Polaris

Leading the way to new and better metabolic treatment

Investor Conference
2024/04/01

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Agenda

1 **Polaris Group Snapshot**

2 **New Drug development (ADI-PEG 20)**

3 **Peptide projects and pipeline**

4 **Market outlook and Company position**

5 **Q&A**

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Polaris Group snapshot

Founded in 2006, listed on Taiwan Stock Exchange in 2022

Polaris Group

2023 Acquisition of Genovior Biotech

BU1: Oncology

ADI-PEG20

- MPM
- GBM
- HCC
- Soft Tissue Sarcoma
- NASH

BU2:Peptides

Synthesis and semi-synthesis

- Semaglutide (API+ Injection + Oral)
- Teriparatide
- Liraglutide
- Tirzepatide

Polaris: Leading the Way to New and Better Metabolic Treatments

- Fully integrated biopharmaceutical company with global end-to-end capabilities, business acquisition leads to new peptide pipeline and products
- Well-positioned at the forefront of developing novel metabolic therapies and complex generics for patients worldwide
- Potential first-in-class novel pegylated arginine deiminase as a synergistic backbone for combination therapies
- Strong clinical development platform to bring our pipeline to potential markets
- Well-designed, commercialization-ready CMC and CDMO capabilities with excellent quality and enhanced cost efficiencies
- Seasoned management team with visionary leadership and extensive industry experience

BU 2: Peptide Product Expertise

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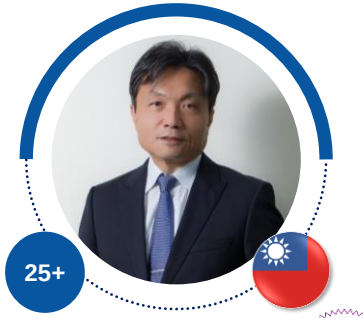
Peptide Product expertise				
Peptide Design	**Robust Synthesis and Manufacturing**	**Comprehensive analytical capabilities**	**Regulatory Compliance**	**Collaborative Research and Development**
• ***Innovative Design Strategies:*** *Polaris employs cutting-edge methodologies for peptide design, ensuring optimal functionality and specificity.*	• ***State-of-the-Art Facilities:*** *Polaris operates advanced peptide synthesis and manufacturing facilities, guaranteeing high-quality and scalable production.*	• ***Advanced Analytical Techniques****: Polaris utilizes advanced analytical tools for in-depth characterization of peptides, ensuring purity and integrity.*	• ***Regulatory Standards****: Polaris maintains strict compliance with international regulatory standards, providing confidence in the safety and efficacy of our peptide products.*	• ***Partnership Opportunities:*** *Polaris welcomes collaborations for joint research and development projects, fostering innovation and expanding peptide applications.*
• ***Tailored Solutions:*** *Our team excels in creating customized peptides to meet diverse therapeutic needs.*	• ***Stringent Quality Control:*** *Rigorous quality assurance protocols ensure the delivery of consistently superior peptide products.*	• ***Quality Assurance:*** *Our commitment to quality extends to thorough analysis at every stage of the production process.*	• ***Documentation Excellence:*** *Robust documentation practices ensure transparency and facilitate regulatory approvals.*	

Proven track record of success: Polaris has a successful history of developing and commercializing peptide products across various therapeutic areas, including Octreotide (TFDA approved),Teriparatide under regulatory fling and 5 other products in the development pipeline.

Seasoned Management Team with Visionary Leadership and Extensive Industry Experience



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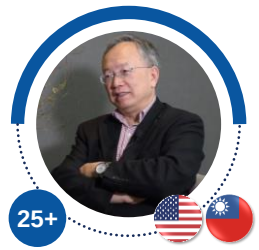

Shaw Chen M.D., Ph.D.
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02.
New Drug Development

Our Pipeline

Indication	Line of Therapy	Therapy	Regulatory Body	Commercial Rights	Pre-Clinical	IND	Ph1	Ph2	Ph3	BLA	Approval / Launch	Next Milestone
Malignant Pleural Mesothelioma (MPM)	1L	Combo w/ SoC Chemo	FDA MRCT	Global	ADI-PEG 20 + Cisplatin + Pemetrexed							Complete BLA Submission to FDA
Soft Tissue Sarcoma (STS)	2L / 2L+	Combo w/ Chemo	FDA	Global	ADI-PEG 20 + Gemcitabine + Docetaxel							Interim data readout
Hepatocellular Carcinoma (HCC)	1L	Mono Precision Treatment	TFDA	Global	ADI-PEG 20							Interim data readout
Glioblastoma (GBM)	1L	Combo w/ SoC Chemo + Radiotherapy	FDA	Global	ADI-PEG 20 + Temozolomide + Radiation ADI PEG 20 + Temozolomide + Radiation (1)							Interim data readout
Acute Myeloid Leukemia (AML)	1L + Relapsed	Combo w/ SoC Chemo	FDA	Global	ADI-PEG 20 + Venetoclax + Azacitidine							Interim data readout
NASH/NAFLD	1L	Mono	TFDA	Global	ADI-PEG 20							Interim data readout
Multiple Preclincal Pipelines	-	-	-	Global	2nd Gen ADI-PEG 20							IND

Source: Company information, FDA
Note: 1. GBM AGILE Platform in the U.S.

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Clinical development Strategy

- **As the best companion drug**

  MPM：ADI-PEG 20 + Cisplatin + Pemetrexed
  STS：ADI-PEG 20 + Gemcitabine + Docetaxel

- **Precision Medicine**

  HCC：ADI-PEG 20 Monotherapy for WWOX GG genotype and high Arginine level

- **Synergy to combine with radiotherapy**

  GBM：ADI-PEG 20 + TMZ + Radiation

- **Pursue a bigger market indication:** NASH

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Market Size of Global Metabolic Therapy Market with Key Drivers

Potential to be a **pan-cancer treatment regimen**

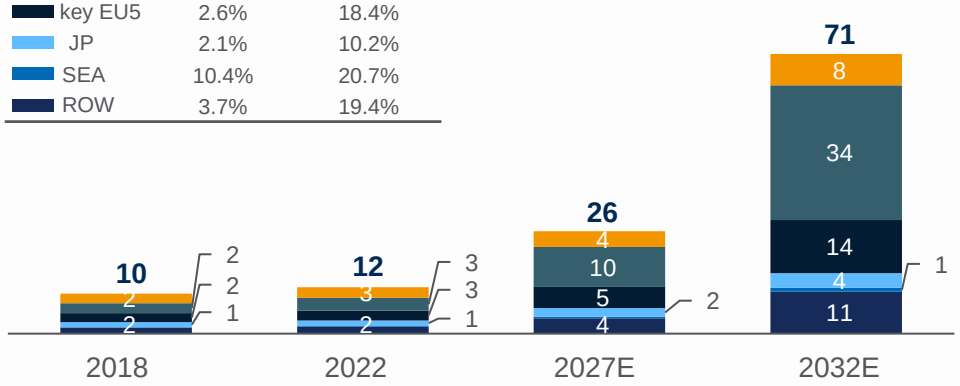
Potential **synergistic effect with other treatment**

Potential to be a **cancer precision treatment regimen**

Targeting cancer metabolic therapy demonstrates **lower side effect**

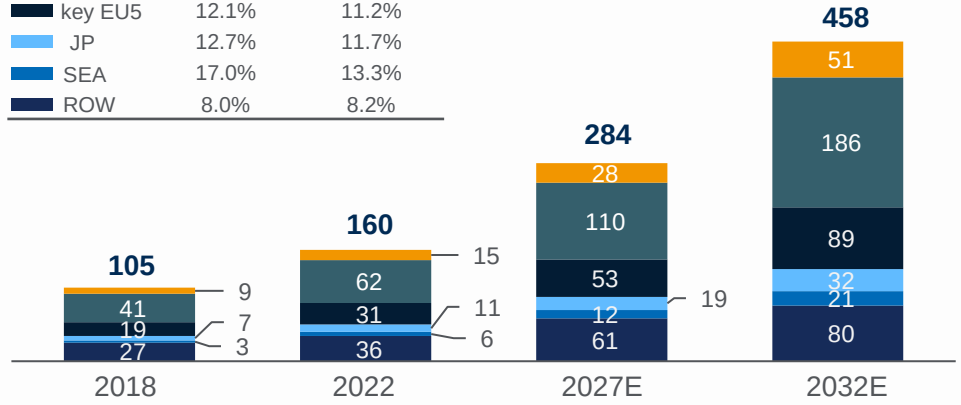
Market size of Global cancer metabolic therapy market (US$bn)

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%



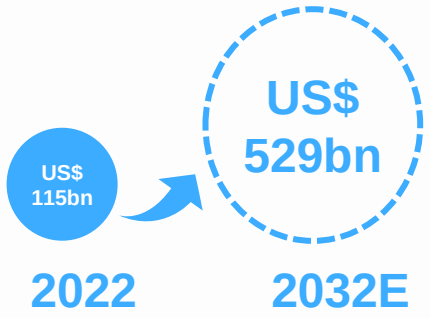
Market size of Global non-cancer metabolic therapy market (US$bn)

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%



Global metabolic therapy market size is expected to expand by

5x



Source: China Insights Consultancy.

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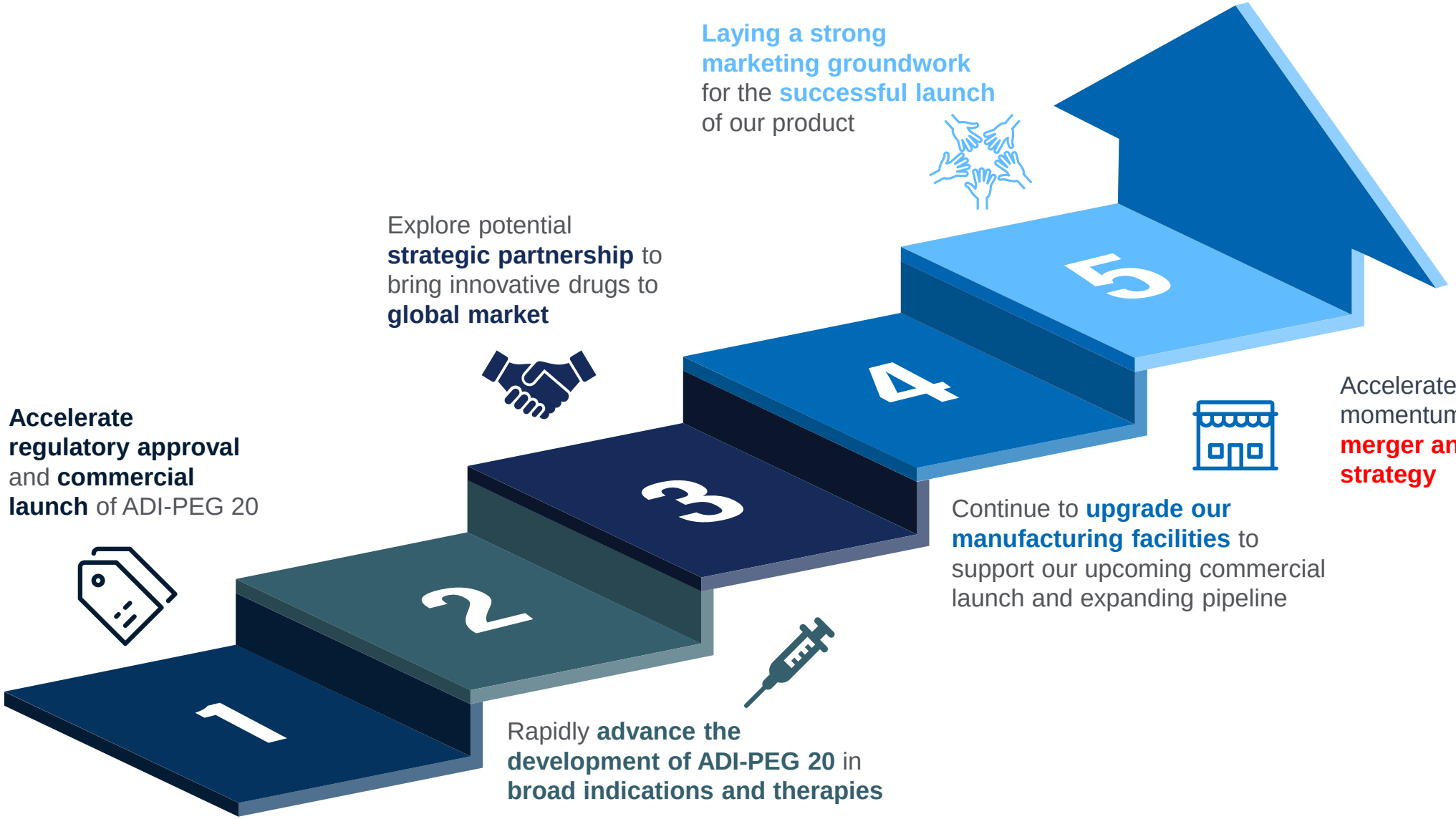
Our Growth Strategies



Accelerate regulatory approval and **commercial launch** of ADI-PEG 20

Rapidly **advance the development of ADI-PEG 20** in **broad indications and therapies**

Explore potential **strategic partnership** to bring innovative drugs to **global market**

Continue to **upgrade our manufacturing facilities** to support our upcoming commercial launch and expanding pipeline

Laying a strong marketing groundwork for the **successful launch** of our product

Accelerate group growth momentum **through a merger and acquisition strategy**

Source: Company information.

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03.
Genovior: peptide pipeline and products

Product Pipeline

Type	Key product	API	Injectable form	Oral form
Biologic	ADI-PEG 20	V	V	
Complex generics: peptide drug	Semaglutide Tirzepatide	V	V	V
Complex generics: Anti-cancer drug	Carfilzomib	V	V	
CDMO	• Biologics • Injectables • Peptide injectables • Anti-cancer injectables • Exosome injectables	V	V	

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Technology Development

Product Type	Process/Technology/Know-how in Hands or under Development
Microbial-based API (B)	• Microbial fermentation and purification related • Exosome process
High-Barrier API (O)	• Total synthesis • Column purification
Peptide API(P)	• Solid-phase synthesis • Column purification • Lyophilization
Specially formulated injectables and oral drugs (IO)	• Sterile technology • Slow release technology • Lyophilization • know-how in regulation requirement for combination of drug and medical devise • New formulation capable of filing 505.B.2.

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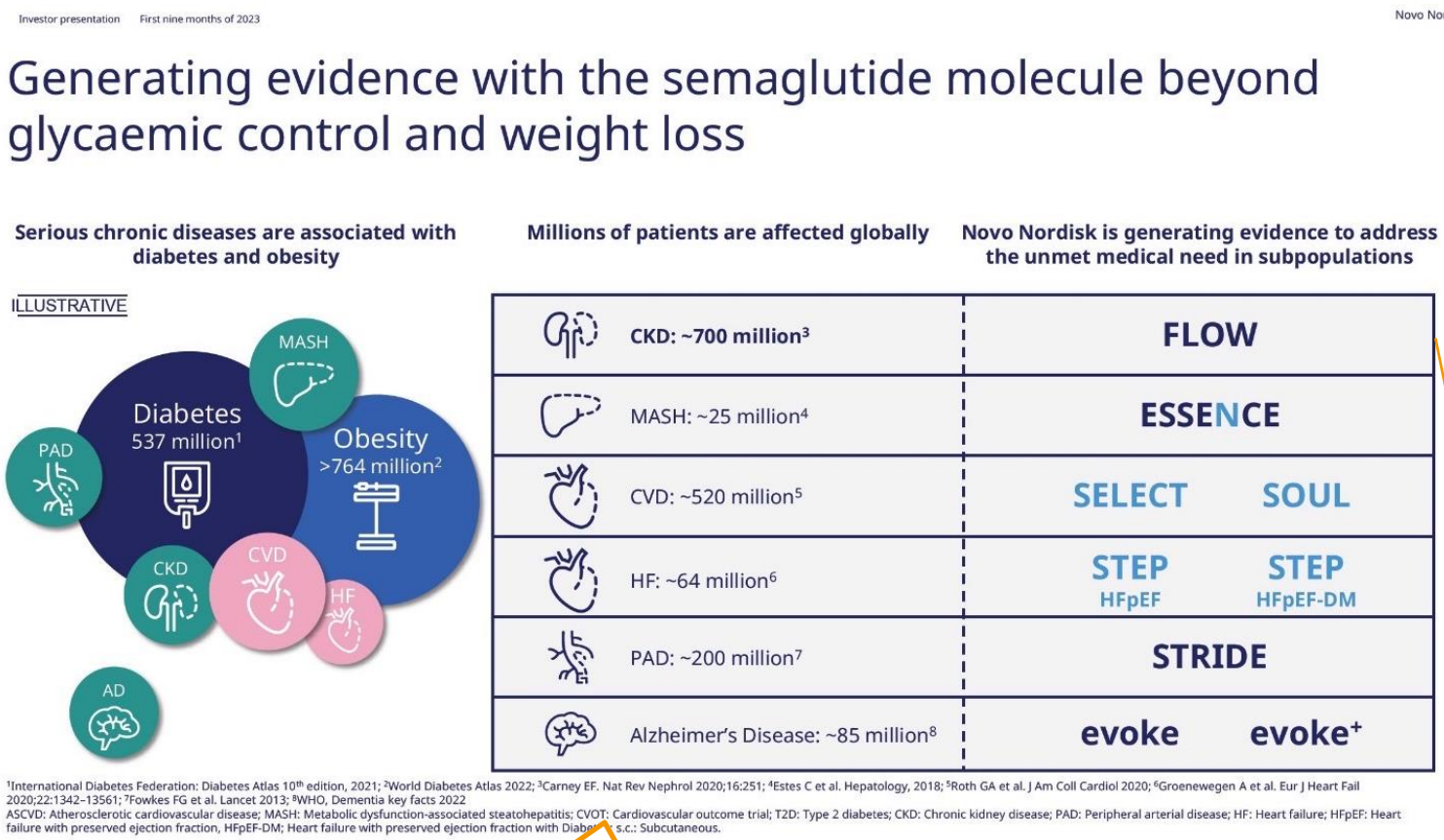
Peptide Products

	Key Features
Peptide	1. Complicated processes in synthesis or fermentation of API. Magnitudes of technical difficulties in impurity controls and identification increase with the number of amino acid inherited in peptide. 2. Finished goods mostly shown as injectables with special formulation or combination with medical devises. 3. Diversified production equipment involved. Regulation requirement and challenges are high.
Industry Shift Before 2023	Number of amino acid is around 10. Annual demand in quantity is relatively small. Most finished goods have formulation forms of slow release.
Industry Shift After 2023	Demand in API quantity is high. # of amino acid > 30. Auto injection pen of finished good is popular. Orals start to show up. Product applications increase.

Peptide Name	Application	Amino acid	API	Formulation
Semaglutide	T2 diabetes,obesity	35	Total synthesis	Injection pen/cartridge, oral
Teriparatide	Osteoporosis	34	Total synthesis	Injection pen/cartridge
Liraglutide	T2 diabetes,obesity	32	Semi-synthesis	Injection pen/cartridge

Key product: Semaglutide and its shortage crisis



- FDA Approves Ozempic (Semaglutide) Injection For the Treatment of Adults with Type 2 Diabetes in 2017.
- Rybelsus (Semaglutide) received FDA approval as first oral GLP-1 treatment for type 2 diabetes in 2019.
- In 2020, FDA approves Ozempic (Semaglutide) for cardiovascular risk reduction in adults with type 2 diabetes and known heart disease.
- Wegovy (Semaglutide) received FDA approval for treating adult obesity in 2021.
- In 2022, a higher-dose formulation of Ozempic (Semaglutide) received FDA approval for treating type 2 diabetes. Additionally, in 2022, Wegovy (Semaglutide) gained FDA approval for treating obesity in adolescents aged 12 and above.

- In October 2023, Novo Nordisk announced to stop the once-weekly injectable semaglutide kidney outcomes trial, FLOW, based on interim analysis

Semaglutide shortage has raised dual concerns for Diabetes and Obesity treatment

expanding indications lead to Potential massive market

Source: Novo Nordisk Corporate deck and annual report, FDA website, Klein, H. E. (2023, December 21). An Ongoing Crisis: Semaglutide Shortage Raises Dual Concerns for Obesity and Diabetes Treatment

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Semaglutide

- Indications：Type 2 diabetes, Obesity
- RLD dosage form：

  Injection pen (Subcutaneous)；Tablet (Oral)
- RLD patents：Denmark's Nova Nordisk, global core compound patents will expire on March 20, 2026.
- RLD global sales：

  From 2022 to 2023, Novo Nordisk's total global revenue of Semaglutide were from US$11.145 bn(2022) to US$21.272 bn.(2023)
  - Rybelsus (oral, type 2 diabetes) US$1.63 billion, to US$2.735billion (yoy+66%)
  - Ozempic (injection, type 2 diabetes) US$8.622 billion, to US$13.965 billion(yoy 71%)
  - Wegovy (injection, Obesity) $893 million to $4.572 bn (yoy +407%)
- API production process ：Chemical Synthesis

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Key Challenges in GLP-1 Drugs

- Technical attention required in producing API and Injectables: combination of chemistry, chem.engineering, biology, and/or medical devise design
- In-house production of raw materials required to lower production cost
- Measures to reduce CoGs is highly required. Example: solvent recovery
- Factors of Competitiveness: sufficient manpower and funding to timely implement cost effective production process
- Special attention required in regulation of world-wide registration

Capacity expansion in Mass Production

Facility	3-year Planning	Operational
Genovior Facility	• An acquisition of new facilities completed in Q1, 2024. • New set-ups: (A) injectable plants of vial, pre-filled, and cartridges and (B) a GLP-1 API plant of 75 kg/year. • Expandable to 1,000 kg API per year to meet future demand.	2H, 2024
Chengdu Facility	• Expansion of the ADI-PEG 20 plant and • Construction of a GLP-1 API plant of 75kg/year.	2H, 2024
Vacaville Facility	• Adjust to provide commercial quantity in 1st phase, up to 130,000 vials/year	
Southeast Asia Facility(TBD)	• Planning phase • Flexible and adjustable depends on different type of partnership	2025/2026

Semaglutide capacity expansion and product timeline

Year	2024	2025	2026	2027
API Phase 1	Chengdu plant expansion，75kg/ annual Taiwan Zhunan plant expansion，75 kg/ annual	API registration (regulatory approval), sales and distribution	Sales and distribution	Sales and distribution
API Phase 2	Plant civil engineering execution	Taiwan Zhunan plant expansion，800 kg/ annual	API registration, sales and distribution	Sales and distribution
Injection	Chengdu plant expansion Taiwan plant expansion	registration	Sales	Sales
Oral tablets	Taiwan plant expansion	RD/clinical development	clinical development	505(b)2 registration
Nasal Spray	RD	plant expansion	clinical development	505(b)2 registration

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Tirzepatide capacity expansion and product timeline

Year	2024	2025	2026	2027
API	RD	RD	Scale-up Manufacturing, Three-batch Validation, Registration	Registration Manufacturing Sales and Distribution
API				Plant expansion

Capital investment for Setting up Semaglutide API & Injectable Plants

Phase 1 Capital US$ 45 m

- Acquisition of 27,000 m2 factory and 2 hectares of science park land
- Completion of 4 production lines for injections and 4 lines for API (Chengdu plant + Taiwan plant)
- Upon completion of Phase 1, the annual production capacity of Semaglutide API is expected to reach 150 kg (75 kg/year in Chengdu and Taiwan each). Expected to be completed in Q3, 2024.
- Initiate Phase 2 expansion construction project.

Phase 2 Capital US$25 m

- With phase 1 capital investment and completion of the project, with additional USD$ 25 millions we can expand production capacity for Semaglutide API to 600kg/annual.

Phase 3 Capital US$40 m

- With another USD$40 millions capital investment, we are able to expand annual production for GLP-1 API to 1,500kg/annual.

Upon securing confirmed orders, production capacity can be scaled up to 1,500 kg annually

Source: company estimate

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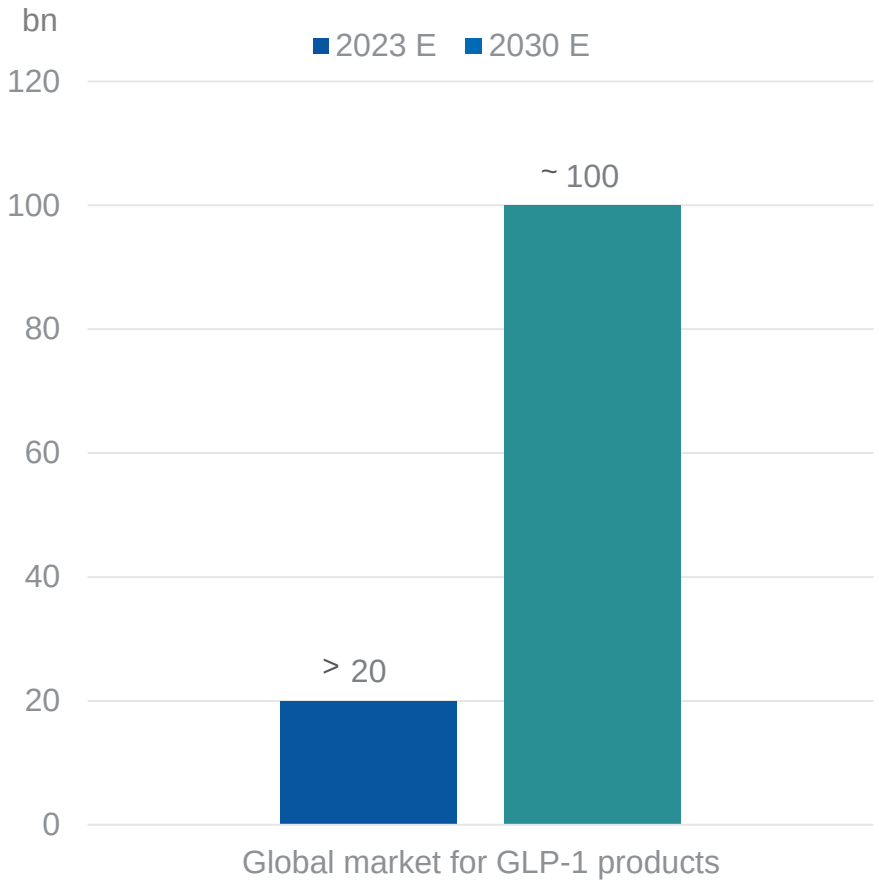
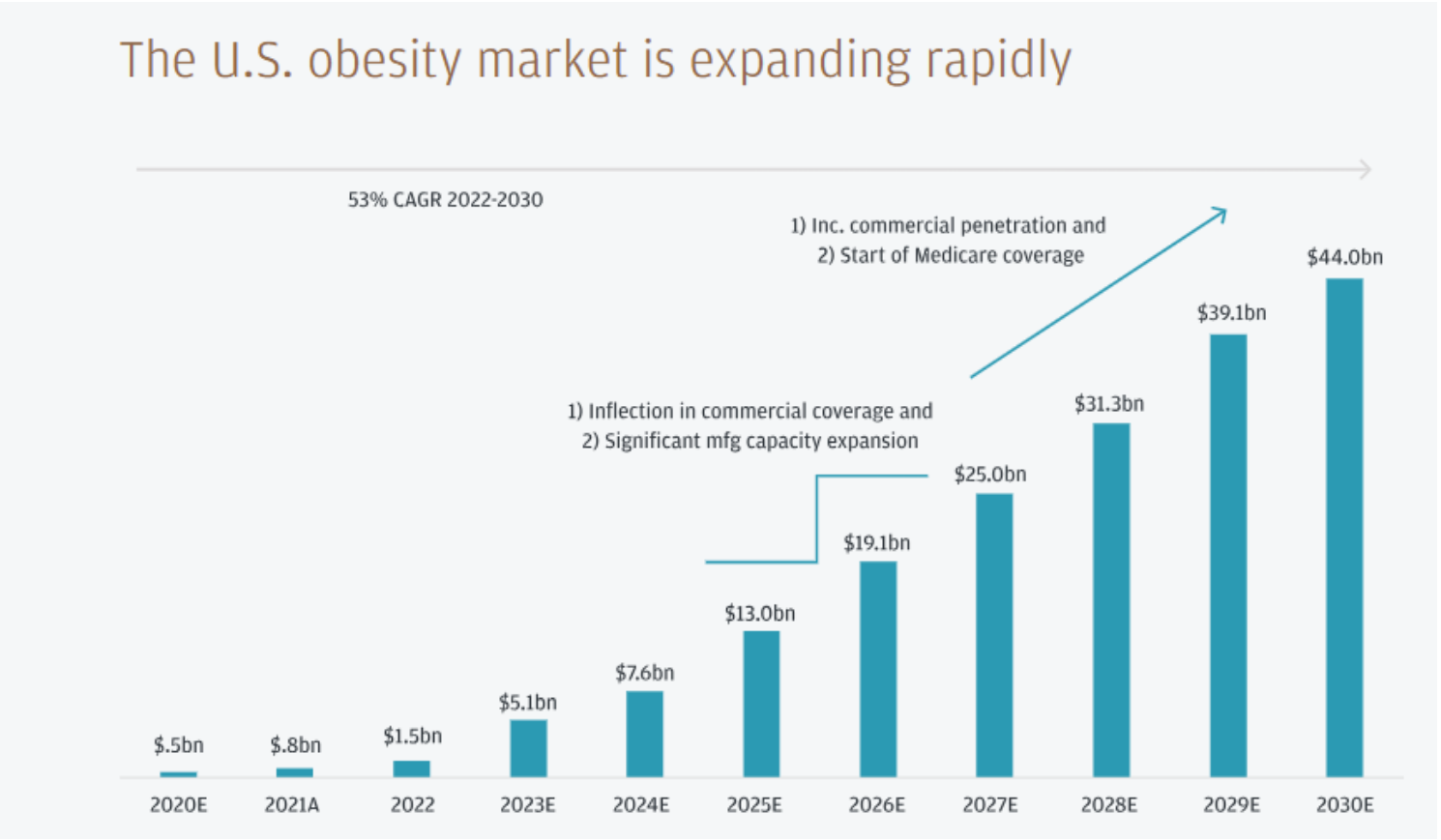
04.
Market outlook and competitive analysis

GLP-1 Market outlook(for obesity and T2D)





Source: [The increase in appetite for obesity drugs | J.P. Morgan Research (jpmorgan.com)]

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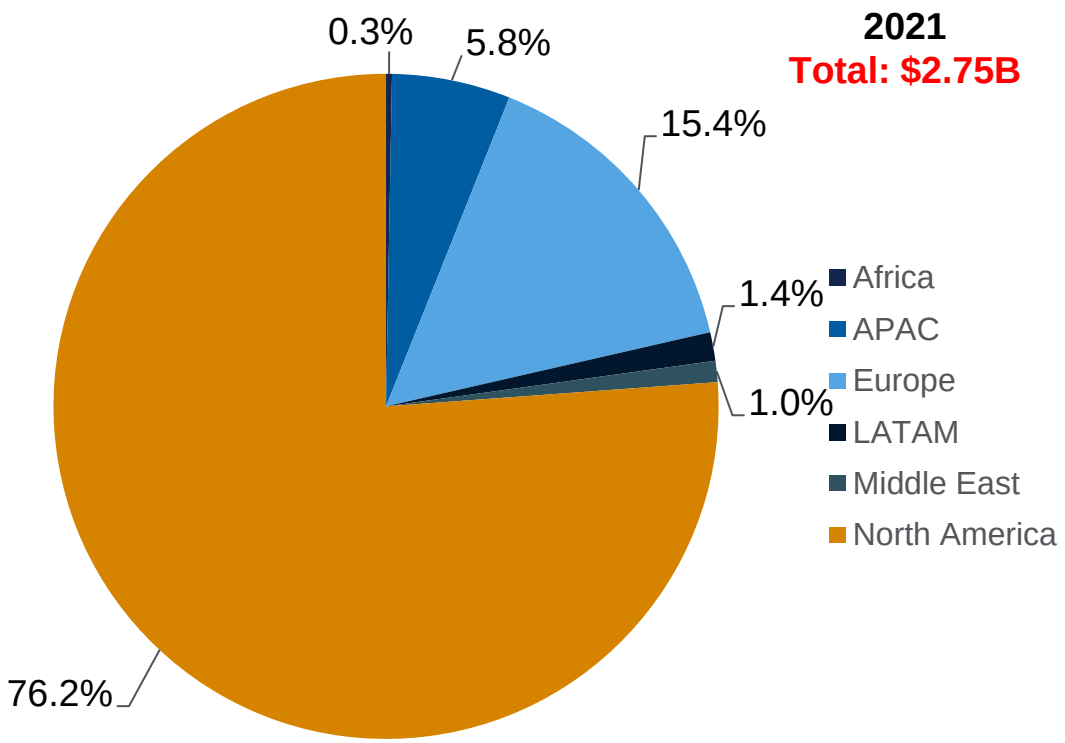
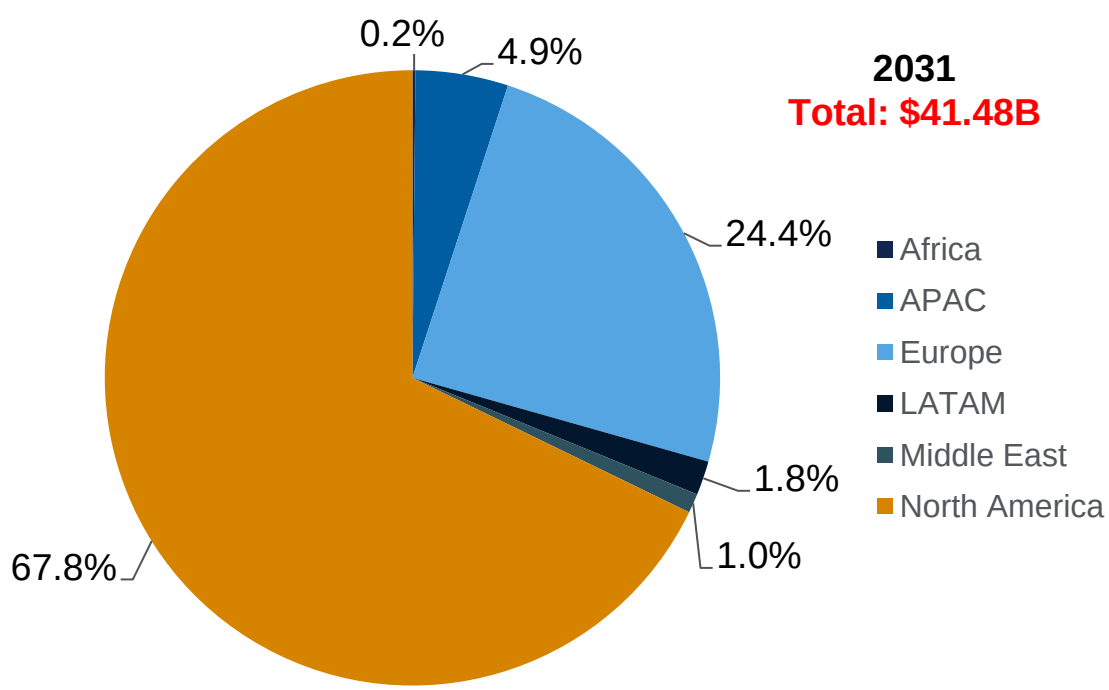
Global Obesity Market outlook





Source: Globaldata, Obesity 68-Market Forecast 2021–2031,Publication Date: March 2023

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Global Market Size for Semaglutide

- Novo Nordisk's financial report reveals that in the first half of 2023, among the three products, the antidiabetic drug Semaglutide injection Ozempic ranked first with sales of US$6.077 billion, a year-on-year increase of 58%; the oral antidiabetic drug Semaglutide tablet Rybelsus ranked last with sales of US$1.215 billion, a year-on-year increase of 97%; while sales of Semaglutide injection Wegovy for weight loss were US$1.759 billion, a year-on-year increase of 367%.
- **Novo Nordisk raised its sales forecast for 2023 from the 13%-19% set at the beginning of the year to 24%-30%, and its operating profit growth forecast from 13%-19% to 28%-34%

		First half of 2023	2023	2024	2025	2026	Remarks
RLD Sales in USD Billion	Injection	78.36	157	204	265	344	RLD sales forecast for 2023 is still underestimated. Forecast is based on 30% growth
	Tablet	12.15	24	32	41	53	
		2027	2028	2029	2030	2031	Remarks
Global demand for injection API（KG）		1,147	3,441	5,735	9,176	9,176	The demand for API in the first year of generic drug is based on the RLD sales, and it will increase by 3 times year-on-year in the next year, 5 times in the third year, 8 times in the fourth year, and remains stable at the peak.
Global demand for oral API（KG）		2,485	7,455	12,425	19,880	19,880	
Global demand for all dosage forms API（ton）		**3.6**	**10.9**	**18.2**	**29.1**	**29.1**	

The global API market potential is still huge, and the market is far from being satisfied.

Competitive landscape of the peptide industry chain

- The GLP-1 drug drives the explosion of demand in the peptide industry: CDMO companies directly benefit from the surge in pharmaceutical market demand

Higher — Profit sources: Midstream to upstream from supply orders, downstream from R &D development, and approved product launches. — Lower

Certainty

Upstream: reagents, consumables, equipment	Midstream: API, and CDMO	Downstream: R&D pharma companies
Peptide Synthesis Reagents: Merck Millipore Iris Biotech Highfine **Solid Phase Synthesis Carriers:** Dow Chemical Sunresin **Synthesis Equipment:** CSBio **Injection Pens:** Ypsomed and etc	Bachem Polypeptide Corden Pharma Lonza Catalent(acquired by Novo Feb 2024) WuXi AppTec Jiangsu Sinopep-Allsino Biopharm Hansoh Pharma, and etc	Novo Nordisk Eli Lily Pfizer Sanofi GSK Innovent Biologics Huadong Medicine, and etc

Market size

Lower — Polaris Group — Higher

source: company websites, multiple investment reports

3-year strategic goal and expected milestone

BU1- New Drug Development

Actively advancing clinical trials and global regulatory submissions, accelerating negotiations for global and regional partnership, and progressing with market approval plan

Milestone and key catalyst timeline:

- **2024:** Complete Submission of MPM (Malignant Pleural Mesothelioma) BLA to FDA, advancing global and regional licensing negotiations.
- **2025:** Obtain the first BLA approval and launch the drug in the market.
- **2026-2027:** Phase III clinical data for GBM, LMS and HCC.

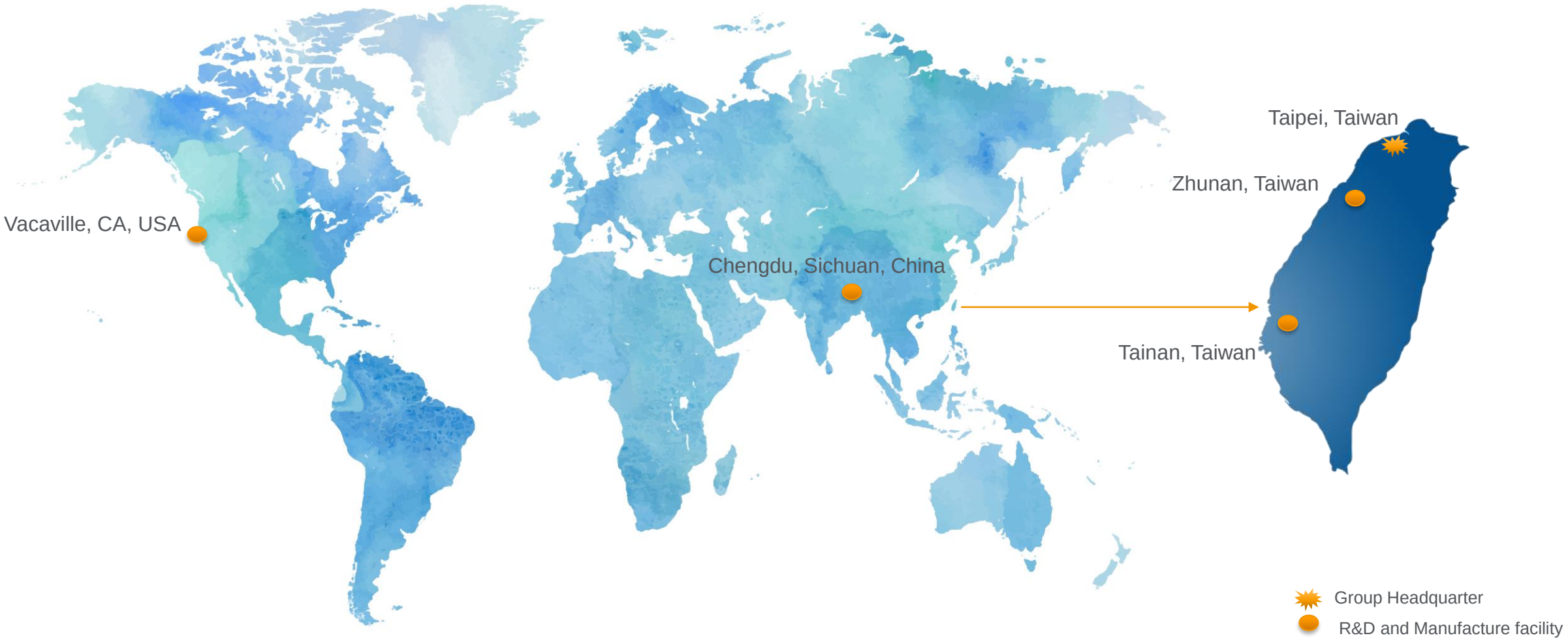
BU-2 Peptide product pipeline and development

Continuously investing in technology and products, efficiently leveraging existing business platforms, and expanding growth momentum.

Milestone and key catalyst timeline:

- **2024 Q4:** Completion of the peptide production line, advancing research and development projects.
- **2025:** Submission of API (Active Pharmaceutical Ingredient), obtaining certificate, and commencing mass production and shipment. Collaborate on development projects with internationally renowned generic drug manufacturers.
- **2026:** Entry of investigational products into clinical trials.

Polaris Group Vision



Thank you
and
Q&A

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Appendix

MPM – Summary of Clinical Design and Clinical Data

Study design - a MRCT, randomized, double-blind, phase 2/3 clinical study

To evaluate ADI-PEG 20 or Placebo with pemetrexed and cisplatin[1] (ATOMIC) in patients with MPM

MPM Patients (N=249)

Route of Administration: Intramuscular (IM) + Intravenous (IV)

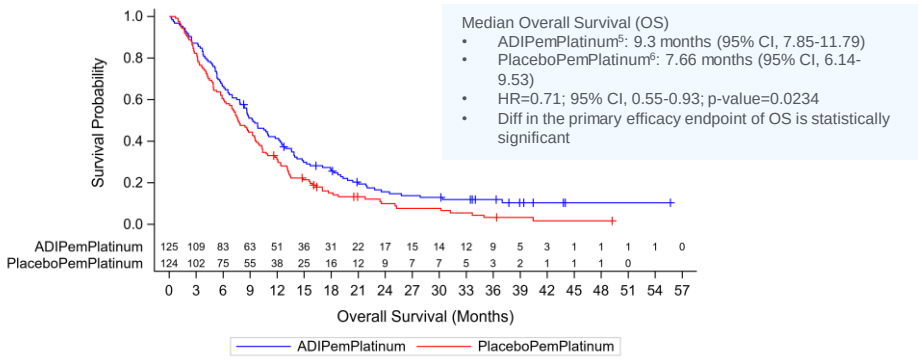
	ADI-PEG 20 Dose: 36 mg/m² given weekly	Pemetrexed Dose: 500 mg/m² every 3 weeks	Cisplatin[1] Dose: 75 mg/m² every 3 weeks
ADI-PEG 20 Combo (N=125)			
Placebo Combo (N=124)	**Placebo Dose:** 36 mg/m² given weekly	**Pemetrexed Dose:** 500 mg/m² every 3 weeks	**Cisplatin[1] Dose:** 75 mg/m² every 3 weeks

Primary End-point (EP)
- OS[2]

Secondary End-point (EP)
- PFS[3]

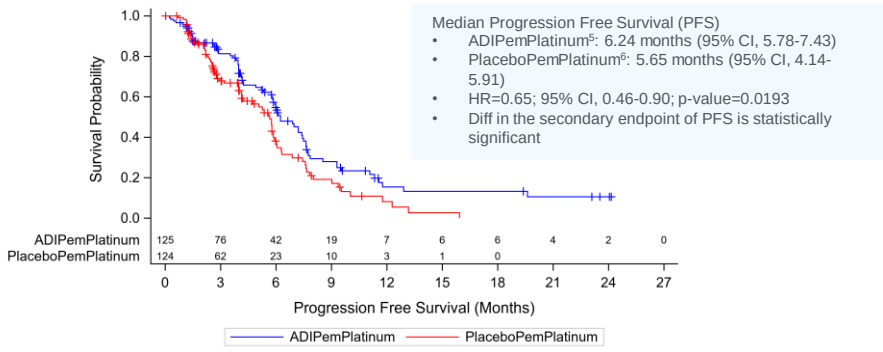
Clinical data summary

Kaplan-Meier Plot of Overall Survival (OS) - ITT Population[4]



Median Overall Survival (OS)
- ADIPemPlatinum[5]: 9.3 months (95% CI, 7.85-11.79)
- PlaceboPemPlatinum[6]: 7.66 months (95% CI, 6.14-9.53)
- HR=0.71; 95% CI, 0.55-0.93; p-value=0.0234
- Diff in the primary efficacy endpoint of OS is statistically significant

Kaplan-Meier Plot of Progression Free Survival (PFS) - ITT Population[4]



Median Progression Free Survival (PFS)
- ADIPemPlatinum[5]: 6.24 months (95% CI, 5.78-7.43)
- PlaceboPemPlatinum[6]: 5.65 months (95% CI, 4.14-5.91)
- HR=0.65; 95% CI, 0.46-0.90; p-value=0.0193
- Diff in the secondary endpoint of PFS is statistically significant

- *Overall Survival is calculated as the time from randomization until death. In the event that no death is documented prior to study termination or analysis cutoff, OS was censored at the last known date the subject is known to be alive (using last contact day or last dose day).*
- *Total number of subjects from the analysis population is 249, including 25 censored subjects (17 from ADIPemPlatinum, 8 from PlaceboPemPlatinum) and 224 subjects with OS events (108 from ADIPemPlatinum, 116 from PlaceboPemPlatinum).*

- *Progression-free survival is calculated as the time from randomization until date of tumor progression or death. In the event that no tumor progression or death is documented prior to end of treatment, analysis cutoff, or the start of confounding anticancer therapy, PFS was censored at the date of the last tumor assessment demonstrating no tumor progression.*
- *Total number of subjects from the analysis population is 249, including 104 censored subjects (54 from ADIPemPlatinum, 50 from PlaceboPemPlatinum) and 145 subjects with PFS events (71 from ADIPemPlatinum, 74 from PlaceboPemPlatinum).*

Source: Company information, Literature Review.
Notes: (1) Subjects who did not tolerate cisplatin were allowed carboplatin area under the plasma concentration–time curve (AUC) 5 mg/mL/m². (2) Overall survival. (3) Progression-free survival. (4) ITT = Intent-to-Treat. Analysis population is the ITT Population: Includes all randomized subjects. (5) ADIPemPlatinum refers to the ADI-PEG 20 Group (ADI-PEG 20 + cisplatin + pemetrexed). (6) PlaceboPemPlatinum refers to the Control Group (Placebo + cisplatin + pemetrexed).

STS – Summary of Clinical Design and Clinical Data

Study design - an open label, non-randomized, phase 2 clinical study

To evaluate ADI-PEG 20 with gemcitabine and docetaxel improved clinical outcomes for patients with STS

STS Patients (N=75)

- **Cohort 1**[1]
- **Cohort 2**[2]

Route of Administration: Intramuscular (IM) + Intravenous (IV)

ADI-PEG 20 Dose:	**Gemcitabine Dose:**	**Docetaxel Dose:**
36 mg/m2 Day -7 of Cycle 1 and then on Days 1, 8, and 15 of each subsequent cycle (1 Cycle = 21 days)	600 mg/m2 over 90 minutes on Days 1 and 8 of each cycle (1 Cycle = 21 days)	60 mg/m2 over 60 minutes on Day 8 of each cycle (1 Cycle = 21 days)

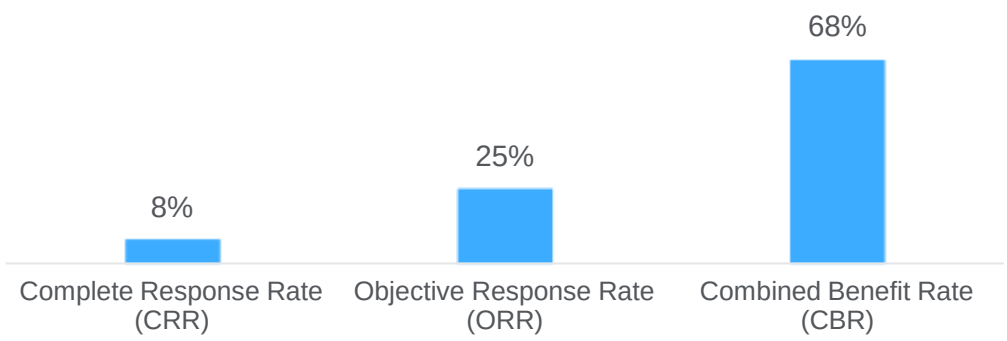
Primary End-point
- PFS[3]

Secondary End-point
- OS[4]
- Clinical benefit rate (CBR)
- Safety and tolerability
- Cancer-related mortality

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.

Clinical data summary



Results showed that sarcoma patients **demonstrated improved response rates** when combining docetaxel and gemcitabine with arginine starvation. The **complete response rate tripled** compared to previous trials, and **the amount of gemcitabine required could be reduced by a third**, **reducing the need for high-dose gemcitabine and mitigating toxicity**.

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

Source: Company information, Literature Review.
Notes: (3). Progression-free survival. (4). Overall survival. (5). Advancing Next-Generation Cancer Metabolic Therapy by Targeting Critical Amino Acid Metabolic Pathways: An Interview with Brian A. Van Tine, MD, PhD

Polaris

Polaris at a Glance

Platform

1,600+
Patients Treated with ADI-PEG 20

In-house
Arginine Degradation Development Platform

Proprietary
State-of-the-art Manufacturing Facilities

Pipeline

1
BLA[1] Submission under Preparation

7
Ongoing Clinical Trials[2]

5
Tumor Types in Clinical

2
Fast Track Designations[3]

3
Orphan Drug Designations[4]

People and Assets

~$118M
Cash Position[5] as of Dec 31, 2023

60+
US / International Patents

~400
Employees Globally

Partners and Collaborators

NIH NATIONAL CANCER INSTITUTE

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

Memorial Sloan Kettering Cancer Center

Barts Cancer Institute

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.

Polaris

ADI-PEG 20 Next Steps to Commercialization

Data and Path to Approval

- ✓ Completion of filing for Biologics License Application (BLA) to U.S. Food and Drug Administration (FDA) in 2024
- ✓ Filings of EU and UK marketing authorization applications planned 2H 2024
- ✓ Program has Fast Track and ODD designations

Manufacturing

- ✓ Full characterization of Vacaville facility
- ✓ State licenses for distribution planned for 1H 2024
- ✓ Facility has initial capacity to produce up to 300,000 doses PA; sufficient for demand in MPM major markets

Commercialization

- ✓ Ongoing evaluation of strategic partnerships and infrastructure required to bring to market
- ✓ Continue focus from 2023 on Medical Affairs, value and HEOR evidence generation
- ✓ Focus in 2024 on launch preparation and execution
- ✓ Anticipated PDUFA date in 2025

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