



POLYPHOR

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2020 Half Year Results and Business Update

September 3rd 2020

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Results and Priorities Moving Forward

Strong progress in first half of 2020



2020 YTD Highlights:

- Strong progress in Ph III trial for balixafortide enrollment despite COVID-19 and 2 positive DSMB decisions
- Completion of exclusive licensing agreement for balixafortide in China with Fosun Pharma with a deal value size of up to USD 182m and royalties on sales
- Cash position* extended to finance operations well into Q3 2021. Operating expenses guidance for 2020 CHF 57m – CHF 59m
- Equity-linked financing arrangement with IRIS up to CHF 19.3 million providing additional flexibility to extend current cash if needed

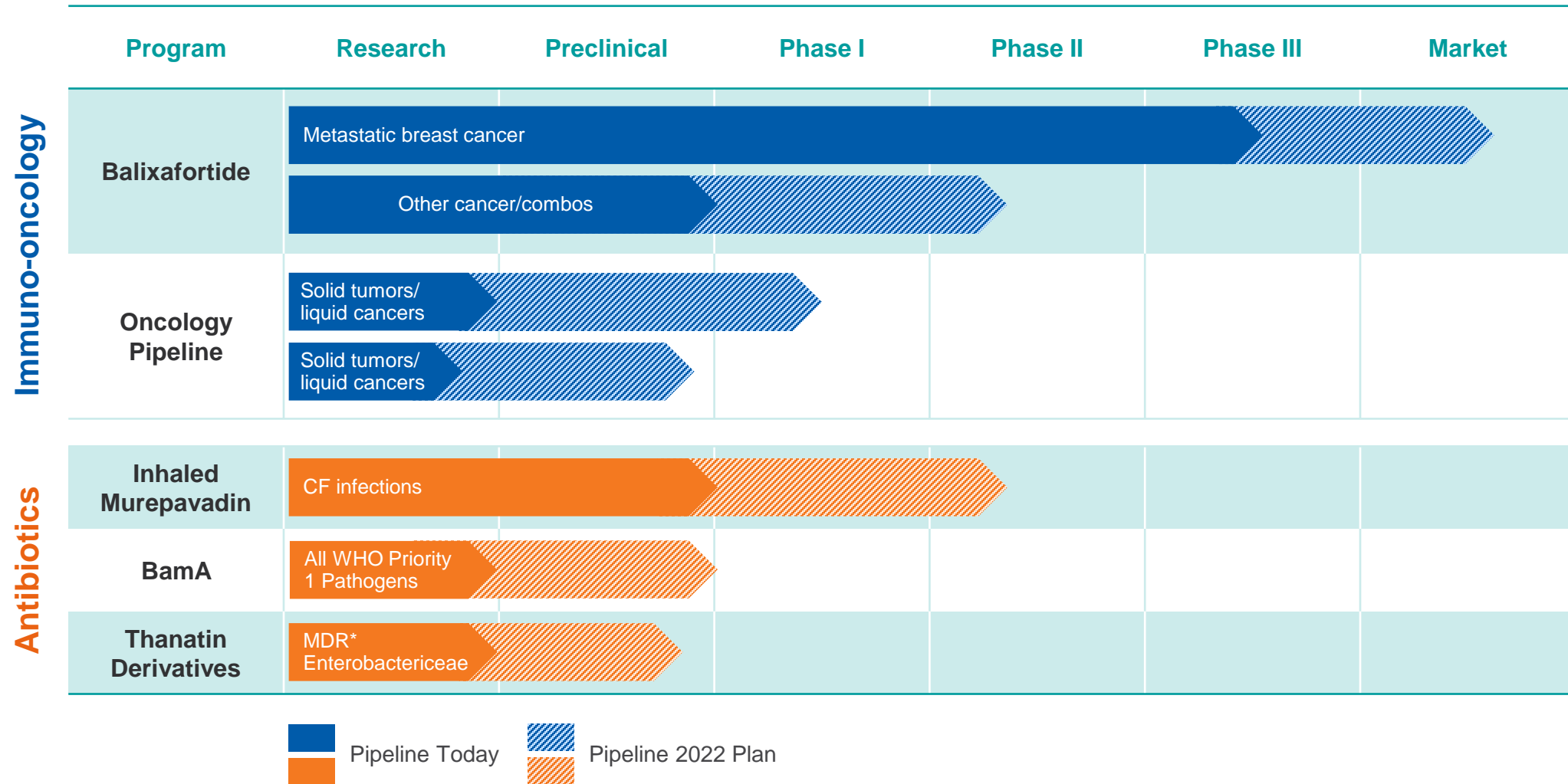
Polyphor Priorities Moving Forward:

- Continue strong execution in Phase III trial for balixafortide achieving key near-term milestones:
 - Patient enrollment completion expected in coming weeks
 - ORR: Q2 2021
 - PFS: Q4 2021
- Plan to initiate Phase Ib/II trial in earlier lines of breast cancer in Q4 2020
- Inhaled murepavadin CTA submission and Phase I study start planned in Q4 2020
- Continue OMPTA BamA program in partnership with CARBX to identify new leads
- Continue non-dilutive financing efforts with key institutions for the antibiotics portfolio

* Includes planned near-term upfront payment from Fosun Pharma

Pipeline Development Programs On Track

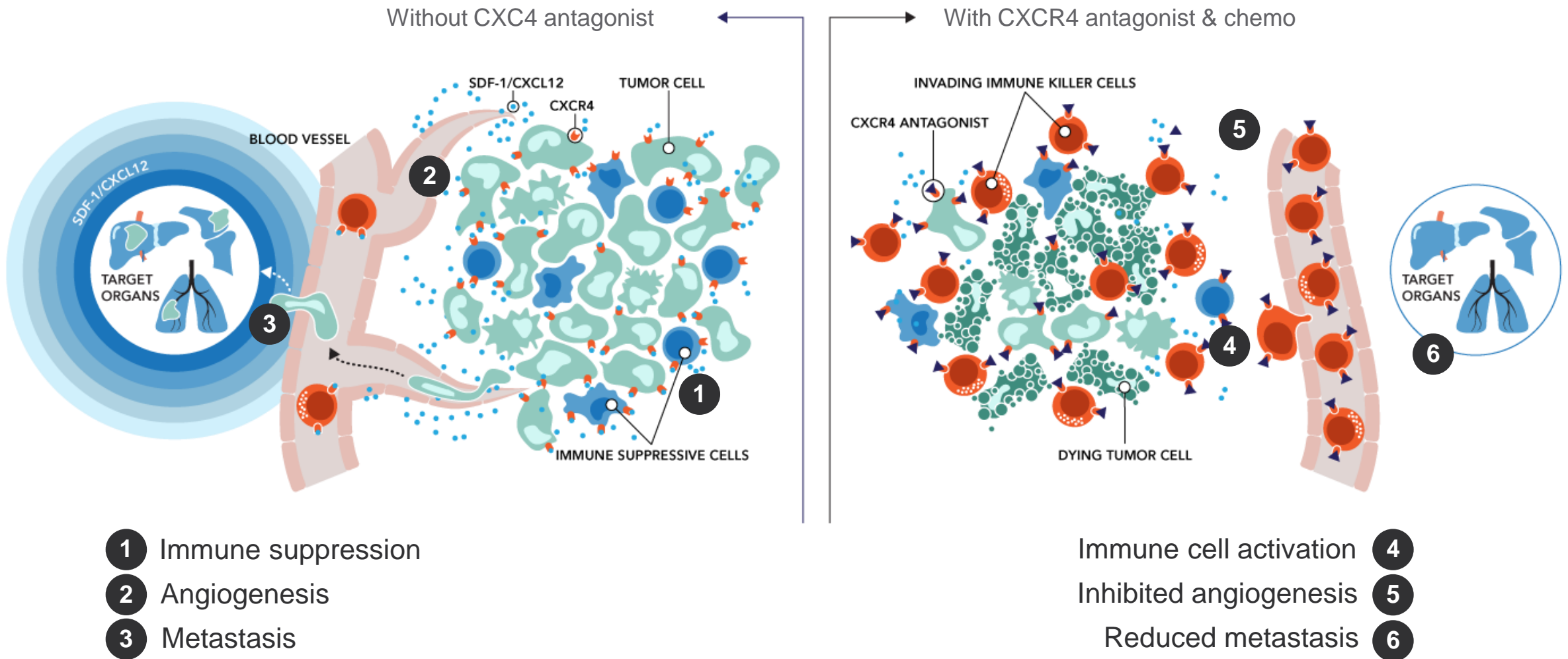
Multiple milestones and key inflection points to 2022



*Multidrug Resistant

CXCR4 overexpression is a key mechanism of cancer prognosis

CXCR4 promotes breast cancer growth through increased signaling pathways, angiogenesis, metastasis and immune cell modulation



* SDF-1/CXCL12: CXCR4 ligand
Xu *et al.*, 2015, modified

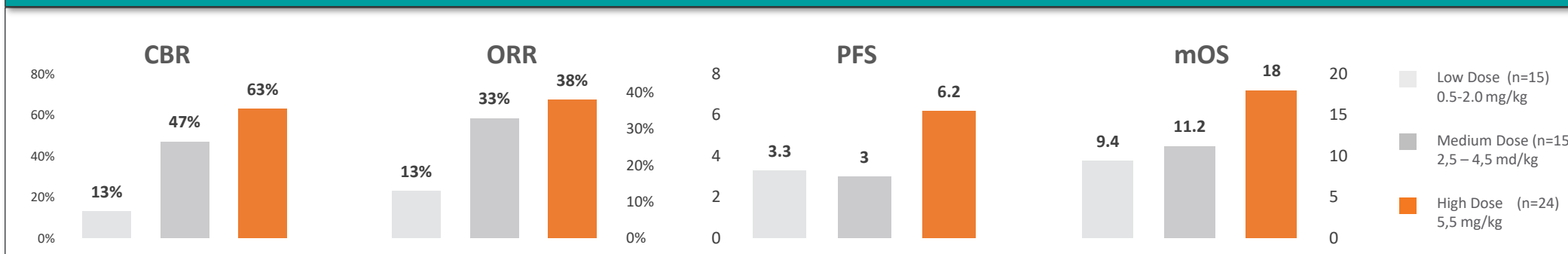
Balixafortide has potentially the best in class efficacy amongst CXCR4s*

Highest exposure among CXCR4 inhibitors – and importance of it shown by dose-response



Molecule	Origin	Phase III Indication	Phase II Pipeline	Administration	Clinical Dose	IC50 coverage ratio by clinical exposure	
						Cmax	AUC
Plerixafor ¹ <i>Sanofi</i>	Small molecule	Hematopoietic stem cell mobilization (Approved)		Subcutaneous	0.24 mg / kg	1	1
Mavorixafor ² <i>X4 Pharma</i>	Small molecule	WHIM syndrome	CC renal cell carcinoma (combination with axitinib)	Oral	6-7 mg / kg (MTD)	106	100
Motixafortide ³ <i>BiolineRx</i>	Cyclic peptide 1 st generation PD	Mobilization of HSCs for autologous transplantation (on top of G-CSF)	Pancreatic Cancer (comb. with pembro and chemo) AML (comb. with cytarabine)	Subcutaneous	1.25 mg / kg	211	66
Balixafortide ⁴ <i>Polyphor</i>	Cyclic peptide 3 rd generation PD	Metastatic Breast Cancer (combination with eribulin)	Metastatic Breast Cancer (earlier lines in combination with chemo planned Q4 2020)	IV	5.5 mg / kg (5-8 times safety margin)**	790	1064

Impact of High Dose to Response Across all Efficacy Endpoints in Phase Ib Trial Balixafortide



* Compounds disclosed on company websites

¹ FDA CDER Pharmacology Review: application number 22-311, FDA CDER Clinical Pharmacology Review: application number 22-311, mean of studies at 0.24 mg/kg dose

² Wong, RS et al. Mol Pharmacol. 2008 Dec;74(6):1485-95. doi: 10.1124/mol.108.049775 Stone_Hendrix_2007, Antimicrob Agents Chemother 51(7):2351-2358

³ Tamamura H, et al. FEBS Lett. 2003 Aug 28;550(1-3):79-83, calculated from Abraham_Peled_2017, Clin Cancer Res 23(22); 6790-801 (supplemental table 2) From ClinicalTrials.gov, accessed 23 January 2018, ongoing trials, e.g. COMBATa (NCT02826486)

⁴ In-house unpublished study POL6326-07. Intra-experiment comparisons must always be interpreted with caution

** Safety Margins are calculated as multiples of Balixafortide plasma concentration at No Observed Adverse Effect Level (NOAEL) in 13 week NHP toxicology study compared to balixafortide plasma concentration in humans at 5.5mg/kg dose, which is the dose in the Phase 3 FORTRESS study.

Phase III Pivotal Study FORTRESS

Eribulin +/- Balixafortide in advanced BC



Study objectives, patient population & randomization status

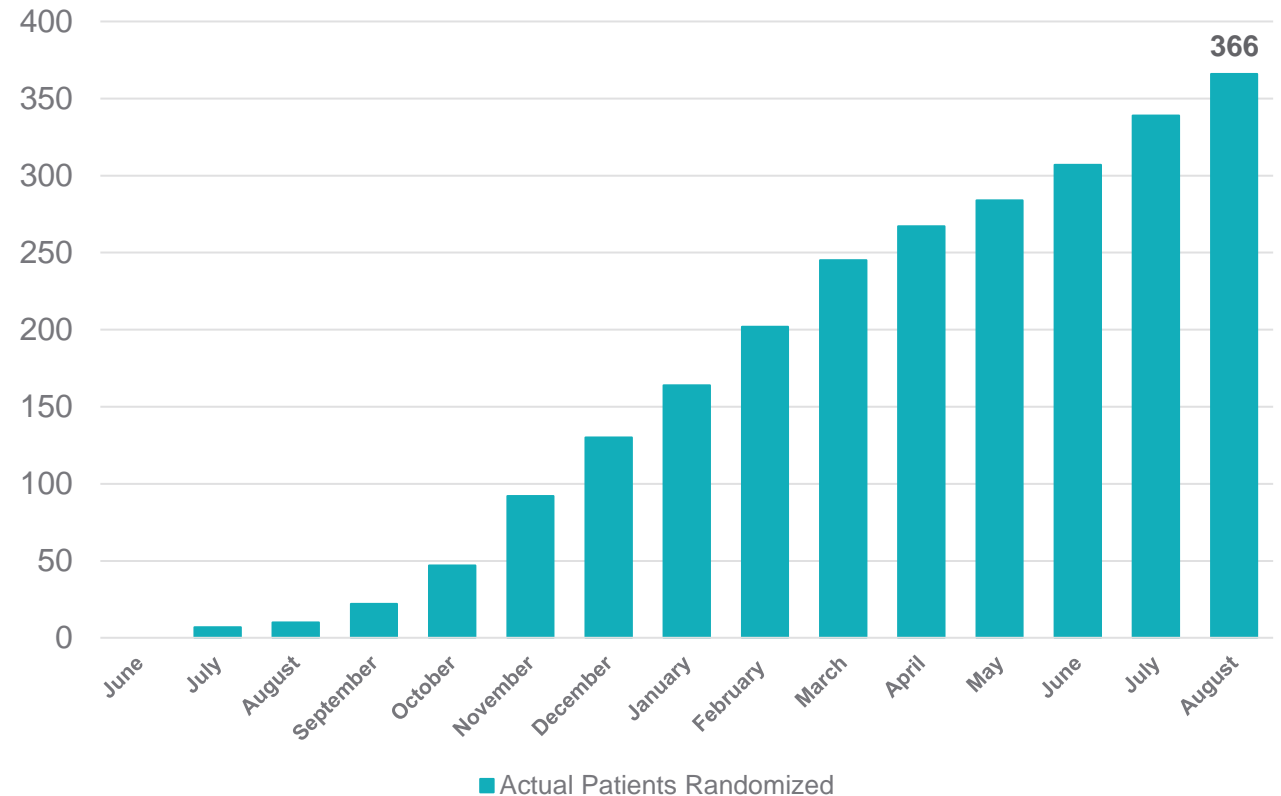
Objectives:

- **Key primary endpoint:** Progression free survival at 12 months after the last patient is randomized
- **Co-primary endpoint:** Objective Response Rate at 6 months after the last patient is randomized

Patient Population:

- Locally recurrent or metastatic breast cancer (BC)
- HER2 negative, with any ER/PR
- Previously treated with 1–4 chemotherapeutic regimens for locally recurrent or metastatic BC
- Previously received an anthracycline and a taxane in either the adjuvant or metastatic setting, unless contra-indicated for safety reasons

FORTRESS Randomization Curve



FORTRESS recruitment update



Original patient recruitment plan:

- 3rd line mBC - 320 patients: supports US guidelines for use of eribulin
- 2nd line mBC - 64 patients: supports EU guidelines for use of eribulin
- 384 patients: on track to fulfil in September

Status:

- 366 patients recruited to date:
 - ✓ 3rd line+ patients: 279 recruited → a further of 41 patients (3rd line+) to be recruited meet the objective of 320 patients
 - ✓ 2nd line patients: 87 recruited
- Recruitment of 41 patients to be completed within next weeks

FORTRESS Patient Recruitment



FORTRESS: Measuring Outcomes

Key Primary Objective:

- PFS at 12 months after the last patient is randomized
- Timing: Q4 2021
- Fast track granted (US) with potential filing when PFS at $p < 0.05$

Co-primary analysis of objective response rate endpoint

- Objective Response Rate, 6 months after the last patient is randomized
- Assessed in patients with 3rd line or later mBC with measurable disease, est. 66-75% of total study population
- Timing: Q2 2021

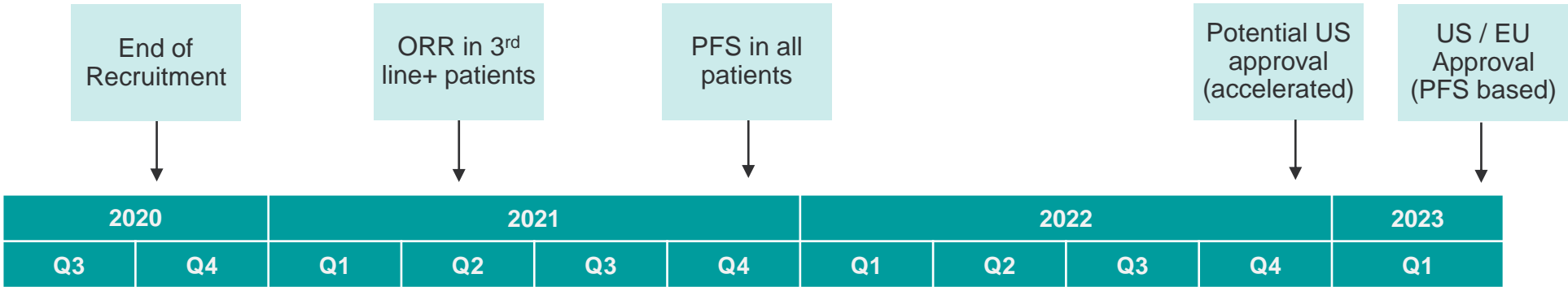
Potential implications of first ORR Analysis in the US:

- Potential Breakthrough Designation: Based on outstanding ORR ($p=0.001$) provides upside for earlier filing
- Continue Fast Track Designation: Positive ORR data provide supportive evidence for balixafortide activity, specifically in the context of duration of response and stable disease
- ORR in patients with 3rd line mBC and later → an important catalyst in Q2 2021

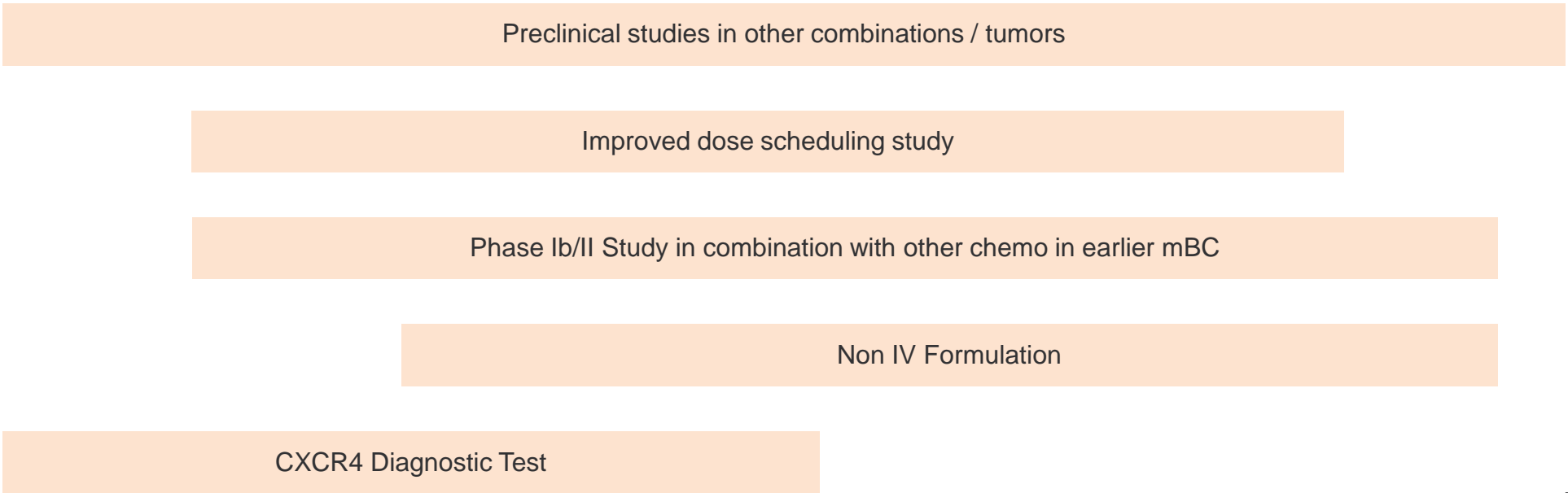
Balixafortide Strategy – Initial Indication and Expansion Plan



Initial Indication



Future Indication Expansion Plan



Key enablers for expanding beyond the initial indication to earlier lines / other tumors and combos and building value for potential future partnerships.

Balixafortide China Licensing Agreement with Fosun Pharma

Strong validation to the scientific value and commercial potential of balixafortide



Balixafortide opportunity in China:

- China is expected to be the 2nd breast cancer market in the world expanding balixafortide opportunity in a large geography
- Fosun Pharma is a leading global Chinese company with:
 - Strong R&D capabilities to bring balixafortide to market in metastatic breast cancer and potentially additional indications / combinations
 - Strong commercial capabilities and oncology pipeline
 - Provides strong validation to the scientific value and commercial potential of balixafortide

Total deal value: Up to \$182M plus royalties

- **\$15M** upfront
- **Up to \$19M** development milestones
- **Up to \$148M** in sales milestones
- **Low to mid teen** royalties on net sales
- Strong value vs. benchmark Ph. III deals in China:
 - Average \$12.0M upfront and \$83.6M total deal size¹

FOSUN PHARMA



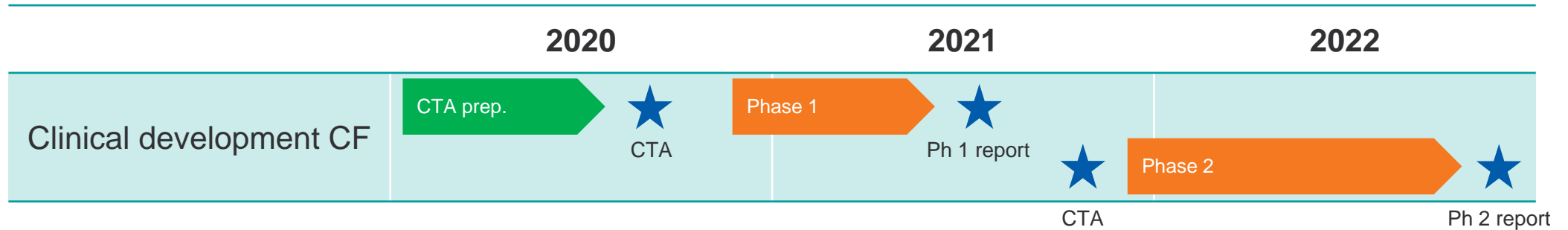
¹ <https://torreya.com/publications/torreya-creating-value-through-china-partnering-oct2018.pdf>

Inhaled Murepavadin for CF

Changing the treatment paradigm in treating chronic *P. aeruginosa* infections in Cystic Fibrosis



Potentially the first pathogen specific new class inhaled antibiotic for *P. aeruginosa*, leading cause of exacerbations, lung function decline and mortality in CF



Clinical Program Plan and Timelines:

- Preclinical program complete suggesting broad safety margin and efficacy; plans to submit CTA and start Phase I program in Q4 2020
- Phase I study design and a refined formulation is ready for study start
- Phase I study plan expanded to include single and multiple dosing in healthy volunteers up to 7 days (IMI alignment including earlier phasing of about 1.8 M Euros financing vs plan)
- Pursue additional external financing while the program already partly financed by IMI until 2021

Targeted and attractive rare disease opportunity:

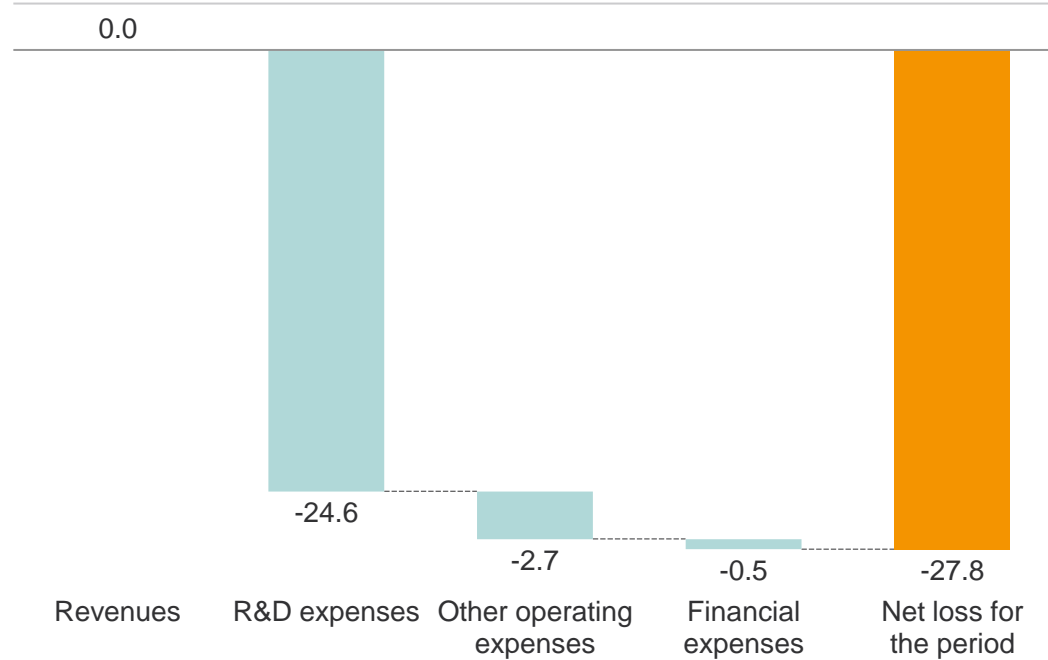
- Attractive orphan market opportunity
- Comparators' * peak sales (200-400m USD)
- Can be expanded from CF to Non Cystic Fibrosis Bronchiectasis and beyond

* Tobis and Cayston

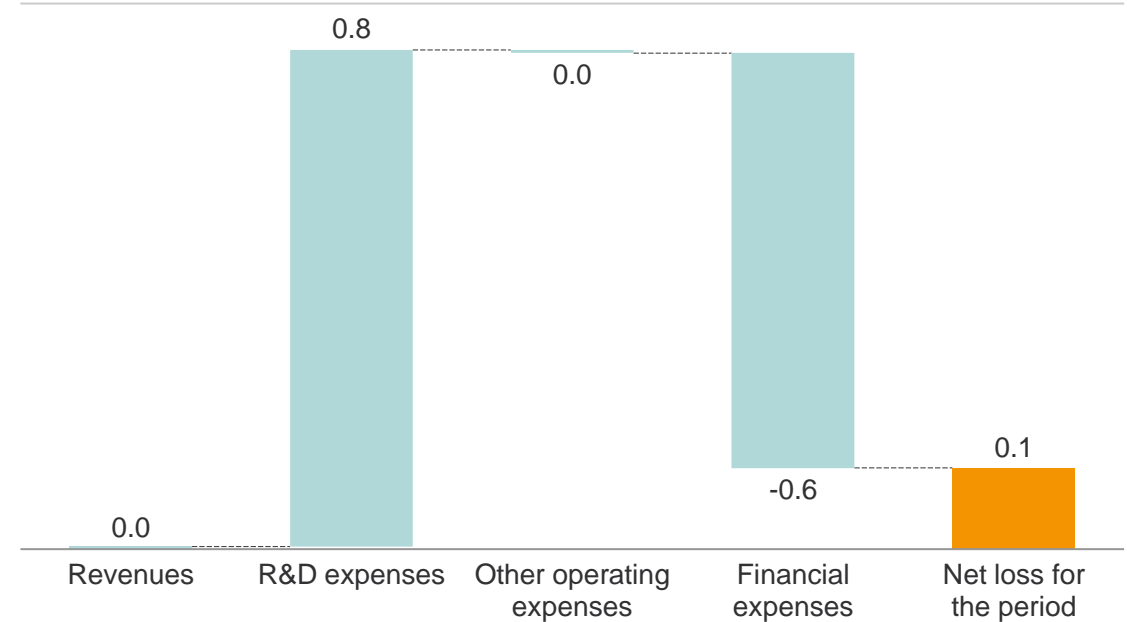
Financial Highlights – Net loss

In CHF million (based on consolidated IFRS financial statements)

Results 1st HY 2020



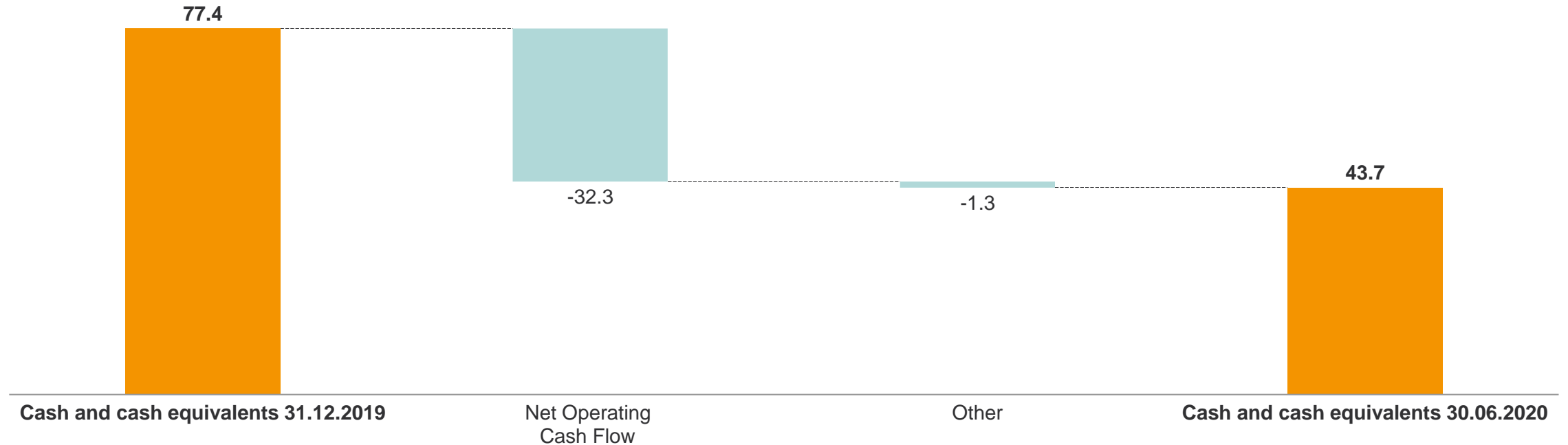
Change vs 1st HY 2019



- H1 2020 net loss of CHF 27.8 million, overall driven by R&D costs reflecting progress on the balixafortide pivotal trial and further build-up of pipeline
- Decrease in R&D expenses of CHF 0.8m versus H1 2019 driven by slightly lower expense level for balixafortide pivotal trial in H1 2020 compared to the two murepavadin pivotal trials in H1 2019
- Other operating expenses include G&A (CHF -2.6m), Marketing & Sales (CHF -0.4m) and other income (CHF 0.3m)
- Sale of Santhera shares led to lower financial expenses in H1 2019, which were CHF 0.6m lower compared to the H1 2020

Financial highlight – Cash Flow

In CHF million (based on consolidated IFRS financial statements)



- Cash and cash equivalents at the of H1 2020 were CHF 43.7 million.
- Cash was deployed to our operating activities, mainly driven by progression of the FORTRESS trial for balixafortide and by the final payments for closed PRISM and UDR murepavadin I.V. trials (accrued for in 2019)
- Other includes mainly repayment of the loan on leasehold improvements and related interest (CHF -0.7m) and net effect of exchange rate movements (CHF -0.6m)

Guidance for 2020



- Cash and cash equivalents as of 30.06.2020 CHF 43.7 million
- For 2020 we expect that operating expenses (excluding share-based payments and IAS 19 pension adjustments) to be in the range of CHF 57 – 59 million, which is lower than the CHF 61 – 64 million range previously provided.
- Upfront of USD 15 million to be added to our cash position as the result of our partnering with Fosun Pharma
- Company's operations funded well into Q3 2021
- Continue discussions with key institutions and attract additional non-dilutive funding for antibiotics
- Financing facility could further extend our cash runway if needed

Strategy to Expand Shareholder Value

Strong progress in near term priorities year to date



Strong Achievements YTD:

- ✓ Strong progress with balixafortide Phase III Trial nearing enrollment completion and 2 positive DSMBs
- ✓ Fosun Pharma China Partnership: strong deal size validating scientific and commercial value & non dilutive financing
- ✓ Extended cash runway well into Q3 2021 through financial stewardship and upcoming China upfront
- ✓ Equity-linked financing arrangement with IRIS up to CHF 19.3 M providing flexibility to extend current cash if needed
- ✓ CTA filing and plan to initiate Phase I for inhaled murepavadin is on track
- ✓ Non-dilutive financing efforts with key institutions on track for the antibiotics portfolio

Near Term Plan and Priorities:

- Complete enrollment and prepare for ORR and PFS data readouts in Q2 and Q4 2021
- Expand balixafortide opportunity in additional indications prior to potential global licensing following PFS data
- Initiate Phase I for inhaled murepavadin in Q4 2020

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Q&A Session



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