



Leading the Way to New and Better Metabolic Treatments

引領創新及更優質的代謝療法治療

2023年第三季受邀證交所
法人說明會
2023/09/11



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01.

公司簡介

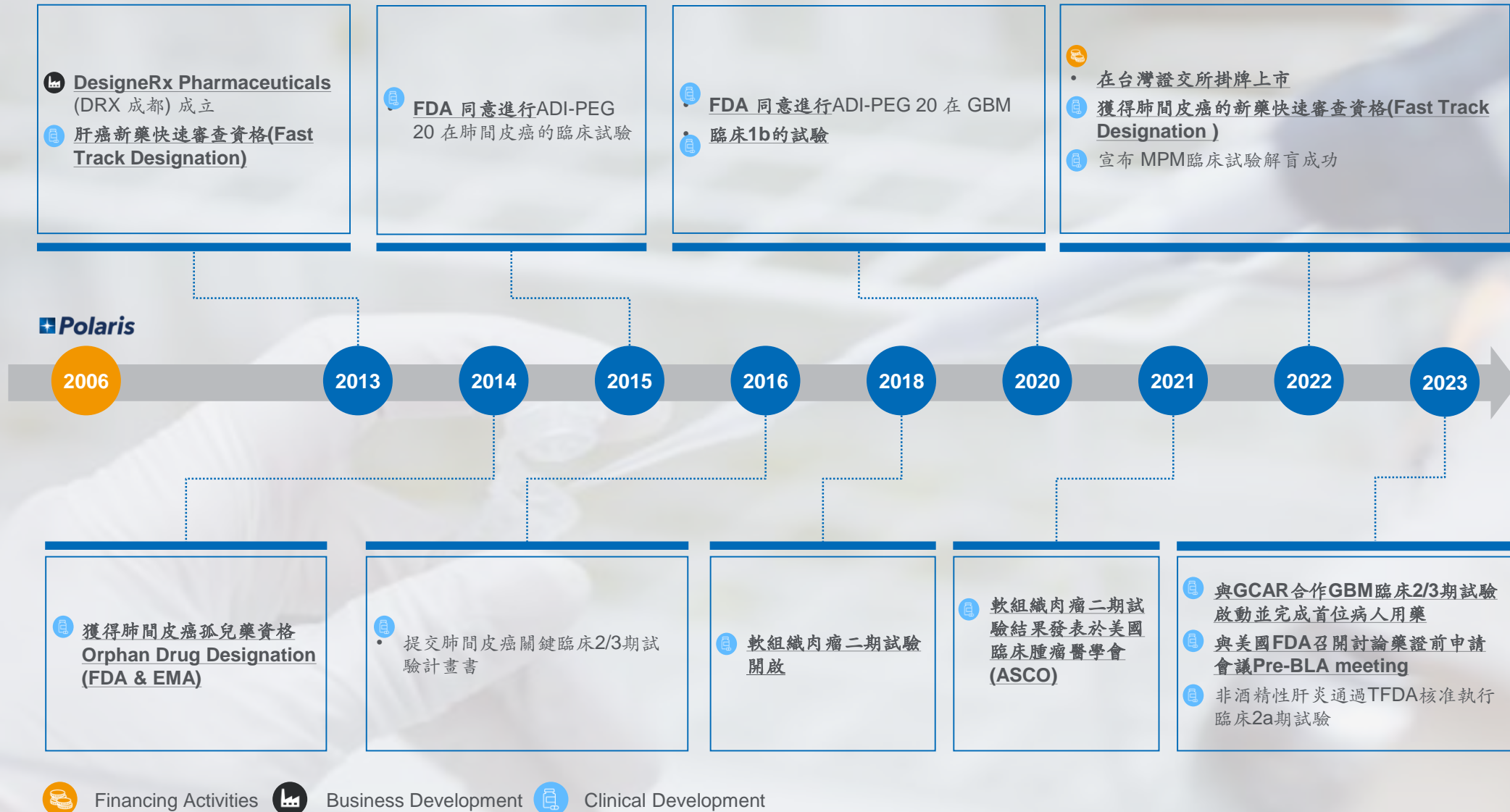
公司簡介

藥物平台	產品線	人才與資產	合作夥伴
1,600+ 使用ADI-PEG 20 治療患者數	1 BLA 藥證 申請準備中	超過\$60億台幣 帳上現金 as of June 30, 2023	 THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
獨家 精氨酸剝奪發展平台	7 臨床試驗進行中	60+ 國際與美國專利	
專業 高質量的製程與管理	2 FDA 快速審查資格	160+ 全球員工人數	Barts Cancer Institute
	3 孤兒藥認可		

Source: Company information.

Notes: 1. Biologics License Application. 2. Include trials which have enrolled at least one subject or are initiating and included on ClinicalTrials.gov. 3. Granted by FDA. 4. Granted by FDA & EMA . 5. Unaudited.

公司發展里程碑



Source: Company information.

營運與發展模式



Source: Company information.

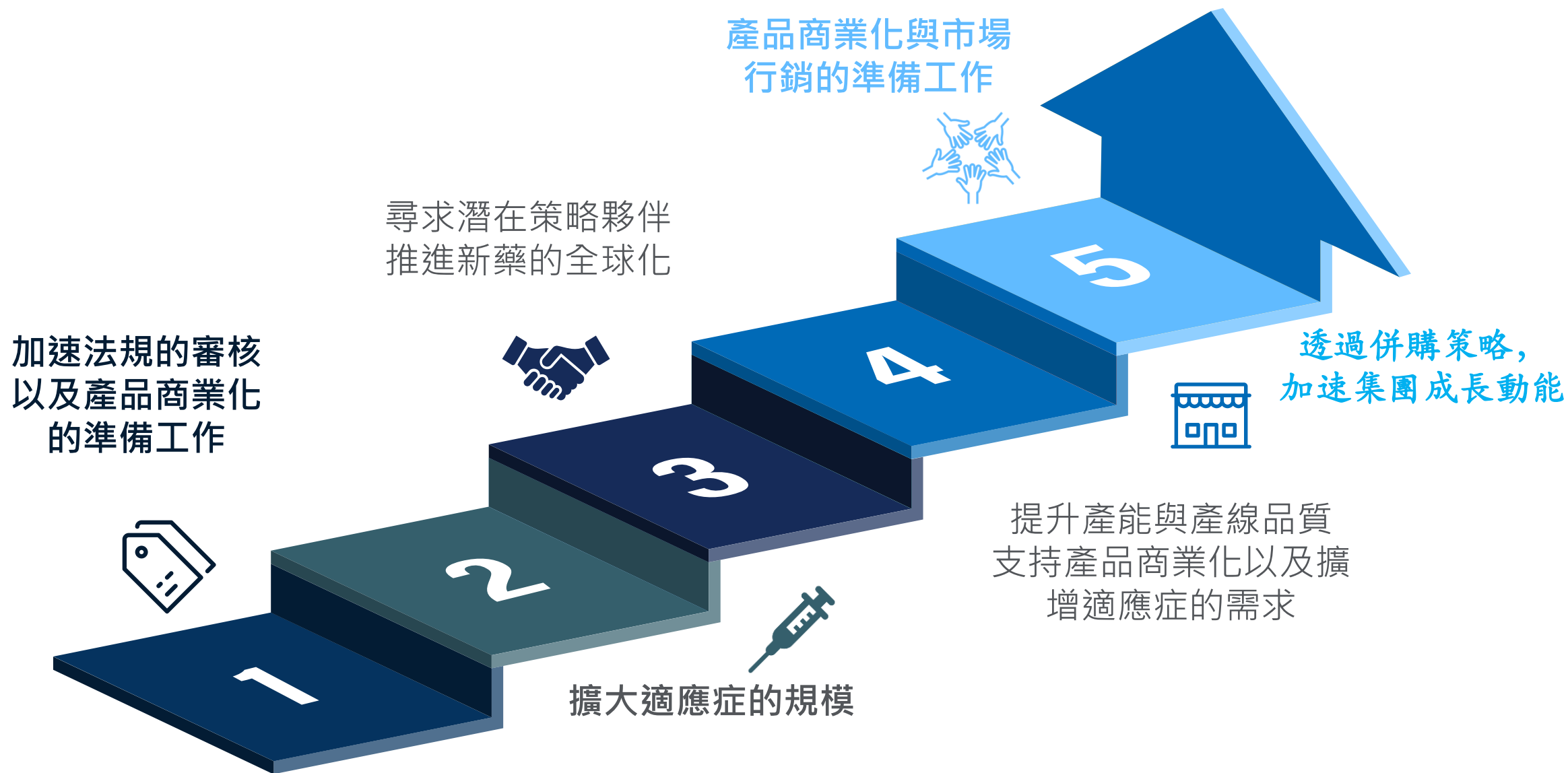
Notes: 1. Standard of Care (SoC). 2. Nonalcoholic steatohepatitis (NASH) and nonalcoholic fatty liver disease (NAFLD).

產品開發進程與臨床試驗進度

適應症	治療階段	治療方式	法規機構	商業化權利	前臨床研究	IND	Ph1	Ph2	Ph3	BLA	Approval / Launch	近期里程碑
肺間皮癌	1L	聯合化療用藥	FDA	全球	ADIPEG 20 + Cisplatin + Pemetrexed							提交BLA申請
軟組織肉瘤	2L / 2L+	聯合化療用藥	FDA	全球	ADIPEG 20 + Gemcitabine + Docetaxel							首位病人用藥
肝癌	1L	單獨用藥	TFDA	全球	ADIPEG 20							期中數據發表
神經膠質母細胞	1L	聯合化療與放射療法	FDA	全球	ADIPEG 20 + Temozolomide + Radiation					(1)		期中數據發表
					ADIPEG 20 + Temozolomide + Radiation							
急性骨髓性白血病	1L + Relapsed	聯合化療用藥	FDA	全球	ADIPEG 20 + Venetoclax + Azacitidine							期中數據發表
非酒精性肝炎	1L	單獨用藥	TFDA	全球	ADIPEG 20							首位病人用藥
其他適應症	-	-	-	Global	2nd Gen ADIPEG 20							IND

Source: Company information, FDA

Note: 1. GBM AGILE Platform in the U.S.





02.

投資亮點

北極星藥業：引領創新及更優質的代謝療法治療



全方位垂直整合綜合型生物製藥公司



研究與發展

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臨床發展與藥物的全球權利

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正在進行的臨床試驗

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已完成的臨床試驗

註冊和批准的重要選擇途徑及策略

快速的執行力

高品質的數據

與監管機關建設性的互動

具有快速審核的資格



化學、製造與監控



San Diego

美國廠生產與製造臨床試驗藥品



Vacaville

• **400,000** 年生產劑量



Chengdu

• **中國成都廠**

• **130,000** 年生產劑量



I-LAN

To Be Completed

• 大規模製造

• **3 百萬劑年產量**



商業發展



積極且系統性的評估藥品的商業價值以及授權的可能性



由 **Dr. Jeff Trickett** 領導的資深商業發展團隊



整合性生物製藥平台，含括所有關鍵藥物研發功能



擁有全球視野並在美國和台灣雙重運營中心具地方專業知識的管理團隊



ADI-PEG 20 的競爭優勢

1

基於代謝療法的方式，具有高安全性並對正常細胞影響較小的不良影響/副作用



ATOMIC Trial (Ph3 MPM) Safety Profile

TEAEs ¹	ADIPemPlatinum (N=125)	PlaceboPemPlatinum (N=124)	Total (N = 249)
Total Number	1,570	1,403	2,973
Number of Subjects Reporting at Least One			
TEAE	123 (98.4%)	123 (99.2%)	246 (98.8%)
TEAE by Severity			
Grade 1 Mild	6 (4.8%)	10 (8.1%)	16 (6.4%)
Grade 2 Moderate	25 (20.0%)	35 (28.2%)	60 (24.1%)
Grade 3 Severe	62 (49.6%)	55 (44.4%)	117 (47%)
Grade 4: Life Threatening	23 (18.4%)	11 (8.9%)	34 (13.7%)
Grade 5 Death	7 (5.6%)	12 (9.7%)	19 (7.6%)

2

廣泛的臨床證據表示，除了在具ASS1缺陷癌症之外，還對諸如NASH / NAFLD等疾病的療效擴展具有顯著效果



3

與眾多現有藥物包括標準治療 (SoC) 在聯合療法中呈現協同效應



與化療聯用



與放射線療法聯用



精準療法單獨用藥



4

治療方式為肌肉注射可減少治療時間



5

複雜的蛋白質結構使競爭對手難以繞過我們的專利



6

研發與製程技術受到多項專利保護



ADI-PEG 20具潛力成為首創的新藥，可作為合併用藥療法的支柱



腫瘤領域

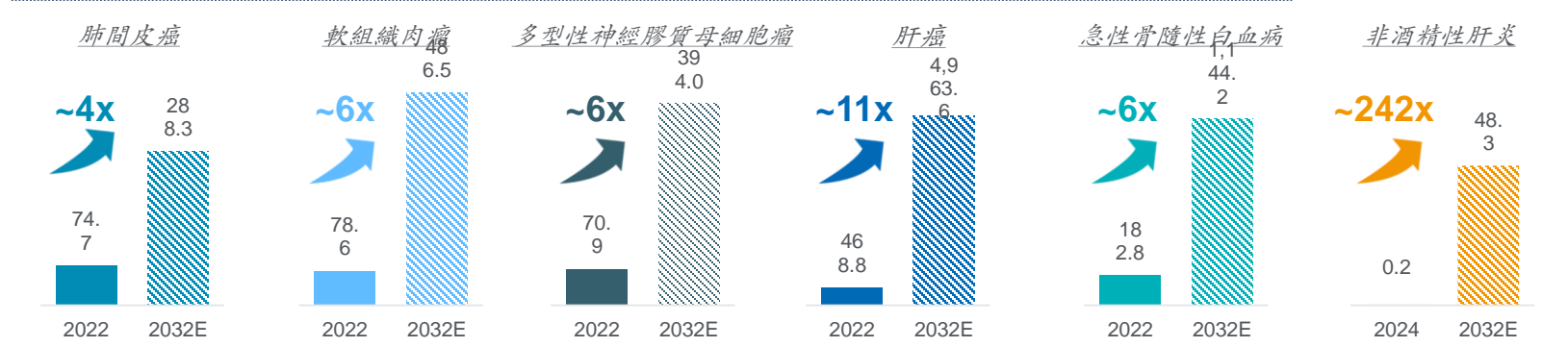
實體腫瘤

血液腫瘤

代謝疾病

 肺間皮癌	 軟組織肉瘤	 多型性神經膠質母細胞瘤	 肝癌	 急性骨隨性白血病	 非酒精性肝炎
<ul style="list-style-type: none"> 聯合化療用藥治療 處在藥證申請階段 潛在市場首見新藥 	<ul style="list-style-type: none"> 聯合化療用藥治療 有潛力降低劑量並改善整體安全性 	<ul style="list-style-type: none"> 聯合化療與放射療法 潛在輔助與增進放射治療 	<ul style="list-style-type: none"> 精準療法單獨用藥 篩選WWOX基因生物標記以及高精氨酸濃度的病患 	<ul style="list-style-type: none"> 聯合化療用藥 在血液腫瘤中的探究 	<ul style="list-style-type: none"> 單獨用藥 動物試驗展現顯著效果 可控治肥胖及相關疾病的途徑

全球癌症代謝療法藥品市場¹ (US\$mm)



US\$56bn
2032E 預計有非常可觀的全球市場

代謝療法藥品佔約
~13.8%
2032E 全球癌症藥品市場

Source: China Insights Consultancy
Notes: 1. Values are not proportionately illustrated against other markets.



擁有強大的臨床試驗開發平台，將產品線帶進潛在市場

臨床開發執行策略著重於質量和效率，由經驗豐富的科學家、醫師和研究員、臨床研究委託機構（CROs）以及醫療機構所組成的臨床團隊所支持。

臨床試驗開發團隊

- 多國多中心的臨床試驗經驗
- 深厚的專業知識
- 目標迅速獲得產品上市批准



7

進行中的臨床試驗



臨床團隊



John Bomalaski, M.D.
Executive VP
Medical Affairs



Chris Huxsoll, Ph.D.
Senior VP
Operations



Richard E. Showalter, B.A.
VP, R&D



Amanda Johnston, Ph.D.
VP, Clinical Affairs

臨床試驗發展能力

- 臨床開發能力建立在一支專注且經驗豐富的科學家和醫師團隊



由Dr. John Bomalaski領導具備 25 年以上的藥物發展經驗



內部團隊在臨床試驗發展核心能力表現卓越



與臨床委託研究機構（CROs）、主要研究者和關鍵意見領袖（KOLs）保持密切合作關係

專注聯合用藥的偕同效果

軟組織肉瘤

與化療聯用

減低化療劑量與毒性

多型性神經膠質母細胞瘤

與化療 + 放療 聯合用藥

高度未滿足的醫療需求

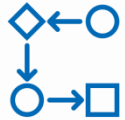
其他代謝疾病

單藥或聯藥

由臨床醫師主導

擁有精心設計、商業化準備就緒的CMC和製造能力，品質優異且具成本效益

核心競爭力



- 20年以上研發能量
- 對於大腸桿菌表達的製程有深厚經驗
- 高水平的重組蛋白製造經驗



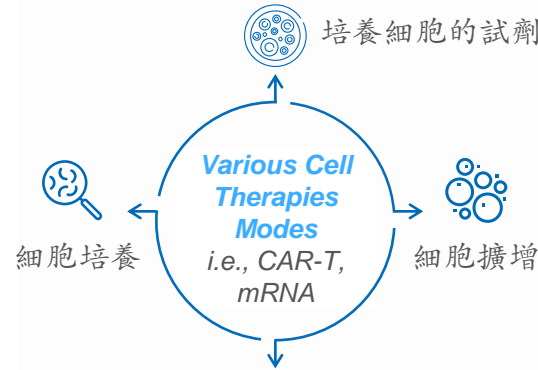
- 具廣泛的內部質量控制和保證的能力
- 透過有效節省成本的流程，確保製造遵守合規性，保持一致性、穩定質量和安全性



- 完整的藥物開發流程
- 從藥物發現到分析開發，GMP製造，產品出產，支援法規申報，以及未來的商業化。

主要能力

完整產品類型



完整藥物開發

- 發酵
- 純化
- 細胞庫生產
- 程序開發
- 品質管理與確效
- 填充
- 倉儲

製造工廠



Vacaville 先導工廠

- 符合cGMP的製造工廠
- ADI-PEG 20年生產劑量 **400,000 劑**



成都製造工廠

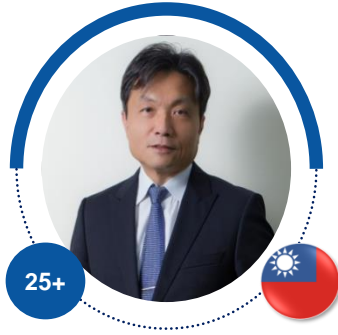
- 年度生產能力為130,000劑。
- 具備世界一流的商業化就緒cGMP設施，能夠生產冷凍乾燥產品



台灣宜蘭製造工廠

- To Be Completed*
- 設計年生產能力為300萬劑（注射藥物），其中50%的生產能力保留給ADI-PEG 20

經驗豐富的管理團隊，具有遠見的領導力和廣泛的產業經驗



25+

陳鴻文
董事長暨CEO



Gemtek

創辦人 & 董事長



創辦人



15+

游輝元, Ph.D.
營運長



Yao Jun
Technology



20+

Samantha Hoopes, Ph.D.
法規副總



25+

Richard E. Showalter, B.A.
研發副總



25+

John Bomalaski, M.D.
醫藥事務執行副總



Co-founded Phoenix
Pharmacologics
Inc.



20+

Amanda Johnston, Ph.D.
臨床發展副總



25+

陳紹琛
M.D., Ph.D.
首席科學顧問



20+

黃藍瑩
財務長



Deloitte. EY



20+

Chris Huxsoll, Ph.D.
營運資深副總



20+

Jeff I. Trickett
Ph.D., M.Sc.
商業發展副總



Source: Company information.
Notes: ○ Years of experience



03.

產業概況

全球代謝療法市場與主要驅動力



有潛力成為治療癌症的方式



能與其他療法產生偕同效應



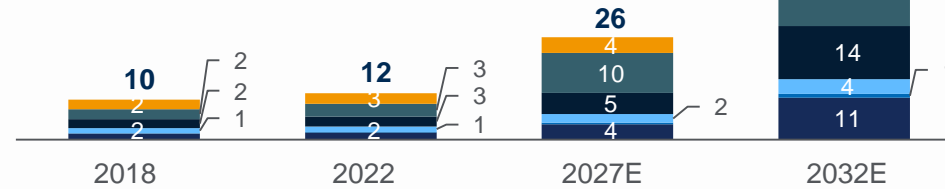
有潛力成為精準醫療的一環



較低的副作用有助病患提高生活品質

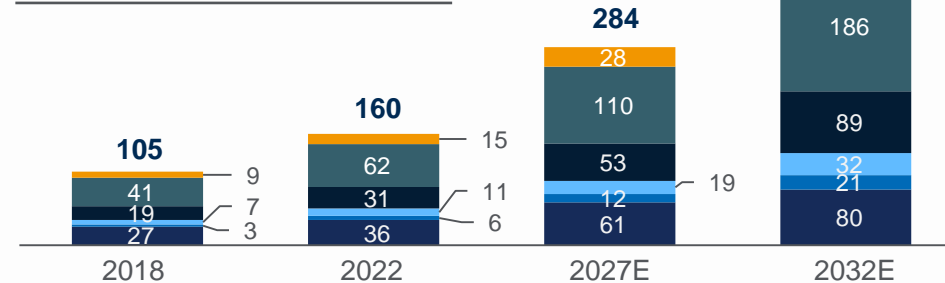
全球癌症代謝療法市場 (US\$bn)

CAGR	2018-2022	2022-2032E
China	2.9%	11.3%
US	6.5%	26.7%
key EU5	2.6%	18.4%
JP	2.1%	10.2%
SEA	10.4%	20.7%
ROW	3.7%	19.4%



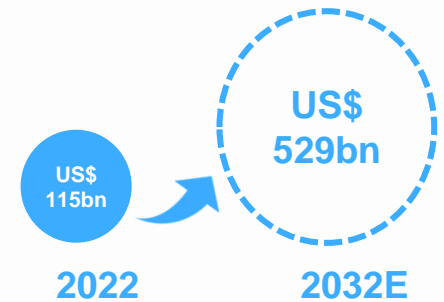
全球非癌症代謝療法市場 (US\$bn)

CAGR	2018-2022	2022-2032E
China	13.1%	13.4%
US	10.9%	11.7%
key EU5	12.1%	11.2%
JP	12.7%	11.7%
SEA	17.0%	13.3%
ROW	8.0%	8.2%



全球代謝療法市場預計自2022年到2032年
成長倍數

5x

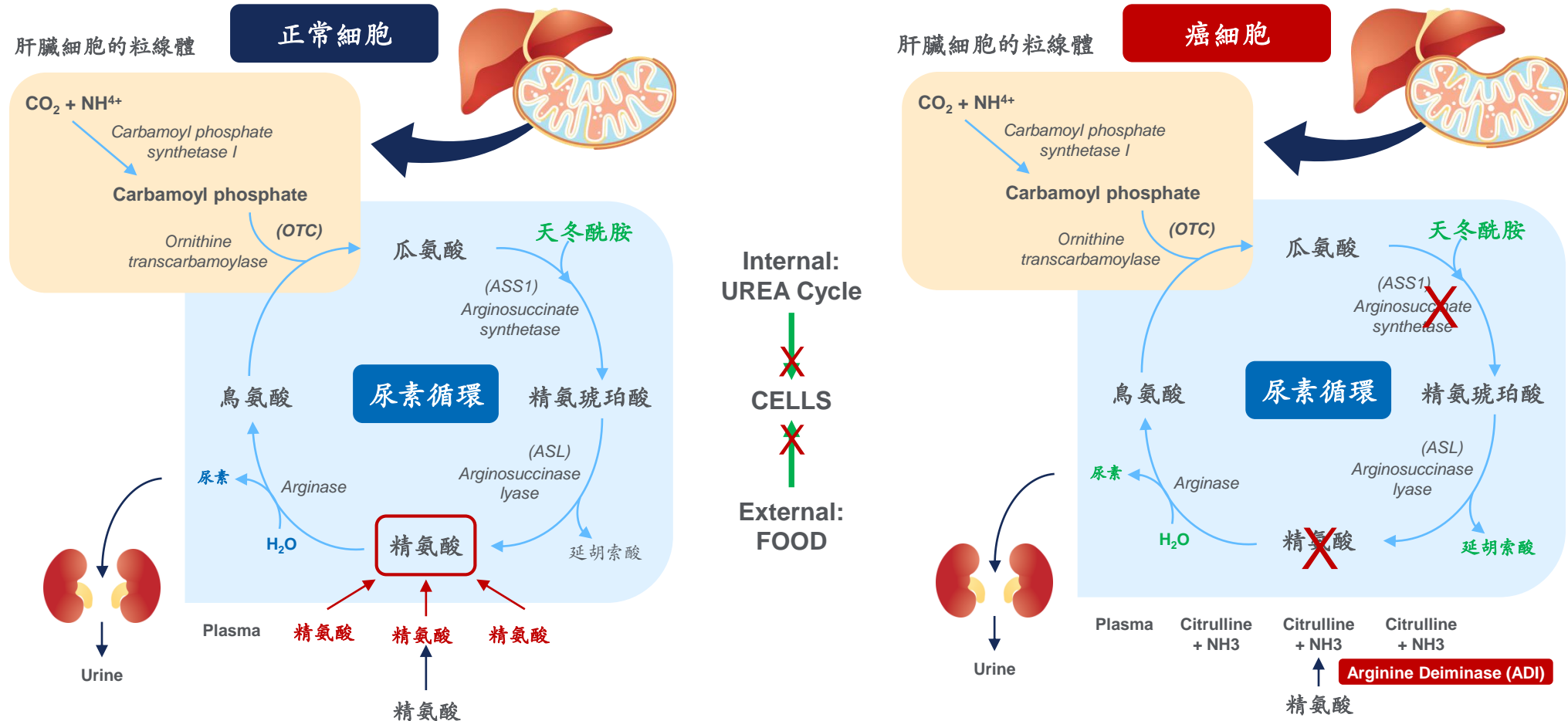




04.
營運簡介

ADI-PEG 20 作用機制

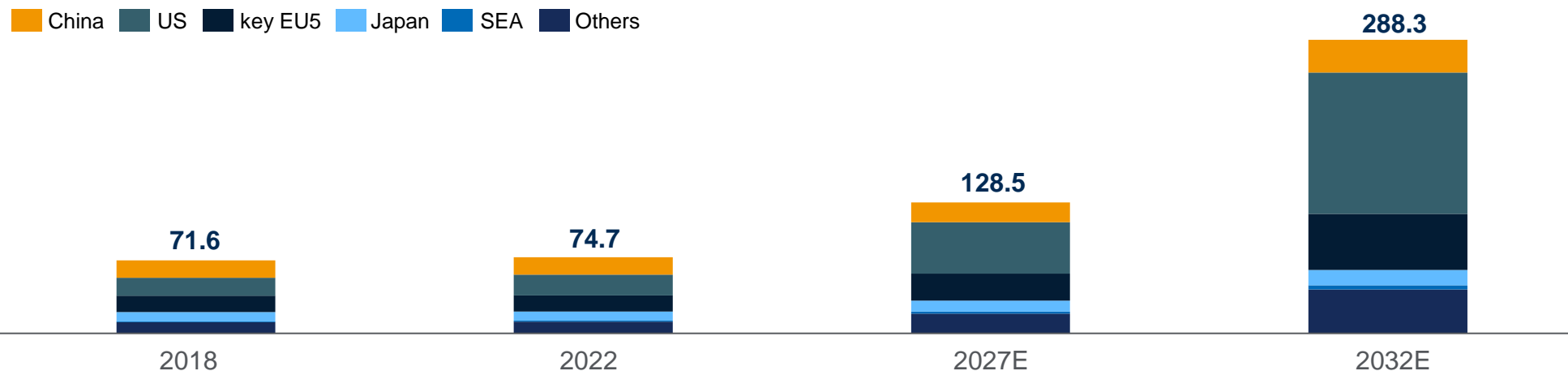
北極星藥業核心產品, ADI-PEG 20, 是一種微生物酵素, 主要在通過消耗精氨酸來治療癌症, 精氨酸對於代謝、生物合成和腫瘤生長的發展至關重要



Source: Company information, Literature Review.

肺間皮癌(MPM)- 市場機會與競爭優勢

MPM代謝藥物的市場規模, 2018-2032E (US\$mm)



MPM代謝療法的相關競爭者

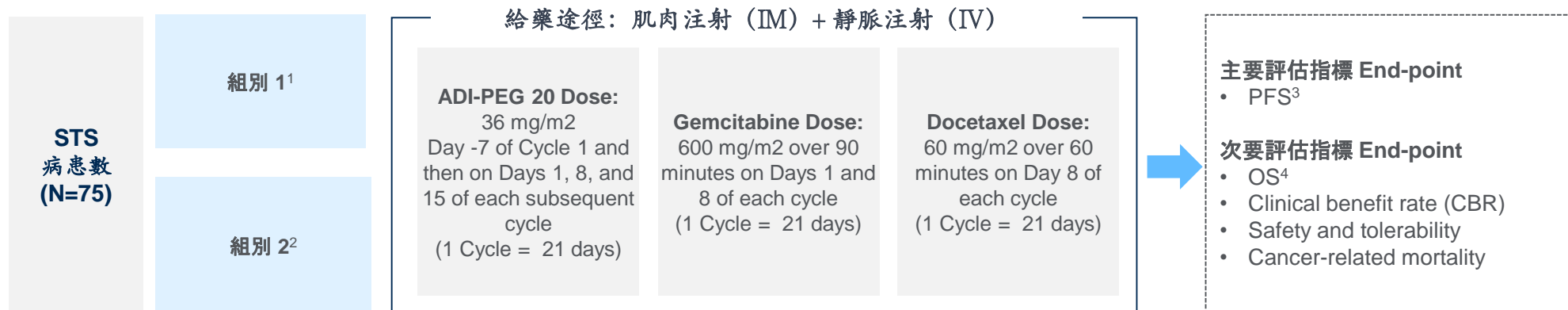
Drug	NCT number	Phase	Status	First posted date	MoA	Sponsor
Cell metabolic pathway: Arginine metabolism						
ADI-PEG 20	NCT02709512	2 and 3	Completed	2016/3/16	Pegylated arginine deiminase	Polaris
INCB001158	NCT02903914	1 and 2	Completed	2016/9/16	Arginase inhibitor	Incyte Corporation

Source: China Insights Consultancy. Notes: Only consider the candidates meeting the following conditions as the competitors: (1) Drug's MoA is targeting one of the major cell metabolic pathway including Glutamine metabolism, Fatty acid synthesis, Nucleotide synthesis, and glucose metabolism. (2) Only including the clinical trial status are Not yet recruiting, Recruiting; Enrolling by invitation; Active but not recruiting, and Completed. (3) Novel drug candidate. The approved drugs are excluded. (4) Clinical trials/drug candidates that have been registered for more than 10 years but have no progression are excluded. (5) At a similar or more advanced stage as compared to Polaris.

軟組織肉瘤(STS) – 臨床設計與數據

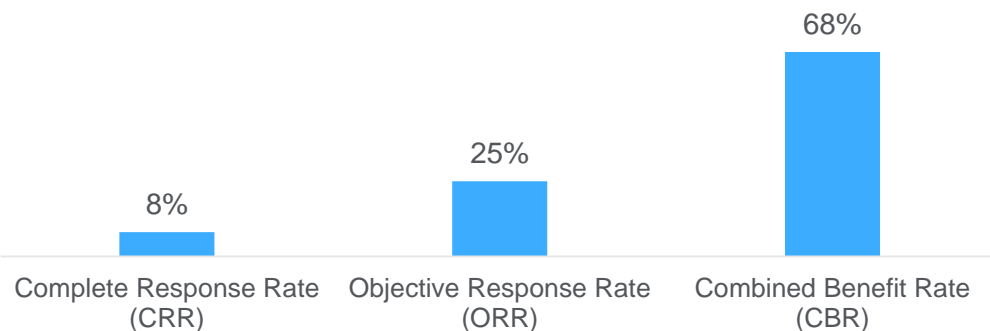
研究設計 – 開放, 非隨機的臨床 2 期臨床試驗

評估ADI-PEG 20聯合Gemcitabine和Docetaxel對軟組織肉瘤患者的臨床結果



Notes: (1). Cohort 1: Histologically or cytologically confirmed grade 2 or 3 soft tissue sarcoma that is unresectable or metastatic that would be standardly treated with gemcitabine or gemcitabine and docetaxel. For all others, please contact the principal investigator. Prior surgery for primary or metastatic disease after chemotherapy following a response is allowed. Cohort 2: Histologically or cytologically confirmed osteosarcoma, Ewing's sarcoma, or small cell lung cancer that is unresectable or metastatic that have either failed standard of care therapy or would be standardly treated with gemcitabine or gemcitabine and docetaxel. Please refer to NCT03449901 for more details.
(2). Patients started on gemcitabine at a dose of 900 mg/m² or 750 mg/m² or docetaxel at a dose of 75 mg/m² per previous protocol version will be allowed to continue at that dose level. After Cycle 8, patients may continue on ADI-PEG 20 alone (without gemcitabine and docetaxel) upon request.

臨床結果數據

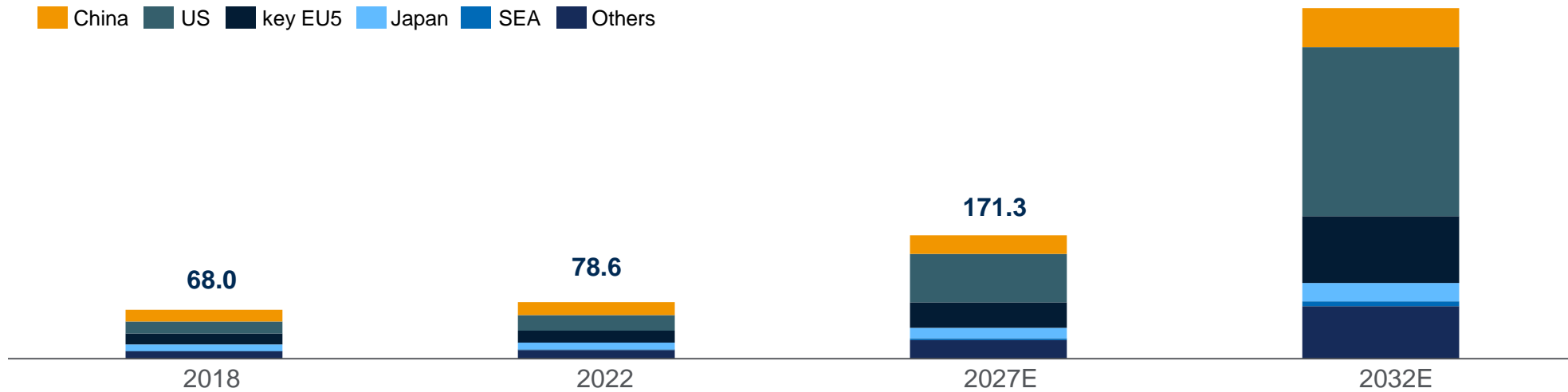


該研究結果顯示，將Gemcitabine和Docetaxel與ADI-PEG 20結合治療軟組織肉瘤患者時，患者的反應率有所提高。與之前的試驗相比，腫瘤完全反應率增加了三倍，所需的Gemcitabine量減少了三分之一，從而減少了對高劑量Gemcitabine的需求，並減輕其毒性

- Interview with Brian A. Van Tine, M.D., Ph.D.⁵

軟組織肉瘤(STS) – 市場機會與競爭優勢

軟組織肉瘤代謝藥物的市場規模, 2018-2032E (US\$mm)



軟組織肉瘤代謝療法相關競爭者

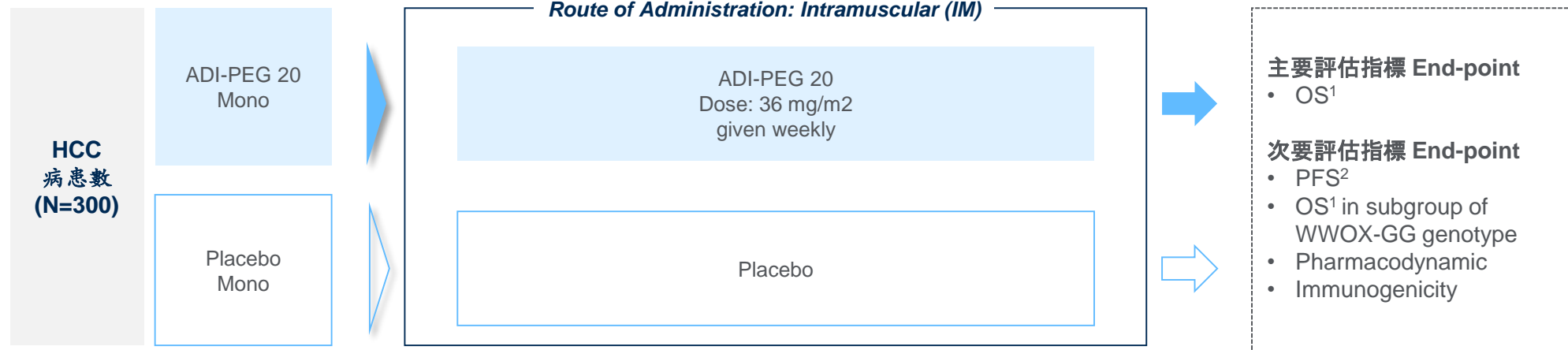
Drug	NCT number	Phase	Status	First posted date	MOA	Sponsor
Cell metabolic pathway: Arginine metabolism						
ADI-PEG 20	NCT05813327	1 and 2	Not yet recruiting	2023/4/14	Pegylated arginine deiminase	Polaris
ADI-PEG 20	NCT05712694	3	Not yet recruiting	2023/2/3	Pegylated arginine deiminase	Polaris

Source: China Insights Consultancy. Notes: Only consider the candidates meeting the following conditions as the competitors (1) Drug's MoA is targeting one of the major cell metabolic pathway including Glutamine metabolism, Fatty acid synthesis, Nucleotide synthesis, and glucose metabolism. (2) Only including the clinical trial status are Not yet recruiting, Recruiting; Enrolling by invitation; Active but not recruiting, and Completed. (3) Novel drug candidate. The approved drugs are excluded. (4) Clinical trials/drug candidates that have been registered for more than 10 years but have no progression are excluded. (5) At a similar or more advanced stage as compared to Polaris.

肝癌(HCC) – 臨床設計

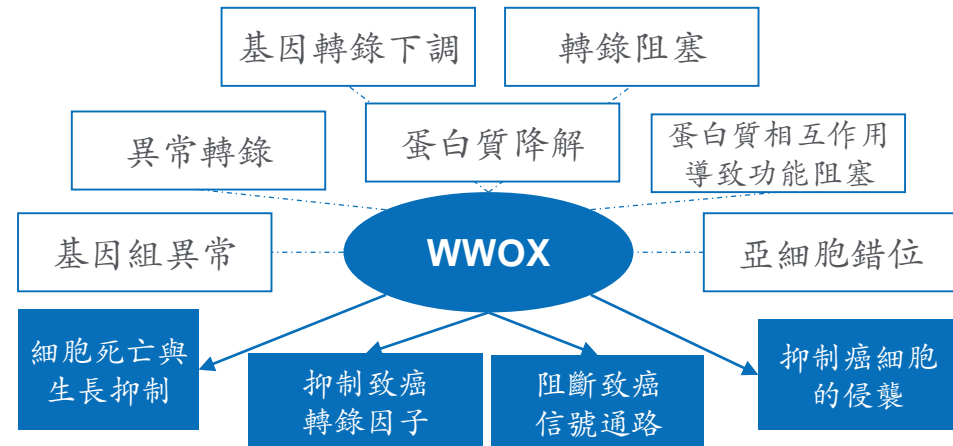
研究設計 - 一項隨機、雙盲、多中心的三期臨床試驗

評估ADI-PEG 20與安慰劑在高精氨酸表現型的晚期不可切除的肝癌 (HCC) 患者全身治療中的療效



Clinical Design Rationale / MoA

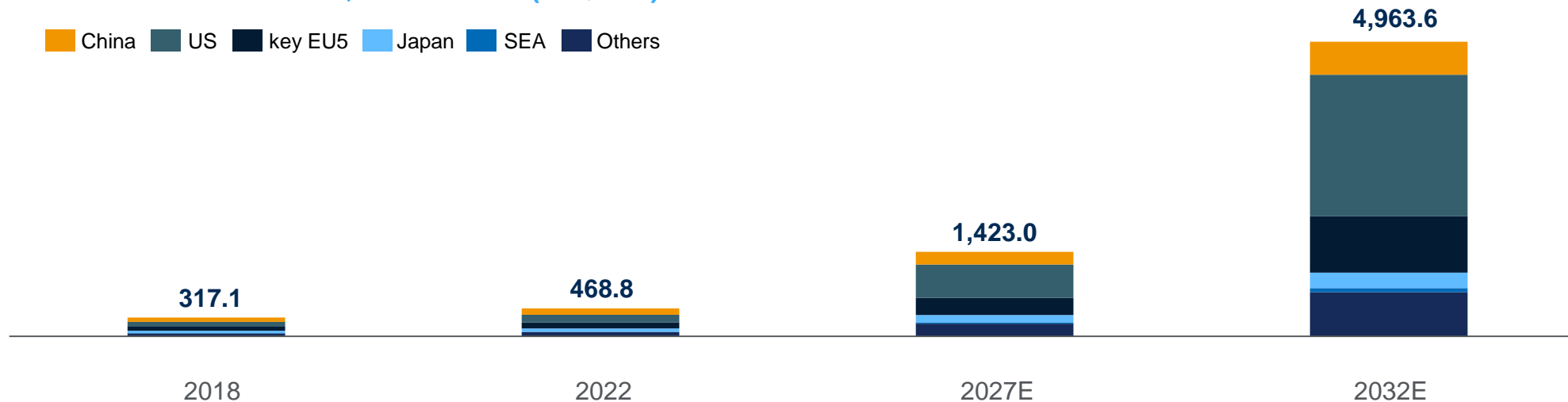
- 具有WWOX-GG 基因型的肝癌 (HCC) 患者組織中 ASS1 和 WWOX 的水平較低，而精氨酸的水平較高
- 這些患者對ADI-PEG 20治療具有較高的敏感性，並且在整體存活方面表現出色
- 精氨酸水平較高的肝癌患者可能代表了一類具有精氨酸依賴性表型的癌症患者，而 WWOX-GG 患者可能代表這一類群體的一個子集



Source: Company information, Literature Review.
Notes: 1. Overall survival. 2. Progression-free survival.

肝癌(HCC) – 市場機會與競爭優勢

肝癌代謝藥物的市場規模, 2018-2032E (US\$mm)



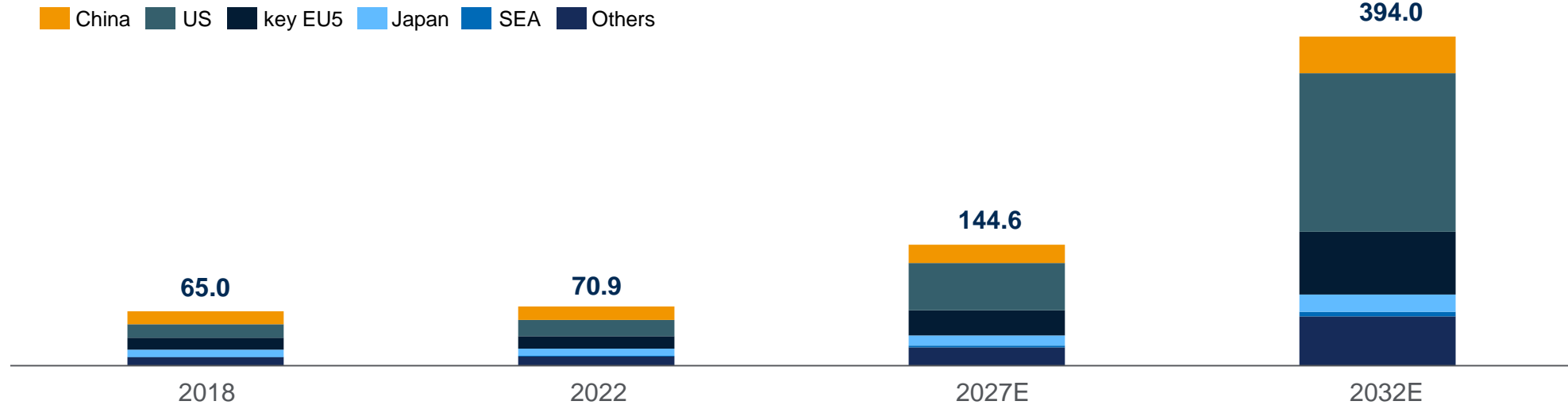
肝癌代謝療法相關競爭者

Drug	NCT number	Phase	Status	First posted date	MOA	Sponsor
Cell metabolic pathway: Arginine metabolism						
ADI-PEG 20	NCT05317819	3	Recruiting	2022/4/8	Pegylated arginine deiminase	Polaris
BCT-100	NCT02089763	2	Completed	2014/3/18	Pegylated recombinant human arginase	Bio-Cancer Treatment International
BCT-100	NCT02089633	2	Completed	2014/3/18	Pegylated recombinant human arginase	Bio-Cancer Treatment International
Cell metabolic pathway: Nucleotide synthesis						
mFOLFOX7	NCT05313282	3	Recruiting	2022/4/6	Thymidylate synthase	Jiangsu HengRui Medicine
mFOLFOX8	NCT04191889	2	Recruiting	2019/12/10	Thymidylate synthase	Jiangsu HengRui Medicine

Source: China Insights Consultancy. Notes: Only consider the candidates meeting the following conditions as the competitors (1) Drug's MoA is targeting one of the major cell metabolic pathway including Glutamine metabolism, Fatty acid synthesis, Nucleotide synthesis, and glucose metabolism. (2) Only including the clinical trial status are Not yet recruiting, Recruiting; Enrolling by invitation; Active but not recruiting, and Completed. (3) Novel drug candidate. The approved drugs are excluded. (4) Clinical trials/drug candidates that have been registered for more than 10 years but have no progression are excluded. (5) At a similar or more advanced stage as compared to Polaris.

腦癌GBM – 市場機會與競爭優勢

GBM 代謝藥物市場規模, 2018-2032E (US\$mm)



GBM 代謝療法相關競爭者

Drug	NCT number	Phase	Status	First posted date	MOA	Sponsor
Cell metabolic pathway: Arginine metabolism						
ADI-PEG 20	NCT04587830	1	Recruiting	2020/10/14	Pegylated arginine deiminase	Polaris
Cell metabolic pathway: Fatty acid synthesis						
TVB-2640	NCT05118776	3	Recruiting	2021/11/12	Fatty acid synthase	Asclepis Pharmaceuticals

Source: China Insights Consultancy. Notes: Only consider the candidates meeting the following conditions as the competitors (1) Drug's MoA is targeting one of the major cell metabolic pathway including Glutamine metabolism, Fatty acid synthesis, Nucleotide synthesis, and glucose metabolism. (2) Only including the clinical trial status are Not yet recruiting, Recruiting; Enrolling by invitation; Active but not recruiting, and Completed. (3) Novel drug candidate. The approved drugs are excluded. (4) Clinical trials/drug candidates that have been registered for more than 10 years but have no progression are excluded. (5) At a similar or more advanced stage as compared to Polaris.

委託發展與製造服務(CDMO)



Source: Company information.



其他研發計畫



ADI-TRAIL Drug



Second Generation
ADI



Antibody Drug
Conjugate (ADCs)



mRNA Drugs



研發夥伴

NANOTEIN
TECHNOLOGIES
Since 2020.9

UCI
Since 2021.11

 **Acepodia**
Since 2022.9

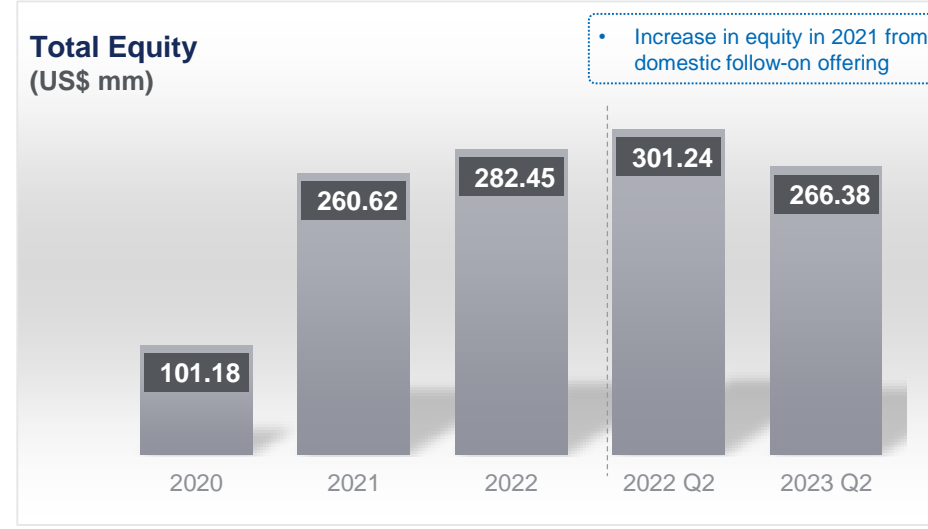
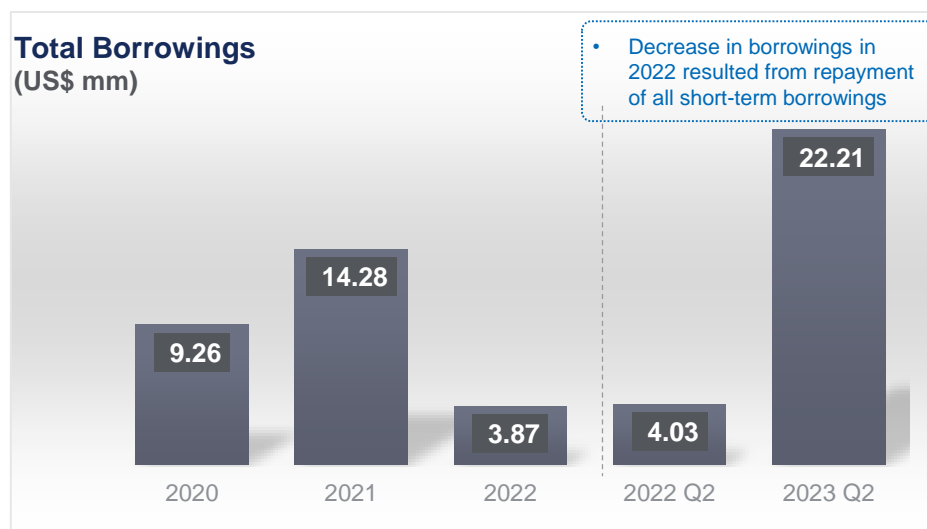
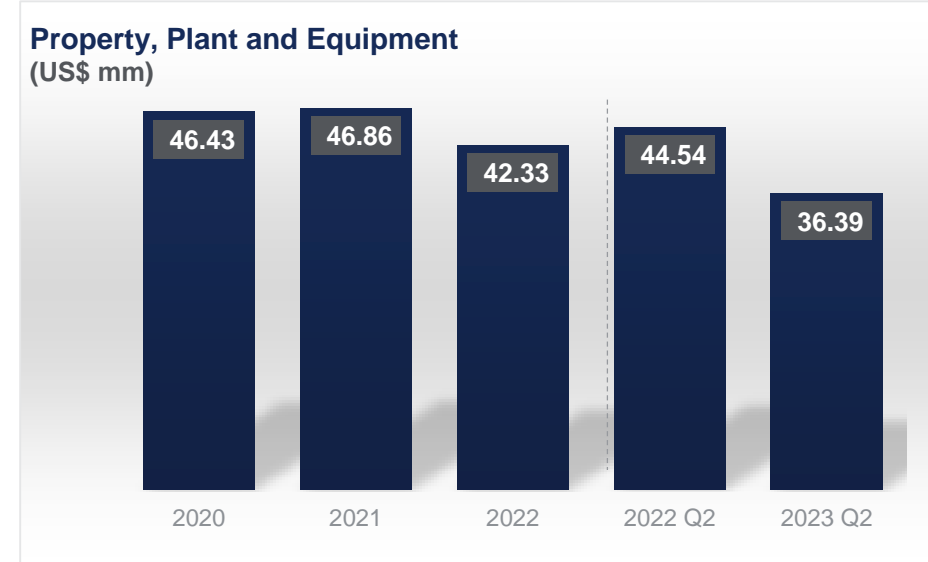
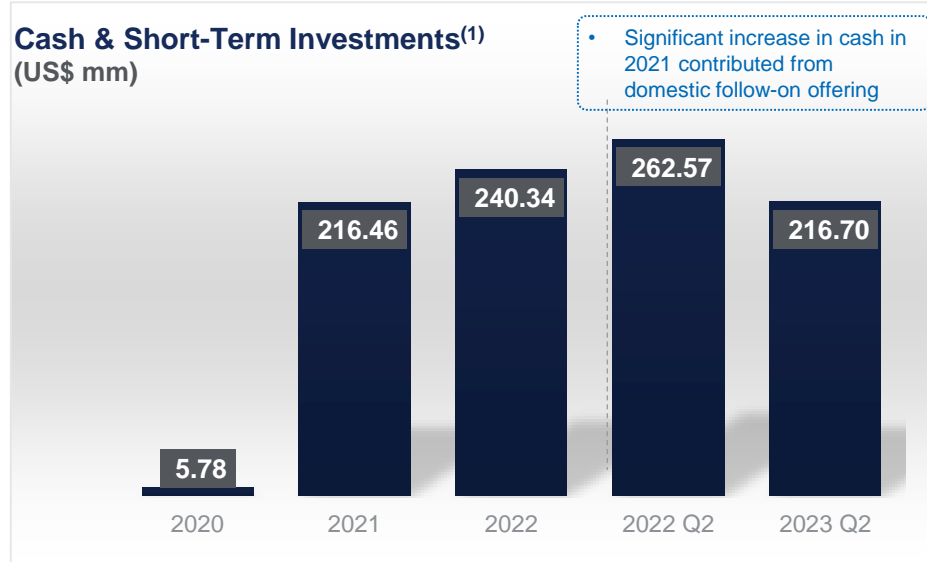
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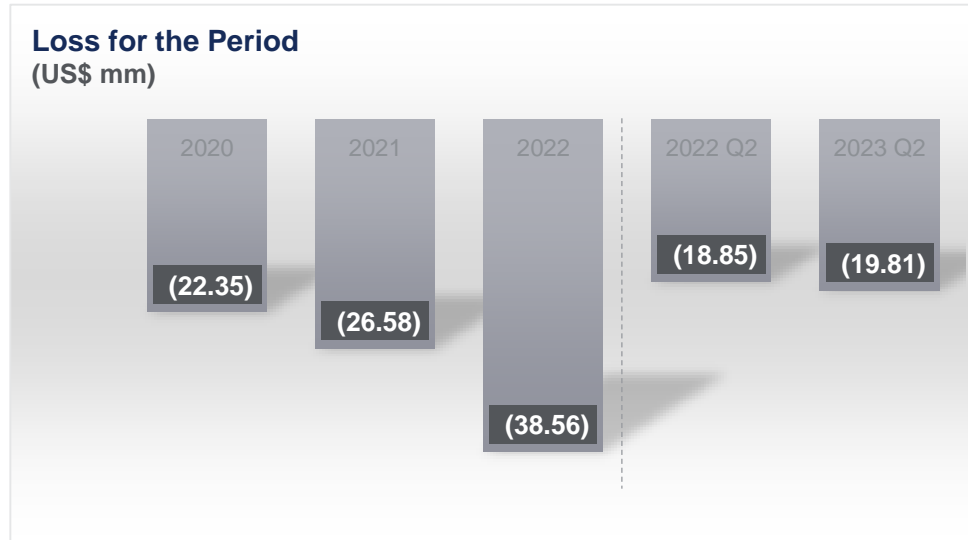
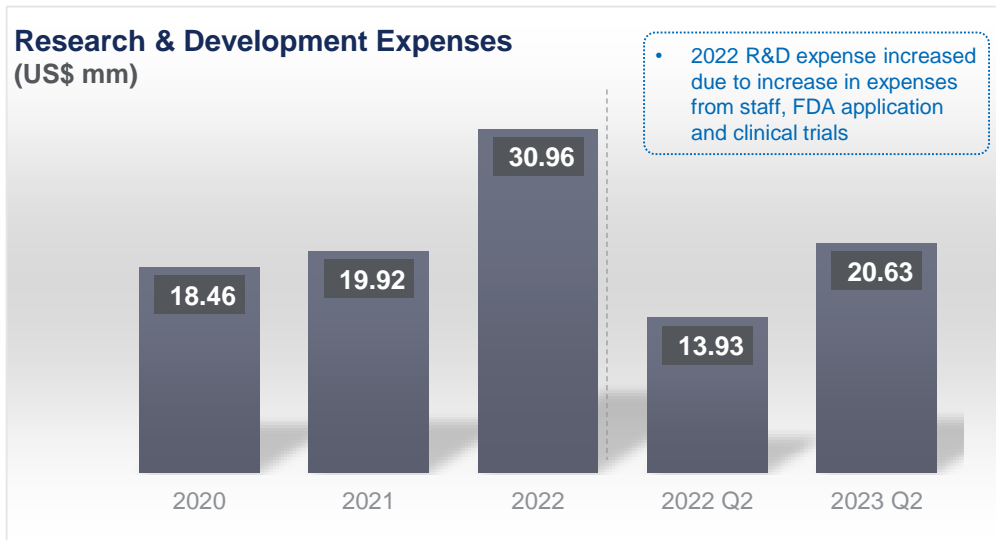
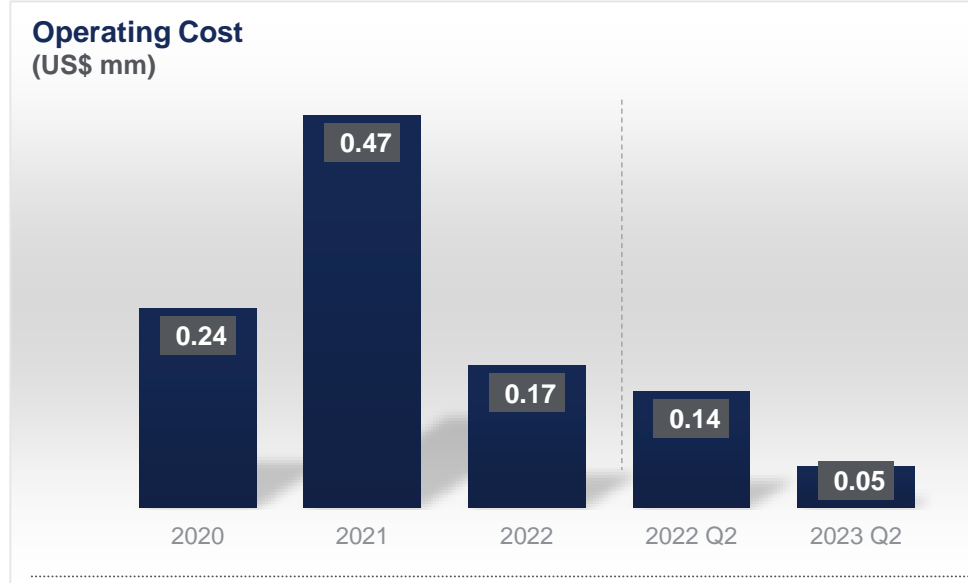
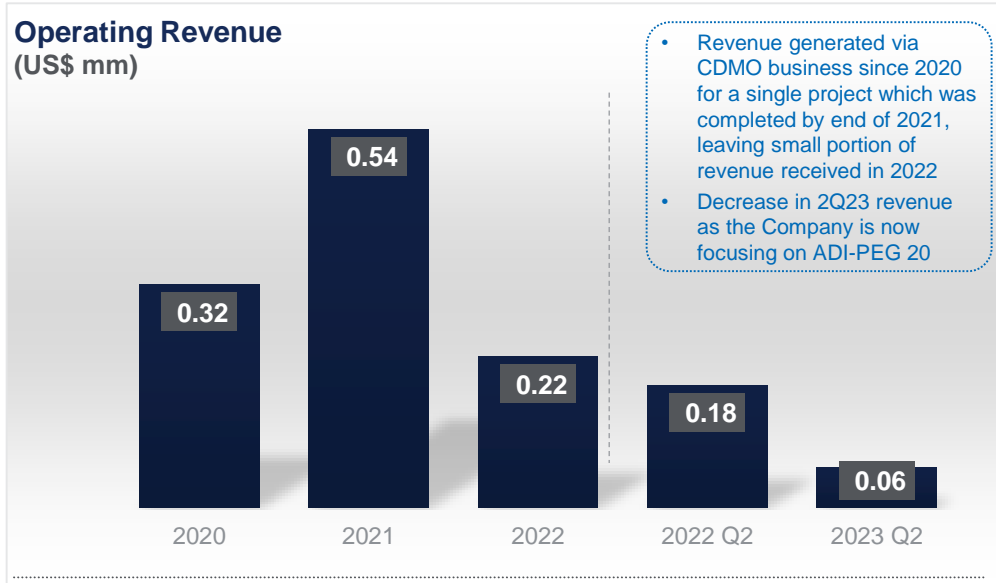
財務資訊

Balance Sheet Summary



Source: Company filings. 1 USD = 30.48 NTD.
 Note: (1) Including cash & cash equivalent and financial assets at fair value through profit or loss - current.

Income Statement Summary



Source: Company filings. 1 USD = 30.48 NTD.

Detailed Balance Sheet

(in US\$ MM)	For the Year ended December 31			6 Months ended June 30	
	2020	2021	2022	2022	2023
Current Assets					
Cash and Cash Equivalents	5.3	212.3	235.3	257.5	211.1
Financial Assets at Fair Value through Profit or Loss - Current	0.5	4.1	5.1	5.1	5.6
Accounts Receivable - Net	-	-	-	-	-
Other Current Assets	60.1	12.8	5.2	1.6	27.1
Total Current Assets	65.9	229.2	245.5	264.2	243.8
Non-current Assets					
Investments accounted for using equity method	1.4	2.3	2.0	2.1	-
Property, Plant and Equipment	46.4	46.9	42.3	44.5	36.4
Right-of-use Assets	3.1	2.4	9.4	9.5	8.7
Investment property	-	-	-	-	5.9
Other Non-current Assets	1.2	1.6	1.0	0.8	7.5
Total Non-current Assets	52.1	53.2	54.7	56.9	58.4
Total Assets	118.0	282.4	300.2	321.1	302.3
Current Liabilities					
Short-term Borrowings	0.8	10.0	-	-	18.5
Other Payables	4.3	5.0	4.2	6.1	4.8
Current Lease Liabilities	0.7	0.7	1.1	1.1	1.0
Long-term liabilities, current portion	4.1	-	2.9	-	2.7
Total Current Liabilities	9.8	15.8	8.2	7.1	27.0
Non-current Liabilities					
Long-term borrowings	4.4	4.2	1.0	4.0	1.0
Non-current Lease Liabilities	1.5	0.8	7.5	7.6	6.9
Other Non-current Liabilities	1.2	1.2	1.1	1.1	1.0
Total Non-current Liabilities	7.1	6.2	9.6	12.7	8.9
Total Liabilities	16.9	22.0	17.8	19.9	35.9
Equity					
Ordinary share	229.2	259.7	241.6	249.3	236.5
Capital collected in advance	-	-	-	0.1	0.1
Capital Surplus	185.8	354.9	373.7	383.6	368.9
Accumulated Deficit	(304.8)	(340.4)	(344.3)	(335.7)	(355.8)
Other Equity Interest	(9.0)	(13.6)	11.4	4.0	13.7
Non-controlling interest	-	-	-	-	3.1
Total Equity	101.2	260.6	282.5	301.2	266.4
Total Liabilities and Equity	118.1	282.6	300.2	321.1	302.3

Source: Company filings. 1 USD = 30.48 NTD.

Detailed Income Statement

(in US\$ MM)	For the Year ended December 31			6 Months ended June 30	
	2020	2021	2022	2022	2023
Operating Revenue	0.3	0.5	0.2	0.2	0.1
Yo Y Groth	--	69.6%	-60.1%	16.1%	-67.1%
Operating Costs	(0.2)	(0.5)	(0.2)	(0.1)	(0.0)
Gross Profit	0.1	0.1	0.0	0.0	0.0
Gross Profit Margin	25.8%	13.9%	22.0%	21.3%	15.7%
Operating Expenses					
Administrative Expenses	(4.6)	(6.5)	(7.9)	(4.1)	(4.1)
Research and Development Expenses	(18.5)	(19.9)	(31.0)	(13.9)	(20.6)
Total Operating Expenses	(23.0)	(26.4)	(38.8)	(18.1)	(24.8)
Operating Loss	(23.0)	(26.3)	(38.8)	(18.0)	(24.7)
Non-Operatnig Income and Expenses					
Interest Income	0.9	0.3	2.2	0.3	5.4
Other Gains and Losses	0.1	0.3	(1.1)	(0.8)	0.3
Finance Costs	(0.2)	(0.5)	(0.4)	(0.2)	(0.3)
Share of Loss of Associates Accounted for Under Equity Method	(0.2)	(0.3)	(0.3)	(0.1)	(0.2)
Total Non-operating Income and Expenses	0.6	(0.3)	0.4	(0.8)	5.2
Loss Before Tax	(22.4)	(26.6)	(38.4)	(18.9)	(19.6)
Income Tax Expense	-	-	(0.2)	(0.0)	(0.2)
Loss for the Period	(22.4)	(26.6)	(38.6)	(18.9)	(19.8)

Source: Company filings. 1 USD = 30.48 NTD.



06.
Q&A