

Q2 webcast

August 19, 2021

Participants



Marty J Duvall
Chief Executive Officer



Klaas Bakker
Chief Medical Officer



Anders Martin-Löf
Chief Financial Officer

Disclaimer

IMPORTANT: You must read the following before continuing. The following applies to this document, the oral presentation of the information in this document by Oncopeptides AB (the “Company”) or any person on behalf of the Company, and any question-and-answer session that follows the oral presentation (collectively, the “Information”).

On 26 February 2021, the U.S. Food and Drug Administration (“FDA”) approved PEPAXTO® (melphalan flufenamide, also known as melflufen), in combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. This indication has been granted under accelerated approval based upon data from the HORIZON study. Melflufen is not approved by any other registration authorities.

Melflufen is an abbreviated form of the international non-proprietary name (INN) melphalan flufenamide

The Information contains forward-looking statements. All statements other than statements of historical fact included in the Information are forward-looking statements. Forward-looking statements give the Company’s current expectations and projections relating to its financial condition, results of operations, plans, objectives, future performance and business. These statements may include, without limitation, any statements preceded by, followed by or including words such as “target,” “believe,” “expect,” “aim,” “intend,” “may,” “anticipate,” “estimate,” “plan,” “project,” “will,” “can have,” “likely,” “should,” “would,” “could” and other words and terms of similar meaning or the negative thereof. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors beyond the Company’s control that could cause the Company’s actual results, performance or achievements to be materially different from the expected results, performance or achievements expressed or implied by such forward-looking statements. Such forward-looking statements are based on numerous assumptions regarding the Company’s present and future business strategies and the environment in which it will operate in the future.

No representation, warranty or undertaking, express or implied, is made as to, and no reliance should be placed on, the fairness, accuracy, completeness or correctness of the Information or the opinions contained therein. The Information has not been independently verified and will not be updated. The Information, including but not limited to forward-looking statements, applies only as of the date of this document and is not intended to give any assurances as to future results. The Company expressly disclaims any obligation or undertaking to disseminate any updates or revisions to the Information, including any financial data or forward-looking statements, and will not publicly release any revisions it may make to the Information that may result from any change in the Company’s expectations, any change in events, conditions or circumstances on which these forward-looking statements are based, or other events or circumstances arising after the date of this document. Market data used in the Information not attributed to a specific source are estimates of the Company and have not been independently verified.

Q2 – Key takeaway messages

- First full quarter with revenue
 - Strong interest in PEPAXTO
 - Double-digit demand growth on a month-to-month basis
- Q2 net sales of SEK 66.4 M (\$7.2M) and YTD net sales of SEK 85.7 M (\$10.2M) since launch in mid-March
- Updated OCEAN data – study met primary endpoint
 - Head-2-Head success versus pomalidomide and melflufen demonstrated superiority on PFS
 - Secondary end-point of overall survival in favor of pomalidomide in ITT population
- Progressing on key work streams related to partial clinical hold





COMMERICAL UPDATE

Marty Duvall, CEO

PEPAXTO granted accelerated approval on February 26 by FDA

Offers hope to RRMM patients with high unmet needs

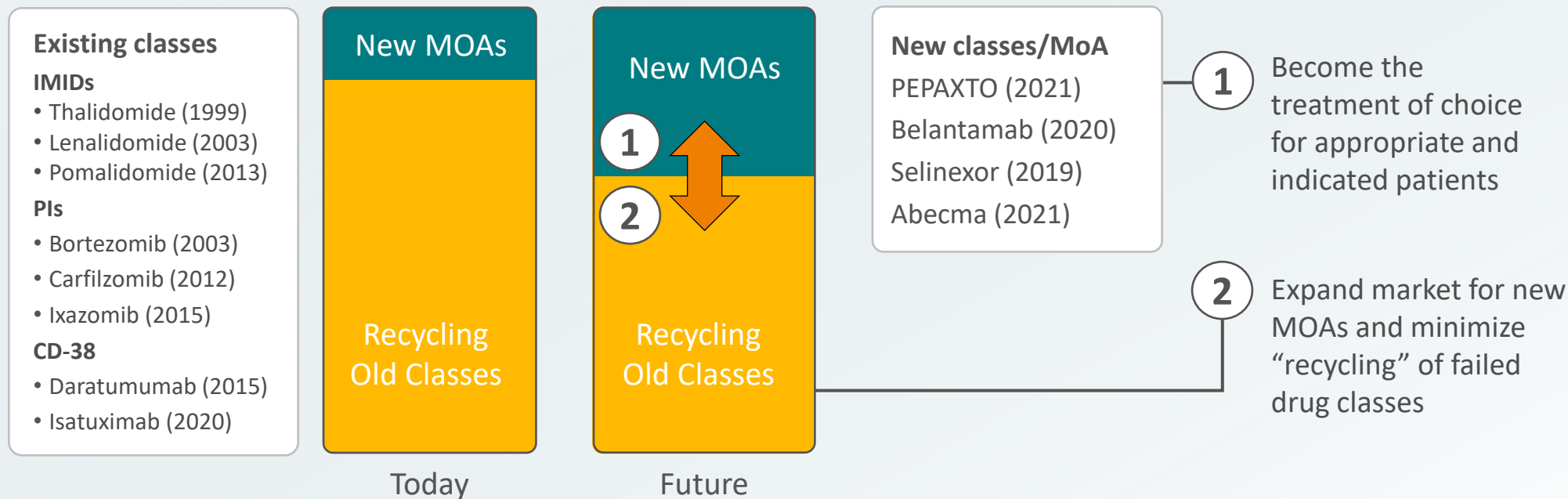
- Initial label targets patients with relapsed or refractory multiple myeloma
 - whose disease is refractory to at least;
 - one proteasome inhibitor,
 - one immuno-modulatory agent
 - one CD38-directed antibody,
 - who have received at least four prior lines of therapy
- FDA approval based on a sub population of the HORIZON study (n=97) with high unmet medical of which 41% had extramedullary disease (EMD)
- Commercial drug available to patients beginning from March 15



PEPAXTO strategy - Two-pronged approach

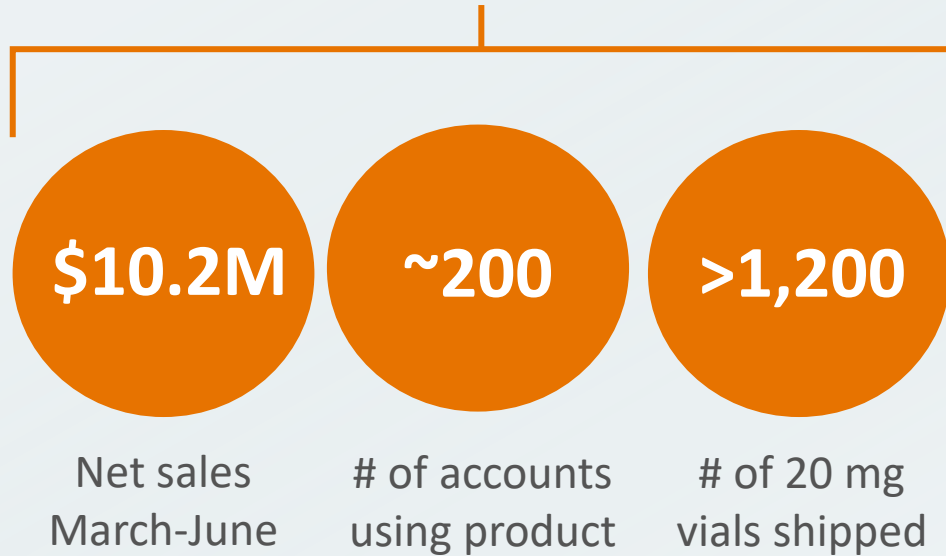
Becoming a foundational treatment in RRMM

Driving change in today's RRMM treatment paradigm where drug classes are "recycled"



PEPAXTO off to a strong start through the first full quarter

Revenue metrics

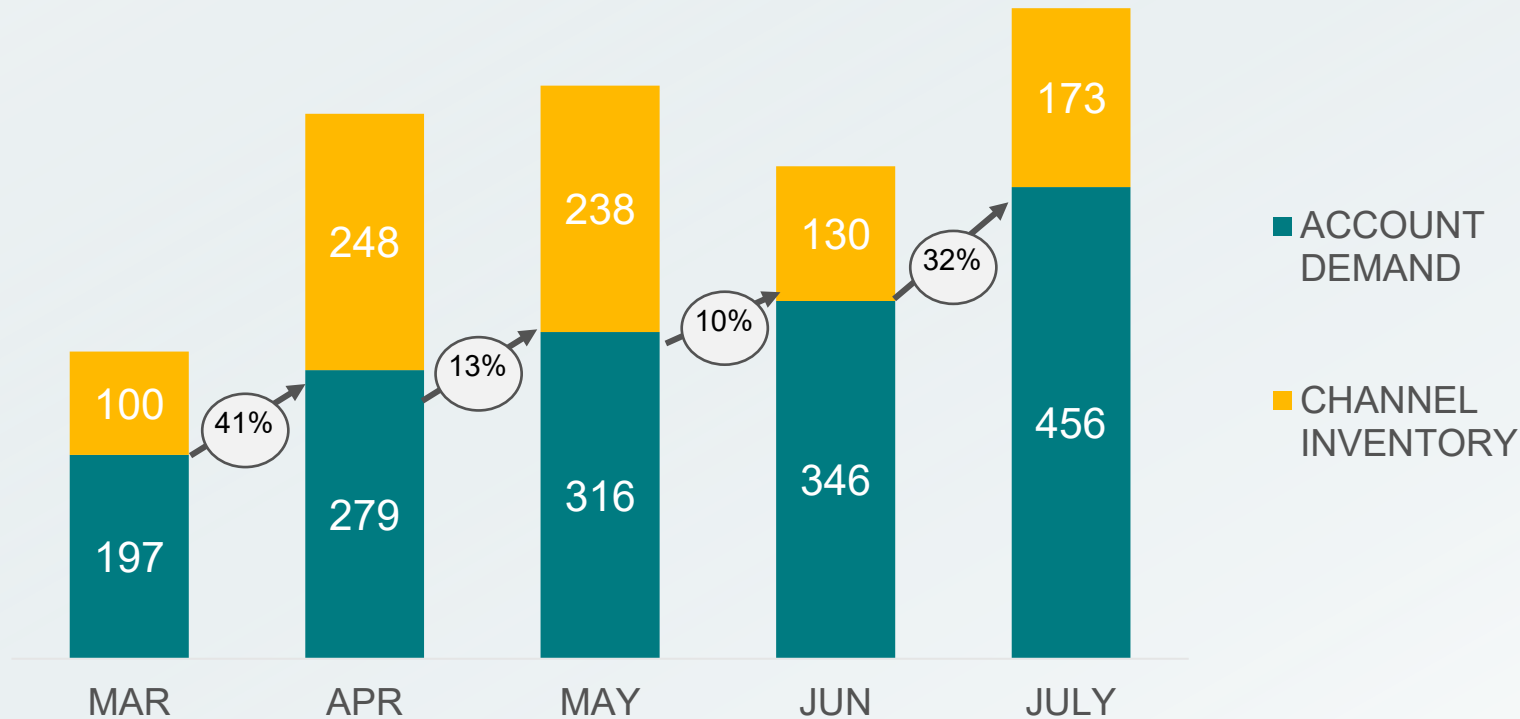


Field team metrics



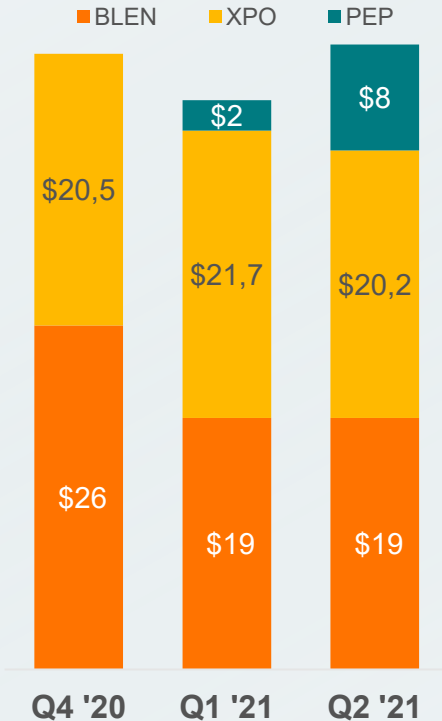
Double digit growth and accelerating demand through July

Monthly demand growth and inventory position
PEPAXTO 20 mg vials



PEPAXTO gaining on key competitors in 5L+ MM

US quarterly net revenue

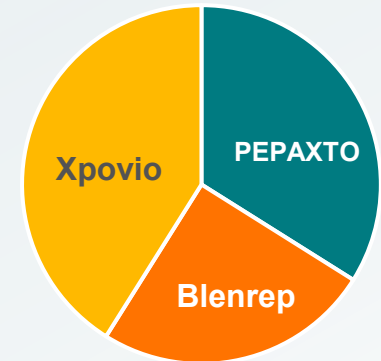


Product key revenue drivers

	PEPAXTO	Blenrep	Xpovio
5L+ MM doublet/SA approval	✓	✓	✓
Earlier lines MM doublet/SA approval		✓	✓
MM triplet approval			✓
Approval outside MM			✓
Price	\$\$	\$\$\$	\$\$\$

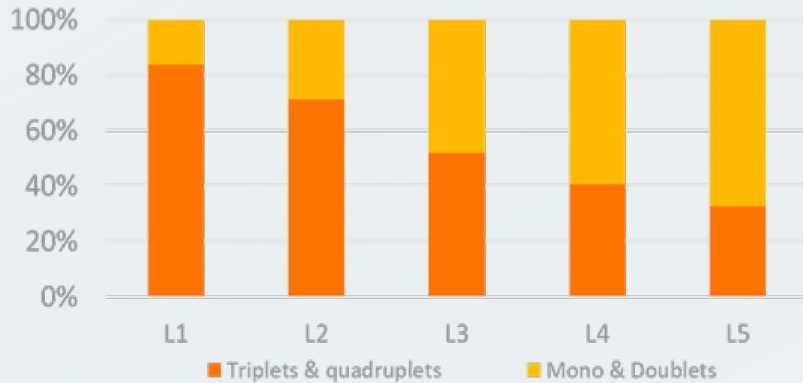
5L+ new patient share
Among key competitors

Three months total
(March – June 2021)



PEPAXTO well positioned for community-based care

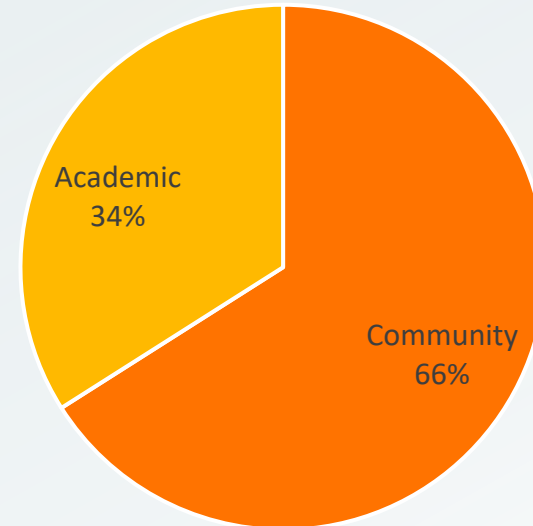
Use of Doublet “Mono and Doublet” therapy is higher in later lines of therapy



Source: Kantar Health 2020 report, Team Analysis

- Efficacy in later lines of therapy
- Manageable safety profile
- Convenient administration and better compliance

PEPAXTO accounts – Community vs Academic



Impressive breadth of use of PEPAXTO

Including leading academic centers and community practices

Nearly 200 unique accounts have ordered PEPAXTO through June



PEPAXTO gets permanent J-code J9247, effective October 1

Replaces the use of a miscellaneous J-code or hospital C-code

Benefits of a permanent J-code J9247 include the following:

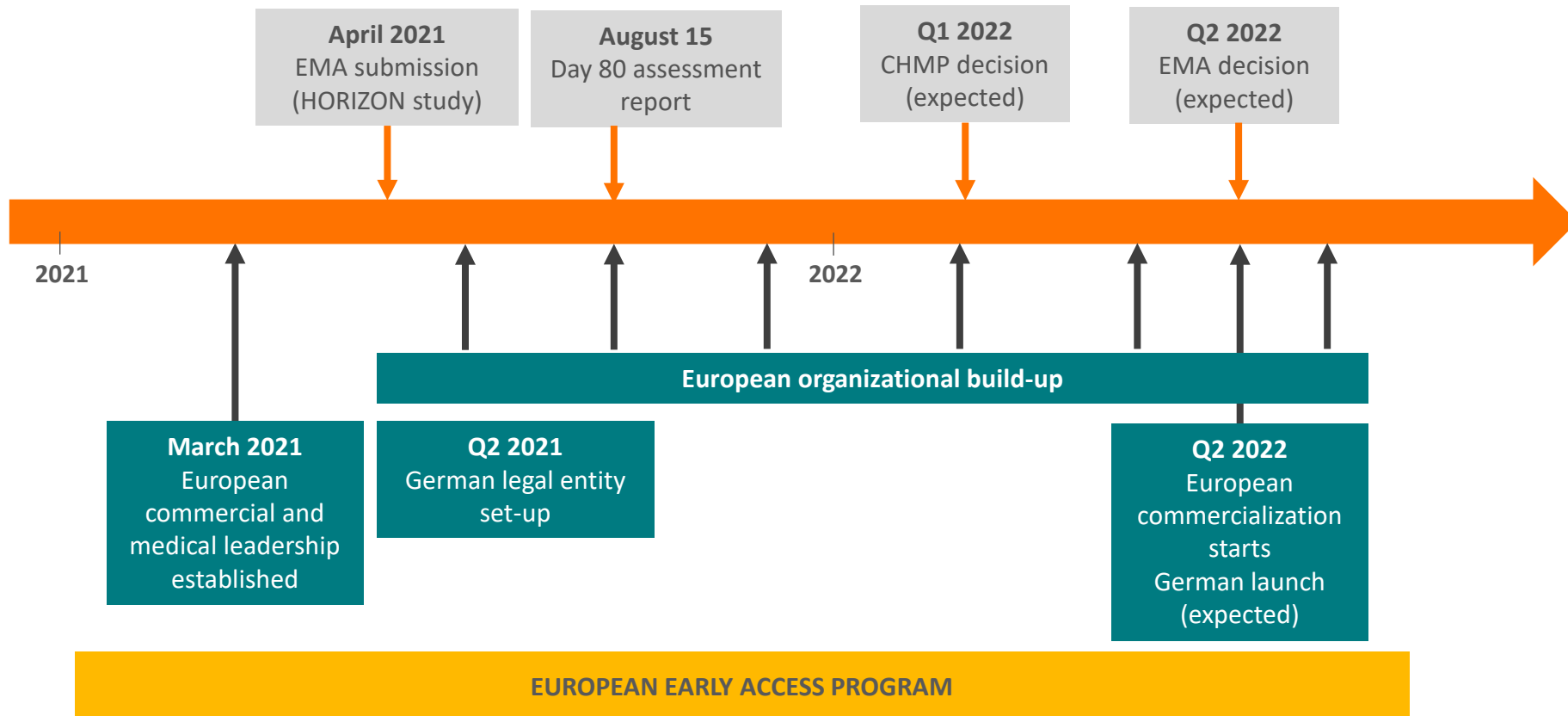
- Reduce billing and coding errors
- Decreases the time to reimburse sites of care
- Ensures more accurate reimbursement from payers
- Increase confidence in reimbursement among providers and practice management staff, especially in community oncology practices



European commercialization start in Q2 2022 on track

REGULATORY
TIMELINES &
ACCESS

ONCOPEPTIDES
MILESTONES



FDA Safety notification posted on July 28

FDA alerts patients and healthcare professionals about clinical trial result showing an increased risk of death associated with PEPAXTO (melphalan flufenamide)

STUDY OP-103 FDA ANALYSIS 07/26/2021

Following is a summary of findings from the OCEAN clinical trial.

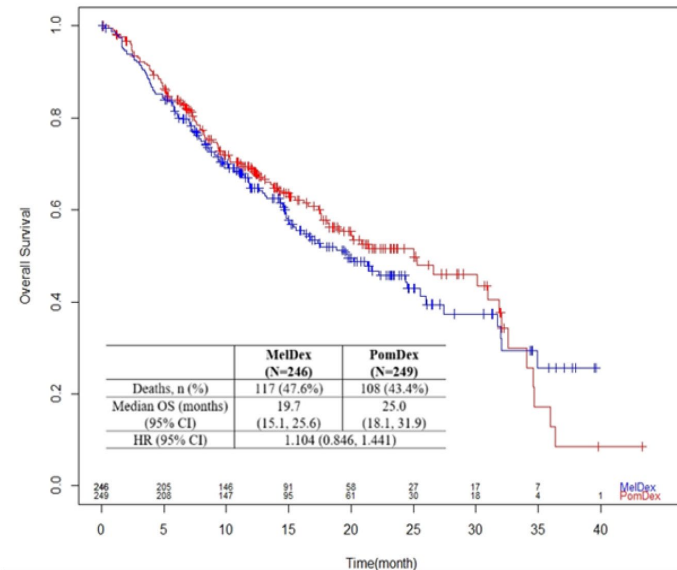
OCEAN is a randomized, controlled, open label, multicenter trial of melphalan flufenamide and low dose dexamethasone compared to pomalidomide and low dose dexamethasone in patients with relapsed or refractory multiple myeloma following 2-4 lines of prior therapy and who are refractory to lenalidomide in the last line of therapy.

FDA conducted an efficacy and safety evaluation of the OCEAN trial using a data cut-off date of February 3, 2021. There were 495 randomized patients included in the efficacy analysis.

For overall survival, there were 117/246 (48%) deaths on the melphalan flufenamide investigational arm and 108/249 (43%) deaths on the pomalidomide control arm.

The hazard ratio (HR) for overall survival (OS) of the melphalan flufenamide containing investigational arm compared to the control arm of pomalidomide was 1.104 (95% CI: 0.846, 1.441), indicating a detriment in survival in the melphalan flufenamide arm compared to the pomalidomide control arm.

The median OS in the melphalan flufenamide containing investigational arm was 19.7 months (95% CI: 15.1, 25.6) compared to 25.0 months (95% CI: 18.1, 31.9) in the pomalidomide containing control arm. The median follow-up for survival was 19.1 months.



MelDex: Melflufen + Dexamethasone; PomDex: Pomalidomide + Dexamethasone

Source: FDA analysis

Additional FDA analyses of safety and efficacy are ongoing.



CLINICAL STUDIES UPDATE

Klaas Bakker, CMO

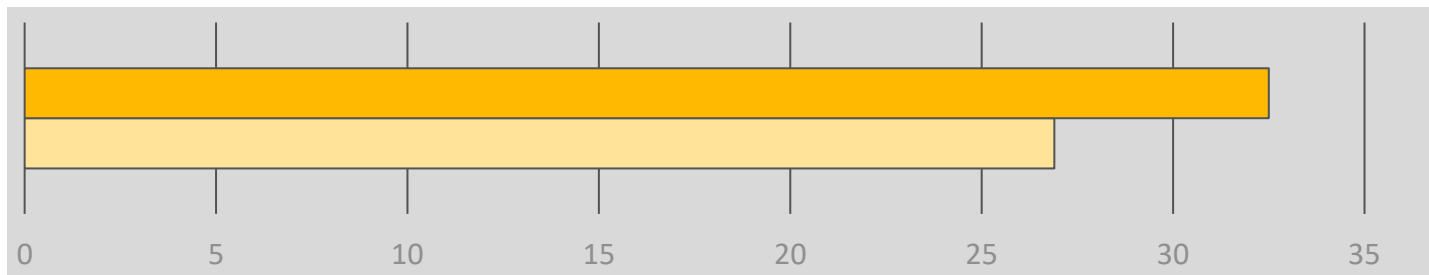
OCEAN topline results



- Primary endpoint – Progression Free Survival (PFS)

	Hazard Ratio (95% CI)	P-Value	Relative mPFS improvement	Outcome
Independent Review Committee (IRC)	0.792 (0.640-0.979)	0.0311	+39%	Superiority

- Secondary Endpoint - Overall Response Rate 32.5% for melflufen vs 26.9% for pomalidomide



- Secondary Endpoint – Overall Survival HR of 1.104 favoring pomalidomide

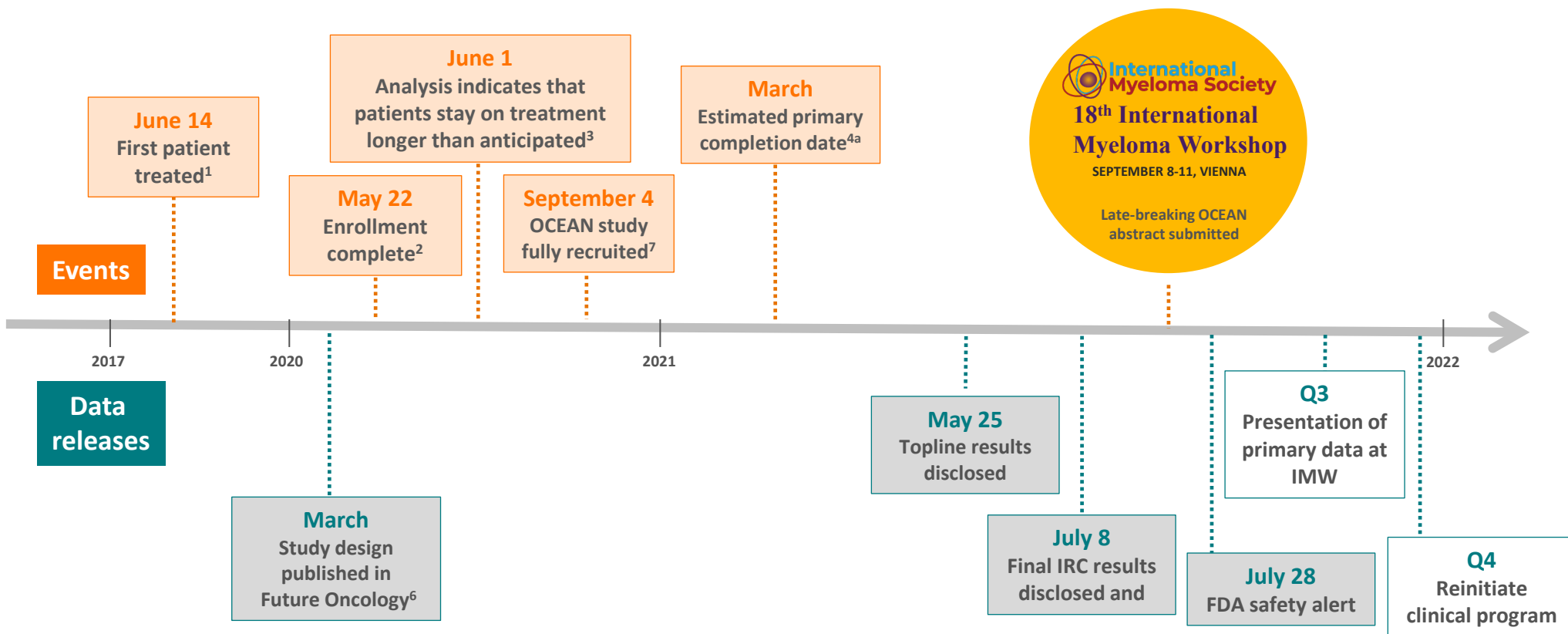
Clinical hold

- FDA requested a partial clinical hold on the melflufen program
 - OCEAN, LIGHTHOUSE, HORIZON, ANCHOR, BRIDGE, PORT, ASCENT
- FDA requested a full clinical hold on the OPD5 program
 - COAST
- Over 300 patients on clinical trials, all but two have reconsented to continue
- Regular contact with the FDA
- Progressing on key work streams related to partial clinical hold

Range of outcomes with full FDA review of OCEAN trial

- OCEAN data review at FDA and/or EMA result in a label that includes 3rd and 4th line
- OCEAN data is viewed as “hypothesis generating” and that we need to confirm in our clinical development program while promoting “after 4 prior lines of therapy”
- OCEAN data results generate a level of concern around OS that challenges the continued “accelerated approval” of PEPAXTO
- FDA may hold a future public meeting to discuss melflufen

OCEAN study – detailed timeline and upcoming events



^aEvent-driven; ^bCurrent assumption and plan.

1. Oncopeptides [Press Release](#). June 14, 2017; 2. Oncopeptides [Press Release](#). May 22, 2020; 3. Oncopeptides [Press Release](#). June 01, 2020; 4. ClinicalTrials.gov Identifier: [NCT03151811](#); 5. Sonneveld P, et al. [Poster Presentation P-036] Lymphoma & Myeloma Congress 2019; 6. Schjesvold F, et al. *Future Oncol*. 2020;16:631–641. 7. Oncopeptides [Press Release](#). Sep 4, 2020

IMW Meeting – September 8-11



18th International Myeloma Workshop

SEPTEMBER 8-11, VIENNA AUSTRIA





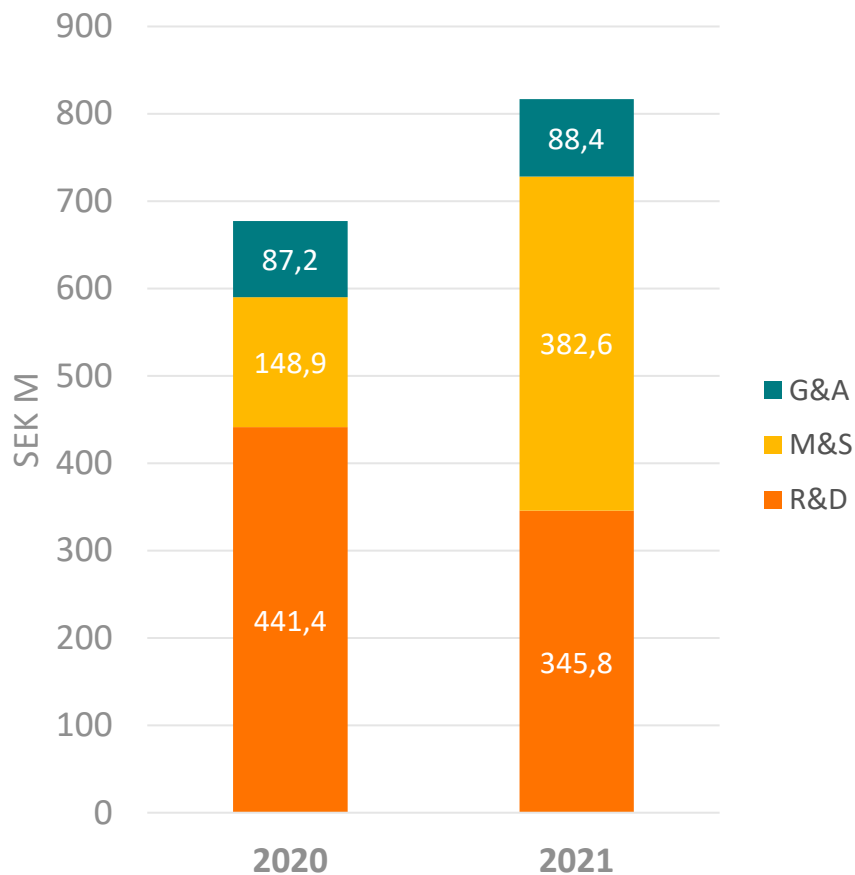
FINANCIAL UPDATE AND SUMMARY

Anders Martin-Löf, CFO

Marty J Duvall, CEO

Financial results for January – June 2021

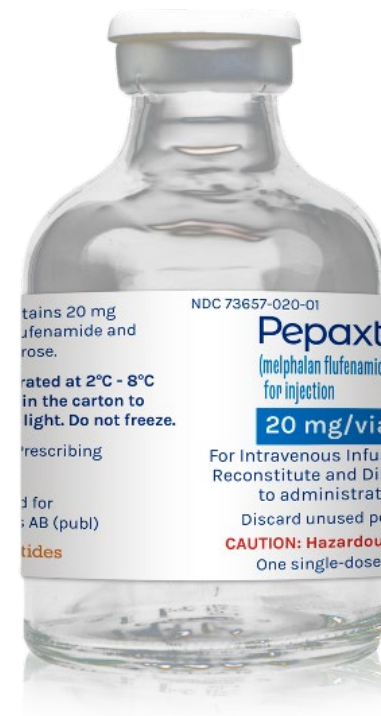
Operating Costs Jan-Jun



- Revenues amounted to SEK 85.7 M (-) for H1 66.4 M (-) for Q2
 - Gross margin of 96%
- Operating loss decreased to SEK 692.2 M (loss: 696.2) for H1 and 344.8 M (loss: 399.3) for Q2
 - R&D decreased primarily due to less cost in OCEAN and HORIZON projects
 - OCEAN SEK 78 M (177)
 - Number of co-workers increased to 313 (154) as of June 30
 - 142 (56) in US subsidiary
- Cash flow from operating activities neg. SEK 733.4 M (neg. 598.5) for H1 and neg. 346.7 M (neg. 285.7) for Q2
 - Neg. exchange rate effect of SEK 146.0 M
- Cash position was SEK 999.4 M (937.8) as of Jun 30, 2021
 - €40 M EIB loan facility unutilized
 - Measures to preserve cash implemented due to regulatory uncertainty

Q2 – Key takeaway messages

- First full quarter with revenue
 - Strong interest in PEPAXTO
 - Double-digit demand growth on a month-to-month basis
- Q2 net sales of SEK 66.4 M (\$7.2M) and YTD net sales of SEK 85.7 M (\$10.2M) since launch in mid-March
- Updated OCEAN data – study met primary endpoint
 - Head-2-Head success versus pomalidomide and melflufen demonstrated superiority on PFS
 - Secondary end-point of overall survival in favor of pomalidomide in ITT population
 - Clinical hold and FDA safety communication
- Progressing on key work streams related to partial clinical hold
- Webcast to be hosted in connection with IMW in September



Addressing a growing unmet medical need

Pepaxto[®]
(melphalan flufenamide)
injection for intravenous use 20 mg/vial





bringing hope through science