

Subject: MTSR1: Weekly Competitive Intelligence Newsletter (May 7 - 13, 2024)
Date: Monday, May 13, 2024 at 7:03:06 AM Eastern Daylight Time
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Hi Metsera Team,

Please find below the weekly 'Competitive Intelligence Newsletter' for the week: May 7 - May 13, 2024

DASHBOARD	
KEY TAKEAWAYS OF THE WEEK (May 7 - 13, 2024)	
<ul style="list-style-type: none"> • Clinical – BioRestorative Therapies announced development of a novel exosome-based biologic program targeting obesity [U.S.] • Regulatory – Eli Lilly Japan has submitted an application for approval of tirzepatide for the treatment of obesity to the regulatory authorities [Japan] • Commercial – Metaphore Biotechnologies and Flagship pioneering announced research collaboration with Novo Nordisk to develop next-generation therapeutics for obesity management [U.S.] • Commercial – Cipla is open to partnering with U.S. Eli Lilly to market its blockbuster obesity treatment drugs in India [India] 	
DETAILED NEWS	
CLINICAL	
1	BioRestorative Therapies enhances preclinical metabolic program with a novel exosome-based biologic targeting obesity [U.S.] <i>May 8, 2024</i> <ul style="list-style-type: none"> • BioRestorative Therapies announced the development of a novel exosome-based biologic program targeting obesity • BioRestorative currently anticipates initiating the formal U.S. FDA process for this ThermoStem-based therapeutic candidate by filing a Drug Master File in Q3 2024 <ul style="list-style-type: none"> ◦ The company aims to initiate first-in-human clinical studies before the end of 2024 • BioRestorative's ThermoStem platform has a comprehensive portfolio of issued patents that cover both the U.S. and international markets • Metabolic Program (ThermoStem): <ul style="list-style-type: none"> ◦ The company is developing cell-based therapy candidates to target obesity and metabolic disorders using brown adipose (fat) derived stem cells (BADSC) to generate brown adipose tissue (BAT), as well as exosomes secreted by BADSC ◦ BAT is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. Initial preclinical research indicates that increased amounts of brown fat in animals may be responsible for additional caloric burning as well as reduced glucose and lipid levels ◦ Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes ◦ BADSC secreted exosomes may also impact weight loss
	<ul style="list-style-type: none"> • Read more: Biospace, BioRestorative Therapies Press Release
	<ul style="list-style-type: none"> • Implications: The use of brown adipose-derived stem cells (BADSC) to generate brown adipose tissue (BAT) is a novel approach for targeting obesity. Cell-based therapies are likely to be confined to a niche market, primarily because these treatments are more challenging to scale and distribute widely compared to traditional pharmacological approaches
2	Trial Update: Research study looking at how well semaglutide tablets taken once daily work in people who have a body weight above the healthy range (OASIS 4) [U.S., Canada, Germany, Poland] <i>May 7, 2024</i> <ul style="list-style-type: none"> • A Phase III trial sponsored by Novo Nordisk titled, "Research study looking at how well semaglutide tablets taken once daily work in people who have a body weight above the healthy range (OASIS 4)" has undergone following changes <ul style="list-style-type: none"> ◦ PCD: Updated from Mar 25, 2024 [Anticipated] to Apr 11, 2025 [Actual]
	<ul style="list-style-type: none"> • Read more: NCT05564117

- **Implications:** This trial could lead to a broader application of semaglutide for weight management, offering a new daily oral treatment option that could be more appealing than injectable forms currently available. The update of the PCD from March 25, 2024, to April 11, 2025, indicates a significant delay in the timeline

3 **Trial Update: A 16-week study to evaluate the efficacy, safety, and tolerability of GLY-200 in participants with obesity [U.S.]** May 7, 2024

- A [Phase II](#) trial sponsored by Glyscend titled, “A 16-week study to evaluate the efficacy, safety, and tolerability of GLY-200 in participants with obesity” has undergone following changes
 - **Overall Status:** Updated from ‘Not yet recruiting’ to ‘Recruiting’
 - **Study Start Date:** Updated from ‘Mar 2024’ to ‘May 2024’

- **Read more:** [NCT06259981](#)

- **Implications:** N/A

4 **Lexaria begins dosing of its second GLP-1 human pilot study [Canada]** May 8, 2024

- Lexaria Bioscience announced that human pilot study #2, GLP-1-H24-2, is underway and the first dosing visit for all nine study participants has concluded
- The study is a three-arm, crossover investigation that will compare three 7 mg semaglutide dose formulations:
 - A positive control RYBELSUS swallowed tablet (already dosed)
 - DehydraTECH-semaglutide swallowed capsules
 - And for the first time ever, an in-mouth dissolvable DehydraTECH-semaglutide oral tablet
- The second DehydraTECH study arm will use a RYBELSUS composition processed with DehydraTECH that is compliant with the U.S. FDA's Inactive Ingredient Database (FDA IID) delivered within swallowed capsules
 - The dosing interval for this study arm is currently anticipated to complete during mid-Jun, after the necessary wash-out period for the study participants from the first Study arm
- The acidic environment of the stomach seriously degrades GLP-1 drugs that are swallowed, resulting in exceptionally low blood absorption rates of less than 1% when an absorption technology is not used
 - For this reason, Lexaria's final DehydraTECH Study arm will investigate an oral dissolvable tablet formulation, also compliant with the U.S. FDA IID, with DehydraTECH powered semaglutide from RYBELSUS
 - This will be the first study designed to investigate whether DehydraTECH-enhanced semaglutide can absorb at any level systemically into the sublingual/buccal tissues of the mouth and throat with fewer side effects than from swallowed administration, and with some effective drug delivery into the bloodstream

- **Read more:** [Lexaria Bioscience Press Release](#)

- **Implications:** N/A

REGULATORY

5 **Eli Lilly notification of new drug application for tirzepatide for obesity and distribution collaboration in Japan [Japan]** May 8, 2024

- Eli Lilly Japan and Mitsubishi Tanabe Pharma Corporation announced that Eli Lilly Japan has submitted an application for approval of tirzepatide for the treatment of obesity to the regulatory authorities
 - The two companies will enter into a sales collaboration in Japan
 - Based on the sales collaboration agreement between the two companies, Eli Lilly Japan will obtain manufacturing and sales approval for this drug, as with MOUNJARO (tirzepatide) SC Injection
- Mitsubishi Tanabe Pharma will distribute and sell the drug after approval
- The two companies will jointly provide information to medical professionals

- **Read more:** [Eli Lilly Press Release](#) (Translated from Japanese)

- **Implications:** N/A

COMMERCIAL

6 **Flagship pioneering and Metaphore Biotechnologies announce research collaboration with Novo Nordisk to develop next-generation therapeutics for obesity management [U.S.]** May 9, 2024

- Metaphore Biotechnologies, a Flagship-founded biotechnology company joined Flagship Pioneering in announcing a research collaboration with Novo Nordisk to develop up to two next-generation therapeutics for obesity management
 - The collaboration was signed under the broader [strategic partnership](#) between Novo Nordisk and Flagship Pioneering to develop a portfolio of novel treatment approaches for cardiometabolic and rare diseases
- Pioneering Medicines, Flagship's in-house drug development and partnerships unit, is responsible for leading the broader partnership together with Novo Nordisk's Bio Innovation Hub, an R&D unit designed to accelerate the development of therapeutics via co-creation partnerships
 - Metaphore will work jointly with Pioneering Medicines and Novo Nordisk to advance the programs through foundational activities and preclinical development, after which point Novo Nordisk could advance the programs into clinical studies
- The collaboration announced will leverage Metaphore's MIMIC platform with the goal to design multitarget therapeutics targeting the GLP-1 receptor and related biology, with the aim to create scalable, long-acting agents that will require infrequent dosing
 - Metaphore is the third Flagship-founded company to advance research programs under the strategic partnership between Novo Nordisk and Flagship Pioneering following programs with Omega Therapeutics and Cellarity which were [announced](#) earlier this year

- Under the terms of the agreement, Novo Nordisk may pay up to \$600 Mn in upfront, development, and commercial milestone payments, as well as tiered royalties on annual net sales of licensed products, to be shared between Metaphore and Pioneering Medicines. Novo Nordisk will also reimburse R&D costs and participate in a future financing round for Metaphore

• **Read more:** [Flagship Pioneering Press Release](#), [Endpoints News](#) (*Subscription required*)

- **Implications:** This collaboration is part of a broader strategic partnership focusing on cardiometabolic and rare diseases, highlighting a significant expansion of Novo Nordisk's portfolio into these areas

7 Biocon Limited signs semi-exclusive distribution and supply deal for the commercialization of generic SAXENDA (Liraglutide) in Mexico with Medix [Mexico]

May 13, 2024

- Biocon announced the signing of a semi-exclusive distribution and supply agreement with Medix, for the commercialization of its vertically integrated drug product, gSAXENDA (liraglutide), used in the treatment of chronic weight management
 - Under the terms of the agreement, Biocon will undertake the responsibility of obtaining regulatory approval, manufacturing and supply of the drug product, and Medix will be responsible for its commercialization in the Mexican market
 - Medix has been working for more than 70 years in developing solutions to address the overweight and obesity burden in a country where 70% of the population are dealing with the disease, to improve their quality of life

• **Read more:** [Biocon Press Release](#)

- **Implications:** N/A

8 India's Cipla open to partnering with Eli Lilly to market their obesity drugs, CEO says [India]

May 10, 2024

- Umang Vohra, CEO, Cipla has confirmed that Cipla is open to partnering with U.S. Eli Lilly to market its blockbuster obesity treatment drugs in India
- Global demand has outpaced supply for Eli Lilly's MOUNJARO (tirzepatide) and ZEPBOUND (tirzepatide) as well as their rival Novo Nordisk's opens new tab WEGOVY (semaglutide) and OZEMPIC (semaglutide)
- Sensing the market opportunity, Indian drugmakers, including Cipla, are working to develop their copycat versions of the weight-loss drugs to aggressively grab a larger share in the market in the world's most populous country
- Eli Lilly [expects](#) to launch MOUNJARO in India as early as next year

• **Read more:** [Reuters](#), [The Economic Times](#)

- **Implications:** N/A

MISCELLANEOUS

9 Noom adds Muscle Defense to its GLP-1 companion program to help prevent muscle-mass loss while taking GLP-1s [U.S.]

May 9, 2024

- Noom launched Noom Move, an on-demand fitness offering, including Muscle Defense, a curated movement program for those taking GLP-1 medications
- In a cutting-edge collaboration with FitOn, the move directly integrates FitOn's extensive library of fitness programming into the Noom app, making exercise available to all Noom members as they build healthy habits
- Noom Move enhances Noom's holistic approach to wellness by offering an array of on-demand workouts designed for individuals at any fitness level
 - Noom members can now enjoy unlimited access to a wide range of classes, including yoga, HIIT, strength training, Pilates, and much more, all led by some of the most sought-after trainers in the fitness industry

• **Read more:** [GlobeNewswire](#)

- **Implications:** N/A

10 Novo asks for more time to answer Sanders on OZEMPIC's price [U.S.]

May 8, 2024

- Novo Nordisk is asking for more time to answer questions from the U.S. Senator Bernie Sanders on the prices of OZEMPIC (semaglutide) and WEGOVY (semaglutide)
- A spokesperson from Novo Nordisk in an email response to questions stated that, "We plan to respond to the latest inquiry in a timely manner; however given the tight turnaround requested, we will need additional time to develop our response"
 - Sanders had set a deadline of May 8, 2024 for Novo Nordisk to respond to a series of questions on the medications' cost and manufacturing
 - Sanders doesn't support broad Medicare coverage of drugs for weight loss at their current prices because of their potential budget impact on the U.S. health program for seniors
- In a [letter](#) dated April 24, 2024, Sanders said his committee was undertaking an investigation into "the outrageously high prices" that the company charges for its drugs in the U.S
- According to Sanders, the cost of OZEMPIC, listed in the U.S. for \$968.52 for a month's supply of weekly injections is "totally absurd"
- The company has been in communication with Sanders' staff, including organizing a recent phone call with Chief Executive Officer Lars Fruergaard Jørgensen
- Sanders' inquiry came after a [study published](#) in *JAMA Network Open* that found a month's supply of OZEMPIC could be profitably made for less than \$5

- **Read more:** [Bloomberg](#)

- **Implications:** The interaction highlights the increasing scrutiny and pressure pharmaceutical companies face regarding drug pricing, particularly from political figures

11 The Vitamin Shoppe launches holistic telehealth service featuring GLP-1 medications, including OZEMPIC, MOUNJARO, and low-cost semaglutide and tirzepatide options [U.S.]

May 8, 2024

- The Vitamin Shoppe announced the launch of Whole Health Rx by The Vitamin Shoppe, an innovative telehealth service that offers a holistic approach to health solutions, encompassing prescription medications, nutritional supplements for whole-body health, and expert guidance on lifestyle practices to support lifelong wellness
- Whole Health Rx is initially launching with a focus on weight-management solutions, offering virtual, streamlined access to GLP-1 agonist medications, including OZEMPIC (semaglutide), MOUNJARO (tirzepatide), RYBELSUS (semaglutide), and compounded versions of semaglutide and tirzepatide, via licensed medical providers
 - These telehealth services are offered alongside The Vitamin Shoppe's industry-leading education resources, as well as nutritionist-recommended supplements to help optimize the weight loss journey for healthy results
- Whole Health Rx enables access to a virtual care platform, powered by WellSync, that safely and seamlessly connects patients with licensed healthcare providers in real time. This innovative service delivers a high standard of personalized care and prescription medications, with lower costs and greater convenience for patients

- **Read more:** [PR Newswire](#)

- **Implications:** N/A

12 Altimmune faces securities class action lawsuit over misleading statements and potential partnership [U.S.]

May 7, 2024

- Altimmune is facing a securities class action lawsuit filed in the U.S. District Court for the District of Maryland. The lawsuit alleges that Altimmune made materially false and misleading statements about its business, operations, and prospects between Dec 1, 2023, and Apr 26, 2024
- According to the complaint, Altimmune overstated the potential of its drug, pemvidutide, to outperform competing GLP-1 agonists based on efficacy and tolerability results from the [MOMENTUM Trial](#)
 - The lawsuit claims that the trial results were not as significant as the company led investors to believe and that Altimmune had exaggerated its chances of finding a strategic partner to develop pemvidutide. As a result, the company's public statements were allegedly misleading
- The litigation also references a report by Kerrisdale Capital, which stated that Altimmune's drug had little chance of competing with existing GLP-1 agonists
 - The report highlighted the superior weight-loss and blood-sugar control benefits of other drugs in comparison to pemvidutide, while also raising concerns about the drug's tolerability
 - The Kerrisdale Report cast doubt on the prospect of prospective partners investing in Altimmune's drug

- **Read more:** [Bit Perfect](#), [GlobeNewswire](#)

- **Implications:** The credibility of Altimmune in the pharmaceutical industry may be compromised, especially concerning its transparency and reliability in reporting trial results. This could affect its ability to forge new partnerships and might deter potential collaborators

13 Together by Renee launches innovative find my meds feature to ensure continuous access to essential GLP-1 and other medications [U.S.]

May 7, 2024

- [Together by Renee](#) announced the launch of a groundbreaking new feature in its platform: Find My Meds
 - This innovative feature is designed to tackle the widespread issue of GLP-1 medication shortages, which affects millions of users nationwide who rely on these drugs for managing diabetes and weight loss
- The introduction of Find My Meds closely follows the ranking of Together by Renee as No. 10 in the wellness and personal care category on [Fast Company's 2024 Most Innovative Companies list](#)
- Together by Renee is available for free for Apple smartphones on the Apple App Store and for Android smartphones on the Google Play Store

- **Read more:** [Businesswire](#)

- **Implications:** N/A

14 Rise in Demand for Novo Nordisk's anti-obesity drug RYBELSUS doubled its sales in India [India]

May 9, 2024

- The oral drug RYBELSUS (semaglutide), developed by Novo Nordisk for diabetes and weight loss, is experiencing heightened sales growth in India. The company has reportedly observed a more than tenfold increase in sales of this drug over two years, from \$2.8 Mn in 2022 to \$43.5 Mn in 2024
- A major contributor to this surge is the expansion of the anti-obesity market in India, growing at a compound annual rate of 32% over the past five years
- Reportedly, RYBELSUS holds around 66% of the market share in the anti-obesity segment
 - The popularity of RYBELSUS seems linked to this rising health concern

- **Read more:** [Navin Daily](#)

- **Implications:** N/A

KEY UPCOMING EVENTS

Q1 2024 Earnings Call:

- **Zealand Pharma:** May 16, 2024 ([Zealand Pharma Investor update](#))

GLP-1-Based Therapeutics Summit:

- **Altimune:** May 15, 2024 ([Altimune Investor update](#))
- **Veru:** May 16, 2024 ([Veru Investor update](#))

Thank you,
Ben

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