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## **Oncopeptides at a glance**

#### Targeted cancer treatments – initial focus on multiple myeloma

- Proprietary peptide-conjugated compounds (PDC)
- Lead compound melflufen (melphalan flufenamide) targeting multiple myeloma (MM)
- Melflufen Phase 2 study, O-12-M1, showed highly competitive survival data

#### Melflufen geared for accelerated approval in the US

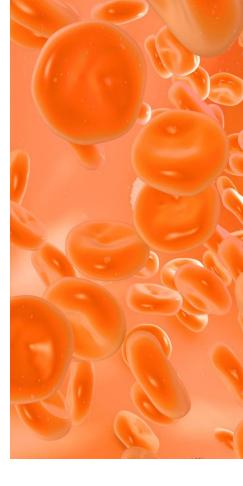
- NDA submission in Q2-2020 based on phase 2 HORIZON data in triple-class refractory MM
- sNDA submission in H2 2021 based on phase 3 OCEAN data in earlier lines
- Randomized phase 3 study LIGHTHOUSE, to be initiated H2 2020

#### PDC platform supports new indications

- Phase 1/2 study addressing AL amyloidosis started
- New NCE:s from the PDC platform to enter clinical studies 2021

#### **Strong financial position**

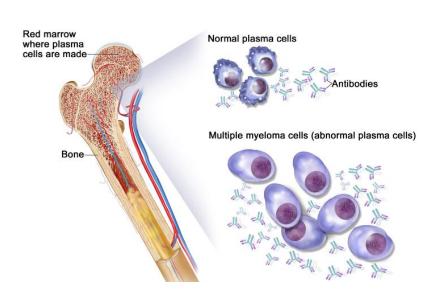
- Market cap: SEK ~8 B, listed on NASDAQ Stockholm
- Cash position: SEK 618 M as of March 31 plus approx. SEK 1,400 M raised in Q2



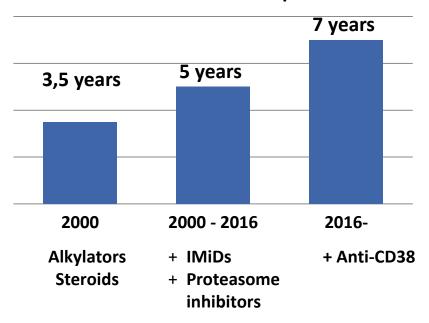


## Multiple myeloma a hematological cancer with no cure

#### Myeloma – uncontrolled plasma cell proliferation

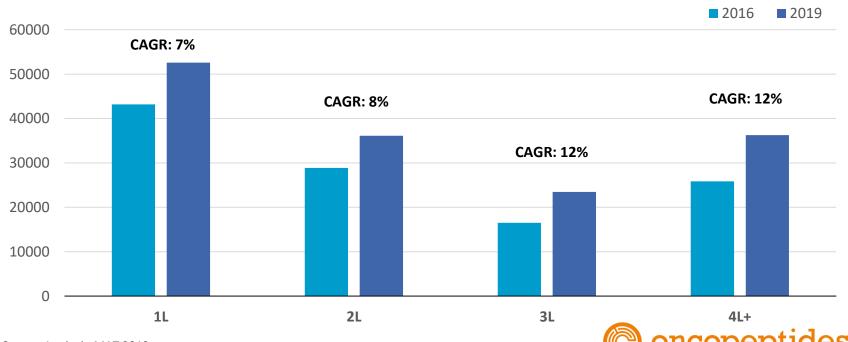


#### Median survival increasing with more available treatment options



## Improved outcomes lead to fast growth in number of treated patients in later lines of therapy

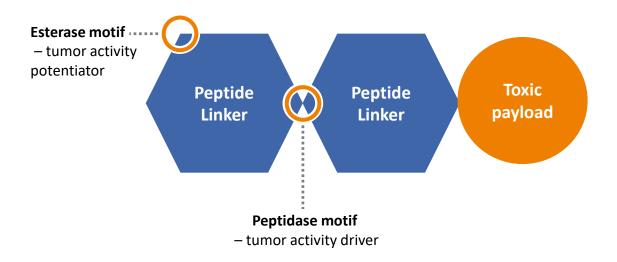
#### Projected US multiple myeloma patients by line of therapy



Source: Intrinsig MAT 2019

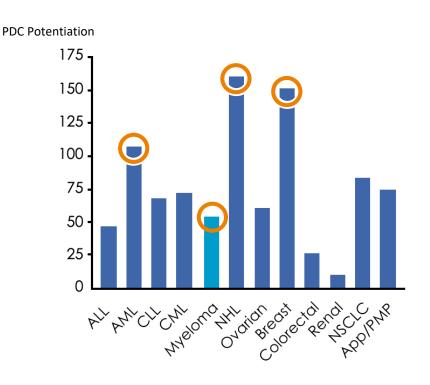
Note: 3-yr annual growth rate for 4Q2016-4Q2019

## **Unique Peptide Drug Conjugate (PDC) platform**



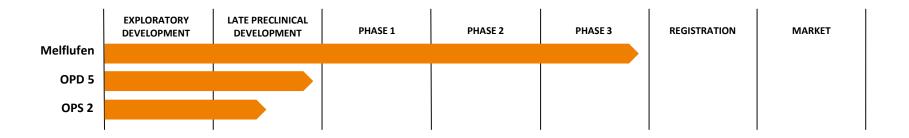
- Targeted delivery of toxins
- Utilizing enzymatic motifs

## PDC platform has therapeutic activity in most cancers



- The PDC platform shows activity across a most cancers (data to the left; patients)
- Based on the PDC platform, Oncopeptides has developed novel molecules
- Lead compound melflufen is focused on multiple myeloma and AL amyloidosis
- Indication expansion in patients suffering from AML, NHL and breast cancer

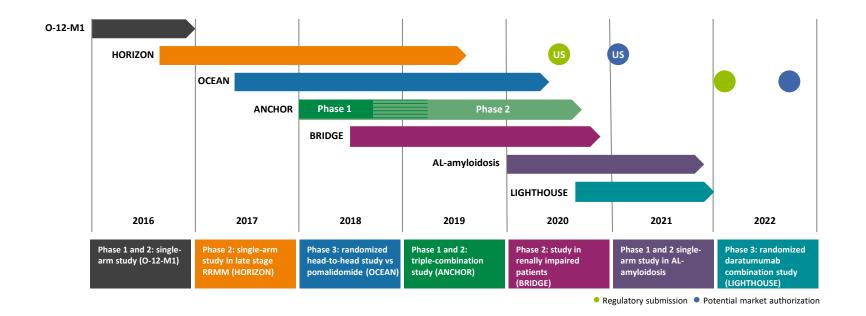
## PDC candidates enters clinical development in 2020-21



- OPD5 and OPS2 will be ready for the clinic in 2020 and 2021 respectively
  - OPD5 specialized alkylating PDC candidate for high-dose treatment of patients (i.e. bone-marrow transplantation)
  - OPS2 second generation PDC compound with an alkylating payload
- Both are novel molecules with composition of matter patents
- Options to fully explore PDC platform in 2021 and beyond

## Melflufen clinical development program

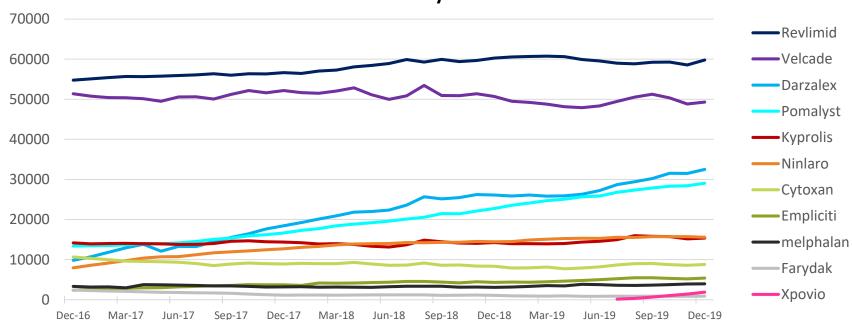
#### Potential to provide a broad set of data in different patient populations





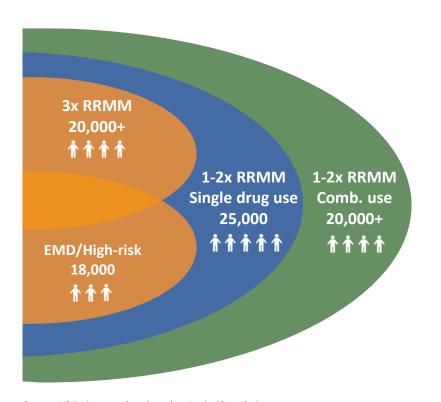
## Newer products used in addition to older products as survival improves





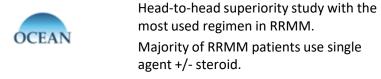


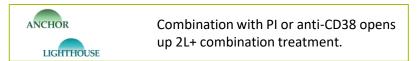
## Significant market opportunities for melflufen



#### **Clinical Program supports expanding label**









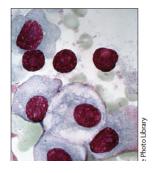
## **Editorial in Lancet Haematology on melflufen**

## Is there a role for new drugs with alkylating properties in multiple myeloma?



Multiple myeloma, a complex disease originating in plasma cells, was primarily treated with melphalan until the last years of the 20th century. Advances in knowledge of the biology of the disease have led to the introduction of new drugs, and its transition of new drugs from the relapse setting to first-line treatment has been fast and as a result, most patients with multiple myeloma will receive protessome inhibitors

intravenously every 4 weeks in combination with weekly dexamethasone can lead to clinical improvement (overall response rate was 31% [14 of 45 patients; 95% CI 18–47]; median progression-free survival was 5.7 months [95% CI 3.7–9.2]; and overall survival was 20.7 months [11.8 to not reached]). The most common toxicities were haematological toxicity and grade 3-4 thrombocytonenia and neutronenia



## Final HORIZON data in triple-class refractory RRMM



#### **Independent Review Committee (IRC) data**

Primary End-Point	Investigator Ass. Data Jan 14 <sup>th</sup>	IRC Data Jan14 <sup>th</sup>	Incl. unconfirmed responses Jan 14 <sup>th</sup>
Overall Response Rate (ORR) – ITT n=157	29%	30%	31% (inv. and IRC)
ORR – 3x RRMM n=119	26%	26%	27% (inv. and IRC)
ORR – EMD n=55	24%	27%	NA

Note: Two unconfirmed responses on January 14th have later been confirmed.

Safety profile comparable to what was reported at ASH 2019, i.e. hematological toxicities were common but manageable – non-hematological toxicities were infrequent

## Competitive melflufen data in triple-class RRMM



	Melflufen Interim data ASH except ORR	<b>Xpovio</b> Karyopharm US approval July 2019	Belantamab GSK In filing	
Number of patients studied	93	122	97	
Overall Response/Clinical Benefit Rate	26%*/37%	25%/39%	31%/34%	
Duration of response	7.5 months	4.4 months	NR (≈7-8months)	
Progression-free survival	4.0 months	3.7 months	2.9 months	
Overall survival	11.3 months	8.0 months	NR (≈10months)	
Share of patients with EMD	34%	22%	23%	
Serious Adverse Event Rate	51%	58%	36% (excl. ocular tox.)	
Non-hematologic toxicity (grade 3/4) reported in >5% of patients	Pneumonia 8.4%	Fatigue 25.2% Hyponatremia 20.3% Nausea 9.8% Pneumonia 8.9% Diarrhea 7.3% Sepsis 5.7% Hypokalemia 5.7% Mental status 5.7% General det. 5.7%	Keratopathy/ 27.4% Blurred vision Hypercalcaemia 7.4% Pneumonia/ 6.3% Lung infections	

<sup>\*</sup> ORR number is final ORR, all other melflufen data from Interim presentation at ASH, ORR was 24% at ASH



#### FDA submission and commercialization on track

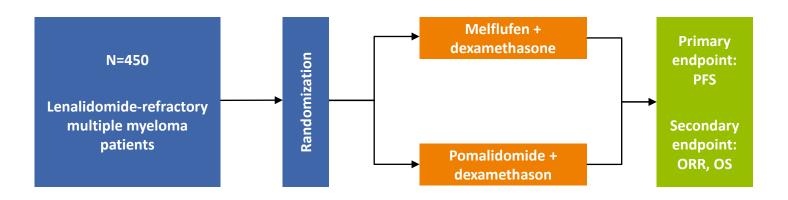


- FDA submission for accelerated approval in triple-class refractory MM is on track for end of Q2 2020
- Early Access Program for RRMM patients in the US to be launched end of Q2
- US Commercialization build-up ongoing, 30 FTE by March 31, key positions in place
- Accelerated approval around the year end 2020

#### OCEAN compares melflufen with SoC in RRMM



450 patients recruited with ongoing enrollment – top-line results in H1 2021



#### RRMM data from pomalidomide FDA label and O-12-M1 study

Treatment	ORR	CBR	Median PFS	Median DOR	Median OS
Melflufen + Dexamethasone	31%	49%	5.7 months	8.8 months	20.7 months
Pomalidomide + Dexamethasone	24%	NR	3.6 months	7.0 months	12.4 months

## Pomalidomide shares resistance mechanism with lenalidomide



Average IMiD free period significant in pomalidomide registration study

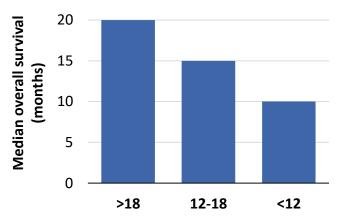
- Only 29% received lenalidomide as last treatment Lenalidomide used more aggressively today
- Median maintenance duration 24 months (not 10 months)

All lenalidomide patients in OCEAN failed in 18 months

Vast majority has lenalidomide as last treatment

No assumptions in OCEAN to account for increased cross resistance

#### Pomalidomide efficacy decreases for recent lenalidomide failures



IMiD-free period before start of pomalidomide treatment (months)

#### **Combination study LIGHTHOUSE**



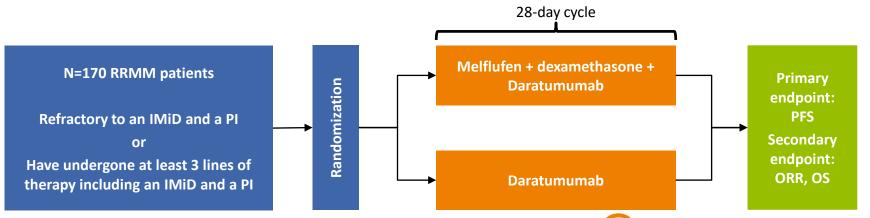
#### Our second confirmatory phase 3 study – initiation H2 2020

#### Second phase 3 study with melflufen in multiple myeloma

- Melflufen + daratumumab vs daratumumab randomized 2:1
- Subcutaneous version on Daratumumab

#### Two objectives:

- Expand market potential extend label with melflufen in combination with daratumumab in earlier lines
- De-risk development program add study that can drive market registration in the EU and US



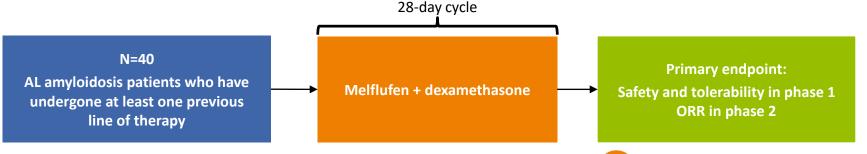
## Phase 1/2 study in AL amyloidosis – recently initiated

Corresponding to myeloma, AL amyloidosis is a disease of the B-cell system

- Antibody light-chains misfold and form deposits in multiple organs with organ dysfunction as a result
- Orphan disease 30-45,000 patients in the USA and the EU<sup>1)</sup>
- Majority of patients >65 years old

Similar drug used as in myeloma – drugs efficacious in myeloma are frequently used in AL amyloidosis

Limited treatment options with median overall survival of 1.5-2.0 years (1995-2013) with a trend towards improved survival (3.5 years for the period 2010-2013)<sup>2)</sup>



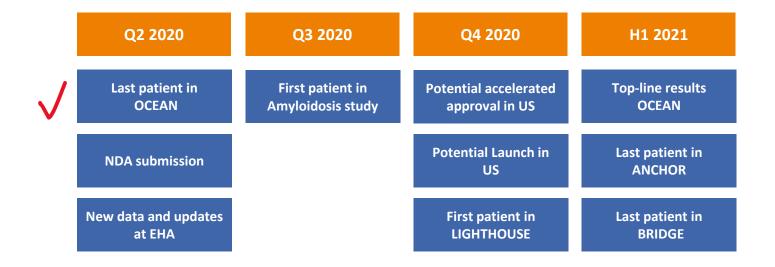
Oncopeptides

## Financial results for the period Jan – Mar 2020



- Operating loss increased to SEK 296.9 M (loss:133.8)
  - R&D increase primarily due to increase in clinical & drug supply: SEK 158.3
     M (73.1)
    - OCEAN SEK 77.7 M (37.6)
    - HORIZON SEK 25.8 M (11.0)
    - LIGHTHOUSE SEK 17.0 M (-)
    - ANCHOR SEK 7.4 M (13.2)
  - Build-up of commercial and medical relations explains increase in M&S
    - US subsidiary incl. admin SEK 44.3 M (8.5)
  - Limited effect of non-cash costs for incentive programs SEK 5.0 M (7.9)
- Cash flow from operating activities neg. SEK 312.8 M (neg. 142.8)
- Cash position was SEK 617.8 M (747.5) as of Mar 31, 2020
  - Directed share issue raising SEK 682.9 M in July 2019
  - Directed share issue raising SEK 1,413.9 M before issue costs after end of period in May 2020

## News flow 2020 and early 2021



# Thank you for your attention!

