

# CAPITAL SECURITIES BIOTECH CORPORATE DAY 2024/06/12



Jackie Chang, Investor Relations

# Disclaimer

This presentation contains certain forward-looking statements.

These forward-looking statements may be identified by words such as ‘believes,’ ‘expects,’ ‘anticipates,’ ‘projects,’ ‘intends,’ ‘should,’ ‘seeks,’ ‘estimates,’ ‘future,’ or similar expressions or by discussion of, among other things, strategy, goals, plans, or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation, among others:

1. Pricing and product initiatives of competitors
2. Legislative and regulatory developments and economic conditions
3. Delay or inability in obtaining regulatory approvals or bringing products to market
4. Fluctuations in currency exchange rates and general financial market conditions
5. Uncertainties in the discovery, development, or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side effects of pipeline or marketed products
6. Increased government pricing pressures
7. Interruptions in production
8. Loss of or inability to obtain adequate protection for intellectual property rights
9. Litigation
10. Loss of key executives or other employees
11. Adverse publicity and news coverage

PharmaEngine cautions that this foregoing list of factors is not exhaustive. There may also be other risks that management is unable to predict at this time that may cause actual results to differ materially from those in forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. PharmaEngine undertakes no obligation to update publicly or revise any forward-looking statements. Any statements regarding earnings growth is not a profit forecast and should not be interpreted to mean that PharmaEngine’s earnings or earnings per share for this year or any subsequent period will necessarily match or exceed published earnings or earnings per share forecasts of PharmaEngine, Inc.



## AGENDA

1. 1Q24 Operational Highlights
2. 1Q24 Operational Overview
3. Research and Development
  - ONIVYDE®
  - Pipeline
4. Vision for 2024
5. Q&A

# 1Q24 Operational Highlights: Sustainable Growth and Enhanced Pipeline

## COMMERCIAL

### ONIVYDE® new indication expansion

In 2024, ONIVYDE® regimen (NALIRIFOX) for 1L PDAC received sNDA approvals from the US FDA, Australia TGA, Taiwan FDA, and EU EMA and has been launched in Germany.

## PIPELINE

### New project R&D progress accelerated

1. Phase 1 clinical trial of PEP07 for **hematologic cancers** continues
2. Phase 1 clinical trial of PEP07 for **solid tumors** began and first patient dosed
3. Multiple projects meet expectations with external AI/CADD collaboration
4. R&D investment for new drugs continues to grow

## OPERATION

### Operation with sustainable growth

1. 1Q24 cash and cash equivalents and current financial assets (>3 months time deposits) at amortized cost: **NT\$37 bn**
2. Kicked off the initial phase of scope 3 GHG inventory, scheduled to be completed before end of 2024



# 1Q24 OPERATIONAL OVERVIEW

# Sales and Royalties Drive Long-term Growth

NT\$(000)

Items \ Year	2018	2019	2020	2021	2022	2023	1Q24 YoY (%)
Taiwan Sales	87,384	180,389	214,828	235,469	277,594	278,547	65,271 (-10.9%)
Royalties from Europe and Asia	109,825	133,651	271,584	419,366	376,789	426,652	99,200 (+4.3%)
Milestone	96,221	0	569,600	0	0	62,470	0
<b>Total</b>	<b>293,430</b>	<b>314,040</b>	<b>1,056,012</b>	<b>654,835</b>	<b>654,383</b>	<b>767,669</b>	<b>164,471 (-2.3%)</b>

Taiwan Sales belongs to PharmaEngine, Inc.  
Tiered royalties (high single-low double digit) in Europe/Asia (excl. TW) from Servier/IPSEN

# 1Q24 Financial Results

NT\$(000)	1Q24	1Q23	Amount Change	% Change
<b>Operating revenue</b>	<b>164,471</b>	<b>168,333</b>	<b>(3,862)</b>	<b>(2%)</b>
<b>Operating costs</b>	<b>11,045</b>	<b>13,628</b>	<b>(2,583)</b>	<b>(19%)</b>
<b>Gross profit</b>	<b>153,426</b>	<b>154,705</b>	<b>(1,279)</b>	<b>(1%)</b>
<b>Sales expenses</b>	<b>7,152</b>	<b>9,676</b>	<b>(2,524)</b>	<b>(26%)</b>
<b>G&amp;A expenses</b>	<b>22,375</b>	<b>24,326</b>	<b>(1,951)</b>	<b>(8%)</b>
<b>R&amp;D expenses</b>	<b>56,521</b>	<b>39,611</b>	<b>16,910</b>	<b>43%</b>
<b>Total operating expenses</b>	<b>86,048</b>	<b>73,613</b>	<b>12,435</b>	<b>17%</b>
<b>Operating income</b>	<b>67,378</b>	<b>81,092</b>	<b>(13,714)</b>	<b>(17%)</b>
<b>Total non-operating income and expenses</b>	<b>35,367</b>	<b>21,360</b>	<b>14,007</b>	<b>66%</b>
<b>Income before income tax</b>	<b>102,745</b>	<b>102,452</b>	<b>293</b>	<b>0%</b>
<b>Income tax expense</b>	<b>21,019</b>	<b>21,072</b>	<b>(53)</b>	<b>(0%)</b>
<b>Profit for the period</b>	<b>81,726</b>	<b>81,380</b>	<b>346</b>	<b>0%</b>
<b>EPS(NT\$)</b>	<b>0.57</b>	<b>0.57</b>	<b>0</b>	<b>0%</b>

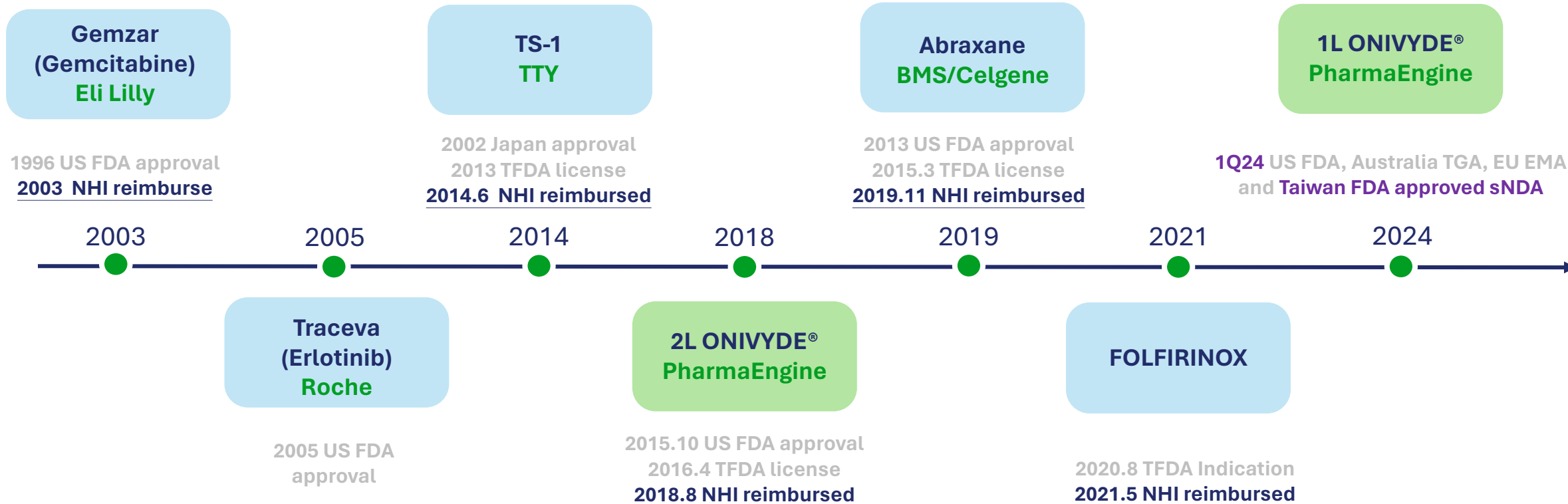


## ONIVYDE® STATUS & MARKET ANALYSIS

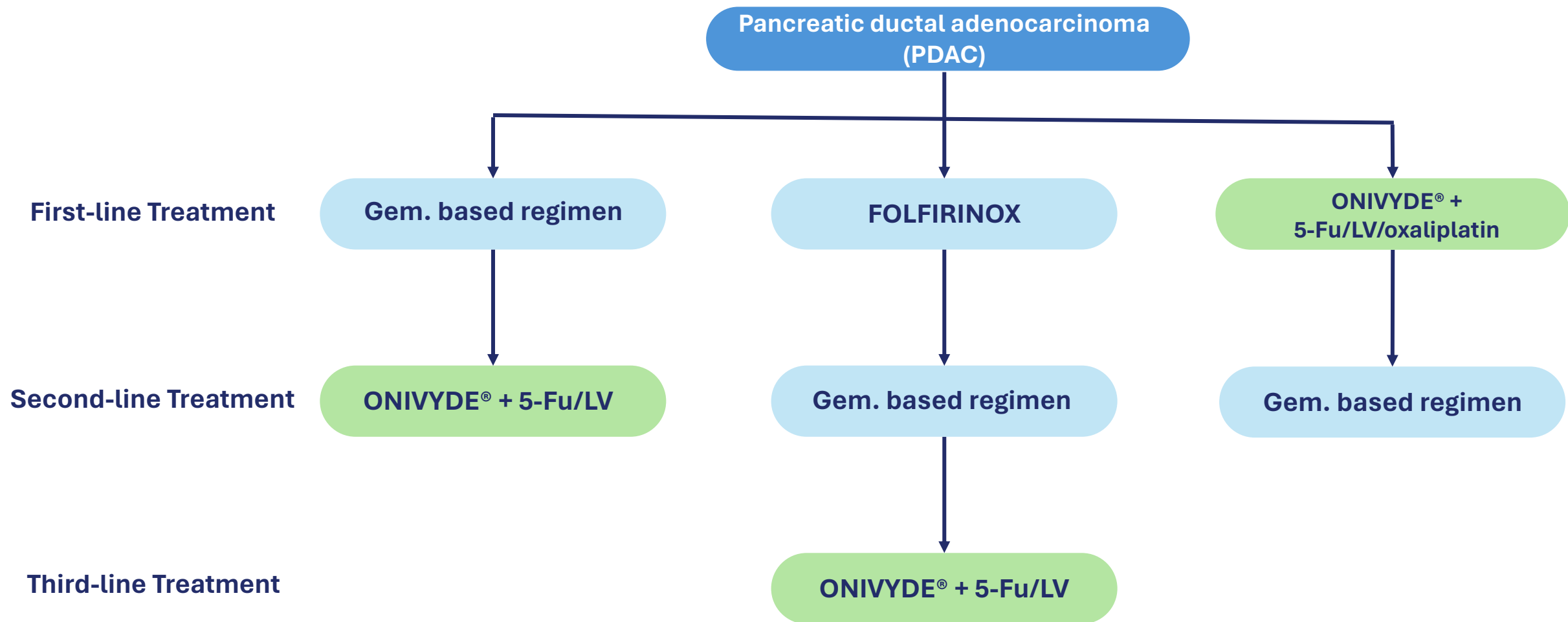
- ONIVYDE® regimen (NALIRIFOX) for 1L PDAC received sNDA from US FDA, Australia TGA, and Taiwan TFDA, and EU EMA and has been launched in Germany.



# Development of Pancreatic Cancer Therapy in Taiwan





# Taiwan PDAC Therapy Market Analysis



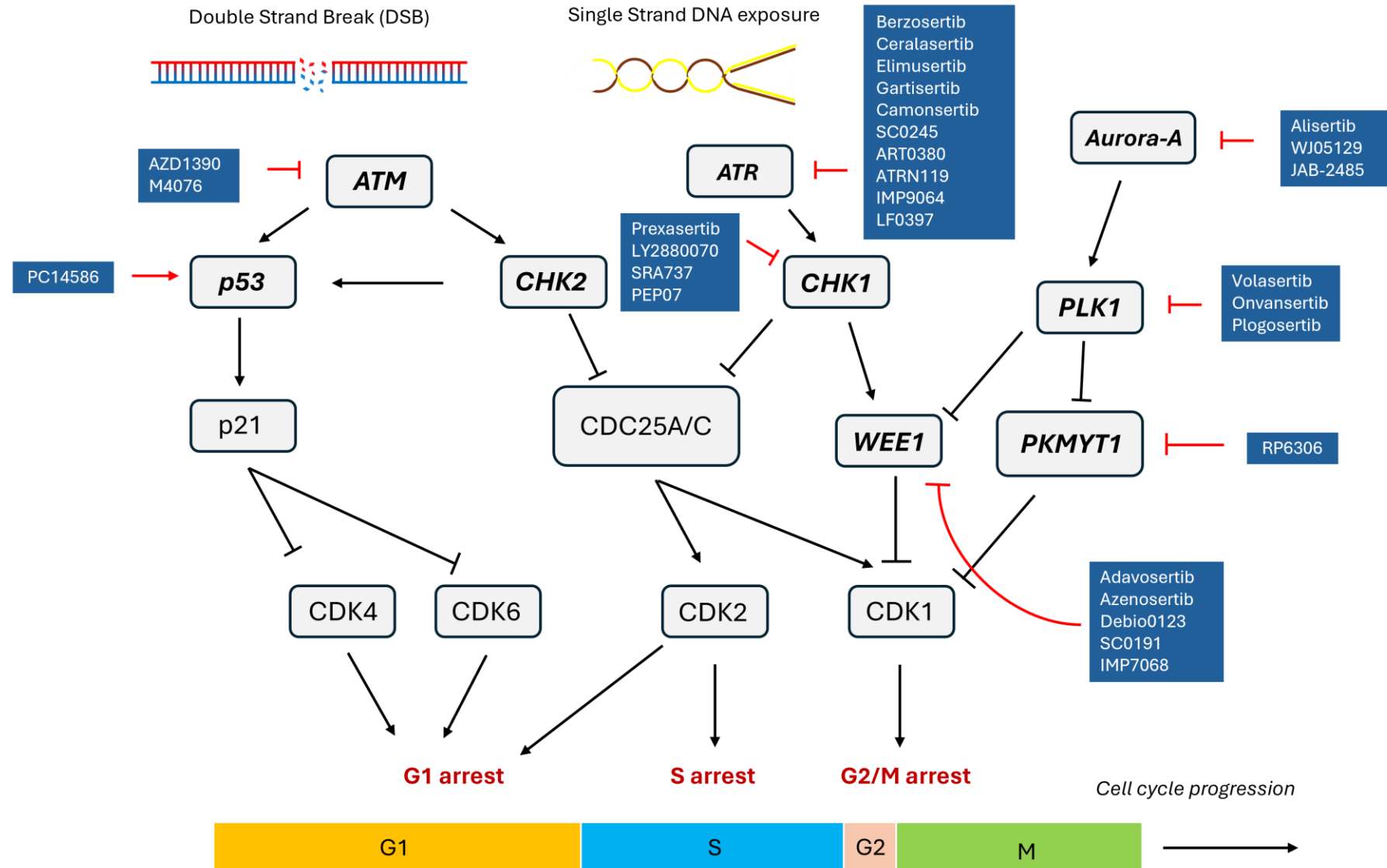


# R&D PIPELINE

# 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	[Green bar spanning Lead, Preclinical, Phase I, Phase II, Phase III]					Approval	EU/Asia	 Innovation for patient care
	1L PDAC	[Green bar spanning Lead, Preclinical, Phase I, Phase II, Phase III]					Approval		
DNA Damage Response (DDR) & Precision Oncology	PEP07 (CHK1i)	Hematologic Cancers/Solid Tumors	[Blue bar spanning Lead, Preclinical, Phase I]					Global	
	PEP08	Undisclosed (Predictive Biomarker)	[Blue bar spanning Lead, Preclinical, Phase I]					Global	PEI Owned
	PEP09	Undisclosed	[Blue bar spanning Lead, Preclinical]					Global	Undisclosed
	PEP10	Undisclosed (Predictive Biomarker)	[Blue bar spanning Lead]					Global	PEI Owned

# A New Wave of Innovations within the DNA Damage Response (DDR)



# PEP07 Phase 1 Clinical Trials



dose escalation/expansion in **hematologic cancers**  
(first patient dosed in 2023/08)



dose finding/expansion in selected **hematologic cancers**,  
e.g., **AML or MCL**



dose escalation/expansion in advanced or metastatic **solid tumors**  
(first patient dosed in 2024/04)




dose finding/expansion in selected **solid tumors**



# VISION FOR 2024

# 2024年營運目標

**1** ONIVYDE® 1L PDAC sNDA certification obtained in US, AU, and Taiwan 

**2** ONIVYDE® 1L PDAC sNDA certification in EU (1H24) 

**3** PEP07 Phase 1 studies in hematologic cancers and solid tumors continue 

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

**5** Continue to advance pipeline progress toward preclinical stage

**6** Complete initial scope 3 emissions data collection and analysis





THANK YOU

**PharmaEngine, Inc.**