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# Company profile ①



# Innovative biotech focusing on GLP-1 class peptide for obesity / MASH therapy

#### **Company Profile**

Company	D&D Pharmatech Inc.	CEO	Seulki Lee
Founded	November 28, 2014	Employees	62 (Ph.D., M.S. 88.4%)
IPO (KRX)	May 2, 2024 (KOSDAQ: 347850)	Business area	Development of metabolic disorder (obesity, MASH) treatments
Market Cap	KRW 961 B (as of May 13, 2025)	Address	4 <sup>th</sup> floor, 27, Geumto-ro 80 Beon-gil, Sujeng-gu, Seongnam-si, Gyeonggi-do, 13453 Rep. of Korea
Capital	KRW 5.27 B (as of Dec 31, 2024)	Website	www.ddpharmatech.com

#### **CEO** introduction

Expert in peptide design & development

Inventor of oral peptide platform technology

**Top 1%** 

Highly cited researchers (Clarivate analytics, 2017)

Associate professor, Johns Hopkins University

**US National Institute of Health** 

19 grants, USD 16.5M

Department of Defense National Institute of Health National Academy of Science

# Seulki Lee

CEO, D&D Pharmatech

✓ CEO, Neuraly

- · B.S. Sungkyunkwan University
- M.S., Ph.D., GIST / Postdoc, KIST
- · Postdoc, Stanford Medical School
- Postdoc, National Institute of Health



# **Company profile 2**



# Peptide discovery by D&D and global clinical development by Neuraly



# **NEURALY**

#### Peptide discovery and preclinical research

DD01 Phase 2 MET-002o Phase 1 MET-224o/MET-097o
IND enabling

**Holder of major composition of matter patents** 







#### Clinical development of D&D derived drug candidates

NLY01
Phase 2 completed

TLY012 IND cleared

PMI04 Phase 1

#### Established clinical team Development of radiopharmaceuticals







#### **Key members**

#### Sungmook Lim PhD

- Co-founder & Head of R&D
- · Research Professor, SKKU

#### Eunji Park PhD | RPh

- Discovery lead
- · Research fellow, CAU

#### Jaehee Shin MS | RPh

- · Development lead
- · Hanmi, Dong-A

#### Yen-Huei Lin PhD

CTMO

Neuraly 15%

Novavax, Teva

#### Adam Bell PhD

- Head of translational medicine and RA
- ICON, Teva

#### Svetlana Sosnovtseva MS

- Head of Assay dev.
- MedImmune, Teva

Other D&D subsidiary and affiliated companies





Alpha radiotherapy



Anti-microbial peptide

# **Company profile 3**



# Advancing into a GLP-1 specialized company through global clinical development & out-licensing

Building business foundation		Securing growth foundation		Advancement of Business	
2007~2014	Oral & long-acting peptide research	2019	Jun Series B funding (KRW 141B)	2022	Aug Established z-alpha (JV) through asset investment
2014	Nov Establishment of D&D Pharmatech		DD01 patent registered	2023	(40% share) Jan NLY01 US PD Phase 2 completion
2015	Jan Initiation of DD01 & MET-002o peptide development	2020	Feb NLY01 US PD Phase 2 initiation		Feb DD01 US MASH Phase 1 completion
	Nov NLY01 & TLY012 composition of matter patent secured		Jul DD01 granted Start-up leap project by Ministry of SMEs & Startups		Apr MET-002o & MET-GGGo Global L/O with Metsera (Total: USD 422.5M)
2016	Jul Establishment of Neuraly, a subsidiary	2021	Mar DD01 US MASH Phase 1 initiation	2024	Mar Scope expansion of existing agreement and
2017	specialized for global clinical development  Jan NLY01 neurodegenerative disease Nature		Sep PMI07 Global L/O with Global Company A (Total: USD 60.4M)		additional L/O with Metsera (Cumulative: USD 803.55M)
	publication		DD01 China L/O with Salubris		May Listed in KOSDAQ
	<b>Nov</b> Secured NLY01 NDD method of use patent from JHU (Exclusive License)		(Total: USD 192M)		Aug DD01 MASH Phase 2 first patient dosed
2018	Mar Series A funding (KRW 19B)		Oct Series C funding (KRW 59B)		Nov MET-002o Phase 1 first patient dosed
	Jun NLY01 published in Nature Medicine for PD			2025	Jan DD01 Phase 2 patient enrollment completion
	Sep NLY01 US Phase 1 initiation				Apr DD01 Phase 2 12-week treatment completion

### **Key Performance Index**



# Company profile @



# Biotech with feasibility & efficacy confirmed GLP-1 class portfolio



▼ Korea's largest GLP-1 class portfolio

Developing a clinical efficacy-confirmed MASH therapy

**GLP-1** franchise licensed-out to Metsera (oral pipeline)

Clinical developments in the US targeting Global Market

**Targeting large therapeutic markets** 

MASH market to enter a full-fledged growth phase with its first MASH treatment approval

**MASH** 

#### USD 100B USD 108.4B

('23~'30(E) CAGR 60.1%) 2030(E) Global market size

#### T2DM

Gradual expansion of the market due to increase in patient number and emerging new drugs

#### USD 136.2B

('19~'29(E) CAGR 11.5%) 2029(E) Global market size

#### Parkinson's disease

Increase in disease prevalence with aging population with fundamental treatment absent

#### **USD 11.5B**

('19~'29(E) CAGR 12.6%) 2029(E) Global market size

Obesity

Overwhelming patient population

High demand due to

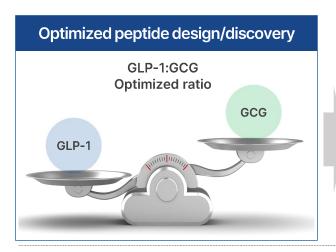
increase in obese population

('23~'30(E) CAGR 49.5%)

2030(E) Global market size



# Optimized ratio of GLP-1:GCG potency + Increased half-life based on PEGylation

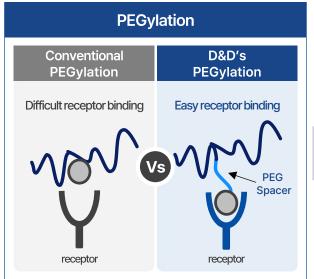


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#### Similarity with survodutide

Company	D&D pharmatech	Boehringer Ingelheim	
Program	DD01	Survodutide	
MoA	GLP-1/GCG	dual agonist	
GLP-1:GCG ratio	11:1	8:1	

• Favorable GLP-1 to GCG potency profile yields enhanced glycemic control



## Differentiated from survodutide

Program	DD01	Survodutide
Long-acting tech.	PEGylation	Lipidation
T <sub>max</sub>	108 hours	24 hours
Half-life	~8 days (~192 hours)	~6 days (~144 hours)
PTR* (Steady state)	1.31	2.28

- Improved safety and tolerability based on increased T<sub>max</sub> and half-life
- \*Peak-to-trough ratio: Lower PTR may <u>reduce adverse events</u>

# MASH Treatment DD01 – Development landscape



# Rapid and effective liver fat reduction: Unprecedented potential as a MASH treatment

Drug	DD01	Survodutide	Efinopegdutide	Pemvidutide	Tirzepatide	Semaglutide	Resmetirom	VK2809
Company	Pa	Boehringer Ingelheim	<b>♦</b> MSD	<b>alt</b> immune	Lilly	novo nordisk <sup>®</sup>	<b>Madrigal</b> Pharmaceuticals	VIKING
Market cap <sup>1</sup>	0.6B	private (Zealand: 5.2B)	209B	0.4B	740B	310B	7B	3.3B
Development phase (MASH)	Phase 2	Phase 2	Phase 2b	Phase 2b	Phase 2	Phase 3	Approved	Phase 2b
Target	GLP-1/GCG	GLP-1/GCG	GLP-1/GCG	GLP-1/GCG	GLP-1/GIP	GLP-1	THR-β	THR-β
Route of administration	Once-weekly (S.C.)	Once-weekly (S.C.)	Once-weekly (S.C.)	Once-weekly (S.C.)	Once-weekly (S.C.)	Once-weekly (S.C.)	Once-daily (P.O.)	Once-daily (P.O.)
Subjects	Overweight/ obesity, T2DM, MASLD	MASH (F1~F3)	MASLD	Obesity, MASLD	MASH (F2~F3)	MASH (F2~F3)	MASH (F2~F3)	MASH (F2~F3)
Treatment duration	4 weeks	48 weeks	24 weeks	24 weeks	52 weeks	72 weeks	52 weeks	12 weeks
Liver fat reduction <sup>2</sup>	<b>-51</b> % (n=9)	-64.3% (n=46)	-72.7% (n=72)	-76.4% (n=11)	-57% (n=48)	-57% <sup>5</sup> (n=34)	-46.6% (n=323)	-55.3% (n=49)
Patients with >30% liver fat reduction <sup>2</sup>	100%	76.9%	81.9%	100%	N/A	73.5% <sup>5</sup>	N/A	87.8%
MASH resolution w/o worsening fibrosis <sup>3</sup>	N/A	47.7% <sup>4</sup> (n=34)	N/A	N/A	52.6% (n=48)	28.8%	20.2% (n=321)	45.7% (n=44)
Fibrosis improvement w/o worsening MASH <sup>3</sup>	N/A	36.6% <sup>4</sup> (n=34)	N/A	N/A	21.3% (n=48)	14.5%	11.7% (n=321)	22.7% (n=44)

Note 1: Market cap as of March 3, 2025, 1 USD = 1,400 KRW

Note 2: Confirmed through MRI-PDFF images. To compare liver fat reduction, clinical trials with MRI-PDFF results were referenced. Results compared to baseline.

Note 3: Placebo adjusted results

Note 4: Results from F2-F3 patients

Note 5: P2 results are shown (NCT02970942, 0.4 mg QD). Semaglutide MASH P3 data not publicly available.

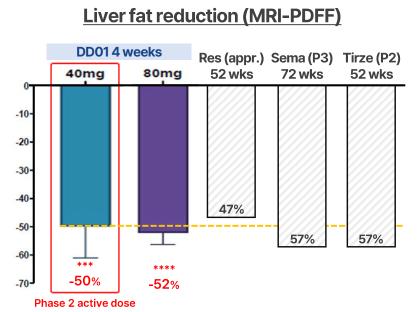
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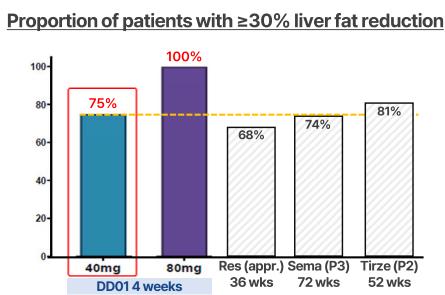


# Robust liver fat reduction observed at Week 4 in Phase 1, supporting a positive outlook for the Phase 2 primary endpoint at Week 12

# DD01 Phase 1 efficacy results

Retrieved from ADA2023 and EASL2023 posters





- DD01 Phase 1 participants: patients included
  - ✓ Confirmed <u>superior/comparable liver fat reduction efficacy</u> after 4 weeks of treatment
  - ✓ Achieved 75% in proportion of patients with ≥30% liver fat reduction in Phase 1 (4 weeks), which is the primary endpoint of Phase 2 (confirmed within a relatively short treatment period)
    - ➤ <u>High likelihood of achieving Phase 2 primary endpoint with a longer treatment duration (12 weeks) and a larger patient population compared to the successful Phase 1 trial</u>



# Primary endpoint at week 12; FDA approval criteria to be confirmed at week 48 Short titration (2 weeks) followed by a longer treatment period at the target dose (40mg)

## Study design (NCT06410924)

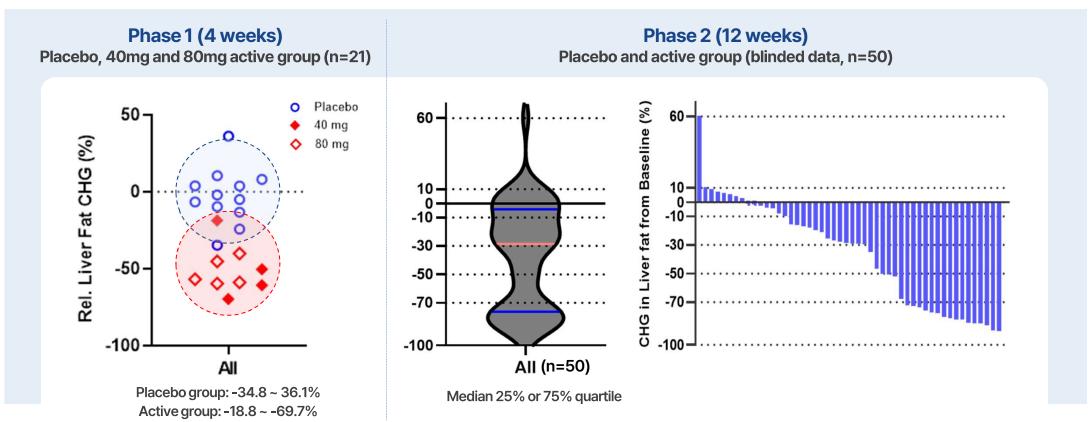
Objective	To evaluate the efficacy of DD01 in patients with MASLD/MASH compared to placebo (N=67)			
Primary endpoint	MRI-PDFF at week 12 (proportion of patients achieving more than 30% liver fat reduction)			
Secondary and explanatory endpoints	<ul> <li>Liver fat reduction at week 12 and week 48</li> <li>Biopsy at week 48 (MASH resolution, Fibrosis improvement)</li> </ul>			
Additional study design	Randomized, double-blind, placebo-controlled, once weekly S.C. administration for 48 weeks  Dose Titration: 40 mg (2-week titration with 20mg, 46-week therapeutic dose with 40 mg)  Study period  Week 1-24  Week 25-48  DD01  2-week titration followed by 46-week at target dose  Survodutide  24-week titration followed by 24-week at target dose			



MRI-PDFF in 50 patients who have completed 12-week treatment (as of end of MAR 2025)

More than 30% of the participants have shown ≥70% liver fat reduction

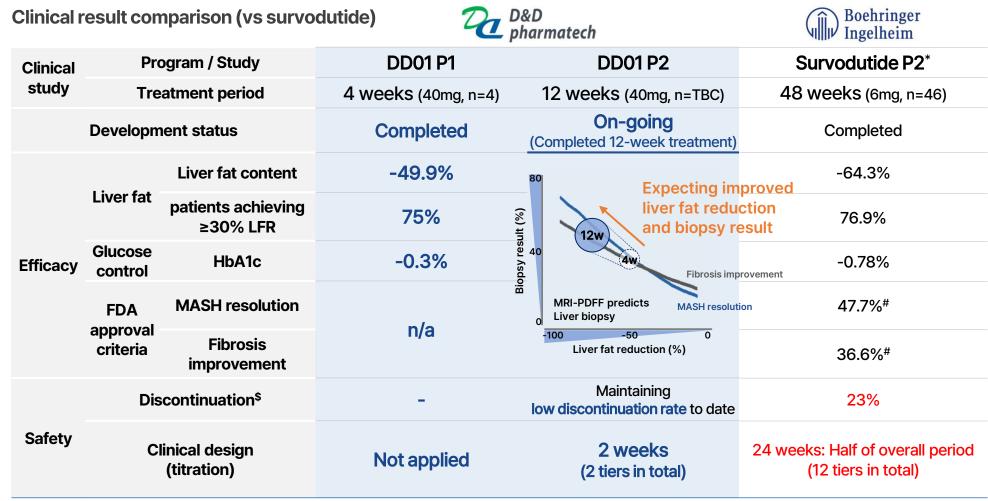
# DD01 Phase 1 & Phase 2 Liver fat reduction profile



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# Superior/comparable efficacy and safety profile compared to the competitor are expected



<sup>\*</sup>Actual treatment (All)

<sup>#</sup>F2-F3 patients, same criteria as the participants targeted for FDA approval, placebo-adjusted (n=34)

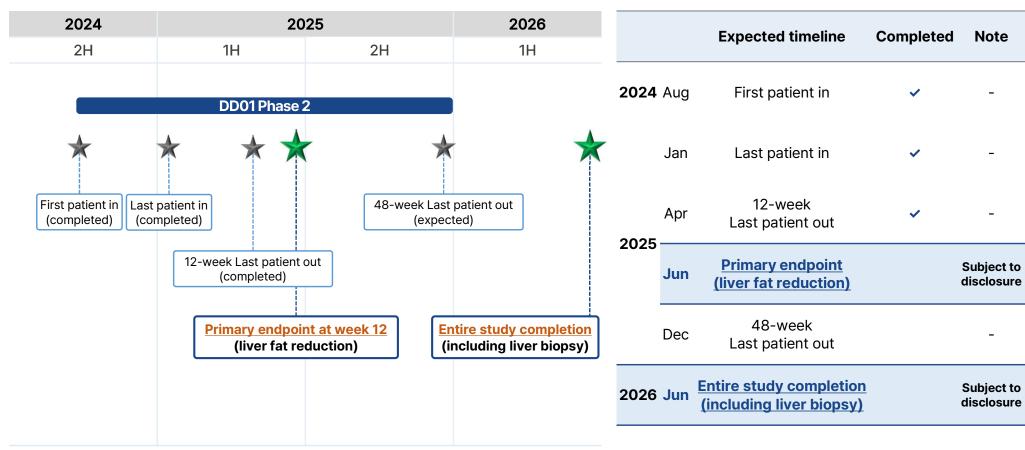
<sup>\$</sup>Discontinuation rate in subjects meeting the same eligibility criteria as in DD01 Phase 2



# All patients completed 12-week treatment and underwent MRI-PDFF in April 2025 Topline data to be unveiled in June 2025

#### Phase 2 expected timeline

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# D&D pharmatech

# **Obesity treatment - Partner's (Metsera's) clinical pipeline**

Metsera has secured more than \$800M within 2 years since its founding, including IPO Oral program in clinical stage in-licensed from D&D; additional products to follow

#### **Clinical pipeline (Metsera)**

#### STRATEGY **PROGRAM** DISCOVERY IND / CTA-PHASE I PHASE 2 ANTICIPATED **ENABLING MILESTONES** Target / Mechanism **FULLY BIASED,** MET-097i Phase 2b weekly preliminary readout mid MONTHLY Fully Biased GLP-1 RA 2025. Phase 2b monthly preliminary Phase 2b ongoing GLP-I RA readout year end 2025 / early 2026. **AMYLIN** MET-233i Phase 1 preliminary readout mid 2025 AGONISM + Amylin Analog Phase 1 ongoing GLP-I RA MET-233i + MET-097i Phase 1 preliminary readout late 2025, if Amylin Analog + Fully Biased sufficient safety has been established in GLP-1 RA MET-233i Phase 1 and if successful in initiating Phase 1 **ORAL PEPTIDE** MET-224, / MET-097, Phase 1/2 preliminary readout late 2025. IND-enabling **PLATFORM** Fully Biased GLP-1 RA after completion of IND-enabling studies (MOMENTUM) and if successful in initiating study studies ongoing MET-002 GLP-1 RA Phase 1 ongoing Phase 1 preliminary readout late 2025 if **NEXT-GENERATION** MET-034i IND-enabling **COMBINATIONS** GIP RA successful in initiating study studies ongoing MET-067i IND-enabling Glucagon Analog studies ongoing

Oral pipeline (disclosed)

# Metsera's oral NuSH pipeline

0	MET-002 <sub>o</sub>
-	Prototype MOMENTUM peptide







MET-GGG<sub>o</sub>
HALO-lipidated triple agonist

# **Obesity treatment – License deal overview**



# All oral pipeline and a triple agonist in-licensed from D&D Simultaneous development of multiple products fueled by substantial funding

• GLP-1 agonist

#### Injectable

#### MET-097i MET-233i • GLP-1 agonist · Applied Metsera's long- Amylin agonist acting tech.; HALOTM HALO<sup>TM</sup> applied (Half-life 380 hrs: longest For combination therapy among existing products) (GLP-1 + Amylin) • 11.3% WL in 12 weeks Phase 1 on-going (Phase 2a) • Phase 2b on-going

#### Oral

MET-002o	MET-224o	MET-097o	MET-AMYo
GLP-1 agonist Prototype for ORALINK evaluation and formulation optimization Phase 1 on- going  Optimized formulation to be applied	<ul> <li>GLP-1 agonist</li> <li>HALO<sup>TM</sup>applied (Comparable half-life to MET-097i)</li> <li>To apply optimal formulation studied from MET-002o</li> <li>IND enabling</li> <li>Preliminary efficacy result within 2025</li> </ul>	<ul> <li>GLP-1 agonist</li> <li>Oral MET-097i</li> <li>IND enabling</li> <li>Preliminary efficacy result within 2025</li> </ul>	<ul> <li>Amylin</li> <li>HALO<sup>TM</sup> applied</li> <li>Preclinical</li> </ul>

# Mullti-agonist

Mono-agonist

Triple agonist (DD15)	MET-097i Combo
<ul> <li>GLP-1/GCG/GIP triple agonist</li> <li>Development status undisclosed</li> </ul>	Combination therapy with MET-097i GIP (MET-034i) GCG (MET-067i)

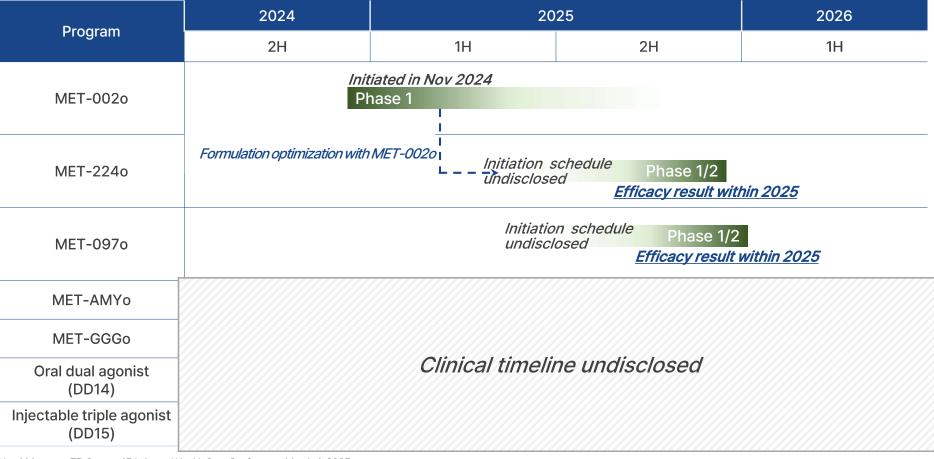
MET-GGGo	Dual agonist (DD14)
<ul> <li>GLP-1/GCG/GIP triple agonist</li> <li>HALO™ applied</li> <li>Preclinical</li> </ul>	GLP-1/GIP dual agonist     Development status undisclosed



# MET-002o formulation study on-going; MET-224o/MET-097o efficacy readout expected within 2025

#### **Expected timeline**

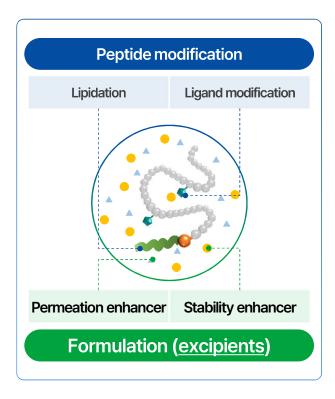
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Multiple excipients required to enhance oral peptide absorption Safety and scalability are critical criteria for commercialization

# Oral peptide technology (ORALINK)



## **Key considerations**

# Safety of excipients

 Safety study is required for excipients used in oral peptide technologies

# **Scalability**

 Scalability for commercial manufacturing must be validated

#### **ORALINK** evaluation

- ✓ Active licensing deal with partner (Metsera) → Completed feasibility evaluation
- ✓ Confirmed safety through Phase 1 and GLP toxicity studies
- ✓ No specialized or dedicated manufacturing facilities required
- ✓ <u>Reduced CoGS</u> based on improved oral bioavailability



# DD01 Phase 2 topline data to be available by June 2025 MET-224o/MET-097o weight loss effect to be confirmed within 2025 (by Metsera)

#### Major catalyst events (2025-1H26)

	Mid 2025	End 2025	Mid 2026
MASH Treatment (DD01)	<ul> <li>✓ Phase 2 primary         endpoint results         (Liver fat reduction at week 12)</li> </ul>	<ul> <li>Phase 2 last patient out (n=67)</li> <li>Licensing deal to be pursued based on primary endpoint results</li> </ul>	<ul> <li>✓ <u>Biopsy results at week</u></li> <li><u>48 (including FDA</u></li> <li><u>approval criteria)</u></li> </ul>
Obesity Treatment (with Metsera)	✓ MET-224o phase 1 initiation (expected)	✓ MET-224o/MET-097o weight loss effect	✓ IND ready for additional programs