

**PharmaEngine**

智 擎 生 技 製 藥

**3Q 2023 Financial Results**

**2023/11/02**

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# Agenda

1. 3Q 2023 Operational Highlights
2. 3Q 2023 Operational Overview
3. Research and Development
  - ONIVYDE®
  - PEP07
4. Vision for 2024
5. Q&A



# 3Q 2023 Operational Highlights- Keep Deliver Sustainable Growth and Enhanced Value



## COMMERCIAL



### ONIVYDE® market and new indication expansion

1. Taiwan FDA sNDA submission (PharmaEngine)
2. EMA Type II Variation submission (Servier)
3. USA FDA sNDA submission (Ipsen)

## PIPELINE



### New project RD progress accelerated

1. Phase 1 clinical studies of PEP07 for hematologic and solid tumor cancers continue.
2. Multiple projects meet expectations with external AI/CADD collaboration
3. >20% regular operation revenue as RD expenses

## OPERATION



### Operation with a sustainable growth

1. Approved by the Ministry of Economic Affairs as a “Biotech and Pharmaceutical Company”
2. Jan-Sep 2023 Cash and cash equivalents: NT\$3.56 bn
3. Completed the scope 1 & 2 emissions data collection, analysis and third-party assurance

# 3Q 2023 Operational Overview



# Sales and Royalties Drives Long-term Growth



NT\$(000)

Items \ Year	2017	2018	2019	2020	2021	2022	3Q 2023/3Q 2022 YoY (%)
Taiwan Sales	40,651	87,384	180,389	214,828	235,469	277,594	216,084 (+2%)
Royalties from Europe and Asia	63,526	109,825	133,651	271,584	419,366	376,789	301,791 (6%)
Milestone	749,500	96,221	0	569,600	0	0	62,470 (-)
Total	853,677	293,430	314,040	1,056,012	654,835	654,383	580,345 (17%)

# 1Q-3Q 2023 Financial Results



NT\$(000)	1Q-3Q 2023	1Q-3Q 2022	Amount Change	% Change
<b>Operating revenue</b>	580,345	495,910	84,435	17.03
<b>Operating costs</b>	37,860	37,416	444	1.19
<b>Gross profit</b>	542,485	458,494	83,991	18.32
<b>Sales expenses</b>	28,650	29,111	(461)	(1.58)
<b>G&amp;A expenses</b>	70,470	74,226	(3,756)	(5.06)
<b>R&amp;D expenses</b>	231,346	122,037	109,309	89.57
<b>Total operating expenses</b>	330,466	225,374	105,092	46.63
<b>Operating income</b>	212,019	233,120	(21,101)	(9.05)
<b>Total non-operating income and expenses</b>	65,709	94,987	(29,278)	(30.82)
<b>Income before income tax</b>	277,728	328,107	(50,379)	(15.35)
<b>Income tax expense</b>	40,451	62,941	(22,490)	(35.73)
<b>Profit for the period</b>	237,277	265,166	(27,889)	(10.52)
<b>EPS(NT\$)</b>	1.65	1.85	(0.20)	(10.81)

# Research and Development

- ONIVYDE® 1L PDAC NDA submission
- **First patient dosed** in PEP07 phase 1 for hematologic cancers
- PEP07 phase 1 for **solid cancer** approved by TFDA
- Multiple projects in collaboration with external AI/CADD

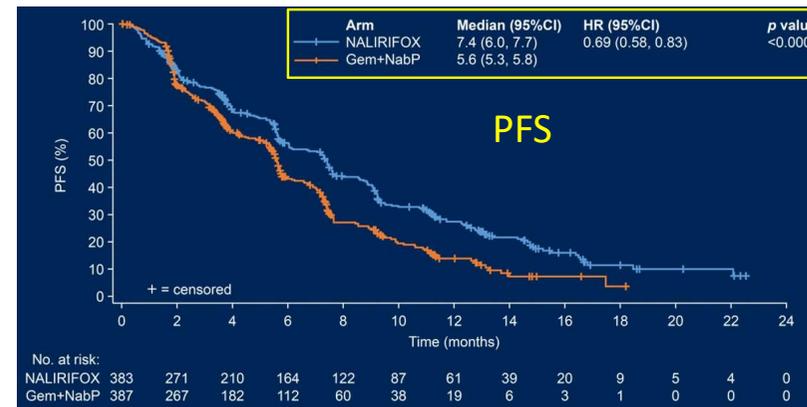
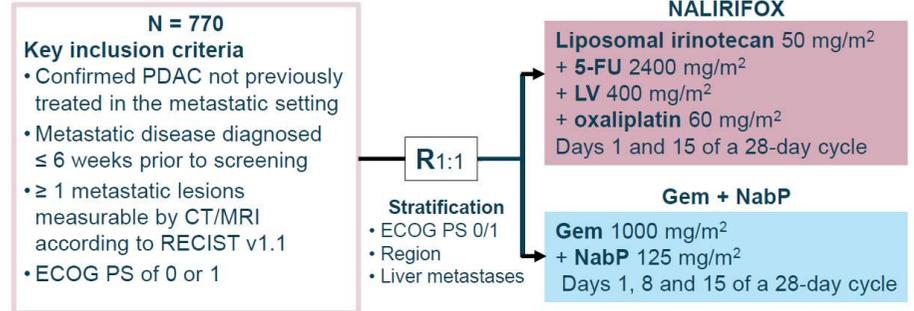


# NAPOLI-3

A randomized, Open Label Phase 3 Study of Liposomal Irinotecan + 5-FU/LV + Oxaliplatin (NALIRIFOX) versus Nab-Paclitaxel + Gemecitabine in Treatment-naïve Patients with Metastatic Pancreatic Ductal Adenocarcinoma



- ◆ NALIRIFOX (n = 383) vs. Gem + NabP (n = 387), 770 patients enrolled
- ◆ Study endpoints:
  - Primary endpoint – OS (Overall Survival)
  - Secondary endpoints – PFS (Progression Free Survival), ORR (Objective Response Rate)
- ◆ First Patient Enrolled: Feb. 2020; Data cut-off: July 23, 2022
- ◆ Topline results presented in 2023 ASCO GI



## Conclusion

- The NALIRIFOX regimen met its primary endpoint demonstrating a statistically significant improvement in OS of 11.1 in months compared to 9.2 months for patients treated with Gem + NabP (HR 0.83 [95% CI 0.70–0.99]; p=0.04).
- The trial met its secondary endpoint showing patients treated with NALIRIFOX had a statistically significant improvement in mPFS of 7.4 months versus 5.6 months for Gem + NabP (p < 0.0001); ORR was 41.8% (36.8%-46.9%; 95% CI) for patients treated with the NALIRIFOX versus 36.2% with Gem + NabP (31.4%-41.2%; 95% CI).
- Overall, the safety profile of NALIRIFOX in NAPOLI 3 was manageable. No new safety concerns with the NALIRIFOX regimen were identified.

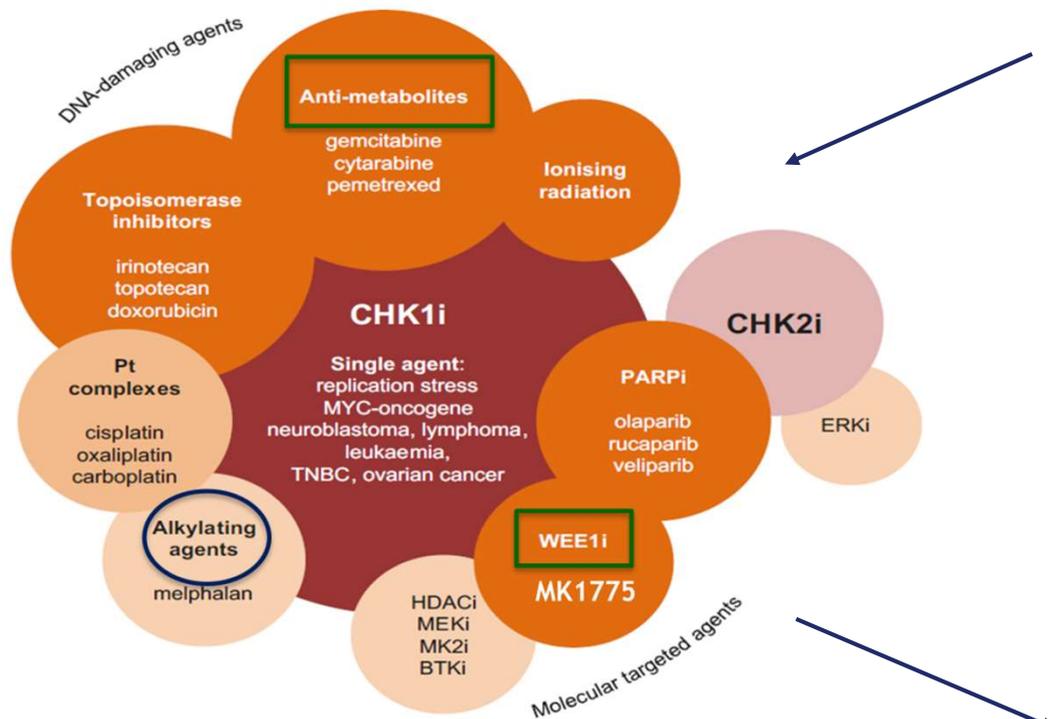
# PEP07 – Potential Best in Class CHK1 Inhibitor

PEP07 is a brain penetrating oral inhibitor which is more potent and selective than the competitors.

	Drug	Stage	Potency	Selectivity	Oral Bioavailability
Acrivon (Eli Lilly)	Prexasertib	Ph II	●	●	●
Genetech	GDC-0575	Discontinued	●	●	●
GSK (Sierra Oncology)	SRA-737	Ph I / II (Complete)	●	●	●
Esperas Pharma	LY2880070	Ph I / II (Complete)	●	●	●
PharmaEngine	PEP07	Ph I Ready	●	●	●

● Excellent    ● Good    ● Fair    ● Poor    ● Unknown

# PEP07 for Potential Combination Therapies



- Synergistic effect verified in PEP07
- Additive effect observed in PEP07

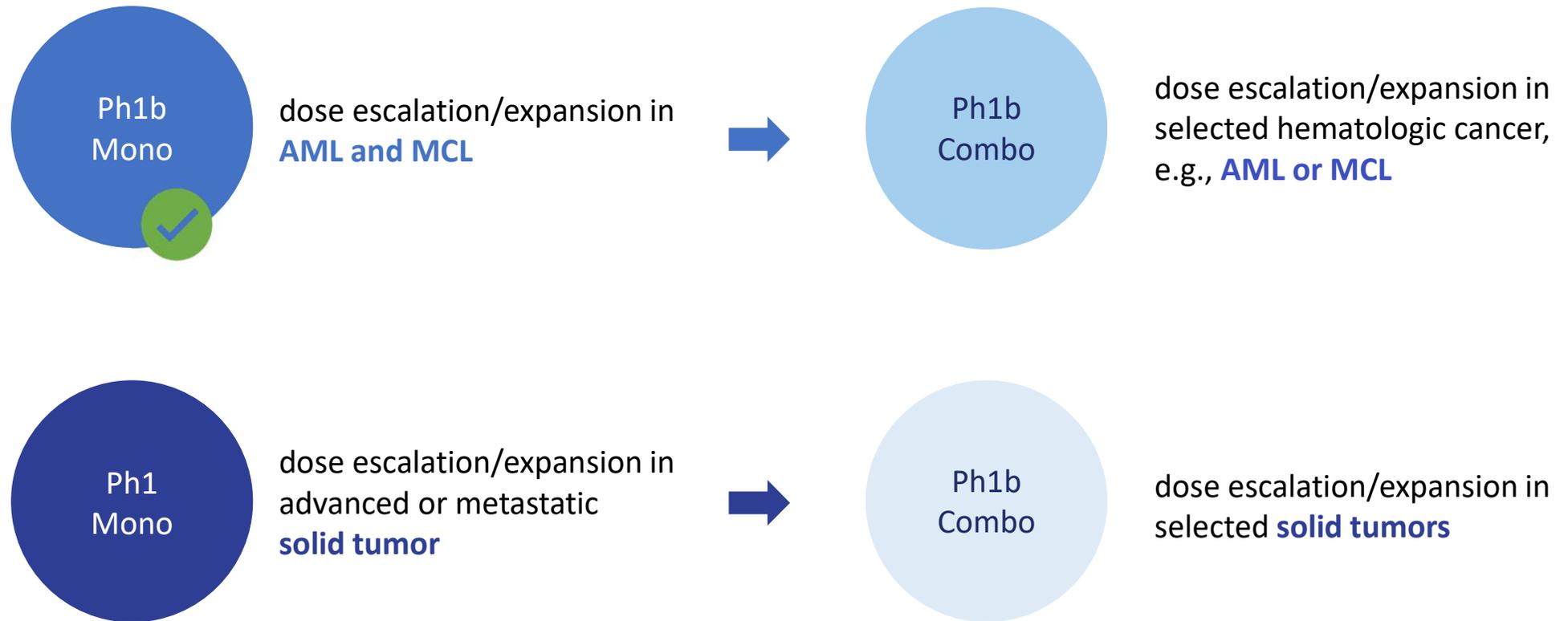
## In vitro Combo Treatment

SoC agents	Indication	Cell line
Ara-C	AML	MV4-11 / THP-1
Gemcitabine	NSCLC	NCI-H1703
5-Fu	Esophagus	KYSE-270
5-Fu	Stomach	MKN-45, SNU-16, SNU-5,
5-Fu	CRC	DLD-1, HT-29, SW480
TMZ	Brain	IMR-32
Sorafenib	RCC	A498

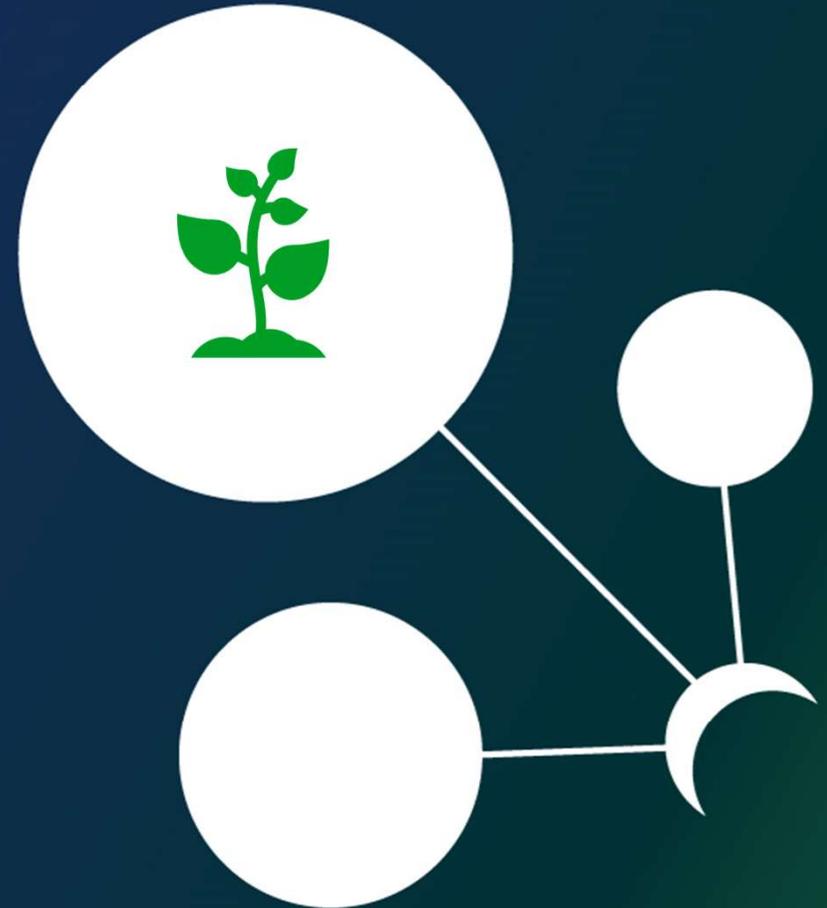
**Green: Synergism; Blue: Additivity**

## Clinical Trial Designs and Indications Guidance

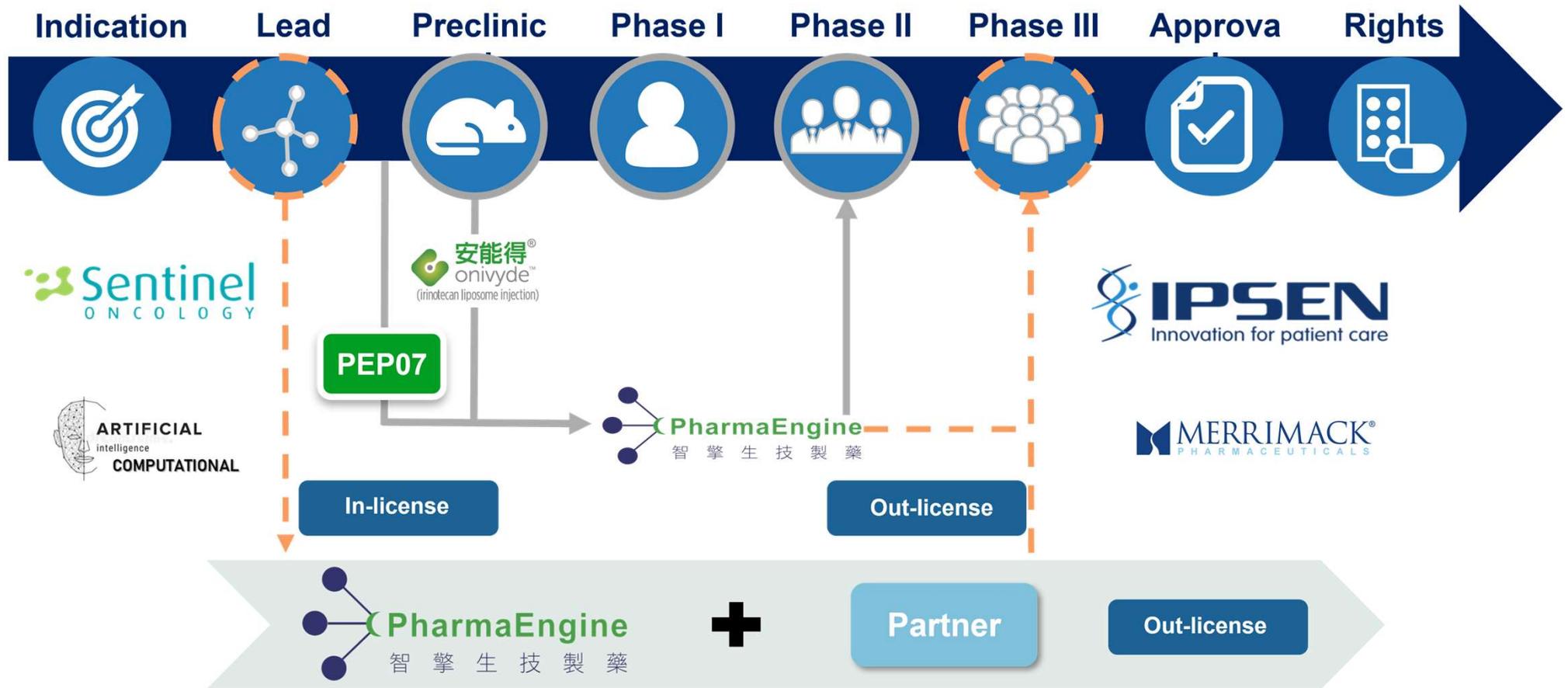
# PEP07 Early-Stage Clinical Development Strategy



# Vision for 2024



# Virtual Pharmaceutical Company Business Model



# Pipeline Portfolio Focus on Precision Oncology



Program	Indications	Lead	Preclinical	Phase I	Phase II	Phase III	Approval	Commercial Rights	Partner
ONIVYDE® (liposomal irinotecan)	2L PDAC		Approval					EU/Asia	
	1L PDAC		Primary Endpoint met (2022/11)						
DDR	PEP07 (CHK1i)	AML/Solid Tumors						Global	
DNA Damage Response	PEP09	Undisclosed						Global	Undisclosed
	PEP10	Undisclosed (Predictive Biomarker)						Global	PEI Owned
Precision Oncology	PEP08	Undisclosed (Predictive Biomarker)						Global	PEI Owned

DDR: DNA Damage Response ( BRCA ½, CHK ½, Wee1, etc...)

# Continuous Advancement of Pipelines



**2023-2024**

ONIVYDE® 1L PDAC NDA certification in TW & EU (1H24)

PEP07 Phase 1 studies in AML/MCL and solid tumors continue

One project in pipeline may reach IND ready stage (2H24)

Continue to advance pipeline progress toward preclinical stage

Complete initial scope 3 emissions data collection and analysis



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