter. Results after financial items amounted to SEKK -22,137 (-32,127) for the quarter. No income tax was reported for the periods. Result per share before and after dilution amounted to SEK -0.5 (-0.7) for the quarter.

### FINANCIAL POSITION

#### Cash

Cash at December 31, 2018 amounted to SEKK 229,876 (309,531).

#### Cash flow

Cash flow from operating activities amounted to SEKK -20,392 (-45,377) for the quarter. Cash flow amounted to SEKK -21,045 (-44,812) for the quarter.

#### Equity and equity ratio

At December 31, 2018 equity amounted to SEKK 219,362 (303,711). Shareholders' equity per share amounted to SEK 4.5 (6.2), at the end of the period. The company's equity ratio was 91 (96) %.

#### Debts and receivables

No long-term debts were outstanding. Current liabilities amounted to SEKK 15,174 (5,972). Accounts receivables amounted to SEKK 9,444 (2,566).

### INVESTMENTS, TANGIBLE AND INTANGIBLE ASSETS

During the period, investments in tangible and intangible fixed assets corresponded to SEKK 0 (0).

### SHARE

The number of shares at December 31, 2018 were 48 666 656. PledPharma's shares are listed on Nasdaq First North since April 7, 2011.

### WARRANT PROGRAM

The 2018 Annual General Meeting resolved on a warrants program for employees of PledPharma of 779,500 warrants, each warrant entitles the holder to subscribe for one (1) new share in the company at a subscription price of SEK 26 per share. As of December 31, 2018, 285,000 warrants were subscribed for by employees, of which CFO and CMO subscribed for maximum allowed allocation of 100,000 each. 1,526,500 warrants had been subscribed for by employees and board members of PledPharma from the previous warrants program of which the CEO holds 500,000 warrants.

At full utilization of all warrants, the company's shares will be increased by 2 306 000 to 50 972 656.

### EMPLOYEES

Number of employees as of December 31, 2018 were 8 (7) persons, 2 women and 6 men.

### PARENT COMPANY

The parent company's revenues for the quarter amounted to SEKK 11,098 (13,608). Expenses for the quarter amounted to SEKK 34,134 (45,777).

The parent company's result amounted to SEKK -21,483 (-30,044) for the quarter.

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

| SEKk  | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|---|-----------------|-----------------|-----------------|-----------------|
| <b>Revenue</b>  |                 |                 |                 |                 |
| Sales   | 11,098          | 13,563          | 28,211          | 13,585          |
| Other operating income  | -               | 46              | 2               | 302             |
|   | <b>11,098</b>   | <b>13,608</b>   | <b>28,212</b>   | <b>13,886</b>   |
| <b>Operating expenses</b>   |                 |                 |                 |                 |
| Project costs   | -24,248         | -37,022         | -83,855         | -76,974         |
| Other external costs  | -2,591          | -3,984          | -11,325         | -12,849         |
| Employee benefit costs  | -6,188          | -3,643          | -20,034         | -10,895         |
| Depreciation and impairment   | -               | -               | -               | -               |
| Other operating expenses  | -1,107          | -1,128          | -5,511          | -1,266          |
| <b>Operating result</b>   | <b>-23,037</b>  | <b>-32,169</b>  | <b>-92,514</b>  | <b>-88,097</b>  |
| <b>Financial items</b>  |                 |                 |                 |                 |
| Interest income and similar items   | 899             | 41              | 7,511           | 163             |
| Interest expense and similar items  | -1              | 0               | -1              | 0               |
| <b>Result after financial net</b>   | <b>-22,138</b>  | <b>-32,127</b>  | <b>-85,003</b>  | <b>-87,935</b>  |
| <b>Result before tax</b>  |                 |                 |                 |                 |
| Tax   | -               | -               | -               | -               |
| <b>Result after tax</b>   | <b>-22,138</b>  | <b>-32,127</b>  | <b>-85,003</b>  | <b>-87,935</b>  |
| <b>Statement of comprehensive income</b>  |                 |                 |                 |                 |
| Other comprehensive income  | -               | -               | -               | -               |
| <b>Comprehensive income for the period</b>  | <b>-22,138</b>  | <b>-32,127</b>  | <b>-85,003</b>  | <b>-87,935</b>  |
| Net earnings and comprehensive income is entirely attributable to parent company shareholders |                 |                 |                 |                 |
| <b>Share Data</b>   |                 |                 |                 |                 |
| Number of shares at the end of period   | 48,666,656      | 48,666,656      | 48,666,656      | 48,666,656      |
| Average number of shares during period  | 48,666,656      | 48,666,656      | 48,666,656      | 48,666,656      |
| Result per share before dilution (SEK)  | -0.5            | -0.7            | -1.7            | -1.8            |
| Result per share after dilution (SEK)   | -0.5            | -0.7            | -1.7            | -1.8            |
| Equity per share (SEK)  | 4.5             | 6.2             | 4.5             | 6.2             |
| Equity per share after dilution (SEK)   | 4.5             | 6.2             | 4.5             | 6.2             |

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

| SEKk                                 | 12/31/2018     | 12/31/2017     |
|--------------------------------------|----------------|----------------|
| <b>ASSETS</b>                        |                |                |
| <b>Non-current assets</b>            |                |                |
| <b>Total non-current assets</b>      | -              | -              |
| <b>Current assets</b>                |                |                |
| Accounts receivables                 | 9,444          | 2,566          |
| Other receivables                    | 624            | 1,436          |
| Prepaid expenses and accrued income  | 2,093          | 1,836          |
|                                      | 12,161         | 5,838          |
| <i>Cash and bank balance</i>         | 229,876        | 309,531        |
| <b>Total current assets</b>          | <b>242,037</b> | <b>315,368</b> |
| <b>Total assets</b>                  | <b>242,037</b> | <b>315,368</b> |
| SEKk                                 | 12/31/2018     | 12/31/2017     |
| <b>Equity</b>                        |                |                |
| Share capital                        | 2,561          | 2,561          |
| Other capital contributions          | 618,597        | 617,944        |
| Accumulated loss including net loss  | -401,797       | -316,794       |
| <b>Total equity</b>                  | <b>219,362</b> | <b>303,711</b> |
| <b>Current liabilities</b>           |                |                |
| Accounts payable                     | 15,174         | 5,972          |
| Other liabilities                    | 1,205          | 733            |
| Accrued expenses and deferred income | 6,296          | 4,953          |
| <b>Total current liabilities</b>     | <b>22,675</b>  | <b>11,657</b>  |
| <b>Total equity and liabilities</b>  | <b>242,037</b> | <b>315,368</b> |

## CONSOLIDATED STATEMENT OF CASH FLOWS

| SEKk   | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|--|-----------------|-----------------|-----------------|-----------------|
| <b>OPERATING ACTIVITIES</b>  |                 |                 |                 |                 |
| Result after financial net   | -22,138         | -32,127         | -85,003         | -87,935         |
| Adjustments for non-cash items   | -               | -               | -               | -               |
| <b>Cash flow from operating activities before changes in working capital</b> | <b>-22,138</b>  | <b>-32,127</b>  | <b>-85,003</b>  | <b>-87,935</b>  |
| Changes in short term receivables  | -8,137          | -2,949          | -6,273          | -3,143          |
| Changes in accounts payable  | 8,360           | -13,051         | 9,202           | 1,294           |
| Changes in other liabilities   | 1,523           | 2,751           | 1,765           | 3,232           |
| <b>Cash flow from operating activities</b>                                   | <b>-20,392</b>  | <b>-45,377</b>  | <b>-80,310</b>  | <b>-86,551</b>  |
| <b>INVESTING ACTIVITIES</b>  |                 |                 |                 |                 |
| <b>Cash flow from investing activities</b>                                   | -               | -               | -               | -               |
| <b>FINANCING ACTIVITIES</b>  |                 |                 |                 |                 |
| New share/Warrants issue   | -               | 566             | 655             | 2,083           |
| <b>Cash flow from financing activities</b>                                   | -               | <b>566</b>      | <b>655</b>      | <b>2,083</b>    |
| <b>Cash flow for the period</b>  |                 |                 |                 |                 |
| Balance at beginning of period   | 250,267         | 354,342         | 309,531         | 393,998         |
| Change in cash   | -20,392         | -44,812         | -79,655         | -84,468         |
| <b>CASH BALANCE AT THE END OF THE PERIOD</b>                                 | <b>229,876</b>  | <b>309,531</b>  | <b>229,876</b>  | <b>309,531</b>  |

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

| SEKk                            | Share capital | Other capital contributions | Accumulated loss incl. net result for the period | Total equity   |
|---------------------------------|---------------|-----------------------------|--|----------------|
| <b>Opening balance 20170101</b> | <b>2,561</b>  | <b>615,861</b>              | <b>-228,860</b>                                  | <b>389,562</b> |
| Incentive program               | -             | 2,083                       | -  | 2,083          |
| Comprehensive income for period | -             | -                           | -87,935  | -87,935        |
| <b>Closing balance 20171231</b> | <b>2,561</b>  | <b>617,944</b>              | <b>-316,794</b>                                  | <b>303,711</b> |
| <b>Opening balance 20180101</b> | <b>2,561</b>  | <b>617,944</b>              | <b>-316,794</b>                                  | <b>303,711</b> |
| Incentive program               | -             | 654                         | -  | 654            |
| Comprehensive income for period | -             | -                           | -85,003  | -85,003        |
| <b>Closing balance 20181231</b> | <b>2,561</b>  | <b>618,597</b>              | <b>-401,798</b>                                  | <b>219,361</b> |

## CONSOLIDATED KEY RATIOS

The key ratios below are useful to those who read the financial statements and a complement to other performance targets in evaluating strategic investment implementation and the Group's ability to achieve financial goals and commitments.

| SEKk   | 2018       | 2017       | 2018       | 2017       |
|--|------------|------------|------------|------------|
|  | Oct-Dec    | Oct-Dec    | Jan-Dec    | Jan-Dec    |
| Equity   | 219,362    | 303,711    | 241,499    | 303,711    |
| Equity ratio %   | 91%        | 96%        | 91%        | 96%        |
| Return on equity %                                       | neg.       | neg.       | neg.       | neg.       |
| Number of shares at the end of the period                | 48,666,656 | 48,666,656 | 48,666,656 | 48,666,656 |
| Number of shares at the end of the period after dilution | 48,666,656 | 48,666,656 | 48,666,656 | 48,666,656 |
| Average number of shares under the period                | 48,666,656 | 48,666,656 | 48,666,656 | 48,666,656 |
| Average number of shares under the period after dilution | 48,666,656 | 48,666,656 | 48,666,656 | 48,666,656 |

### Share Data

|                                     |      |      |      |      |
|-------------------------------------|------|------|------|------|
| Result per share                    | -0.5 | -0.7 | -1.7 | -1.8 |
| Result per share after dilution*    | -0.5 | -0.7 | -1.7 | -1.8 |
| Cash flow from operating activities | -0.4 | -0.9 | -1.7 | -1.8 |
| Equity per share                    | 4.5  | 6.2  | 4.5  | 6.2  |
| Equity per share after dilution     | 4.5  | 6.2  | 4.5  | 6.2  |
| Dividend                            | -    | -    | -    | -    |
| Average number of employees         | 8    | 7    | 8    | 5    |

\*Effect from dilution is not considered when result is negative.

## KEY RATIOS DEFINITIONS

Ratios that have been calculated according to IFRS

### **Earnings per share**

Net income divided by average number of shares before dilution

### **Number of shares at end of period**

The number of outstanding shares before dilution at the end of the period

### **Number of shares after dilution**

The number of issued shares after dilution effect of potential shares at end of period

### **Average number of shares during the period**

Average number of outstanding shares before dilution for the period

### **Average number of shares during the period after dilution**

Average number of issued shares after dilution effect of potential shares

### **Number of employees (average)**

The average number of employees at the end of each period

## Ratios that have not been calculated in accordance with IFRS

### **Equity ratio, %**

The company defines the ratio as follows; The period's closing equity divided by the period's closing balance sheet. The company uses the alternate ratio Equity as it shows the proportion of total assets represented by shareholders' equity and has been included to allow investors to assess the company's capital structure.

### **Return on equity, %**

The company defines the ratio as follows; Net income divided by shareholders' equity. The company uses the alternate key figure Return on equity, % because the company believes that the key ratio gives investors a better understanding of the return generated on the total capital that the shareholders have invested in the Company.

### **Cash flow from operations per share**

The company defines the ratio as follows; Cash flow from operating activities divided by the number of shares outstanding at the end of the period. The company uses the alternate key figure Cash flow from operations per share because the Company believes that the key ratio gives investors a better understanding of the company's cash flow in relation to its number of shares adjusted for changes in the number of shares outstanding during the period.

### **Equity per share**

The company defines the ratio as follows; Equity divided by number of shares outstanding at the end of the period. The company uses the alternate key ratio equity per share because the Company believes that the key ratio gives investors a better understanding of the historical return per share adjusted for changes in the number of shares outstanding during the period.

## PARENT COMPANY - INCOME STATEMENT

| SEKk                                       | 2018<br>Oct-Dec | 2017<br>Oct-Dec | 2018<br>Jan-Dec | 2017<br>Jan-Dec |
|--|-----------------|-----------------|-----------------|-----------------|
| <b>Revenue</b>                             |                 |                 |                 |                 |
| Sales                                      | 11,098          | 13,563          | 28,211          | 13,585          |
| Other operating income                     | -               | 46              | 2               | 302             |
|  | <b>11,098</b>   | <b>13,608</b>   | <b>28,212</b>   | <b>13,886</b>   |
| <b>Operating expenses</b>                  |                 |                 |                 |                 |
| Project costs                              | -24,248         | -37,022         | -83,855         | -76,974         |
| Other external costs                       | -2,590          | -3,984          | -11,324         | -12,849         |
| Employee benefit costs                     | -6,188          | -3,643          | -20,034         | -10,895         |
| Depreciation and impairment                | -               | -               | -               | -               |
| Other operating expenses                   | -1,107          | -1,128          | -5,511          | -1,266          |
| <b>Operating result</b>                    | <b>-23,036</b>  | <b>-32,169</b>  | <b>-92,513</b>  | <b>-88,097</b>  |
| <b>Financial items</b>                     |                 |                 |                 |                 |
| Interest income and similar items          | 899             | 41              | 7,510           | 163             |
| Interest expense and similar items         | -1              | 0               | -1              | 0               |
| <b>Result after financial net</b>          | <b>-22,137</b>  | <b>-32,127</b>  | <b>-85,003</b>  | <b>-87,935</b>  |
| <b>Result before tax</b>                   |                 |                 |                 |                 |
| Group contribution received                | 654             | 2,083           | 654             | 2,083           |
| Tax  | -               | -               | -               | -               |
| <b>Result after tax</b>                    | <b>-21,483</b>  | <b>-30,044</b>  | <b>-84,350</b>  | <b>-85,851</b>  |
| <b>Statement of comprehensive income</b>   |                 |                 |                 |                 |
| Other comprehensive income                 | -               | -               | -               | -               |
| <b>Comprehensive income for the period</b> | <b>-21,483</b>  | <b>-30,044</b>  | <b>-84,350</b>  | <b>-85,851</b>  |

## PARENT COMPANY - BALANCE SHEET

| SEKk                                | 12/31/2018     | 12/31/2017     |
|-------------------------------------|----------------|----------------|
| <b>ASSETS</b>                       |                |                |
| <b>Non-current assets</b>           |                |                |
| Tangible non-current assets         | -              | -              |
| Financial non-current assets        | 50             | 50             |
| <b>Total non-current assets</b>     | <b>50</b>      | <b>50</b>      |
| <b>Current assets</b>               |                |                |
| Receivables from group companies    | 2,686          | 2,083          |
| Accounts receivables                | 9,444          | 2,566          |
| Other receivables                   | 624            | 1,436          |
| Prepaid expenses and accrued income | 2,093          | 1,836          |
|                                     | 14,848         | 7,921          |
| <i>Cash and bank balance</i>        | 227,139        | 307,447        |
| <b>Total current assets</b>         | <b>241,987</b> | <b>315,368</b> |
| <b>Total assets</b>                 | <b>242,037</b> | <b>315,418</b> |

| SEKk                                 | 12/31/2018     | 12/31/2017     |
|--------------------------------------|----------------|----------------|
| <b>Equity</b>                        |                |                |
| <i>Restricted Equity</i>             |                |                |
| Share capital                        | 2,561          | 2,561          |
| <i>Non-restricted equity</i>         |                |                |
| Share premium reserve                | 617,943        | 615,860        |
| Retained earnings                    | -316,793       | -228,860       |
| Net profit for the year              | -84,350        | -85,851        |
| <b>Total equity</b>                  | <b>219,362</b> | <b>303,710</b> |
| <b>Current liabilities</b>           |                |                |
| Liabilities to group company         | -              | 50             |
| Accounts payable                     | 15,174         | 5,972          |
| Other liabilities                    | 1,205          | 733            |
| Accrued expenses and deferred income | 6,296          | 4,953          |
| <b>Total current liabilities</b>     | <b>22,675</b>  | <b>11,708</b>  |
| <b>Total equity and liabilities</b>  | <b>242,037</b> | <b>315,418</b> |

## NOTES

### NOTE 1 - Accounting principles

PledPharma applies International Financial Reporting Standards (IFRS) as adopted by the EU. This report is prepared in accordance with IAS 34 Interim Financial Reporting and the Annual Accounts Act. The parent company's interim report is prepared in accordance with the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities and the Swedish Annual Accounts Act. Applied accounting principles and calculation methods are the same as in the latest annual report for 2017. Except that the company has shifted to account according to IFRS 9 and IFRS 15.

PledPharma has evaluated the effect of implementation of IFRS 9. The groups financial instruments consists only of accounts receivables and cash balance.

According to PledPharma's assessment, the implementation of IFRS 15 does not have any impact on the accounting, hence this does not add further need for new information which can have any impact for the financial reports. Please see 2017 annual report for further information.

IFRS 16 will enter into force on January 1, 2019. IFRS 16 replaces IAS 17 Lease Agreement, with new accounting requirements for lessee. All leases, except short-term and minor leasing contracts, shall be reported as an asset with right of use and as a corresponding liability in the leaseholder's balance sheet. The standard is expected to provisionally mean that most of the leases reported in these financial statements as operating leases will be reported as assets and liabilities in the financial statement. This will also cause the cost of these to be reported broken down into interest expense and depreciation. PledPharma applies the simplified transition model. Leasing contracts of minor value will henceforth be accounted as operating leases and reported in the income statement. Company's leasing portfolio consists of three agreements which includes operating leases of office, office equipment and cars. Based on available information, PledPharma estimates right of use assets and attributable lease liabilities will increase by approximately SEK 0.2 million as of January 1, 2019. At the entry into 2019 one of the company's rental agreements had a duration of less than 12 months, this agreement falls into the exception of short term leasing contracts.

### NOTE 2 – Additional information

Other information in accordance with IAS 34.16A are found on pages before the income statement and statement of comprehensive income. Information on earnings, cash flow and financial position, see page 8. For events after the period, see page 1.

### NOTE 3 – Financial assets and liabilities

### Group 31 December 2018

The fair value and carrying value are shown in the table below:

| SEKk                     | Hold to collect | Financial debts | Total carrying amount | Fair value     |
|--------------------------|-----------------|-----------------|-----------------------|----------------|
|                          | Amortised cost  | Amortised cost  |                       |                |
| Accounts receivable      | 9,444           | -               | 9,444                 | 9,444          |
| Cash                     | 229,876         | -               | 229,876               | 229,876        |
| <b>Total assets</b>      | <b>239,320</b>  | <b>-</b>        | <b>239,320</b>        | <b>239,320</b> |
| Accounts payable         | -               | 15,174          | 15,174                | 15,174         |
| Other liabilities        | -               | -               | -                     | -              |
| <b>Total liabilities</b> | <b>-</b>        | <b>15,174</b>   | <b>15,174</b>         | <b>15,174</b>  |

### Group 31 December 2017

The fair value and carrying value are shown in the table below:

| SEKk                     | Hold to collect | Financial debts | Total carrying amount | Fair value     |
|--------------------------|-----------------|-----------------|-----------------------|----------------|
|                          | Amortised cost  | Amortised cost  |                       |                |
| Accounts receivable      | 2,566           | -               | 2,566                 | 2,566          |
| Cash                     | 309,531         | -               | 309,531               | 309,531        |
| <b>Total assets</b>      | <b>312,096</b>  | <b>-</b>        | <b>312,096</b>        | <b>312,096</b> |
| Accounts payable         | -               | 5,972           | 5,972                 | 5,972          |
| Other liabilities        | -               | -               | -                     | -              |
| <b>Total liabilities</b> | <b>-</b>        | <b>5,972</b>    | <b>5,972</b>          | <b>5,972</b>   |

### Not 4 – Related parties transactions

There are none transactions to be reported with related parties.

### Not 5 – Reclassification of operating expenses

Reclassification of certain consultancy and supplier expenses have been made. Following amounts have been reclassified SEK 993 and SEK 2,777 for FY 2018 and FY 2017, respectively. These expenses have been reclassified from other external costs to project costs. The reclassification does not impact operating results.

## OTHER INFORMATION

### Next reports

Interim report Jan – Mar 2019, May 6, 2019  
Interim report Jan – Jun 2019, Aug 21, 2019  
Interim report Jan – Sep 2019, Oct 23, 2019

This report, and further information is available on the website, [www.pledpharma.se](http://www.pledpharma.se)

This report has not been reviewed by the company's auditor. This is a translation of the Swedish interim report.

### Annual General Meeting 2019

Annual general meeting will be held May 7, 2019, at 16:00 CET, at Erik Penser Bank, Apelbergsgatan 27, Stockholm.

The Annual report will be published during week 15, 2019.

PledPharma's board of directors recommend zero SEK in dividend for the full-year 2018.

### For further information contact:

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This information is such information as PledPharma AB (publ) is obliged to disclose in accordance with EU market abuse regulation and the Securities Markets Act. The information was submitted, through the above contact persons, for publication on 21 February 2019 at 8.00 am (CET).

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### Certified Adviser

The company's Certified Advisor is Erik Penser Bank (phone +46 8 463 80 00).

### Analysts who follow PledPharma

Redeye, Klas Palin.

Carnegie, Ulrik Trattner.

## CERTIFICATION

This report provides a true and fair overview of the company's business activities, financial position, and results of operations, and describes significant risks and uncertainties to which the company is exposed.

Stockholm, February 21, 2019

Håkan Åström  
*Chairman of the board*

Marie Ekström Trägårdh  
*Board member*

Sten Nilsson  
*Board member*

Gunilla Osswald  
*Board member*

Elisabeth Svanberg  
*Board member*

Nicklas Westerholm  
*President and CEO*