



# Confidence in our data leading the way forward



## Significant events

### OCTOBER–DECEMBER

- **New melflufen data** was presented at the Annual American Society of Hematology Meeting ASH, December 10
- **Jakob Lindberg was appointed CEO** of Oncopeptides and Marty J Duvall left the company on November 15
- **Annika Muskantor** joined as interim CFO on November 8
- **A compassionate use program** was established in the US in consultation with the FDA
- **A focused clinical development effort** was announced on November 4, to increase cash runway
- **Oncopeptides will refocus on R&D**, close the commercial operations in US and Europe, and scale down the Sweden based organization
- **Pepaxto was withdrawn** from the US market on October 22
- **Anders Martin-Löf, CFO**, announced his resignation on October 15

### EVENTS AFTER THE PERIOD

- **A recission of the withdrawal** of Pepaxto in the US was announced on January 21
- **Phase 3 OCEAN study was published** in the Lancet Haematology on January 13
- **Year-end cash 2021** was announced on January 5

Pepaxto® (Melphalan flufenamide) is the US trade name. It is known as melflufen during clinical development.

## Financial overview

### OCTOBER–DECEMBER

- **Net sales** amounted to SEK -21.7 M (0.0)
- **Operating profit** was SEK -389.8 M (- 511.6)
- **Net profit** amounted to SEK -394.0 M (-513.0)
- **Profit per share**, before and after dilution, amounted to SEK -5.23 (-7.59)
- **Cash balances** at the end of the period amounted to SEK 362.2 M (840.3)

### JANUARY–DECEMBER

- **Net sales** amounted to SEK 118.3 M (0.0)
- **Operating profit** was SEK -1,420.9 M (-1,591.3)
- **Net profit** amounted to SEK -1,430.3 (-1,594.7)
- **Profit per share**, before and after dilution, amounted to SEK -19.00 (-25.57)
- **Cash balances** at the end of the period amounted to SEK 362.2 M (840.3)

118.3

Sales  
Jan-Dec  
MSEK

362

Cash  
MSEK

## Selected Key Indicators

(SEK Thousand)	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Net sales	-21 710	-	118 295	-
Gross profit	-40 088	-	65 174	-
Gross margin, %	Neg	N/A	55%	N/A
Operating profit	-389 836	-511 573	-1 420 917	-1 591 279
Profit after tax	-393 991	-512 966	-1 430 317	-1 594 693
Earnings per share before and after dilution (SEK)	-5,23	-7,59	-19,00	-25,57
Cash flow from operating activities	-446 455	-357 162	-1 516 391	-1 296 509
Cash at the end of the period	362 187	840 255	362 187	840 255
R & D expenses/operating expenses, %	53%	45%	46%	54%

## Confidence in our data leading the way forward

On October 22, 2021, Oncopeptides voluntarily withdrew Pepaxto from the US market following in depth discussions with the FDA that made it evident that the agency were unwilling to view the OCEAN study as a confirmatory study. Consequently, we decided to refocus on R&D and dedicate our resources to further develop the next generation of drug candidates from the PDC platform. We closed the commercial operations in the US and Europe, scaled down the organization and discontinued most clinical studies.

### CLOSED COMMERCIAL OPERATIONS AND REFOCUSING CLINICAL PROGRAM

Immediately after the US withdrawal we started to close the business operations in the US and Europe and scale down the organization. It has been a very challenging task, and I am impressed by all employees who have contributed relentlessly throughout this process, even though many of them were aware of, that ultimately, they would have to leave the company.

We have closed most clinical studies and focused the clinical program on studies that may support the regulatory interactions: OCEAN continues with long-term follow-up and documentation; patient recruitment has been completed in both PORT and BRIDGE and these studies are closed with relevant scientific data sets. ANCHOR has been closed without the last 10 previously planned patients in the bortezomib + melflufen study arm. ASCENT, COAST and LIGHTHOUSE have closed with incomplete number of patients. It will not be possible to draw any scientific conclusions from these studies.

All together, these measures led to a

2021 end-of-year cash position of SEK 362 M which according to our previous guidance, will take us through at least 2022, given that the restructuring proceeds according to plan. Our average monthly burn rate in 2021, of SEK 130 M, has been significantly reduced to an estimated base operational burn rate of SEK 12-15 M as of end-of January 2022. The cash flow in 2022 will, in addition to the negative operational cash flow, be impacted by some remaining costs for discontinuation of clinical studies as well as expenses related to the ongoing filing with the European Medicines Agency, EMA. These costs will primarily impact H1 2022.

### OCEAN DATA PUBLISHED IN THE LANCET HAEMATOLOGY

In December 2021 we presented updated data from the OCEAN study at the Annual American Society of Hematology Meeting, ASH. We are committed to share updated data on melflufen with the myeloma community.

On January 13, 2022, we reached an important milestone when the results from the OCEAN study were published in Lancet Hematology. We

hope that melflufen may become an important treatment option for patients with relapsed refractory multiple myeloma, RRMM, and that the comprehensive data further support the ongoing EMA review of melflufen.

### RESICISSON OF WITHDRAWAL OF PEPAXTO IN THE US

Even though we made a voluntary withdrawal of Pepaxto from the US market, we have continued to have a strong belief in our data. The overall assessment of data from the OCEAN study and other relevant trials have convinced us to reconsider our withdrawal. That is why we on January 21, communicated the rescission of our October 22 letter to FDA requesting a withdrawal of Pepaxto from the US market.

We will not re-introduce or market Pepaxto in the US before the new data has been discussed and assessed together with the FDA. At this point it is premature to talk about if, when and how patients in the US would be able to get access to Pepaxto again, but we are confident that we have a drug that helps patients. This is also the reason why

we made this decision.

### LOOKING BACK AT 2021

When I look back at 2021, this has by far has been the most transformative year in Oncopeptides' history. Pepaxto met the primary end-point and showed superior progression free survival, PFS, in the OCEAN study, but with a highly heterogenous overall survival result in comparison with pomalidomide. This caused a huge regulatory setback with the FDA.

Based on the large unmet medical need for patients with RRMM, we continue our dialogue with the FDA and EMA and hope to be able to reach a positive conclusion on how to interpret the highly heterogenous overall survival result in the OCEAN study.

The safety warning from the FDA in July 2021, led to a withdrawal in the US market and a refocus and significant dismantling of the organization. This has been the largest setback in my career.



”When I look back at 2021, this has by far been the most transformative year ever in Oncopeptides history.”

Jakob Lindberg  
CEO

## CEO statement

### MOVING INTO 2022

Even though 2021 took a direction that we did not expect, I have confidence in our data and study results.

We are looking forward to a continued dialogue with FDA and EMA during 2022. A successful interaction with the regulatory authorities will be critical for the future development of Oncopeptides.

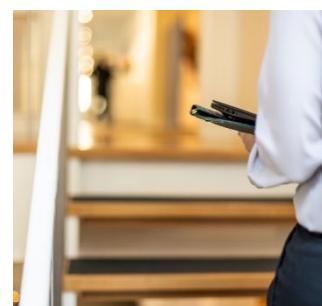
While there is no fixed time-line for our FDA interactions, we look forward to receive the opinion from CHMP, the scientific committee of EMA, around mid-year 2022.

Currently, almost 70 patients are treated with melflufen through the Early Access Program in Europe which highlights the large unmet medical need for patients with RRMM.

2021 was indeed a challenging year, but it is with increasing confidence we now move into 2022. I would like to thank all employees for your dedicated contributions during this tough year, and all shareholders for your continued belief in Oncopeptides. ■

Stockholm, February 17, 2022

Jakob Lindberg  
CEO



### REVENUE

Net sales in the quarter were negative, amounting to SEK -21.7 M (0.0), and SEK 118.3 M (0.0) for the full year. Net sales were negative during the quarter since actual returns and provisions for returns exceeded sales as a result of the withdrawal of Pepaxto from the US market.

The provision for returns that, contractually, can be remitted in Q2 2022 amounted to SEK 48.6 M.

Cost of goods sold for the quarter amounted to SEK 18.4 M (0.0) and to SEK 53.1 M (0.0) for the full year.

Gross profit for the quarter amounted to SEK -40.1 M (-) and SEK 65.2 M (-) for the full year.

The gross margin for the quarter has been affected by returns, and accruals for anticipated returns, and can not be deemed relevant.

### OPERATING EXPENSES

Operating expenses, excluding cost of goods sold, for the quarter amounted to SEK 349.7 M (511.6) and to SEK 1,486.1 M (1,591.3) for the full year.

Accruals relating to closing of clinical studies and staff redundancies, driven by the communicated restructuring, amounted to SEK 41.1 M for the quarter and for the year.

In addition, the withdrawal of Pepaxto has driven the need for a non-recurring write-down of assets in the amount of SEK 16.6 M for the Group, of which

- Inventory; SEK 9.0 M
- Right to use assets; SEK 2.2 M
- Other fixed assets; SEK 4.1 M
- Group receivables; SEK 19.4 M

### RESEARCH AND DEVELOPMENT EXPENSES

Expenses relating to research and development amounted to SEK 184.3 M (231.4) for the quarter and SEK 679.9 M (866.2) for the full year. Accruals relating to already communicated close of studies amounted to SEK 37.6 M for the quarter and year.

Reduced expenses in clinical studies, as well as the decision to rapidly close ongoing studies, were key drivers behind the cost reduction.

### MARKETING AND SALES EXPENSES

Marketing and sales related expenses amounted to SEK 167.8 M (173.6) for the quarter and SEK 698.3 M (456.5) for the year. Year end accruals, relating to the closing of commercial operations, amounted to SEK 3.0 M.

The rapid downsizing of marketing and sales activities relating to Pepaxto in the US are the key drivers behind the reduction.

### GENERAL AND ADMINISTRATIVE EXPENSES

General and administrative expenses amounted to SEK 33.6 M (60.7) during the quarter, and SEK 175.5 (197.7) for the year. Year end accruals, relating to the downsizing of the administrative functions, amounted to SEK 0.5 M.

### EXPENSES FOR SHARE BASED INCENTIVE PROGRAMS

Expenses relating to provisions for social security costs vary each quarter with changes in the underlying share price. Given that

the share price has declined during the year, the taxable benefit and related social security charges have decreased. Such provisions are reported under long- and short-term liabilities.

Exercisable instruments, held by the employees made redundant in the restructuring, will be revoked. The costs for share based related incentive programs was thereby reduced during the year and amounted to SEK -12.1 M (29.9) for the quarter, and SEK -34.2 M (68.2) for the year; of which provisions and payments for social security related expenses amounted to SEK -48.4 M (29.5), and expenses relating to share-based remuneration amounted to SEK 14.2 M (38.7). The expenses have no cash impact.

The company has, in line with authorization given by the relevant AGMs, issued warrants to cover social security contribution expenses exceeding the paid premiums that could arise when employees exercise granted stock options. See note 9.

### EFFECTS OF COVID-19

The effects of Covid-19 were reduced as restrictions eased in the countries where the Company operates. The pandemic is therefore not deemed to have any material effects on the financial statements.

### TAX AND EARNINGS

Earnings before taxes amounted to SEK -389.5 M (-511.8) for the quarter and to SEK -1,421.4 M (-1,592.4) for the year.

Up until the withdrawal of the

product from the US market in October 2021, a deferred tax asset arose as a consequence of temporary differences in sales of intra-group stock items. The internal profit was reversed in its entirety as inventory was returned to the Parent Company. The temporary deferred tax benefit has thus been fully reversed by year end, without any cash impact. See note 7.

Net profit amounted to SEK -394.0 M (-513.0) for the quarter and to SEK -1,430.3 M (-1,594.7) for the year; corresponding to a loss per share, before and after dilution, of SEK -5.23 (-7.59) for the quarter and to a loss per share of SEK -19.00 (-25.57) for the year.

### CASH FLOW, INVESTMENTS AND FINANCIAL POSITION

Cash flow from operating activities amounted to SEK -446.5 M (-357.2) for the quarter and SEK -1,516.4 M (-1,296.5) for the year.

The negative cash flow was primarily driven by the Company's efforts to build a sales and marketing organization, as well as by the downsizing of the same after the withdrawal from the US market.

Cash flow from investment activities amounted to SEK 0.0 M (-4.5) for the quarter and SEK -0.3 M (-20.1) for the year.

Cash flow from financing activities amounted to -4.0 (3.7) MSEK for the quarter and SEK 1,034.0 M (-1,323.5) for the year. Cash-flow for the quarter amounted to SEK -450.4 M (-358.0) and to SEK -482.7 M (6.8) for the year.

Cash balances at the end of the

period amounted to SEK 362.2 M (840.3).

The Company has an unutilized loan facility of EUR 40 M with EIB. The terms enabling draw down of the facility are to be renegotiated.

Equity amounted to SEK 210.9 M (576.9) at the end of the period.

### FINANCING AND GOING CONCERN

The Company decided, in dialogue with the FDA, to voluntarily withdraw Pepaxto from the US market on October 22, 2021. As a consequence, the Board decided to immediately change the direction of the company and revert to an R&D based company focusing on developing the patent protected PDC-platform including the next generation drug candidates OPD5 and OPDC3 alongside seeking approval for Melflufen with the EMA. The rescindment of the voluntary withdrawal in January of 2022, has not altered the strategy.

The rescinding of the voluntary withdrawal from the US market, as published on January 21, 2022, will not lead to marketing of Pepaxto in the US until the new data has been discussed and assessed together with the FDA. Thus, no revenue from the US has been included in the assessment of going concern in the next 12 months.

The swift and decisive reduction of operational costs will improve Group revenues in line with previously published assumptions. Closing costs related to the down-sizing (staff reductions and closing of clinical studies) as well as specific costs relating to the EMA application, will burden the first half of 2022.

However, the underlying operational burn-rate has been radically reduced already from the start of the year.

The Board and the Managing Direction continuously assess the Groups financial viability and access to cash.

This report is issued based on the assumption of going concern for at least 12 months.

As Oncopeptides reverts to an R&D based company with limited revenue generation prior to a potential approval by the relevant medical agencies, the Company is unlikely to generate positive cash flows from running operations. During the R&D phase, and until the company has a commercially launched product, the Company does not have a revenue source and can require additional cash contributions.

Provided that the restructuring proceeds as planned, it is the assessment of the Board and the CEO that the Group has the necessary funds to continue operations during at least the coming twelve months. Would the above conditions not be fulfilled, for example if the company's restructuring becomes costlier than expected, the Group's continued operations are at risk.

In aggregate, the above indicates that there are considerations that could raise to significant doubt as to the Company's continued ability to continue operations. ■

## Other information

### EMPLOYEES

At the end of the year the Company had 162 (280) coworkers.

### PARENT COMPANY

Parent company operations are aligned with those of the Group, why the comments for the Group are also relevant for the Parent company.

### ONCOPEPTIDES SHARE

The number of registered shares at the end of the reporting period amounted to 75,291,841.

### EVENTS AFTER THE PERIOD

- **Voluntary withdrawal of** Pepaxto in the US was rescinded on January 21
- **Phase 3 OCEAN study was published** in the Lancet Haematology on January 13
- **Year-end cash 2021** was announced on January 5

### DIVIDEND

In accordance with the dividend policy adopted by the board, no dividend is proposed for the year 2021.

### AUDIT

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

## Signatures

The Board and the CEO confirm that the interim report provides a true and fair overview of the Group's and the Parent Company's operations, position and earnings and describes the material risks and uncertainty factors faced by the Parent Company and the companies within the Group.

Stockholm, Februari 17, 2022

**Per Wold-Olsen**  
Chairman

**Jenifer Jackson**  
Board member

**Cecilia Daun-Wennborg**  
Board member

**Per Samuelsson**  
Board member

**Jarl Ulf Jungnelius**  
Board member

**Jakob Lindberg**  
CEO

**Brian Stuglik**  
Board member

## Condensed consolidated statement of comprehensive income

SEK thousand	Note	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
Net sales	5	-21 710	-	118 295	-
Cost of Goods Sold		-18 378	-	-53 121	-
<b>Gross profit</b>		<b>-40 088</b>	<b>-</b>	<b>65 174</b>	<b>-</b>
Research and development expenses		-184 294	-231 416	-679 926	-866 214
Marketing and distribution expenses		-167 832	-173 611	-698 346	-456 529
Administrative expenses		-33 632	-60 697	-175 459	-197 662
Other operating income/expenses <sup>1)</sup>		36 010	-45 849	67 640	-70 874
<b>Total operating expenses</b>		<b>-349 748</b>	<b>-511 573</b>	<b>-1 486 091</b>	<b>-1 591 279</b>
<b>EBIT; Operating profit/loss</b>		<b>-389 836</b>	<b>-511 573</b>	<b>-1 420 917</b>	<b>-1 591 279</b>
Net financial items		344	-216	-455	-1 163
<b>EBT; Earnings before taxes</b>		<b>-389 492</b>	<b>-511 789</b>	<b>-1 421 372</b>	<b>-1 592 442</b>
Tax	7	-4 499	-1 177	-8 946	-2 251
<b>Net profit</b>		<b>-393 991</b>	<b>-512 966</b>	<b>-1 430 317</b>	<b>-1 594 693</b>
<b>Other comprehensive income</b>					
<i>Items to be reclassified as profit or loss</i>					
Translation variances		173	-1 426	624	-1 544
<b>Other comprehensive income after tax</b>		<b>173</b>	<b>-1 426</b>	<b>624</b>	<b>-1 544</b>
<b>Total comprehensive income<sup>2)</sup></b>		<b>-393 818</b>	<b>-514 392</b>	<b>-1 429 693</b>	<b>-1 596 237</b>
Earnings per share before and after dilution (SEK)		<b>-5,23</b>	<b>-7,59</b>	<b>-19,00</b>	<b>-25,57</b>

1) Exchange rate differences on assets and liabilities in operational activities.

2) Losses for the period are in total attributable to parent company shareholders.

## Condensed consolidated statement of financial position

SEK thousand	Note	2021-12-31	2020-12-31
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets		1 408	1 830
Property, plant and equipment		10 348	17 273
Right-of-use assets		14 396	21 057
Financial non-current assets		851	3 622
Deferred tax assets		-	8 175
<b>Total non-current assets</b>		<b>27 003</b>	<b>51 957</b>
<b>Current assets</b>			
Inventory		-	8 665
Accounts receivable		11 910	-
Other current receivables		26 087 <sup>1)</sup>	23 229
Prepaid expenses		12 189	22 650
Cash and cash equivalents		362 187	840 255
<b>Total current assets</b>		<b>412 373</b>	<b>894 799</b>
<b>TOTAL ASSETS</b>		<b>439 376</b>	<b>946 756</b>
<b>EQUITY AND LIABILITIES</b>			
Share capital		8 366	7 549
Additional paid-in capital		4 981 883	3 919 036
Reserves		-918	-1 542
Retained earnings (including net profit/loss for the period)		-4 778 463	-3 348 146
<b>Total Equity</b>		<b>210 868</b>	<b>576 897</b>
<b>Long-term liabilities</b>			
Provisions for social security contributions, incentive programs		13	8 530
Other long-term liabilities		3 206	6 929
<b>Total long-term liabilities</b>		<b>3 219</b>	<b>15 459</b>
<b>Current liabilities</b>			
Provisions for social security contributions, incentive programs		45	47 202
Trade payables		35 702	136 135
Other current liabilities		18 057	35 045
Accrued expenses and deferred income		171 485	136 018
<b>Total current liabilities</b>		<b>225 288</b>	<b>354 400</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>439 376</b>	<b>946 756</b>

1) 3.1 MSEK pertains to credited accounts payable.

## Condensed consolidated statement of changes in equity

SEK thousand	Note	2021	2020	2021	2020
		Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
<b>Opening Balance</b>		<b>612 068</b>	<b>1 071 471</b>	<b>576 897</b>	<b>797 013</b>
Net profit		-393 991	-512 966	-1 430 317	-1 594 693
Other comprehensive income		173	-1 426	624	-1 544
<b>Total comprehensive income</b>		<b>-393 818</b>	<b>-514 392</b>	<b>-1 429 693</b>	<b>-1 596 237</b>
<b>Transactions with owners</b>					
New issue		-	-	1 106 000	1 413 925
Costs related to new issues		-	-3	-67 053	-85 231
Share based compensation		-7 383	12 618	14 229	38 398
Exercised warrants		-	7 203	10 488	9 029
<b>Total transactions with owners</b>		<b>-7 383</b>	<b>19 818</b>	<b>1 063 664</b>	<b>1 376 121</b>
<b>Ending balance</b>		<b>210 868</b>	<b>576 897</b>	<b>210 868</b>	<b>576 897</b>

## Condensed consolidated statement of cash flow

SEK thousand	Note	2021	2020	2021	2020
		Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
<i>Operating activities</i>					
Operating profit/loss		-389 836	-511 573	-1 420 917	-1 591 279
Adjustment for non-cash items		-184 523	77 528	-44 325	160 906
Interest received		91	120	96	322
Interest paid		-235	-336	-948	-1 485
Taxes paid		-146	-3 771	-12 216	-7 243
<b>Cash-flow from operating activities before change in working capital</b>		<b>-574 648</b>	<b>-438 032</b>	<b>-1 478 309</b>	<b>-1 438 779</b>
Change in working capital		128 194	80 870	-38 082	142 270
<b>Cash-flow from operating activities</b>		<b>-446 455</b>	<b>-357 162</b>	<b>-1 516 391</b>	<b>-1 296 509</b>
Cash-flow from investment activities		-	-4 496	-339	-20 127
Cash-flow from financing activities		-3 984	3 671	1 034 030	1 323 461
<b>Cash-flow for the period</b>		<b>-450 438</b>	<b>-357 987</b>	<b>-482 701</b>	<b>6 825</b>
Cash at the beginning of the period		671 269	1 251 629	840 255	926 186
Change in cash		-450 438	-357 987	-482 701	6 825
Effect of exchange rate changes on cash		141 356	-53 387	4 633	-92 756
<b>Cash at the end of the period</b>		<b>362 187</b>	<b>840 255</b>	<b>362 187</b>	<b>840 255</b>

1) Pertains mainly to changes in share-based remuneration programs including social security contributions and exchange rate differences as well as depreciation and impairment.

## Condensed Parent Company income statement

SEK thousand	Not	2021 okt-dec	2020 okt-dec	2021 jan-dec	2020 jan-dec
Net sales <sup>1)</sup>		-62 762	-	97 577	-
Cost of Goods Sold		8 097	-	-12 182	-
<b>Gross profit</b>		<b>-54 665</b>	<b>-</b>	<b>85 395</b>	<b>-</b>
Research and development expenses		-183 491	-231 432	-676 375	-866 509
Marketing and distribution expenses		-170 815	-174 599	-728 382	-460 860
Administrative expenses		-22 005	-63 029	-161 814	-201 751
Other operating income/expenses <sup>1)</sup>		40 062	-45 849	71 362	-70 874
<b>Total operating expenses</b>		<b>-336 249</b>	<b>-514 909</b>	<b>-1 495 209</b>	<b>-1 599 994</b>
<b>EBIT; Operating profit/loss</b>		<b>-390 914</b>	<b>-514 909</b>	<b>-1 409 814</b>	<b>-1 599 994</b>
Net financial items		125 403	146	-18 725	375
<b>EBT; Earnings before taxes</b>		<b>-265 511</b>	<b>-514 764</b>	<b>-1 428 539</b>	<b>-1 599 620</b>
Tax		-	-	-	-
<b>EBT; Earnings before taxes</b>		<b>-265 511</b>	<b>-514 764</b>	<b>-1 428 539</b>	<b>-1 599 620</b>

## Condensed Parent Company statement of comprehensive income

SEK thousand	Not	2021 okt-dec	2020 okt-dec	2021 jan-dec	2020 jan-dec
<b>EBT; Earnings before taxes</b>		<b>-265 511</b>	<b>-514 764</b>	<b>-1 428 539</b>	<b>-1 599 620</b>
<b>Other comprehensive income</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Other comprehensive income after tax</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Net Profit</b>		<b>-265 511</b>	<b>-514 764</b>	<b>-1 428 539</b>	<b>-1 599 620</b>

## Parent Company balance sheet

SEK thousand	2021 Dec 31	2020 Dec 31
<b>ASSETS</b>		
<b>Non-current assets</b>		
Intangible assets	1 408	1 830
Property, plant and equipment	10 348	12 097
Financial non-current assets	1 155	8 664
<b>Total non-current assets</b>	<b>12 910</b>	<b>22 591</b>
<b>Current assets</b>		
Inventory	-	8 665
Other current receivables	14 502 <sup>1)</sup>	10 668
Prepaid expenses	14 250	17 057
Cash and cash equivalents	321 832	785 972
<b>Total current assets</b>	<b>350 584</b>	<b>822 362</b>
<b>TOTAL ASSETS</b>	<b>363 495</b>	<b>844 953</b>
<b>EQUITY AND LIABILITIES</b>		
<i>Restricted equity</i>		
Share capital	8 366	7 549
Reserve fund	10 209	10 209
<b>Total restricted capital<sup>1)</sup></b>	<b>18 575</b>	<b>17 758</b>
<i>Non-restricted equity</i>		
Share premium reserve	4 871 586	3 822 968
Retained earnings	-3 256 968	-1 671 578
Net profit for the period	-1 428 539	-1 599 620
<b>Total non-restricted capital</b>	<b>204 653</b>	<b>569 528</b>
<b>Long-term liabilities</b>		
Provisions for social security contributions, incentive programs	13	8 404
<b>Total long-term liabilities</b>	<b>13</b>	<b>8 404</b>
<b>Current liabilities</b>		
Provisions for social security contributions, incentive programs	45	46 997
Trade payables	34 875	115 574
Other current liabilities	7 322	31 003
Accrued expenses and deferred income	116 586	73 447
<b>Total current liabilities</b>	<b>158 829</b>	<b>267 021</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>363 494</b>	<b>844 953</b>

1) 3.1 MSEK pertains to credited accounts payable.



## Note 1 General Information

This report covers the Swedish parent company Oncopeptides AB (publ), Swedish corporate identity no. 556596-6438 and its subsidiary Oncopeptides Incentive AB, Oncopeptides GmbH and Oncopeptides Inc, USA. The parent company is a Swedish public limited company registered in and with its registered office in Stockholm. Numbers in parentheses in the report refer to the figures for the corresponding period the previous year. The interim report Jan-Dec 2021 was approved for publication on February 17, 2022.

## Note 2 Accounting Principles

The interim report for the Group has been prepared in accordance with IAS 34 Interim Financial Reporting. The parent company applies the Swedish Financial Reporting Board recommendation RFR2 Accounting for legal entities. Oncopeptides applies, except as described below, the same accounting principles as in the last Annual Report. Relevant accounting and valuation principles could be found on pages 60-63 of the Annual Report for 2020.

Revenue is reported at the transaction price of goods sold with deductions for VAT, discounts and returns, see further Note 5. When inventory items are sold, the value of these items are, in accordance with IAS 2, reported as a cost in the same period as the corresponding income. In addition, any impairment of goods in stock and losses relating to goods in stock are reported as an expense in the period in which the impairment is made, or the loss is incurred. Any reversal of impairment related to goods in stock, due to increased net sales value, is reported as a reduction of cost of goods sold in the income statement in the same period as the reversal.

No new or amended standards that became effective January 1, 2021, have had a significant impact on the company's financial reporting.

Oncopeptides applies ESMA's (European Securities and Markets Authority) guidelines on alternative performance measures.

## Note 3 Risks and uncertainties

### Operational risks

Research and drug development is, up until an approved registration, subject to considerable risk – and is a capital-intensive process. The majority of all initiated projects will never reach market registration due to technological risks such as insufficient efficacy, intolerable side effects, or manufacturing problems. If competing pharmaceuticals capture market share or reach the market faster, or if competing research projects achieve better product profiles, the future value of the product portfolio may be lower than expected.

The operations may also be impacted negatively by regulatory decisions,

such as approvals and price changes. External factors such as COVID-19 may also impact the company negatively by hampering the company's opportunity to conduct clinical trials, attain necessary regulatory approvals or conduct sales related activities. A more detailed description of the company's risk exposure and risk management can be found in the Annual Report for 2020 on page 53.

### Financial risks

Oncopeptides' financial policy, governing the management of financial risks, has been drafted by the Board of Directors and covers guidelines, rules, risk profiles and limits for financial operations. Foreign exchange variances constitute the primary financial operational risk since development costs are mainly paid in USD and EUR. In accordance with the company's policy for financial risk management, expected foreign currency hedging is aligned with signed contracts and obligations. For further information, see note 3 in the 2020 Annual Report.

As declared in the section "Financing and going concern", there are conditions that can give rise to significant doubts regarding the Company's ability to continue operations.

### Credit risks

Oncopeptides' credit risk is managed at Group level and arises through credit exposure in the form of outstanding receivables from customers. Accounts receivable arise when an item has been delivered and invoiced and accounted with the amount that is expected to be received. The need for impairment of accounts receivable are continuously evaluated as they approach the due date and are considered in this financial statement to the amount of SEK 1.2 M per December 31.

## Note 4 Estimates and considerations

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 financial outcomes. There are also external conditions, e.g., the economic climate, political changes and competing research projects that may affect Oncopeptides net profit and cash.

As a result of the company's restructuring, balance sheet items that are not considered to generate future positive cash flows have been reevaluated.

### Impairments, write-downs, accruals and provisions

Net sales are reported including expected returns resulting from the withdrawal of Pepaxto from the US market. The estimated provision for returns amounts to SEK 48.6 million and corresponds to expected returns of product sold and not consumed during the last two quarters

of the year. Until finally confirmed, the outcome may vary from the assumptions in this financial statement. The Parent Company has not reported any accruals for returns as inventory balances, held by the subsidiary prior to the withdrawal, have been fully reversed. As a consequence of the withdrawal, a one-time write-down of assets to the amount of SEK 16.6 M for the Group affected the quarter, of which

- Inventory; SEK 9.0 M, where of SEK 8.2 million in the Parent Company
- Right to use assets; SEK 2.2 M in the Group, 0 in the Parent Company
- Other fixed assets; SEK 4.1 M, 0 in the Parent Company
- Group receivables; SEK 19.4 M in the Parent Company

All write-downs are of a non-recurring nature, directly connected to the downsizing of the business as previously communicated.

## Note 5 Revenue recognition

Revenue is reported at the transaction value of goods sold excluding VAT, discounts and returns. At the time of delivery, when the ownership of the goods passes to the customer, the revenue is reported in full. Customers are defined as the retailers, who act as middlemen and in turn sell the goods to the end user.

As the final price is related to the discount granted the patients' insurance company, the transaction price is not known upon delivery. An estimated discount deduction accrual, based on calculation models considering statistical sales data and relevant discount programs, is therefore made.

In addition, the Company has, as previously discussed, a provision for additional return related to the withdrawal of Pepaxto from the US market. It is stated in the consolidated balance sheet under Accrued expenses and deferred income and amounted to SEK 48.6 million at year end.

The Company has no further performance commitments.

## Notes to the consolidated and Parent Company financial statements

GROUP REVENUE	2021	2020	2021	2020
SEK thousand	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
<b>Net sales; customer contracts</b>				
Goods <sup>1)</sup>	-21 710	-	118 295	-
<b>Total net revenue</b>	<b>-21 710</b>	<b>-</b>	<b>118 295</b>	<b>-</b>
<b>Geographic market</b>				
North America <sup>2)</sup>	-21 710	-	118 295	-

1) PEPAXTO (melphalan flufenamide, also known as melflufen), in combination with dexamethasone, is used for the treatment of adult patients with relapsed or refractory multiple myeloma.

2) Approval was only obtained in the United States, which explains why all revenue refers to one market.

PARENT COMPANY REVENUE	2021	2020	2021	2020
SEK thousand	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
<b>Net sales; customer contracts</b>				
Goods	-62 762 <sup>1)</sup>	-	97 577	-
<b>Total net revenue</b>	<b>-62 762</b>	<b>-</b>	<b>97 577</b>	<b>-</b>
<b>Geographic market</b>				
North America <sup>2)</sup>	-62 762	-	97 577	-

1) Refers to reversed intra-group sales of inventories.

2) Refers to intra-group sales to the subsidiary in the USA.

### Note 6 Segment reporting

The financial information reported to the chief operating decision maker and used as a basis for the distribution of resources and the assessment of the Group's results, is not split across operating segment. Hence, the Group is reported as one single operating segment.

### Note 7 Deferred tax

	2021	2020	2021	2020
SEK thousand	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
<b>Tax for the period</b>				
Current tax	6 056	-7 460	-339	-9 247
Deferred tax on intra-group sales of goods	-	-	-	-
Other deferred tax	-10 554	6 283	-8 607	6 996
<b>Reported tax</b>	<b>-4 499</b>	<b>-1 177</b>	<b>-8 945</b>	<b>-2 251</b>

Other deferred tax is, in its entirety, attributable to staff related costs in the subsidiary and will be utilized.

### Note 8 Related party transactions

Remuneration to senior management has been paid in accordance with current policies. No other transactions with related parties occurred during the period.

### Note 9 Share based incentive programs

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, founders, and other co-workers in line with the interest of the shareholders. Oncopeptides has currently nine active programs that include the management team, certain board members, founders and employees.

Program

- 2016; "Employee option program 2016/2023".
- 2017; "Co-worker LTIP 2017".
- 2018; "Co-worker LTIP 2018" and "Board LTIP 2018", of which the latter expired during the second quarter of 2021. At the Extraordinary General Meeting held in December of 2018, it was resolved to introduce "Board LTIP 2018.2".
- 2019; "Co-worker LTIP 2019" and "Board LTIP 2019"
- 2020; "Board LTIP 2020" and "US Co-worker LTIP 2020"
- 2021; "Board LTIP 2021" and "Co-worker LTIP 2021"

For more information on the programs see Agendas and Minutes from the relevant Annual General Meetings on the company's website [www.oncopeptides.com](http://www.oncopeptides.com). Full utilization of granted options and share awards at the end of the period, corresponding to 2,254,457 shares, would result in a dilution for shareholders of 2.9 percent. Full utilization of all options and share awards, corresponding to 4,397,484 shares (i.e., including non-granted employee options and warrants set off as hedge for social security contributions), would result in a dilution of 5.5 percent.

Below follows a summary of the changes in existing incentive programs during the reporting year, and the total number of shares that granted employee stock options and share awards may entitle to as of the end of the reporting period.

### CHANGES IN EXISTING INCENTIVE PROGRAMS DURING JAN-DEC 2021

Number of shares	
Granted instruments	
Co-worker LTIP 2019	726 301
US Co-worker LTIP 2020	41 371
US Co-worker LTIP 2021	92 090
Board LTIP 2021	35 000
Exercised instruments	
Employee option program 2016/2023	-180 900
Co-worker LTIP 2017	-119 351
Revoked instruments	
Co-worker LTIP 2017	-6 000
Co-worker LTIP 2018	-143 458
Co-worker LTIP 2019	-808 217
US Co-worker LTIP 2020	-680 381
Co-worker LTIP 2021	-77 592
Expired instruments	
Board LTIP 2018	-30 451
<b>Total change</b>	<b>-1 151 597</b>

### NUMBER OF SHARES POTENTIALLY AVAILABLE PER DEC 31, 2021

Employee option program 2016/2023	65 700
Co-worker LTIP 2017	1 228 582
Co-worker LTIP 2018	185 191
Co-worker LTIP 2019	672 903
<b>Number of shares employee stock options may entitle to</b>	<b>2 152 376</b>
US Co-worker LTIP 2020	0
US Co-worker LTIP 2021	14 489
Board LTIP 2018.2	2 170
Board LTIP 2019	23 491
Board LTIP 2020	26 931
Board LTIP 2021	35 000
<b>Total number of shares allocated share awards may entitle to</b>	<b>102 081</b>
<b>Total number of shares employee stock options and share awards may entitle to</b>	<b>2 254 457</b>

## Key performance measures

In this report, certain key performance measures are presented, including measures that are not defined under IFRS,

- Research and development / operating expenses, %,
- Gross margin, MSEK, %.

The company believes that these measurements provides valuable additional information when evaluating the company's

economic trends. These financial performance measures should not be viewed in isolation, nor be considered in replacement of performance indicators that are prepared in accordance with IFRS.

Further, such performance measures, as the company has defined them, should not be compared with other performance measures with similar names used

by other companies since definitions and calculation methods may vary between companies.

	2021	2020	2021	2020
SEK thousand	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Net revenue	-21 710	-	118 295	-
Gross profit <sup>1)</sup>	-40 088	-	65 174	-
Gross margin <sup>2)</sup>	-	-	55%	-
Total registered shares at the end of the period	75 291 841	67 770 683	67 939 715	55 413 417
No of registered shares at the beginning of the period	75 291 841	67 939 715	75 291 841	67 939 715
No of shares that the outstanding employee options entitle to	2 254 457	3 406 054	2 254 457	3 406 054
Share capital at the end of period	8 366	7 549	8 366	7 549
Equity at the end of period	210 868	576 897	210 868	576 897
Earnings per share before and after dilution, SEK <sup>3)</sup>	-5,23	-7,59	-19,00	-25,57
Operating loss	-389 836	-511 573	-1 420 917	-1 591 279
Research and development expenses	-184 294	-231 416	-679 926	-866 214
Research and development expenses/operating expenses, % <sup>4)</sup>	53%	45%	46%	54%

1) Defined by subtracting cost of goods sold from total sales. The key figure shows the gross profitability of cost of goods sold in absolute numbers.

2) Defined by dividing the sum of the company's gross profit by total sales. The key figure aims to clarify the relative profitability of goods sold.

3) Earnings per share before dilution are calculated by dividing earnings attributable to shareholders of the Parent Company by a weighted average number of outstanding shares during the period. There is no dilution effect driven by the employee stock option program, as earnings for the periods have been negative.

4) Defined by dividing the research and development costs with total operating expenses. The key performance measure provides an indication of the proportion of expenses that are attributable to the company's core business.

**AE** Adverse events.

**Alkylator** A broad spectrum cytotoxic chemotherapy.

**Aminopeptidases** Enzymes that hydrolyze peptides. These are overrepresented in cancer cells.

**Anti-CD38** A monoclonal antibody targeted to CD 38.

#### **Autologous Stem cell transplant**

Stem cells are taken from the patient when the disease is in a calm stage, so-called remission. They are given back to the patient after, for example, chemotherapy.

**CBR** Clinical benefit rate, measures the number of patients with multiple myeloma who have lost 25 percent or more of their tumor mass.

**CDMO** Contract development and manufacturing organization.

**CHMP** Committee for Medicinal Products for Human Use. European Medicines Agency's (EMA) committee responsible for human medicines.

**Clinical studies** Studies to define doses and evaluate safety and efficacy on healthy volunteers and patients.

**CR** Complete tumor response.

**CRO** Contract research organization.

**Dexamethasone** A powerful steroid used in cancer treatment.

**DOR** Duration of response refers to the period from an initial tumor reduction until it begins to grow.

**Double-refractory** Resistant to two drugs.

**EHA** European Hematology Association

**EMA** European Medicines Agency.

**Entrapped** How a hydrophilic alkylator payload stays inside a cell.

**FDA** US Food and Drug Administration.

**Hazard ratio** A measure of the relative risk of an event at each time point during follow-up when receiving melflufen in relation to pomalidomide. A value below 1 indicates a better treatment effect for melflufen, and a value above 1 indicates a better treatment effect for pomalidomide.

**Hematology** The science of blood, blood-forming organs, and blood diseases. It includes the treatment of blood disorders and malignancies, including hemophilia, leukemia, lymphoma, and sickle cell anemia.

**IMiDs** Immunomodulatory imide drugs, used in the treatment of

multiple myeloma.

**Interim results** Partial results in ongoing trials

**IND-submission** Application to enable clinical development of a drug candidate.

**INN** International non-proprietary Name.

**ITT** Intention To Treat population.

**Late-stage RRMM** Late-stage relapsed refractory multiple myeloma.

**Lines of therapy** After a cancer diagnosis and decision to treat the patient, the first treatment attempt is known as the first line of therapy, followed by a second line of therapy, etc.

**Lipophilicity** is a key parameter that determines cell uptake of small molecules.

**MAA** Marketing Authorization Application.

**Melflufen** A first-in-class anti-cancer peptide drug conjugate targeting aminopeptidases and releases alkylating agents into tumor cells.

**Melphalan flufenamide** INN (see above) name for melflufen.

**MM** Multiple myeloma, a rare blood cancer that forms in plasma cells. Cancerous plasma cells accumulate

in the bone marrow and crowd out healthy blood cells.

#### **Monoclonal antibodies**

Laboratory-produced molecules engineered to serve as substitute antibodies that restore, enhance, or mimic the immune system's attacks on cancer cells.

**MR** Minimal response refers to a 25–50 percent tumor reduction

**Multi-refractory** Resistant to several different drugs

**Multiple myeloma** A rare blood-based cancer.

**NDA** New Drug Application.

**OPD5** The second drug candidate coming out of the peptide drug conjugate platform.

**Orphan drug** A drug used to treat a rare disease, life threatening diseases or diseases in very small patient populations

**ORR** Overall response rate, the number of patients who have lost 50 percent or more of their tumor mass.

**OS** Overall survival, the length of time a patient survives from the start of the treatment.

**Payload** Highly active molecules that are too toxic to be administered in untargeted forms at therapeutic doses.

**PD** Progressive disease, where the tumor mass has grown by at least 25 percent

**PDC** Peptide-drug conjugate. The class of agents that includes melflufen and OPD5.

**Peptidases** Enzymes that break down peptides.

**Peptide** A molecule comprising a chain of amino acids. A key attribute of melflufen.

**PFS** Progression-free survival, measures the length of time from the start of a patient's treatment until the tumor has grown by at least 25 percent

**Pharmacokinetics** Data that describe how a drug is distributed and metabolized in the body.

**Phase 1,2,3 (studies)** Various phases of clinical development.

**Phase 1** A clinical study to identify appropriate doses of a drug candidate and evaluate safety in healthy volunteers.

**Phase 2** A clinical study to evaluate efficacy and safety of a drug candidate in patients ahead of phase 3.

**Phase 3** A clinical study that repeats phase 2 processes in larger patient groups and compares drug candidates with other treatments.

**Chemotherapy** Cancer treatment involving one or more drugs to kill cancer cells.

## Telephone conference

The Year End report for 2021 and an operational update will be presented by CEO Jakob Lindberg and members of Oncopeptides Leadership team, Thursday February 17, 2022, at 15:00 (CET).

The conference call will be streamed via a link on the website: [www.oncopeptides.com](http://www.oncopeptides.com).

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Europe:  
+44 333 300 9270

USA:  
+1 833 526 8384

## Calendar

Report	Datum
Annual report, 2021	21 April, 2022
Interim report Q1, 2022	4 May, 2022
AGM 2022	19 May, 2022
Interim report Q2, 2022	11 August, 2022
Interim report Q3, 2022	9 November, 2022
Year End report, 2022	16 February, 2023

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