GLP-1 Therapeutic Platforms to Transform Obesity Treatment

Executive Summary

We believe that GLP-1 analogues have an unprecedented combination of safety and clinical efficacy regarding blood sugar reduction and weight loss that will facilitate significant public health improvements and generate compelling investment opportunities. Novo Nordisk and Eli Lilly are each cultivating the GLP-1 mechanism as a foundational "platform" to support an exciting scientific roadmap for further innovation and an evolving ecosystem of tech-enabled, behavioral obesity treatment regimens. We anticipate that physicians and patients will eagerly incorporate GLP-1 drugs into their weight-loss paradigm. GLP-1 medication uptake can dramatically ameliorate the public health burden of obesity and reduce $1.4 trillion of direct and indirect economic costs in the United States.[i] Although the anti-obesity medication (AOM) market is nascent, we expect government and commercial insurance plans to increasingly reimburse patients for GLP-1 obesity treatments, thereby unlocking a potential total addressable market of more than 650 million patients worldwide[ii] and $100 billion annually.

What are GLP-1 Analogues?

GLP-1 analogues were originally commercialized to treat type 2 diabetes (T2D), but healthcare participants are increasingly leveraging their unique clinical traits to combat the obesity epidemic. They emulate glucagon-like peptide-1 (GLP-1), a native incretin hormone that manages blood sugar levels and appetite. Endogenous GLP-1 is naturally produced in the L-cells of the gut.[iii] GLP-1 binds to and activates GLP-1 receptors in the pancreas, a process that enables glucose-dependent insulin secretion and decreased glucagon release.[iv] This joint mechanism reduces blood sugar levels by facilitating uptake of glucose into the cells and lowering the amount of glucose released from the liver into the bloodstream. GLP-1 also decreases appetite by suppressing gastric emptying and signaling satiety to the brain. Commercially manufactured analogues have more than 90% sequence homology to human GLP-1 but incorporate structural amino acid substitutions that protect the molecules from the rapid metabolic degradation inherent to native GLP-1. Extended release GLP-1 receptor agonist medication can be taken as a once-weekly subcutaneous injection or a once-daily oral tablet.

Brief History of GLP-1 Therapeutic Development

The discovery of the GLP-1 sequence stemmed from the application of recombinant DNA approaches in the early 1970s, a revolutionary technology that "allowed for a rapid and accurate prediction of the amino acid sequences of proteins by decoding the nucleotide sequences of cloned recombinant cDNA copies of messenger RNAs."[v] The first study of GLP-1 in man was completed in 1987 and demonstrated statistically significant stimulation of insulin production.[vi] In 2005, twice-daily exenatide (a peptide originally isolated from lizard venom by researcher Dr. John Eng in 1992) became the first GLP-1 receptor agonist approved by the FDA for clinical use in patients with T2D. Amylin Pharmaceuticals established an early lead in the GLP-1 treatment

market after purchasing licensing rights to exenatide from Dr. Eng in 1996. However, Novo Nordisk and Eli Lilly subsequently leveraged their scientific expertise to elevate the clinical efficacy and safety profile of the GLP-1 treatment pathway, allowing the two pharmaceutical heavyweights to establish an effective duopoly.

The two most widely available GLP-1 analogue brands for T2D treatment are Novo Nordisk's once-weekly Ozempic (semaglutide) and Eli Lilly's once-weekly Trulicity (dulaglutide), which generated approximately $11 billion combined sales during 2021 and accounted for two-thirds of the total $16.5 billion GLP-1 diabetes treatment market. Semaglutide, which was developed by Novo Nordisk researchers in 2012 and received FDA approval in 2017, lowered HbA1c (glycated hemoglobin) levels by 1.6 points from 8.2% to 6.6% at 1mg dosage in its landmark clinical trial.[vii] A1c levels below 5.7% are considered healthy, whereas readings above 6.5% indicate diabetes. Oral semaglutide (Rybelsus) received FDA approval in the U.S. in 2019, which drove appreciable market expansion by enabling GLP-1 drugs to penetrate the oral antidiabetic drug opportunity.

Researchers, physicians, and patients alike consistently observed the material weight loss inherent to GLP-1 treatments throughout their 17-year tenure as approved drugs. Given the high correlation between type 2 diabetes and obesity, this quality represents a significant competitive advantage versus other diabetes therapeutics like DPP-4 inhibitors and SGLT2 inhibitors. Novo Nordisk and Eli Lilly successfully completed clinical trials to spotlight this statistically significant and medically relevant attribute of GLP-1 drugs. Liraglutide, an early iteration of Novo Nordisk's GLP-1 technology, was the first GLP-1 analogue to receive FDA approval for obesity in 2014 under the "Saxenda" brand. In June 2021, Novo Nordisk announced FDA approval for semaglutide in the treatment of obesity under the "Wegovy" brand, attributable to Phase III clinical data that demonstrated 14.9% reduction in body weight from baseline at the 2.4mg dosage.[viii] The clinical efficacy of Wegovy considerably outperformed that of Saxenda and received a positive response from medical centers, physicians, and patients.

Clinical data from Eli Lilly's tirzepatide was even more encouraging for the medical community as the 15mg dosage led to a 20.9% reduction in body weight and a 2.58% reduction in HbA1c, according to the company's SURMOUNT-1 and SURPASS-4 trials.[ix] Tirzepatide received FDA approval as "Mounjaro" for T2D treatment in May 2022 and is expected to receive an obesity indication in 2023, becoming the third GLP-1 receptor agonist approved for weight loss. Tirzepatide is a GIP analogue that activates both GLP-1 and GIP receptors, which may lead to even greater clinical efficacy for blood sugar reduction and weight loss.

Obesity is an Epidemic

We believe that obesity is an underrecognized public health epidemic that generates a substantial economic burden on individuals, businesses, and governments. According to the World Health Organization (WHO), obesity is characterized by "abnormal or excessive fat accumulation that presents a risk to health."[x] A body mass index (BMI) greater than 25.0 is considered overweight, whereas a BMI over 30.0 is considered obese. BMI is

calculated as a person's weight in kg divided by the square of their height in meters. Obesity has historically been regarded as a public health challenge unique to high-income nations like the United States due to the proliferation of energy-dense, ultra-processed foods and the changing nature of work, transportation, and urban organization. Although weight gain is often influenced by a combination of genetic, physiological, and environmental factors, obesity's root cause is an imbalance of calories consumed and calories expended. The most effective way to lower the risk of obesity is to engage in regular physical activity, limit caloric intake from fats and sugars, and increase consumption of fruits and vegetables.

More than 1.9 billion people worldwide are overweight, and more than 650 million people are obese (~13% of adults). Obesity rates have tripled since 1975, and the global prevalence of overweight children increased from 4% in 1975 to 18% in 2016. These statistics are concerning because obesity is a major risk factor for several leading causes of death, including musculoskeletal disorders, cancer, and chronic diseases like diabetes and cardiovascular disease. Heart disease and stroke cause over 800,000 deaths in the United States per year, accounting for one out of every three deaths (Figure 1).[xi]

The burden of obesity is most pronounced in the U.S., where more than 100 million adults are obese. This represents 42% of the population and marks an 11-point increase from 31% in 1999 (Figure 2).[xii] The estimated annual medical cost of obesity in the U.S. is $173 billion, and individuals with obesity pay $1,861 more in medical costs per year than people with healthy weight. According to the Milken Institute, the combined direct and indirect costs of obesity account for $1.4 trillion, or 6.8% of U.S. gross domestic product (GDP). The COVID-19 pandemic reinforced the reality that excess body fat leads to significant health complications, as the negative health impact of SARS-CoV-2 was positively correlated with BMI. We are optimistic that growing utilization of GLP-1 drugs will reduce the prevalence of obesity, limit associated adverse health events, and ultimately lower the economic and social weight on taxpayers and healthcare providers.

Figure 1 - Number of Deaths for Leading Causes of Death in the U.S. (2020)

Source: CDC; MayTech Global Investments

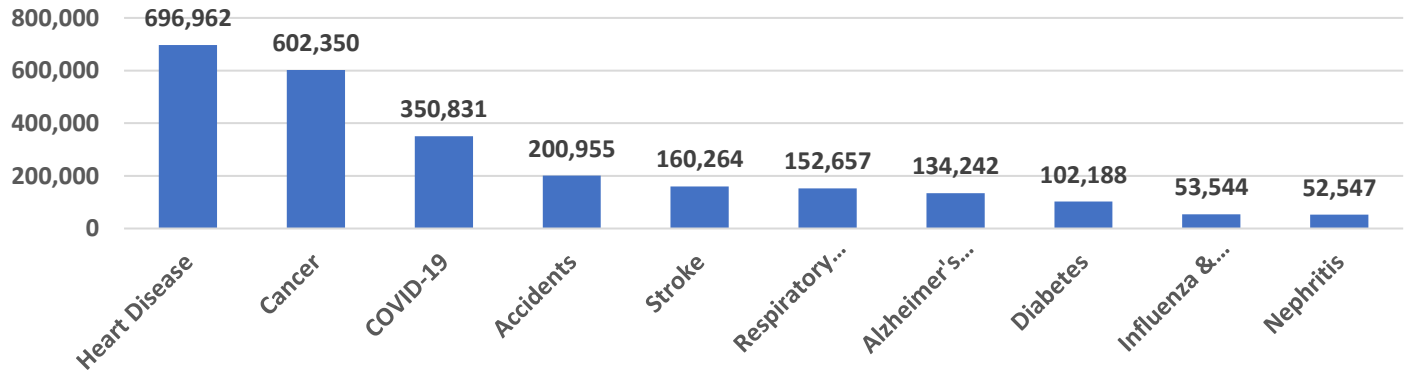
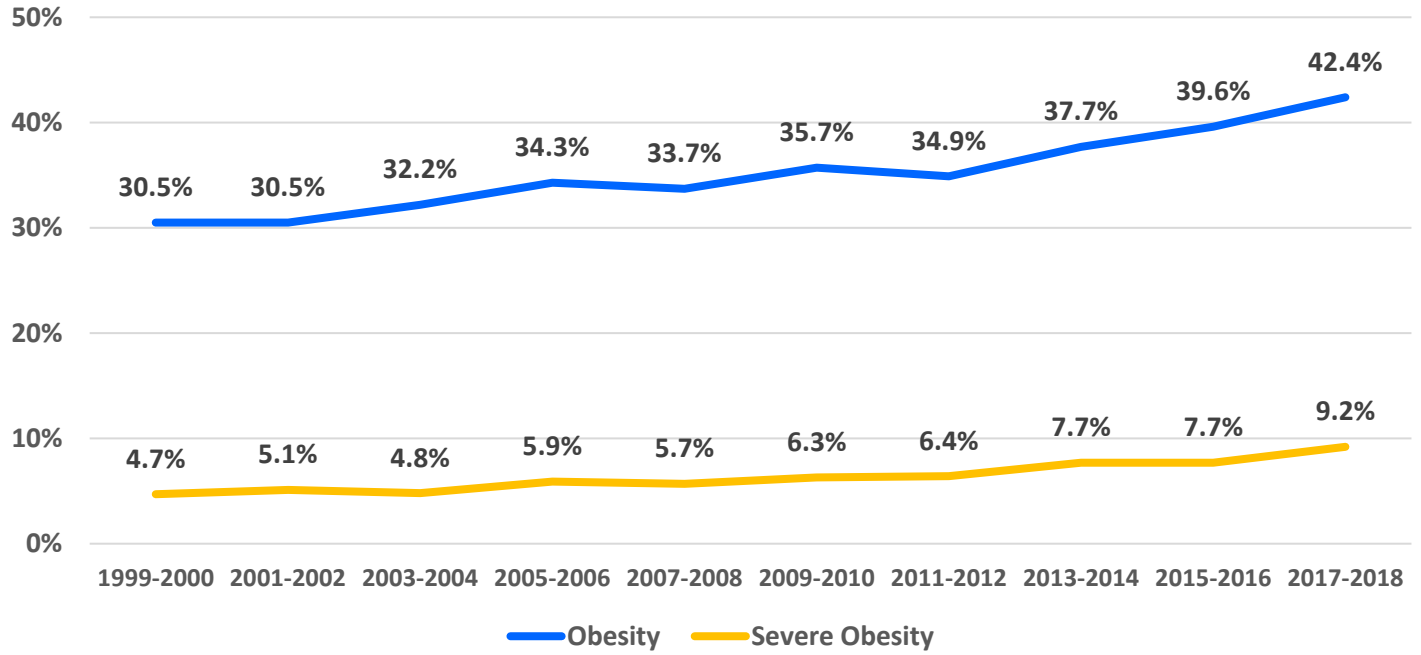


Figure 2 - Prevalence (%) of Adult Obesity in the United States

Source: National Center for Health Statistics; MayTech Global Investments



Standard of Care

We believe that the current standard of care is insufficient to meaningfully enhance patients' quality of life, improve healthcare outcomes, or reduce the economic costs of obesity on society. The healthcare system provides only minimal support to patients and inadequately elucidates the urgency of weight loss for obese patients given the plethora of correlated health risks. Healthcare infrastructure and insurance coverage are designed to treat the adverse consequences of obesity, such as heart attack and stroke, as opposed to proactively treating obesity itself. This strategy burdens society with substantial, yet largely preventable, economic costs and weighs on overall healthcare outcomes by diverting critical labor (doctors, nurses, etc.) and spatial resources like beds and hospital rooms.

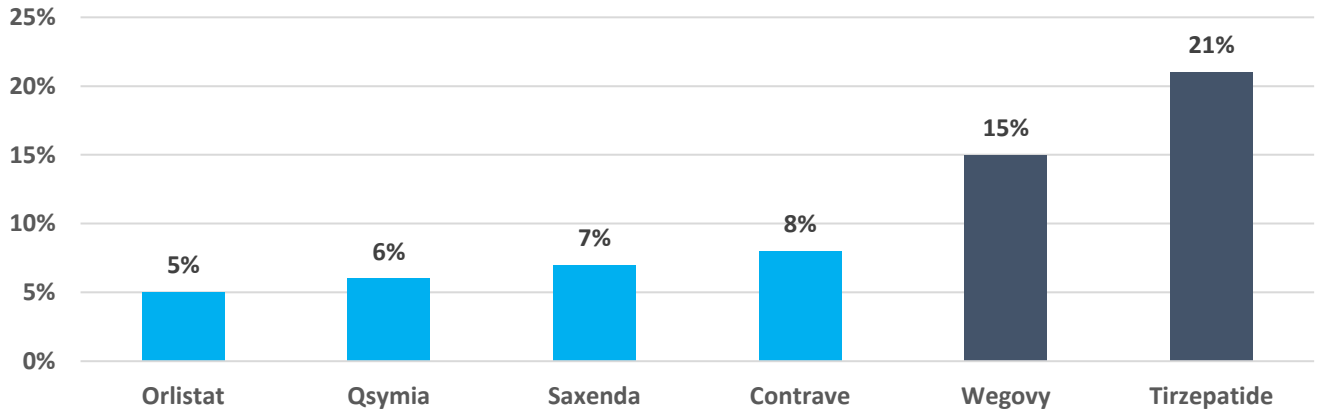
For most obese and overweight patients, the first line of treatment to reduce BMI consists of a combination of healthy dieting and regular exercise, which leads to weight loss through a sustained calorie deficit. However, these plans require stringent consistency and dedicated habit formation, which is difficult to achieve for many individuals. In addition to behavioral changes, there are various physical interventions that can be employed, including gastric pacemakers (send electrical signals to promote feelings of fullness in the brain) and intra-gastric balloon placement (saline-filled silicone balloons that induce the feeling of fullness sooner when eating).

Although these treatments can lead to considerable weight loss, they can also cause discomfort for patients and pose health risks including stomach ulcers, acute pancreatitis, and perforation of the stomach wall.

Healthcare providers will often refer extremely obese patients for bariatric surgery, an umbrella term encompassing many procedures that alter the structure of the digestive system to support weight loss. Nearly 580,000 people worldwide undergo bariatric surgery annually, including more than 250,000 people in the United States.[xiii] The most common type of bariatric surgery is sleeve gastrectomy, which is an irreversible laparoscopic procedure that reduces the stomach's size by ~15% through the removal of a large portion of the stomach along the greater curvature, resulting in a tube-like stomach structure. Although bariatric surgery has widely recognized clinical efficacy, only 1% of eligible patients choose bariatric surgery due to its high costs ($10,000+) and perceived danger of surgical intervention. According to a survey conducted by the National Opinion Research Center (NORC) at the University of Chicago, 37% of Americans believe that weight loss surgery is unsafe, a perspective that is likely to support patient-driven adoption of medication.[xiv]

Prior to the introduction of GLP-1 drugs, patients averse to the dangers of surgery were limited to utilizing one of three legacy FDA-approved anti-obesity medications (AOMs), including orlistat, phentermine-topiramate (Qsymia), and naltrexone-bupropion (Contrave). Medicare and Medicaid do not currently reimburse AOMs due to their dubious clinical efficacy and material adverse side effects. For example, Contrave leads to 8.1% reduction in body weight from baseline but carries a black box warning for increased risk of suicidal thoughts and behaviors.[xv] The history of AOM drug development is rife with cautionary tales of poor clinical efficacy and insurmountable safety concerns. However, Wegovy and tirzepatide offer a meaningful step-change in efficacy and safety that is currently underappreciated by legislators and payers alike (Figure 3).

Figure 3 - Approximate Percentage Reduction in Body Weight from Baseline
Source: GoodRx; Company Reports; MayTech Global Investments



Insurance Coverage

GLP-1 drugs are uniquely positioned to fundamentally change the insurance coverage landscape for AOMs. The clinical efficacy of GLP-1 agonists is rapidly converging on that of bariatric surgery, which is covered by U.S. government insurance plans and enables individuals with BMIs over 35.0 to shed 50% to 70% of their excess body weight. GLP-1 therapeutics also maintain a highly attractive safety profile. For example, only 4.5% of participants discontinued treatment of Wegovy and just 6.2% of participants discontinued treatment of tirzepatide in their respective trials, owing only to moderate gastrointestinal discomfort in most cases.[xvi]

We expect growing awareness regarding the success and safety of GLP-1 drugs to drive a fundamental paradigm shift in the healthcare ecosystem as obesity is increasingly viewed as a treatable "disease" rather than a cosmetic or lifestyle choice. According to a 2022 survey conducted by Food Insight in the U.S., 38% of respondents would rather take a medication for a health condition than change their lifestyle, a significant increase from just 16% of respondents in 2012.[xvii]

The American Medical Association (AMA) designated obesity as a disease in 2013, but public and private insurance has been slow to embrace this stance given the historical lack of viable therapeutics. However, we believe perspectives are rapidly changing. In March 2021, Senator Thomas Carper sponsored the bipartisan *Treat and Reduce Obesity Act*, which would allow the Centers for Medicare & Medicaid Services to expand Medicare Part D coverage to include FDA-approved AOMs. Although progress on this specific bill has slowed, we think there is a significant economic incentive for payers to proactively reimburse patients for GLP-1 treatments that can help minimize costly, life-threatening adverse events in the future. We anticipate Novo Nordisk's SELECT trial, expected to complete in mid-2023 with a sample size of 17,500 people, will successfully demonstrate that Wegovy lowers the incidence rate of major adverse cardiac events (MACE), potentially representing a watershed moment that leads to widespread insurance coverage for GLP-1 analogues.

Total Addressable Market (TAM), Penetration, and Revenue Opportunity

Although 650 million people worldwide are currently living with obesity, the likelihood of seeking and receiving medical treatment for this disease remains very low due to insufficient awareness and lack of insurance coverage. According to Novo Nordisk, only 13 million people are treated with anti-obesity medication and just 2.5 million people are seen by obesity experts.[xviii] Therefore, the penetration of AOMs is 2% and the penetration of obesity expert care is 0.4%. Novo Nordisk treats ~1 million people with Saxenda and ~125k people with Wegovy, representing 0.2% combined penetration of the global addressable population. The company disclosed that U.S. commercial insurance could reimburse 60 million people for Wegovy, but employer opt-ins for formulary access only cover 30 million people, accounting for just 30% of the nation's obese population.

We believe that the global AOM market is highly under-penetrated and could eventually account for more than $100 billion in annual sales as GLP-1 insurance coverage expands. As of November 2022, the annual AOM market is sized at $3.2 billion and growing at 110% year-over-year. Novo Nordisk's obesity segment is growing at 148% year-over-year, enabling the company to expand its market share of industry revenue by 16 points to 86%.[xix]

We believe further AOM market expansion will be driven primarily by improving clinical efficacy, enhanced reimbursement and formulary access, growing physician awareness, and consistent supply chain availability of GLP-1 agonist therapeutics. A 28-day supply of Wegovy costs approximately ~$1,350, representing an annual revenue opportunity of $16,200 per patient.[xx] Assuming all 60 million people with commercial insurance for Wegovy were granted access, this would represent a potential total addressable market (TAM) of $97 billion in the United States alone, more than 30x larger than the current worldwide AOM market.

We believe greater adoption of GLP-1 therapeutics will drive an inflection in underlying revenue growth and profitability for Novo Nordisk and Eli Lilly. In our base case, we expect Novo Nordisk to grow its obesity franchise from $1.3 billion in 2021 to $21.8 billion in 2031E, representing a compound annual growth rate (CAGR) of 33%. Considering their differentiated scientific approaches and competitive therapeutic portfolios, we anticipate Novo Nordisk and Eli Lilly will split the GLP-1 agonist obesity treatment market, which we expect to grow to $38.7 billion in 2031E (Figure 4). Consequently, we forecast Novo Nordisk to grow its total revenue from DKK141 billion in 2021 to DKK401 billion ($55.8 billion) in 2031E (Figure 5), in addition to expanding its net margin by 310 bps from 33.9% in 2021 to 37.0% in 2031E.

Figure 4 - Worldwide GLP-1 Agonist Obesity Treatment Revenue (US$ millions)

Source: Company Reports; MayTech Global Investments

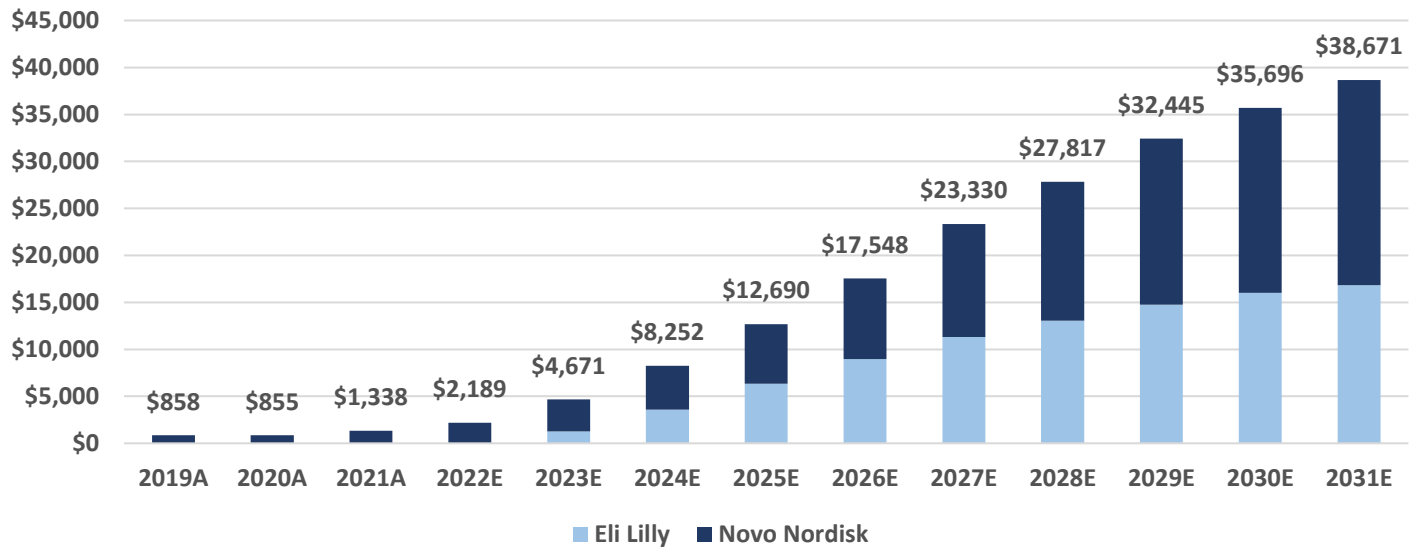
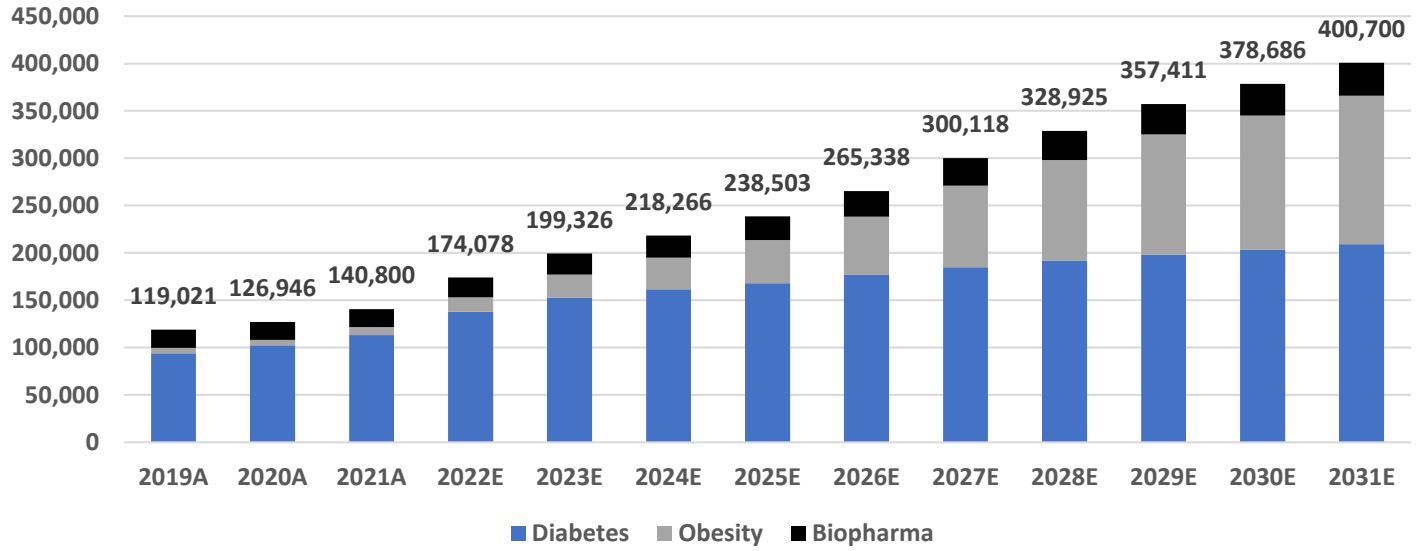


Figure 5 - Novo Nordisk Annual Revenue (Values in DKK millions)

Source: Company Reports; MayTech Global Investments



GLP-1 Represents a "Platform" Opportunity for an Emerging Services Ecosystem

GLP-1 analogues are serving as the bedrock for a burgeoning ecosystem of technology-assisted services to combat obesity. Traditional weight loss technology platforms like Weight Watchers have historically relied on a strategic combination of dieting, exercise, coaching, and communal motivation. Though we recognize the value in this approach, we believe GLP-1 therapeutics are a critical "force multiplier" that should be central to an effective weight loss strategy. A new generation of technology vendors based around GLP-1 medication is emerging, including Calibrate, a digital health startup that has raised $128 million from investors including Founders Fund and Forerunner Ventures.[xxi] Calibrate costs $138 per month and incorporates 1:1 video coaching and a holistic education curriculum alongside GLP-1 analogues. We think Novo Nordisk and Eli Lilly are well-positioned to capitalize on further technology services innovation in the future, which can grow awareness for GLP-1 receptor agonists and enhance medication adherence.

Scientific Roadmap and Investment Opportunities

We believe that the FDA's approval of tirzepatide in mid-2022 heralds a new era of GLP-1 receptor agonist commercialization. Novo Nordisk, Eli Lilly, and other major biotech companies like Amgen are aggressively developing obesity drug candidates that target several insulinogenic and weight loss pathways simultaneously, which can improve clinical outcomes without compromising on safety metrics.

We are positive on the prospects for Novo Nordisk's CagriSema, a once-weekly subcutaneous combination of semaglutide and a novel amylin analogue called cagrilintide, in addition to Eli Lilly's "triple G" (LY3437943) agonist of GIP, GLP-1, and glucagon receptors. Novo Nordisk released Phase 2 clinical data on CagriSema in August 2022, demonstrating that people in the treatment group achieved an average HbA1c reduction of 2.18% and body weight reduction of 15.6% after 32 weeks of treatment. In comparison, the semaglutide-only group experienced average HbA1c reduction of 1.79% and weight loss of 5.1%.[xxii] These findings support the clinical utility of multi-pathway and combination GLP-1 agonist treatments.

We believe that the efficacy of novel GLP-1 agonist therapeutics will continue to leapfrog prior generations, improving clinical outcomes for patients living with chronic diseases like obesity and diabetes and limiting financial strain on the healthcare system. As clinical data continues to improve, pressure is mounting on public and private insurance plans to provide comprehensive obesity coverage that incorporates GLP-1 drugs.

Novo Nordisk and Eli Lilly possess scientific capabilities, technical know-how, and global supply chain infrastructure that can cement their joint dominance of the GLP-1 receptor agonist market. For example, Novo Nordisk has 10 global R&D centers, conducts clinical trials in more than 50 countries, and manages manufacturing centers across Denmark, France, Brazil, China, and the United States. We expect the magnitude of this global footprint and the associated economies of scale to facilitate a "winner-take-all" dynamic in obesity treatment. The obesity end market remains early on the "S-curve" of adoption and exhibits a compelling combination of clinical relevance, lack of current treatment or attention, and enormous economic consequence.

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MayTech clients and employees own Novo Nordisk stock (initially purchased 8/14/2022 at $104.19/share).

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