**Subject:** MTSR1: Weekly Competitive Intelligence Newsletter (May 21 - 27, 2024)
**Date:** Monday, May 27, 2024 at 11:10:18 AM Eastern Daylight Time
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**Attachments:** image002.png



Hi Metsera Team,

Please find below the weekly 'Competitive Intelligence Newsletter' for the week: May 21 - May 27, 2024

# COMPETITIVE INTELLIGENCE NEWSLETTER

DASHBOARD

## KEY TAKEAWAYS OF THE WEEK (May 21 - 27, 2024)

- **Clinical –** Zealand Pharma announced topline results from the DREAM trial (Dapiglutide for the Treatment of Obesity), to evaluate the potential for weight loss and to gain key mechanistic insights into the effects of low doses of GLP-1/GLP-2 receptor dual agonist dapiglutide following a 12-week treatment period [Global]
- **Regulatory –** Australia to ban replicas of OZEMPIC (semaglutide) and MOUNJARO (tirzepatide) in a move set to slash their availability and disrupt the businesses capitalizing on ballooning demand [Australia]
- **Commercial –** Biocon announced the signing of an exclusive licensing and supply agreement with Handok for the commercialization of its vertically integrated, complex drug product, Synthetic Liraglutide [South Korea]

## DETAILED NEWS

### CLINICAL

**1 Zealand Pharma announces topline results from the mechanistic investigator-led DREAM trial with low doses of GLP-1/GLP-2 receptor dual agonist dapiglutide [Global]**

*May 23, 2024*

- Zealand Pharma announced topline results from the DREAM trial (Dapiglutide for the Treatment of Obesity), the investigator-led clinical trial designed to evaluate the potential for weight loss and to gain key mechanistic insights into the effects of low doses of GLP-1/GLP-2 receptor dual agonist dapiglutide following a 12-week treatment period
  - No lifestyle interventions, such as diet or exercise, were part of the trial
- Treatment with dapiglutide at doses of 4 mg and 6 mg resulted in an observed numerical mean weight loss change from baseline of 2.9% (p=0.483) and 4.3% (p=0.077) after 12 weeks, respectively, vs. 2.2% with placebo (primary endpoint)
- Dapiglutide is currently in an ongoing 13-week Phase Ib dose-titration trial evaluating higher doses of dapiglutide up to 13 mg, and based on the tolerability profile observed to date, Zealand will seek to investigate even higher doses going forward
  - The company expect topline results from our Phase Ib trial in H2 2024
- Dapiglutide was assessed to be safe and well-tolerated in the DREAM trial
  - The most common treatment-emergent adverse events were related to the gastrointestinal system, including reduced appetite and nausea
  - Overall, the number of events observed were lower than have been reported from studies of other incretin-based therapies, and none led to treatment discontinuation in this trial
- Additional detailed results on cardiovascular risk, systemic inflammatory markers, as well as data from gut biopsies, will be presented at a future scientific meeting

- **Read more:** Zealand Pharma Press Release

- **Implications:** While the efficacy at lower doses is less than some existing therapies, dapiglutide's safety profile appears favorable at those doses. The detailed future results regarding cardiovascular risks and inflammatory markers will be important for fully understanding dapiglutide's clinical positioning and potential advantages over other options

**2 Scholar Rock announces initiation of Phase II EMBRAZE trial of apitegromab in obesity and new preclinical data supporting SRK-439 (undisclosed) in obesity [U.S.]**

*May 22, 2024*

- Scholar Rock announced the initiation of the Phase II EMBRAZE (*trial not available on ct.gov*) proof-of-concept trial, designed to

assess the safety and efficacy of apitegromab, a highly selective myostatin inhibitor, to preserve lean muscle mass in individuals living with obesity and on background therapy of a GLP-1 receptor agonist
- The results from this trial will inform the development of SRK-439 (undisclosed), a novel investigational selective myostatin inhibitor optimized for the treatment of cardiometabolic disorders, including obesity
- The company also announced new preclinical data from a head-to-head comparison of SRK-439 and an anti-activin receptor II (anti-ActRII) antibody, which demonstrate SRK-439's potential as best in class in preserving lean mass in patients on GLP-1 receptor agonists
  - For the head-to-head preclinical research study, the company generated and tested an anti-ActRII antibody (a murine equivalent of bimagrumab), along with a murine equivalent of SRK-439 in a weight-stable diet induced obesity (DIO) mouse model
- Lean mass differences were significant in all doses of SRK-439 tested, supporting the hypothesis that SRK-439 could be an important therapy to aid in lean mass preservation and is suitable for subcutaneous dosing in a population of adults with obesity

- **Read more:** Scholar Rock Press Release

- **Implications:** Apitegromab, being a highly selective myostatin inhibitor, aims to preserve or even enhance muscle mass in obese individuals, which could differentiate it from other treatments and address an unmet need within this population

**3** **Trial Update: A study of tirzepatide in overweight and very overweight participants [U.S.]**
*May 22, 2024*

- A Phase I trial sponsored by Eli Lilly titled, *"A study of tirzepatide in overweight and very overweight participants"* has undergone the following changes:
  - **Arms and Interventions:** Multiple updates
  - **Outcome Measures:** Multiple updates
  - **Study Results:** Newly posted

- **Read more:** NCT04311411

- **Implications:** N/A

**4** **Trial Update: A study of LY3841136 compared with placebo in adult participants with obesity or overweight [U.S.]**
*May 21, 2024*

- A Phase II trial sponsored by Eli Lilly titled, *"A study of LY3841136 compared with placebo in adult participants with obesity or overweight"* has undergone the following changes:
  - **PCD:** Updated from June 27, 2025 [Anticipated] to June 2025 [Anticipated]
  - **SCD:** Updated from September 5, 2025 [Anticipated] to September 2025 [Anticipated]
  - **Number of Arms:** Updated from 6 to 7
  - **Enrollment:** Updated from 225 to 250 [Anticipated]

- **Read more:** NCT06230523

- **Implications:** N/A

**5** **Trial Update: A 16-week study to evaluate the efficacy, safety, and tolerability of GLY-200 in participants with obesity [U.S.]**
*May 21, 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
  - **SSD:** Updated from May 2024 to May 20, 2024

- **Read more:** NCT06259981

- **Implications:** N/A

**6** **Fractyl Health presents compelling preclinical data from single-administration GLP-1 pancreatic gene therapy Rejuva at Digestive Disease Week 2024 [U.S.]**
*May 20, 2024*

- Fractyl Health presented new data from its preclinical Rejuva pancreatic gene therapy program as part of an oral presentation (abstract number 4029196) on May 19, 2024, at Digestive Disease Week (DDW) 2024 in Washington, D.C.
- In the presentation titled *"Single-Dose GLP-1-Based Pancreatic Gene Therapy Maintains Weight Loss After Semaglutide Withdrawal and Reduces Hepatic Triglycerides in a Murine Model of Obesity,"* data showed that Rejuva reduced liver weight by 42% ($p<0.01$) and liver triglyceride content by 67% ($p<0.0001$) vs. placebo two months after administration
  - Data also showed a reduction of 36% in total cholesterol and 51% in LDL cholesterol compared to placebo two months after administration (both, $p<0.0001$)
  - These results indicate the potential impact of this GLP-1 PGTx candidate to alleviate cardiovascular risk associated with increased levels of cholesterol
- Fractyl plans to nominate its first GLP-1 PGTx candidate for obesity in H2 2024 and is eager to explore potential effects on MASLD/MASH
- Rejuva is the company's modular, physiologic gene therapy platform with three key elements designed to enable successful pancreatic gene therapy:
  - A proprietary delivery catheter designed to enable local, low-dose, therapeutic delivery directly to the pancreas via endoscopic access
  - Vectors with tropism for the pancreatic islet to enable successful transduction and gene delivery with limited biodistribution
- Transgenes with tissue-restricted promoters and metabolically active peptides that can durably impact glucose and weight control

- **Read more:** Fractyl Health Press Release

- **Implications:** The use of a GLP-1-based pancreatic gene therapy represents a novel approach in obesity management. Unlike traditional pharmacological treatments that require ongoing medication, a single administration of gene therapy could offer long-lasting effects

**7** **Lexaria awards contract for third GLP-1 human pilot study [Canada]**
*May 23, 2024*

- Lexaria Bioscience has hired a contract research organization to perform the company's human pilot study, which will evaluate a dual action GLP-1 (glucagon-like peptide) + GIP (glucose-dependent insulintropic peptide)
- The study will be a randomized, crossover investigation that will compare injected ZEPBOUND (tirzepatide) by Eli Lilly to a compound formulated, DehydraTECH-processed tirzepatide derived from ZEPBOUND and rendered into a capsule to be swallowed
- There are two study arms:
  - DehydraTECH-tirzepatide swallowed capsules
  - Injected ZEPBOUND (tirzepatide) by Eli Lilly
- Tirzepatide is currently available only in its injected form, ZEPBOUND by Eli Lilly is not available in the U.S. FDA approved oral dosage format
  - The study will evaluate whether DehydraTECH-processed tirzepatide, when taken orally, offers any absorption into the human bloodstream and, if so, how much
  - Human tolerability, PKs and blood sugar levels will all be recorded and evaluated in this study
- Manufacturing of the test articles for this study is anticipated to be completed within 30 days. Independent Review Board approval is required before the study can commence, and the company will provide next update when IRB approval has been received

- **Read more:** Lexaria Bioscience Press Release

- **Implications:** The study will assess how well the oral formulation is absorbed into the bloodstream, its pharmacokinetic properties, and its tolerability. These are crucial for determining the viability of the oral capsule as an alternative to the injectable form

**8** **Atrogi announces publication on advancements in combatting obesity and metabolic complications [Sweden]**
*May 24, 2024*

- Atrogi published a study in the *Journal of Molecular Metabolism,* where the research paper validates the mechanism of action of the company's first-in-class, small molecule, ATR-127 (undisclosed), in combating obesity and metabolic complications
- Unlike existing anti-obesity therapies that compromise lean muscle mass, ATR-127 induces significant weight loss while preserving crucial lean body mass
  - ATR-127 binds to both the beta-2 and beta-3 adrenergic receptors in a unique manner, allowing for precise modulation of downstream signaling cascades
- Unlike conventional approaches, ATR-127's innovative binding mechanism enables selective activation of specific signalling pathways
  - This unlocks the full therapeutic potential of beta-2 and beta-3 receptor agonism, maximizing beneficial effects on metabolism and body composition while mitigating the cardiovascular side effects commonly associated with indiscriminate receptor activation
- The study found that ATR-127 enhances energy expenditure and promotes beneficial metabolic changes by inducing skeletal muscle glucose uptake and the concomitant activation of brown and beige adipose tissue
  - This results in healthy weight loss – decreasing fat mass but preserving muscle, whilst reducing hepatic inflammation and lipid content
- ATR-127's ability to deliver precise signalling modulation prevents excessive cAMP production thereby lowering cardiac force production and mitigating risks of cardiovascular side effects

- **Read more:** Atrogi Press Release

- **Implications:** Demonstrating a unique mechanism that preserves lean muscle mass while promoting weight loss could set ATR-127 apart from current market offerings. ATR-127 is still in preclinical stage and results need to be validated in clinical setting. As ATR-127 is still in the preclinical phase, there remains significant uncertainty about its efficacy and safety in humans

## REGULATORY

**9** **Rhythm Pharmaceuticals receives positive recommendation from NICE for IMCIVREE (setmelanotide) for treatment of obesity and hyperphagia in patients with Bardet-Biedl Syndrome [UK]**
*May 22, 2024*

- Rhythm Pharmaceuticals announced UK's NICE has issued guidance that recommends IMCIVREE (setmelanotide) as an option for treating obesity and the control of hunger (hyperphagia) in genetically confirmed Bardet-Biedl syndrome (BBS) in people 6 years of age and over, if they are between 6 and 17 years of age when treatment starts
- Patients may remain on reimbursed setmelanotide as adults whilst they continue to benefit from therapy
- Results from clinical trials suggest that setmelanotide may reduce hyperphagia, weight and body mass index (BMI) in people aged 6 years and over
  - The most common adverse events are skin hyperpigmentation, injection site reactions, nausea and headache
- The final NICE recommendation is aligned to the EMA and MHRA approval
  - With this recommendation under the Highly Specialised Technologies (HST) pathway, IMCIVREE is expected to be funded and available for use within three months in the National Health Service covering England and Wales, and Northern Ireland is expected to adopt NICE guidance

- Rhythm is moving ahead with submission to the Scottish Medicines Consortium with a decision expected in 2025

- **Read more:** Rhythm Pharmaceuticals Press Release

- **Implications:** N/A

**10** **Australia to ban replicas of weight loss drugs OZEMPIC and MOUNJARO [Australia]**
*May 21, 2024*

- Australia will ban replicas of OZEMPIC (semaglutide) and MOUNJARO (tirzepatide) in a move set to slash their availability and disrupt the businesses capitalizing on ballooning demand
- Health Minister Mark Butler's decision will limit access for at least 20,000 Australians who have been buying compounded weight loss injections because they cannot get the branded products during massive global supply shortages
- Butler revealed the new regulations would remove GLP-1 receptor agonists from an exemption list that allows pharmacies to compound them, starting from October 2024
- OZEMPIC is subsidized at $31.60 in Australia for type 2 diabetes but is frequently purchased "off-label" for weight loss at a higher price, starting from $130 a month depending on the dosage
  - MOUNJARO hit Australian shelves in 2023 but is not subsidized by the government
- The federal government said stopping the large-scale manufacture of compounded injections had broad support from the health sector, including general practitioners, the Medical Board of Australia, Diabetes Australia, the Eating Disorders Alliance of Australia and state and territory health departments

- **Read more:** Sydney Morning Herald *(Subscription required)*

- **Implications:** N/A

## COMMERCIAL

**11** **Lilly increases manufacturing investment to $9 Bn at newest Indiana site to boost API production for tirzepatide and pipeline medicines [U.S.]**
*May 24, 2024*

- Eli Lilly has more than doubled its investment in its Lebanon, Indiana, manufacturing site with a new $5.3 Bn commitment, increasing the company's total investment in this site from $3.7 Bn to $9 Bn
- This expansion will enhance Eli Lilly's capacity to manufacture active pharmaceutical ingredients (API) for ZEPBOUND (tirzepatide) injection and MOUNJARO (tirzepatide) injection so that more adults with chronic diseases like obesity and type 2 diabetes may benefit from these important treatments
- New locations outside Indiana include Research Triangle Park and Concord, North Carolina; Limerick, Ireland; and Alzey, Germany
  - Separately, the company has invested an additional $1.2 Bn to update existing manufacturing facilities in Indianapolis and recently acquired an injectable manufacturing facility in Pleasant Prairie, Wisconsin, from Nexus Pharmaceuticals. Together, these manufacturing investments total more than $18 Bn
- As part of this additional investment in the Lebanon site, the company expects to add 200 full-time jobs for highly skilled workers such as engineers, scientists, operating personnel and lab technicians, resulting in an estimated 900 full-time employees when the facility is fully operational. Additionally, there will be more than 5,000 construction jobs during the site's development
- Since breaking ground at its Lebanon manufacturing site in 2023, Eli Lilly has transformed a significant portion of the nearly 600 acres within the complex into an active construction site
  - The company expects to begin making medicines in Lebanon toward the end of 2026 – with operations scaling up through 2028

- **Read more:** Eli Lilly Press Release

- **Implications:** Eli Lilly's strategy includes expanding its manufacturing footprint beyond Indiana, with new facilities in Research Triangle Park and Concord in North Carolina, Limerick in Ireland, and Alzey in Germany. This global expansion will not only diversify the company's manufacturing capabilities but also mitigate risks such as regional disruptions or regulatory changes in any one country

**12** **OZEMPIC craze sweeps Greece with demand for weight-loss drug reaching unprecedented heights [Greece]**
*May 27, 2024*

- According to reports, Greece has witnessed a doubling in the import of OZEMPIC (semaglutide) by Novo Nordisk since 2023
- The surge in demand is not limited to locals; foreigners are also flocking to Greek pharmacies to purchase OZEMPIC from Greece at a lower cost compared to other countries
- Chrysanthi Sardeli, Associate Professor,Aristotle University of Thessaloniki, highlighted the lax enforcement of prescription drug laws in Greece, making it easier for individuals to obtain OZEMPIC without a prescription
- In Greece, one can walk into a pharmacy and pay for OZEMPIC, with or without a prescription. Most pharmacies have it because the current laws on prescription drugs are not fully implemented

- **Read more:** Neos Kosmos

- **Implications:** N/A

**13** **Biocon signs exclusive licensing and supply deal for the commercialization of Liraglutide in South Korea with Handok [South Korea]**
*May 24, 2024*

- Biocon announced the signing of an exclusive licensing and supply agreement with Handok, a specialty pharmaceutical company in South Korea, for the commercialization of its vertically integrated, complex drug product, Synthetic Liraglutide
  - Liraglutide is an injection in pre-filled pen, used in the treatment of chronic weight management as an adjunct to a reduced-calorie diet and increased physical activity
- Under the terms of this agreement Biocon will undertake the development, manufacturing and supply of the drug product, and Handok will be responsible for obtaining regulatory approval and commercialization in the South Korean market
- Handok is amongst Korea's leading companies in the management of diabetes, offering a host of solutions from diagnosis to treatment and care
- The company's diabetic portfolio includes products such as AMARYL (glimepiride), TENELIA (teneligliptin) and the recently launched Barozen Fit, a real time glucose monitoring device

- **Read more:** Biocon Press Release

- **Implications:** N/A

## MISCELLANEOUS

**14** **Laxxon Medical announces development program for non-invasive, 3D printed oral GLP-1 asset, offering an alternative to GLP-1 injections on market [Global]**
*May 23, 2024*

- Laxxon Medical announced the development program for LXM.2, a 3D printed oral GLP-1 receptor agonist for the treatment of adults and pediatric patients 12 years and older with obesity
  - LXM.2 is an enterically coated oral solid tablet consisting of a GLP-1 receptor agonist combined with a permeation enhancer intended to increase bioavailability
  - The addition of the permeation enhancer was made possible using Laxxon Medical's SPID (Screen Printed Innovative Drug) platform technology
- The API in LXM.2 has already been approved by the U.S. FDA for use in adults and pediatric patients 12 years and older with obesity
  - LXM.2 is eligible to be developed using the 505(b)2 pathway
  - The Company has designed a streamlined development program and is targeting an NDA submission in early 2027
- Laxxon is seeking to partner or out-license LXM.2

- **Read more:** Laxxon Medical Press Release

- **Implications:** Oral drug delivery platform that could be also used for GLP-1/obesity applications

**15** **Twin Health announces digital Twin AI for sustainable weight loss with GLP-1 elimination [Global]**
*May 22, 2024*

- Twin Health announced it is extending its whole body digital twin AI platform, proven to help members achieve remission of type 2 diabetes and eliminate medications, to address the challenge of obesity and weight loss
- Twin's Healthy Weight solution combines digital twin AI and compassionate clinical care to help members achieve a healthy weight that they can sustain without medication
- The program, offered through employers and health plans, is funded by savings from reduced reliance on GLP-1s and other costly health interventions
- Twin's Healthy Weight solution is being deployed at innovative employers including Applegreen, Bayview and Dayforce. It also enables people to maintain weight loss after stopping GLP-1 use
  - Twin's Healthy Weight program is unique in helping people heal themselves through a much deeper understanding of their body's metabolism, and the satisfaction of achieving small, attainable, and meaningful wins throughout the day
  - Members feel the benefits of increased muscle strength, energy, and blood glucose improvement and stabilization
  - The digital twin AI and clinical team provide precise steps to medication elimination, avoidance of rebound weight gain when a drug such as a GLP-1 is eliminated, and continued healthy weight loss and improved strength
- The app provides deeply individualized insights, it may tell a member to keep doing what they're doing, letting them know that they are 14 days away from eliminating one of their medications

- **Read more:** PR Newswire

- **Implications:** N/A

**16** **Novo Nordisk looks beyond weight loss and diabetes to expand in new illnesses [Global]**
*May 21, 2024*

- Novo Nordisk executives laid out ambitions in a handful of conditions, including liver disease, chronic kidney disease and Alzheimer's
  - And it has the assets to grow — in 2023 it reported net profits of 83.7 Bn Danish kroner ($12.2 Bn)
- The company is currently running a Phase III trials for semaglutide, the main ingredient in OZEMPIC and WEGOVY, in Alzheimer's
  - Researchers think reducing inflammation could benefit patients with the neurodegenerative disease, and the trial is expected to read out in 2025
- Semaglutide is also currently in Phase III for NASH, a liver disease also referred to as metabolic dysfunction-associated steatohepatitis (MASH)
- Novo Nordisk has also been grappling with ongoing supply shortages of its GLP-1 drugs
- Novo executives touted manufacturing expansion efforts, including Novo Holdings' $16.5 Bn deal to acquire Catalent, which is

expected to close later in 2024 and would give Novo Nordisk three additional fill-finish sites
- Some pharmacies, medical spas and digital health companies have begun offering compounded versions of semaglutide, which are not approved by the FDA but are allowed in specific circumstances, including when a drug is in short supply
  - Novo Nordisk has launched a legal campaign against what it believes is improper marketing of some compounded formulation

- **Read more:** Endpoints News *(Subscription required)*

- **Implications:** Novo Nordisk is leveraging its resources to expand into new medical fields beyond obesity, with semaglutide central to its strategy, prompting an increase in manufacturing capacity

**17** **Use of WEGOVY and other weight-loss drugs soars among kids and young adults [U.S.]**
*May 24, 2024*

- According to new research published in the *JAMA Network,* the weight-loss drug WEGOVY helped a patient aged 17, shed 110 pounds in nine months, making the rural Tennessee teen part of a surge of adolescents and young adults using diabetes and obesity medications known as GLP-1 receptor agonists
- Even as millions of older adults demand for drugs such as OZEMPIC and WEGOVY, monthly use of the medications soared in people aged 12 to 25. That's according to the new analysis of dispensing records from nearly 94% of U.S. retail pharmacies from 2020 to 2023
- The report, published used the IQVIA prescription database to compile the first look at the national uptake of GLP-1 drugs among that age group
  - Nearly 31,000 children aged 12 to 17 and more than 162,000 people aged 18 to 25 used the medications in 2023 alone

- **Read more:** Health News Florida

- **Implications:** The use of GLP-1 receptor agonists, originally designed for adults with diabetes and obesity, among younger populations highlights a significant shift in the demographic reach of these medications. This could lead to adjustments in how these drugs are marketed, discussed in medical communities, and prescribed by healthcare providers

**18** **Anti-obesity medications: Noteworthy developments as policymakers weigh coverage considerations [U.S.]**
*May 23, 2024*

- The recent U.S. FDA approvals for GLP-1 receptor agonists has ushered in a new era in anti-obesity medication (AOM) policy considerations, raising questions about patient access amid the current coverage landscape, and challenging the status quo when it comes to treating weight loss
- CMS has taken steps to clarify the current Medicare coverage but is working within statutory constraints that go back to the enactment of the Medicare Modernization Act of 2003
- Bipartisan legislation to provide for Medicare coverage of anti-obesity medications has been introduced in both the House and Senate
- The path forward for anti-obesity medication related legislation is complicated by Congressional Budget Office (CBO) scoring implications
- The Federal Trade Commission (FTC) recently included anti-obesity medications in a group of letters sent to pharmaceutical companies challenging various Orange Book-listed patents

- **Read more:** Akin Press Release

- **Implications:** These policy and regulatory developments indicate a growing recognition of obesity as a critical public health issue that requires comprehensive strategies including medication, which historically has been underutilized due to access and coverage limitations

**19** **Hydreight Technologies through its associated Medical network now offer Tirzepatide to product offering which also features GLP-1 Medications (Low-Cost Semaglutide), NAD+ and more [U.S.]**
*May 23, 2024*

- Hydreight Technologies announced that its over 3,000 nurses, 107 white-label locations and their patients now have access to tirzepatide through the Hydreight platform and its associated Medical network in over 700 cities across 50 states in the U.S.
- Semaglutide was also launched and accessible via the Hydreight platform at the end of 2023
- The company's product offering aims to include various products and category options to ensure the customers' needs are met
  - Every time a product is added, nurses must go through extensive training and onboarding to ensure the product is administered safely and correctly
  - All these products allow healthcare providers using the Hydreight platform to provide a higher level of medicine and provide a pathway to shift into medical essentials

- **Read more:** GlobeNewswire

- **Implications:** N/A

**20** **Click Therapeutics accelerates expansion into obesity and cardiometabolic disease with acquisition of the assets of Better Therapeutics [U.S.]**
*May 22, 2024*

- Click Therapeutics announced plans to accelerate its development initiatives in obesity and cardiometabolic disease through the acquisition of the assets of Better Therapeutics
- Click's advancement into obesity and cardiometabolic disease is a culmination of progress over the past few years including the initiation of CT-181, a prescription digital therapeutic candidate for obesity

- In addition, the company has done extensive research with patients, providers, and payers to evaluate the evolving needs in this rapidly growing therapeutic area
- A key focus has been early discovery efforts to identify innovative features, such as smart titration and personalized side effect management, that can meaningfully enhance anti-obesity and cardiometabolic medication outcomes and value

- Integration of Better Therapeutics' intellectual property with Click's development plans for obesity is expected to both accelerate development timelines and yield a best-in-class digital therapy for chronic weight management
  - The resulting digital therapeutic will be optimized for the treatment of obesity in combination with anti-obesity and diabetes medications such as GLP-1s, including current injectables and future oral formulations
  - It will leverage both AspyreRx's clinically-validated digital behavioral therapy, developed over the course of 9 years, and Click's AI-enabled platform, which combines advanced engagement techniques with proprietary digital mechanisms of action to treat disease
- Similar development opportunities in type 2 diabetes, hypertension, hyperlipidemia and MASH will be enabled by the integration of Better's assets with Click's platform

- **Read more:** Click Therapeutics Press Release

- **Implications:** N/A

**21** **Nestle introduced Vital Pursuit brand to support GLP-1 users, consumers focused on weight management [U.S.]**
*May 21, 2024*

- Nestle introduced Vital Pursuit, a new line of foods intended to be a companion for GLP-1 weight loss medication users and consumers focused on weight management
- The products are high in protein, a good source of fiber, contain essential nutrients, and they are portion-aligned to a weight loss medication user's appetite
  - Vital Pursuit is the first food brand from Nestle intended for GLP-1 users with the goal of complementing the eating habits of millions of Americans who are currently prescribed a weight loss medication or actively working to manage their weight
- The emergence of GLP-1 medications is undeniably shaping how Americans approach weight management, and as the world's largest food and beverage company, Nestle is at the forefront of this growing market opportunity
- Vital Pursuit will be available in market by Q4 2024 with 12 SKUs, hitting shelves at select retailers nationwide

- **Read more:** Nestle Press Release

- **Implications:** N/A

**22** **MangoRx to introduce oral semaglutide and tirzepatide in response to increasing patient demand for GLP-1 medications [U.S.]**
*May 21, 2024*

- Mangoceuticals (MangoRx) announced the development of proprietary oral formulations of Semaglutide ("Slim") and Tirzepatide ("Trim") to aid in weight management
- These drugs, currently available predominantly in injectable form, have demonstrated remarkable efficacy in clinical trials
- MangoRx's new oral formulations are poised to revolutionize the weight loss market and capture significant market share
- The GLP-1 receptor agonists' market, including both semaglutide and tirzepatide, is projected to reach over $164 Bn in combined revenue by 2032, based on Visible Alpha consensus, ramping up from $37.9 Bn in 2023
- The oral formulations of semaglutide and tirzepatide are set to capture a significant share of this market, offering a convenient alternative to injections
- MangoRx plans to have the products available for customers on the company's telemedicine platform in the beginning of Q3 2024, with 'Slim' and 'Trim' competitively priced at $299/month and $399/month, respectively

- **Read more:** Yahoo Finance

- **Implications:** Mangoceuticals' plan to introduce oral versions of semaglutide and tirzepatide could likely lead to patent infringement claims from Eli Lilly and Novo Nordisk, the patent holders of these drugs

**23** **Weight loss, diabetes treatments focus of FTC's second round of patent listing challenges [U.S.]**
*May 21, 2024*

- The article from PinkSheet takes a deep dive into the Federal Trade Commission's second wave of challenges to patents it asserts are improperly listed in the U.S. FDA's Orange Book, including patents covering Novo Nordisk's self-injection pens for SAXENDA (liraglutide) and OZEMPIC (semaglutide)
- The U.S. Federal Trade Commission's second round of challenges to Orange Book-listed drug product patents moves the battle over listing criteria into the high-profile diabetes and weight loss therapeutic categories
  - The FTC recently sent warning letters to 10 companies challenging the listing of 130 patents for 20 branded products indicated for treating asthma, chronic obstructive pulmonary disease, diabetes and weight management
- All of the products at issue are drug/device combinations, and all challenged patents claim some aspect of the product's device, such as an inhaler or an injection pen, according to a Pink Sheet analysis
- In letters to the product sponsors, the FTC asserts the patents at issue have been improperly or inaccurately listed in the Food and Drug Administration's Orange Book. The commission is availing itself of the FDA's regulatory process for disputing the accuracy or relevance of patent information submitted to the agency
- The letters mark another shot across the bow by the FTC, which has moved aggressively in the past year to encourage more generic competition and lower drug prices by challenging the appropriateness of certain types of Orange Book-listed patents

- The FTC's second round of letters moves the challenges to products that are heavily advertised and extensively used in the diabetes and obesity space, including GLP-1 receptor agonists OZEMPIC and SAXENDA
- Novo Nordisk said it is reviewing the FTC's letter and the allegation that we use this listing to keep prices artificially high is simply false. Novo takes its regulatory obligations very seriously for all its products and patenting activities,". "*We believe we have complied with the rules around listing patents in the Orange Book"*

- **Read more:** Pinksheet *(Subscription required)*

- **Implications:** The FTC's focus on high-profile therapeutic categories such as diabetes and weight loss reflects an increased regulatory scrutiny over how patents are listed. This could lead to more stringent criteria and potentially a reevaluation of existing patent listings, especially those related to drug-device combinations

**24** **Roundhill investments launches GLP-1 & weight loss ETF (OZEM) [U.S.]**
*May 21, 2024*

- Roundhill Investments, an ETF sponsor focused on innovative financial products, announced the launch of the Roundhill GLP-1 & Weight Loss ETF (OZEM), which began trading on Nasdaq on May 21, 2024
  - OZEM is the world's first ETF focused exclusively on the rapidly growing sector of GLP-1 receptor agonists and other weight management drugs
- The Roundhill GLP-1 & Weight Loss ETF (OZEM) is an actively-managed ETF that is designed to provide exposure to a global portfolio of companies involved in developing weight loss therapeutics

- **Read more:** PR Newswire

- **Implications:** The Roundhill GLP-1 & Weight Loss ETF (OZEM) reflects a strategic recognition of the growing importance and potential profitability of the obesity treatment market

**25** **QPS expands clinic in Miami, Florida to accommodate increasing demand for obesity trials [U.S.]**
*May 21, 2024*

- QPS, a leading global contract research organization (CRO), continues to expand and align its full-service preclinical, bioanalysis, and clinical capabilities with the evolution of demand for clinical trials
- With the new capacity, QPS is poised to accommodate the rapidly increasing demand for obesity trials, as well as continue to support complex, early phase studies in special populations

- **Read more:** Businesswire

- **Implications:** N/A

**26** **Hims & Hers announces access to GLP-1 injections, passing cost savings onto customers [U.S.]**
*May 20, 2024*

- Hims & Hers Health announced the addition of GLP-1 injections to its comprehensive weight loss portfolio, giving customers an affordable way to consistently access safe, high-quality weight loss treatment
- The company offers access to GLP-1 injections in addition to weight management oral medication kits, so that customers can truly personalize their weight loss experience
  - Providing access to compounded GLP-1s means eligible customers can use medications with the same active ingredient as OZEMPIC (semaglutide) and WEGOVY (semaglutide) without navigating the shortages and costs that are currently limiting access to the branded medications
- Through a partnership with a leading U.S. manufacturer of generic and 503B compounded injectable medications, Hims & Hers can help millions of Americans who have obesity and are looking for help safely managing their weight
- Company believes that there is no one-size-fits-all approach to health and wellness treatments
  - Medical providers need a broad spectrum of solutions to address the needs of customers and that includes those with weight challenges
  - The current Hims & Hers Weight Loss offering is tracking to eclipse $100M in revenue by the end of 2025, as previously discussed, growing faster than any speciality in the company's history
  - Building on that success, offering access to compounded GLP-1s gives medical providers and customers consistent and affordable access to effective, trusted and safe medications
- GLP-1 injections are fulfilled and shipped from Hims & Hers' affiliated pharmacies
- Pricing for weight loss medications starts as low as $79/month for oral medication kits and $199/month for compounded GLP-1 injections

- **Read more:** Businesswire

- **Implications:** N/A

**27** **Medifast continues business transformation, launching national marketing campaign promoting its holistic offering for customers utilizing and considering weight loss medications [U.S.]**
*May 20, 2024*

- Medifast continues its business transformation, launching national marketing campaign promoting its holistic offering for customers utilizing and considering weight loss medications
- Medifast announced the launch of the first phase of its multimillion-dollar national marketing campaign
  - The campaign will highlight OPTAVIA's new offering in collaboration with LifeMD, the GLP-1 Lifestyle Program, a holistic

approach to medical weight loss specifically tailored to support the needs of those utilizing GLP-1 medications
    - This robust offering, incorporating OPTAVIA's lifestyle and personal coaching program, provides a comprehensive solution for individuals seeking a guided approach to weight management and who are committed to embarking on a life-changing health journey
- Through an investment of up to $30 Mn in company-led marketing efforts, Medifast is committed to driving growth and enhancing brand visibility
- The company aims to elevate brand awareness, foster engagement and drive customer conversion, and comes on the heels of the integrated agencies winning the OPTAVIA business following a competitive review

- **Read more:** Businesswire

- **Implications:** N/A

**28** **OZEMPIC's and WEGOVY's price premium 'relatively low' – Novo Nordisk CEO [EU]**
*May 27, 2024*

- According to Lars Fruergaard Jørgensen, Chief Executive Officer, Novo Nordisk, the price premium for OZEMPIC (semaglutide) and WEGOVY (semaglutide) compared to older drugs is relatively low and one must especially consider the positive effects that these therapies can also have on the risk of cardiovascular and kidney disease
    - In the interview, Jørgensen, who is also president of European trade body EFPIA, warned about the detrimental effects of "regulatory frenzy" in the European Union
- The prices of OZEMPIC indicated in type 2 diabetes and WEGOVY in obesity have come under criticism in the U.S. after a study on the cost of production of SGLT2 inhibitors, insulins and GLP1 agonist published in the *JAMA Network Open* estimated that OZEMPIC could cost only $5 per month. The lowest market price for OZEMPIC is in the $38.21 to $353.74 range in the U.S.
- The U.S. senator Bernie Sanders called for price reductions on this basis as well as following a price cut in Denmark

- **Read more:** APM Health *(Subscription required)*

- **Implications:** The CEO's remarks come in the context of ongoing debates about pharmaceutical pricing. His mention of the drugs' positive health effects could be an attempt to justify their cost by highlighting the potential savings on other healthcare expenses related to untreated conditions

**29** **German press – Novo Nordisk and Eli Lilly's duopoly on weight-loss market likely to last [Germany]**
*May 24, 2024*

- On May 24, 2024, Wirtschaftswoche, a German weekly business news magazine reported that the "lucrative duopoly" of Novo Nordisk and Eli Lilly on weight-loss drugs is likely to last some time, even if other companies are lining up
- According to the weekly magazine, Novo Nordisk's OZEMPIC (semaglutide) and WEGOVY (semaglutide) and Eli Lilly's MOUNJARO (tirzapatide) will probably retain the biggest slices of the market due to their pioneer status. However, their inability to fulfil "unprecedented" demand for these drugs is seen as a liability by analysts
- Of the potential competitors, Amgen is currently the most advanced with its Phase II candidate MariTide, also a weekly injectable
    - If Phase III is positive, it could reach the market in 2025
    - However, analysts are worried about the potential effect of the U.S. Inflation Reduction Act (IRA) that can push down its price and Amgen's profits
- While many investors are excited about the opportunities this market offers, there are many risks in it. One is the potential generic competition that can start in 2030 for the oldest drugs in the class
- According to Klaus Winckler from the German Nutritionists Society, in Germany, the high monthly costs - €172 for WEGOVY and €260 for MOUNJARO - that are not covered by statutory payers are limiting demand
    - However, reimbursement by statutory payers is possible in the future based on their positive effects on cardiovascular, kidney and joint health

- **Read more:** APM Health *(Subscription required)*

- **Implications:** Novo Nordisk and Eli Lilly are anticipated to maintain their market leadership due to the pioneering status of their drugs, OZEMPIC, WEGOVY, and MOUNJARO. This entrenched position affords them significant competitive advantages in terms of brand recognition, established safety and efficacy profiles, and existing physician and patient familiarity with their products

**30** **SixPeaks, a new obesity biotech, starts up with an option to sell to AstraZeneca [EU]**
*May 22, 2024*

- SixPeaks Bio AG based in Basel, Switzerland, has emerged from stealth with $30 Mn in Series A financing and a strategic collaboration with AstraZeneca providing up to $80 Mn over the next two years. The company was founded two years ago at Versant's Ridgeline Discovery Engine in the Basel Technology Park and is focused on "developing improved therapies for healthy weight loss
- SixPeaks Bio claims a pipeline of therapies for healthy weight loss including the lead asset which is a ActRIIA/B targeted mAb. Unlike some of the known ActRII targeted therapies in development, this mAb has been engineered for robust preservation of skeletal muscle mass in humans
- According to the press release, this mAb has BIC potential based on the results of preclinical studies
    - In addition, the company has conjugated the mAb with a GLP-1 RA peptide to potentially effect both weight loss and muscle preservation in a single therapy. The conjugation program may be expanded to include other incretin-based therapies
- AstraZeneca participated in the Series A financing and is committing up to $80 Mn in capital including upfront and near-term payments. In exchange, AstraZeneca received an option to acquire SixPeaks at an agreed-upon, but undisclosed, price at the time

of submission of an IND application for the biotech's lead antibody
At the time this email was sent, there is no evidence of a company website. Neither is the company listed on the Versant Ventures webpage at this time. The only online presence is a LinkedIn company profile that doesn't contain any additional company details

- **Read more:** BioPharma Dive, Fierce Biotech

- **Implications:** AstraZeneca's involvement, including a financial commitment up to $80 million and an option to acquire SixPeaks, underscores the potential AstraZeneca sees in this early-stage biotech. The conjugation of the mAb targeting ActRIIA/B with a GLP-1 RA peptide by SixPeaks aims to combine weight loss and muscle preservation in a single therapy

**31** **Second fire at Novo Nordisk in a week now under control [Denmark]**
*May 22, 2024*

- On May 22, 2024, a large fire broke out at Novo Nordisk, the manufacturer of the weight loss drug OZEMPIC, at the pharmaceutical group office building in Copenhagen, Denmark
- The fire first involved 100 firefighters and was described as a "massive fire". However, the first was under control and the number of firefighters went down to about 30
- According to Martin Smith, Fire Brigade Chief of Operations, the fire broke out in a container at Novo Nordisk's construction site and then spread to the roof of an adjacent office building
- In a statement, Novo Nordisk claimed that the smoke was non-toxic and there were no injuries

- **Read more:** Ice News, Pharma Phorum

- **Implications:** N/A

**32** **Health fund wobbles on weight-loss coverage [Australia]**
*May 20, 2024*

- Private health insurer HBF, the fifth-largest health fund in Australia, announced at the beginning of the month that it would be completely cutting benefits for five brands of premanufactured GLP-1 agonists and all compounded GLP-1 agonists on its pharmaceutical extras scheme
- The remaining pre-manufactured formulations of semaglutide, liraglutide, dulaglutide, exenatide and tirzepatide will draw reduced benefits
- A particularly interesting aspect is that Novo Nordisk's SAXENDA (liraglutide) and WEGOVY (semaglutide) are among the brand names with benefits specifically cut, while its original OZEMPIC (semaglutide) formulation is not
- According to Rachel David, CEO, Private Healthcare Australia, funds would be able to subsidize GLP-1 agonists as part of a wraparound-care model with the aim of changing member behavior to achieve "a long-term impact" rather than just subsidizing the drug
  - Given the widespread popularity of the drugs, there's also concern about people trying to gain access to them for non-clinical reasons

- **Read more:** The Medical Republic, ABC News

- **Implications:** N/A

**33** **Novo Nordisk urges UAE users to switch to WEGOVY for weight loss [UAE]**
*May 22, 2024*

- The amount of people using the diabetes medication OZEMPIC (semaglutide) for weight loss led to the manufacturers launching a similar drug to ease supply problems for diabetics
- Novo Nordisk fast-tracked the release of WEGOVY (semaglutide) due to the lack of availability of OZEMPIC, which was creating problems for diabetics who needed the medication
- Although licensed for diabetes, a sharp rise in use of OZEMPIC for its weight loss properties left those with diabetes struggling to access medication in 2022 and 2023
- WEGOVY was launched in the UAE because of concerns over the off-label use of OZEMPIC, with doctors prescribing medication for reasons other than their licensed approval

- **Read more:** The National News

- **Implications:** N/A

**KEY UPCOMING EVENTS**

**The Latest and Greatest on Obesity Treatment to Reduce Risk for Type 2 Diabetes and Cardiovascular Disease:**

- **AJMC:** June 6, 2024 (AJMC Event)

Thank you,
Ben

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Director

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