

# *Emisphere Technologies (EMIS)*

October 2020



Rating: Strong Buy

Price Target: \$20

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### Company Profile

- Founded in 1986
- Based in Roseland, NJ
- Four employees
- Developed the Eligen technology to deliver large molecules through the intestinal lining
- Two marketed drugs: Eligen B12 (Vitamin B12) and Rybelsus (Oral Semaglutide)

### Stock Profile

- Share Price: \$8.05
- Shares Outstanding: 155 million<sup>1</sup>
- Market Capitalization: \$1.25 billion
- Avg Daily Trading Vol: 40k shares
- Exchange: OTC Pink Sheets

<sup>1</sup>Based on SVP estimates

**Emisphere is effectively a private company trading in the public markets**



**We believe Rybelsus (oral semaglutide) will achieve annual sales of > \$10 billion driving royalties to Emisphere of > \$250 million per year**

**Where We are Different:**

Wall Street peak Rybelsus sales estimates are in the range of **\$5-7 billion**

We are modeling peak sales of **> \$10 billion** as our research suggests that Rybelsus will be viewed as a **best-in-class** option



**10% market share of the oral diabetes market equates to almost \$15 billion of Rybelsus sales**

**Key to Achieving our Sales Estimates:**

6,500 Endocrinologists in the US write prescriptions for **injectable** GLP-1s

223,000 general practitioners in the US write prescriptions for **oral** diabetes drugs which represent 70% of the diabetes Rx market



**General practitioners now have access to the GLP-1 class of drugs with the launch of Rybelsus**



The GLP-1 class of drugs is annualizing at \$13 billion in global sales. Victoza sales are declining in favor of the newer agents - Trulicity, Ozempic and Rybelsus. Recent market growth > 20%.

**1<sup>st</sup> generation**  
(1x daily - injection)



**2<sup>nd</sup> generation**  
(1x weekly - injection)



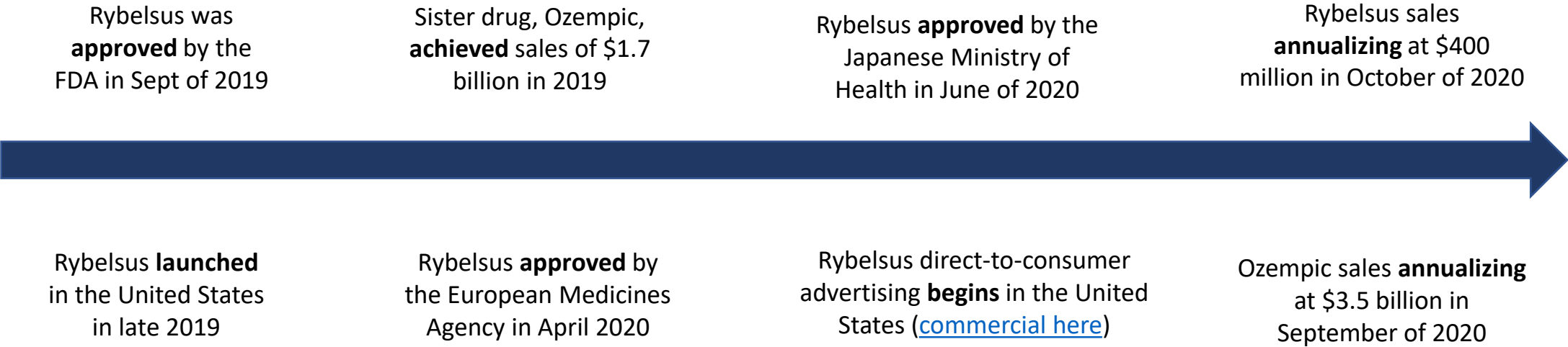
**3<sup>rd</sup> generation**  
(1x daily - oral)



GLP-1 receptor agonists act by **lowering** glucose production, **increasing** insulin production and by **slowing** gastric emptying.

Ozempic and Rybelsus contain the same active ingredient, **semaglutide**. Both are marketed globally by Novo Nordisk.

**Rybelsus is the first and only oral GLP-1 receptor agonist approved for Type 2 Diabetes patients. Rybelsus has a patent life through 2031-2034.**



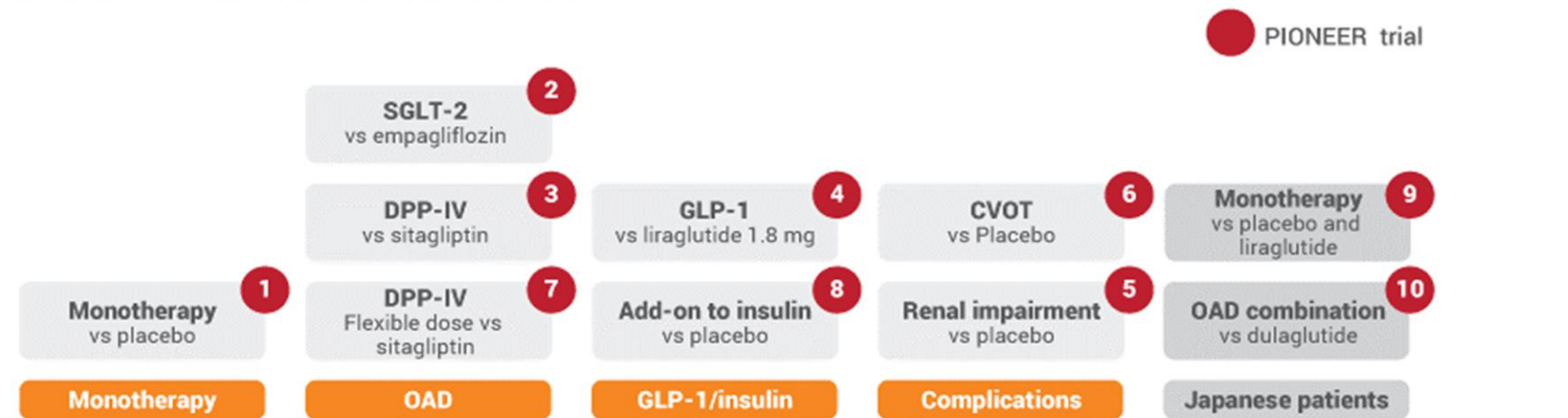
Rybelsus is priced at **\$773 per month** or **\$500 per month** on a net basis (35% gross to net).

Emisphere receives a **2.5% royalty** on global Rybelsus sales. The royalty rate steps up to 4.0% on a next generation formulation.



**Rybelsus was studied in 9,500 patients in the Phase 3 PIONEER trials including head-to-head studies against leading diabetes agents including Januvia, Jardiance, and Victoza.**

**PIONEER program for Oral semaglutide investigates the entire treatment cascade**



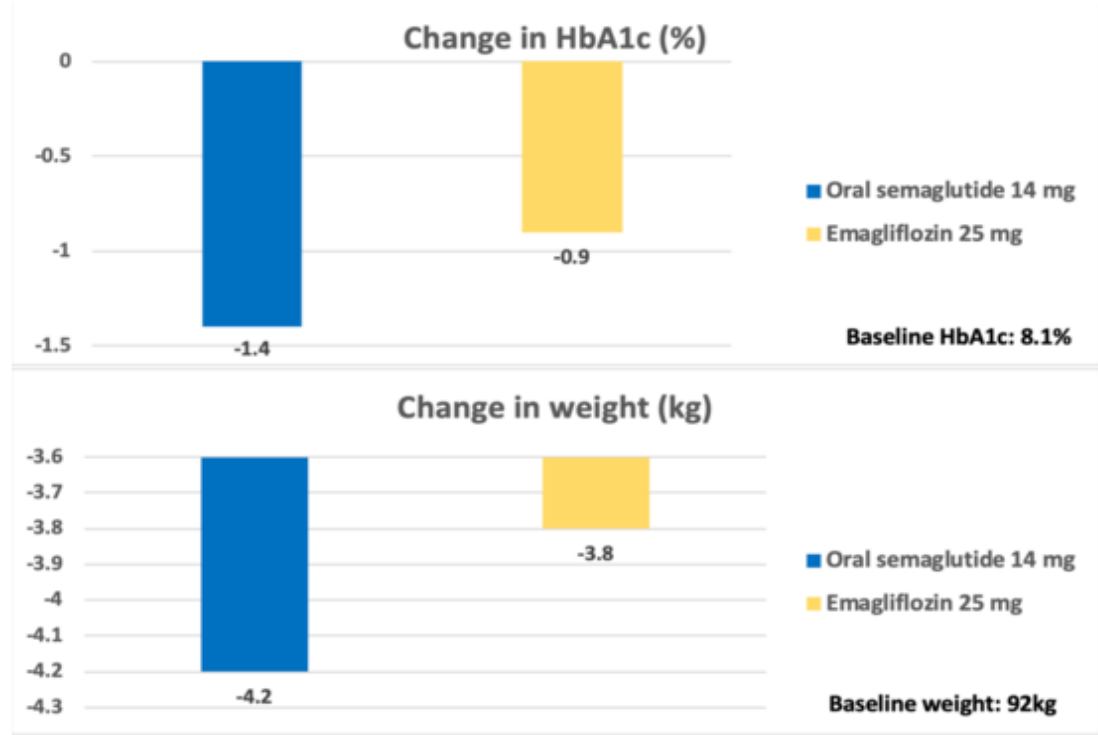
SGLT-2: Sodium-glucose co-transporter-2; DPP-IV: Dipeptidyl peptidase-4; OAD: Oral anti-diabetic; CVOT: Cardiovascular outcomes trial



Source: company reports

**Rybelsus outperformed Jardiance on HbA1C lowering and weight loss. Jardiance sales are > \$1 billion globally.**

PIONEER 2: Daily oral semaglutide versus empagliflozin 25 mg in people with type 2 diabetes

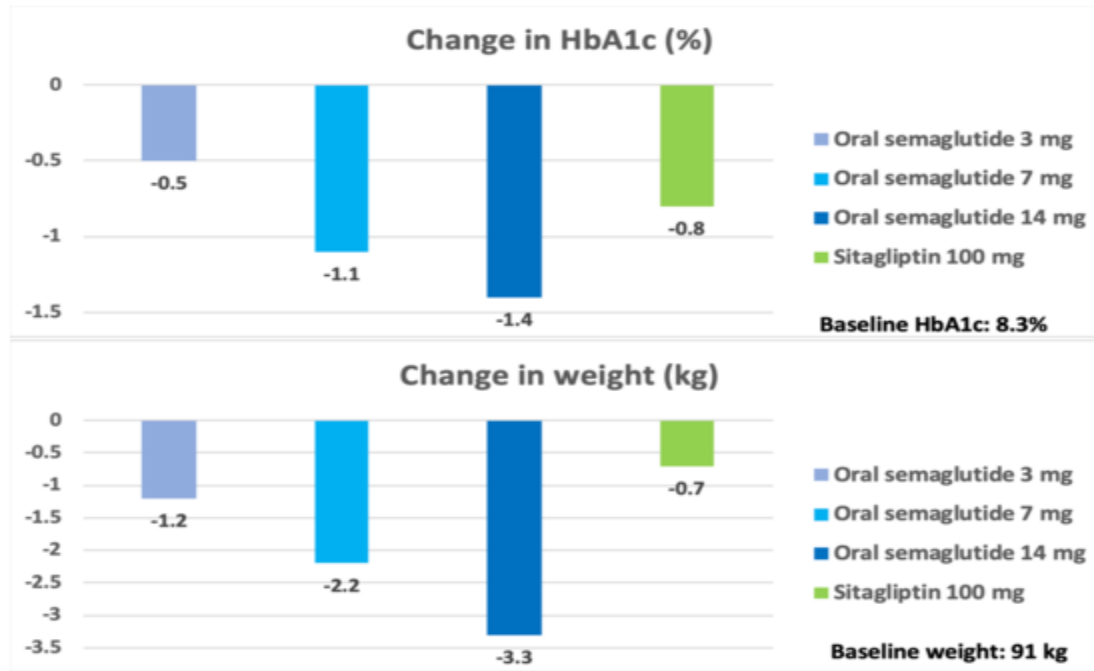


Source: company reports



**Rybelsus outperformed Januvia on HbA1C lowering and weight loss. Januvia sales are > \$5 billion globally.**

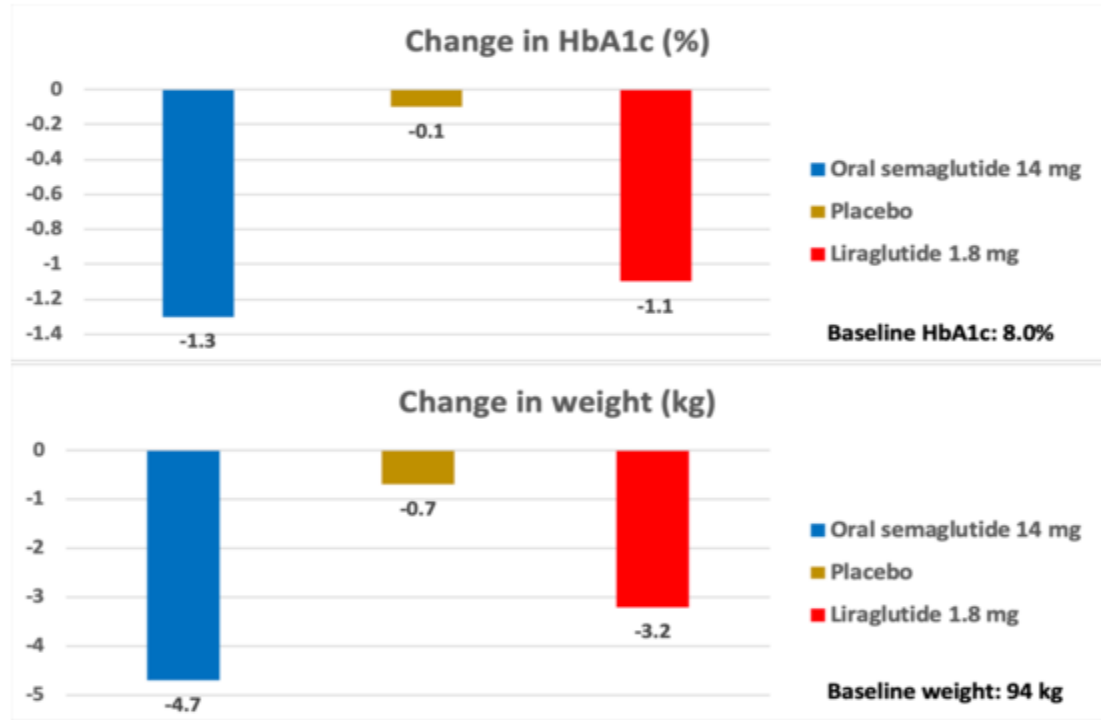
PIONEER 3: Daily oral semaglutide versus sitagliptin 100 mg in people with type 2 diabetes



Source: company reports

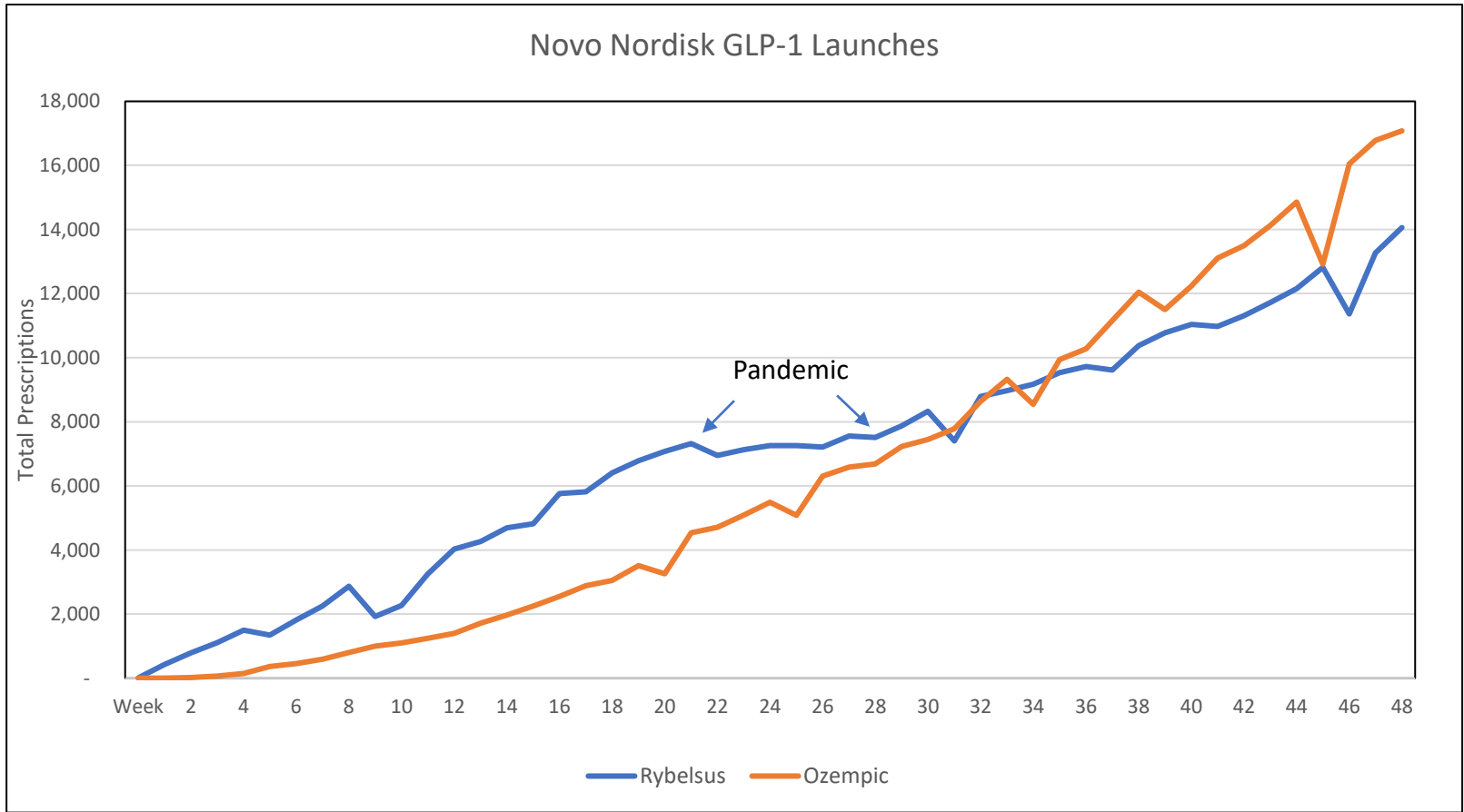
**Rybelsus outperformed Victoza (injectable) on HbA1C lowering and weight loss. Victoza sales are \$2.8 billion globally.**

PIONEER 4: Daily oral semaglutide versus liraglutide 1.8 mg in people with type 2 diabetes



Source: company reports

**Rybelsus is off to a strong start in the United States and is mirroring the highly successful Ozempic launch despite headwinds from the global pandemic.**



Source: IQVIA data

**A proprietary survey of 25 endocrinologists predicts strong Rybelsus uptake over time.**

| GLP-1 Drug | % Use Before Rybelsus | % Use 3 years After Rybelsus |
|------------|-----------------------|------------------------------|
| Trulicity  | 40%                   | 25%                          |
| Victoza    | 30%                   | 18%                          |
| Ozempic    | 19%                   | 16%                          |
| Rybelsus   | 0%                    | 35%                          |
| Bydureon   | 12%                   | 6%                           |

\*\*may not add to 100% based on rounding

Key conclusions:

- Within their GLP-1 use, respondents expect Rybelsus to achieve a 35% share within 3 years.
- 72% of respondents predict that Rybelsus would take meaningful share from the DPP-4 class including Januvia.
- 76% of respondents label Rybelsus as a strong competitor in the GLP-1 class and applicable to many diabetics.



Source: Summers Value Partners LLC research

## Rybelsus has received favorable physician feedback.

"I do think this is a great day for people with diabetes. I do hope that primary care providers whose practice and staffing have difficulty supporting injected therapies will avail themselves of this opportunity. That is the real opportunity afforded by Rybelsus." - **Dr. John Buse, University of North Carolina**

"I'm very happy to see this approval – my hope is access won't be the major challenge as it has been in the past with new GLP-1 receptor agonists due to cost. As a rule, we have under-utilized this class due to cost, side effects, and both patients and their providers not wanting injections – even weekly. At least one of these three challenges is not an issue with this new drug." - **Dr. Irl Hirsch, University of Washington**

"My hope is that this lowers the barrier for use of GLP-1 receptor agonists in primary care. An oral medication is perceived as easier to initiate. The guidelines shouldn't change per se because of this, but the ease of following the guidelines might have just become easier!" - **Dr. Anne Peters, Director, USC Westside Center for Diabetes, Los Angeles**

"This is inspiring news for the diabetes community. This astonishing breakthrough treatment can now be made available to a broader segment of patients with type 2 diabetes. Importantly, this does not replace anything, but rather provides another option for providers and patients who have limitations or reservations in the use of the injectable form of this important new drug that offers so many benefits for vast numbers of patients with type 2 diabetes mellitus. This is a true breakthrough that changes the face of oral therapy in diabetes." - **Dr. James Gavin, Emory**

"Semaglutide already has proven itself to be a highly efficacious GLP-1 receptor agonist. The availability of an oral formulation has the potential to expand opportunities for even more patients to derive benefit from this molecule." - **Dr. Alan Moses, The diaTribe Foundation Board of Directors; former Chief Medical Officer, Joslin Clinic; former global chief medical officer, Novo Nordisk**

The logo for RYBELSUS semaglutide tablets, featuring the word "RYBELSUS" in a large, bold, blue and yellow gradient font, with "semaglutide tablets" in a smaller, blue sans-serif font below it.

Source: [www.diatribefoundation.com](http://www.diatribefoundation.com)

**Rybelsus has received favorable patient feedback.**

Isabel · Taken for 1 to 6 months

September 24, 2020

**For Diabetes, Type 2:** "My endocrinologist prescribed 3 mg to start because the B12 depletion from metformin (I have b12 anemia) was not good and constant yeast infections from Forxiga were very annoying. At first, I noticed a major appetite decline. There was a bit of nausea for the first 2 weeks. I started the 7 mg after a month and while I've been experiencing constipation, I am so happy about the weight loss. I've been on Rybesus for 10 weeks and have lost 10 lbs. My latest random glucose test had me at 5.7, down from 6.3 - 7 over the previous few months. I am happy about fewer carb cravings and will stay on Rybelsus as long as I can. I am lucky my health plan covers it because it's quite expensive."

10 / 10 

Jarin · Taken for 1 to 6 months

August 30, 2020

**For Diabetes, Type 2:** "This med Rybelsus is awesome. It has helped me bring my A1C down to 5.1 from a high of 9.7. I first started with the 3mg and am now on the 14mg. Been on this med since March and while I did experience some nausea and mild upset stomach it went away after about a week. It has also helped me lose 50lbs as well. I also take with metformin. I should be the poster child for this drug...even though I'm 50."

Source: [www.drugs.com](http://www.drugs.com)



Actual Rybelsus patient. Before and after pictures following 6 months on the drug.

Source: [www.Instagram.com](http://www.Instagram.com)

**RYBELSUS**  
semaglutide tablets

Novo Nordisk has invested heavily in Rybelsus and is staking its future on the GLP-1 class.

\$2+ billion on global manufacturing capacity

\$500+ million on clinical studies

\$200 million on a priority review voucher

\$10s of millions on advertising and promotion



While chief executive Lars Fruergaard Jørgensen said the firm was “more and more becoming a GLP-1 based company,” chief scientific officer Mads Krogsgaard Thomsen said Novo was “maybe 8-10 years ahead of competition in oral GLP-1.”



**RYBELSUS**  
semaglutide tablets

Source: company reports and transcripts

**Our global GLP-1 market model estimates a \$29 billion class by 2025.**

| GLP-1 Market Model                      | Administration      | 2018         | 2019         | 1Q20         | 2Q20         | 3Q20e        | 4Q20e        | 2020e         | 1Q21e        | 2Q21e        | 3Q21e        | 4Q21e        | 2021e         | 2022e         | 2023e         | 2024e         | 2025e         |
|---|---------------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|--------------|--------------|--------------|---------------|---------------|---------------|---------------|---------------|
| Trulicity (Dulaglutide) Sales - LLY     | 1x Weekly Injection | 3,199        | 4,127        | 1,229        | 1,230        | 1,250        | 1,475        | 5,184         | 1,450        | 1,500        | 1,475        | 1,750        | 6,175         | 7,150         | 8,000         | 8,750         | 9,400         |
|   | y/y change          | 57.6%        | 29.0%        | 39.9%        | 19.5%        | 23.6%        | 22.1%        | 25.6%         | 17.9%        | 22.0%        | 18.0%        | 18.6%        | 19.1%         | 15.8%         | 11.9%         | 9.4%          | 7.4%          |
| Victoza (Liraglutide) Sales - NVO       | 1x Daily Injection  | 3,682        | 3,285        | 723          | 672          | 650          | 650          | 2,695         | 550          | 500          | 500          | 500          | 2,050         | 1,500         | 1,000         | 750           | 250           |
|   | y/y change          | 5.2%         | -10.8%       | -15.3%       | -14.2%       | -21.3%       | -20.9%       | -18.0%        | -23.9%       | -25.6%       | -23.1%       | -23.1%       | -23.9%        | -26.8%        | -33.3%        | -25.0%        | -66.7%        |
| Ozempic (Semaglutide) Sales - NVO       | 1x Weekly Injection | 272          | 1,662        | 689          | 767          | 900          | 1,100        | 3,456         | 1,100        | 1,100        | 1,250        | 1,450        | 4,900         | 6,150         | 7,350         | 8,500         | 9,500         |
|   | y/y change          |              | 511.0%       | 225.0%       | 126.3%       | 100.0%       | 66.4%        | 107.9%        | 59.7%        | 43.4%        | 38.9%        | 31.8%        | 41.8%         | 25.5%         | 19.5%         | 15.6%         | 11.8%         |
| Rybelsus (Oral Semaglutide) Sales - NVO | 1x Daily Oral       | -            | 7            | 33           | 56           | 86           | 125          | 300           | 210          | 300          | 420          | 525          | 1,455         | 2,900         | 4,700         | 6,900         | 9,500         |
|   | y/y change          |              |              |              |              |              |              |               | 536.4%       | 432.9%       | 388.4%       | 320.0%       | 384.5%        | 99.3%         | 62.1%         | 46.8%         | 37.7%         |
| Bydureon (Exenatide XR) - AZN           | 1x Weekly Injection | 584          | 549          | 100          | 116          | 105          | 95           | 416           | 95           | 95           | 90           | 80           | 360           | 305           | 265           | 225           | 180           |
|   | y/y change          | 1.7%         | -6.0%        | -29.6%       | -17.7%       | -17.3%       | -31.7%       | -24.2%        | -5.0%        | -18.1%       | -14.3%       | -15.8%       | -13.5%        | -15.3%        | -13.1%        | -15.1%        | -20.0%        |
| Byetta (Exenatide) - AZN                | 1x Daily Injection  | 126          | 110          | 20           | 15           | 15           | 15           | 65            | 10           | 10           | 10           | 10           | 40            | 30            | 25            | 20            | 15            |
|   | y/y change          |              | -12.7%       | -33.3%       | -40.0%       | -46.4%       | -44.4%       | -40.9%        | -50.0%       | -33.3%       | -33.3%       | -33.3%       | -38.5%        | -25.0%        | -16.7%        | -20.0%        | -25.0%        |
| <b>Total</b>                            |                     | <b>7,863</b> | <b>9,740</b> | <b>2,794</b> | <b>2,856</b> | <b>3,006</b> | <b>3,460</b> | <b>12,117</b> | <b>3,415</b> | <b>3,505</b> | <b>3,745</b> | <b>4,315</b> | <b>14,980</b> | <b>18,035</b> | <b>21,340</b> | <b>25,145</b> | <b>28,845</b> |
|   | y/y change          | 25.2%        | 23.9%        | 33.9%        | 23.3%        | 23.1%        | 21.1%        | 24.4%         | 22.2%        | 22.7%        | 24.6%        | 24.7%        | 23.6%         | 20.4%         | 18.3%         | 17.8%         | 14.7%         |
| Saxenda (Victoza in obesity)            | 1x Daily Injection  | 586          | 865          | 228          | 207          | 275          | 280          | 990           | 260          | 275          | 300          | 305          | 1,140         | 1,225         | 1,200         | 1,100         | 1,000         |
|   | y/y change          |              | 47.6%        | 24.6%        | -1.4%        | 17.0%        | 18.1%        | 14.5%         | 14.0%        | 32.9%        | 9.1%         | 8.9%         | 15.2%         | 7.5%          | -2.0%         | -8.3%         | -9.1%         |

Source: Summers Value Partners Estimates



**Our Emisphere model predicts strong revenue and profit growth in the future.**

|                | 2019a         | 2020e         | 2021e       | 2022e       | 2023e       | 2024e       | 2025e       |
|----------------|---------------|---------------|-------------|-------------|-------------|-------------|-------------|
| Rybelsus Sales | 7             | 300           | 1,455       | 2,900       | 4,700       | 6,900       | 9,500       |
| y/y growth     |               |               | 384.5%      | 99.3%       | 62.1%       | 46.8%       | 37.7%       |
| Royalty Rate   | 2.5%          | 2.5%          | 2.5%        | 2.5%        | 2.5%        | 2.5%        | 2.5%        |
| Royalties      | 0             | 8             | 36          | 73          | 118         | 173         | 238         |
| Gross Profit   | 0             | 7             | 36          | 72          | 116         | 171         | 235         |
| Margin %       | 99.0%         | 99.0%         | 99.0%       | 99.0%       | 99.0%       | 99.0%       | 99.0%       |
| OpEx           | 3             | 8             | 9           | 10          | 11          | 12          | 13          |
| y/y growth     |               |               | 12.5%       | 11.1%       | 10.0%       | 9.1%        | 8.3%        |
| EBIT           | (3)           | (1)           | 27          | 62          | 105         | 159         | 222         |
| Margin %       | -1556.2%      | -7.6%         | 74.3%       | 85.2%       | 89.6%       | 92.0%       | 93.5%       |
| Pretax Income  | (3)           | (1)           | 27          | 62          | 105         | 159         | 222         |
| Taxes          | -             | -             | -           | -           | -           | -           | -           |
| Tax Rate %     | 0.0%          | 0.0%          | 0.0%        | 0.0%        | 0.0%        | 0.0%        | 0.0%        |
| Net Income     | (3)           | (1)           | 27          | 62          | 105         | 159         | 222         |
| <b>EPS</b>     | <b>(0.02)</b> | <b>(0.00)</b> | <b>0.17</b> | <b>0.38</b> | <b>0.65</b> | <b>0.97</b> | <b>1.35</b> |
| Dil S/O        | 155           | 160           | 161         | 162         | 163         | 164         | 165         |

Source: Summers Value Partners Estimates

**We believe EMIS has 3x appreciation potential within 5 years with embedded optionality for the weight loss opportunity and a step-up in the royalty rate to 4%.**

|                | 2019a  | 2020e  | 2021e | 2022e | 2023e | 2024e | 2025e | 2026e | 2027e | 2028e | 2029e | 2030e |
|----------------|--------|--------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| EPS            | (0.02) | (0.00) | 0.17  | 0.38  | 0.65  | 0.97  | 1.35  | 1.21  | 1.36  | 1.48  | 1.56  | 1.61  |
| Dil S/O        | 155    | 160    | 161   | 162   | 163   | 164   | 165   | 166   | 167   | 168   | 169   | 170   |
| Cash           | 5      | 4      | 31    | 93    | 199   | 357   | 579   | 781   | 1,008 | 1,256 | 1,520 | 1,794 |
| Cash per share | 0.0    | 0.0    | 0.2   | 0.6   | 1.2   | 2.2   | 3.5   | 4.7   | 6.0   | 7.5   | 9.0   | 10.6  |

| Multiple | Price Target |        |      |       |       |       |       |       |       |       |       |       |
|----------|--------------|--------|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 15       | (0.27)       | (0.05) | 2.52 | 5.72  | 9.69  | 14.52 | 20.19 | 18.22 | 20.38 | 22.20 | 23.35 | 24.18 |
| 20       | (0.36)       | (0.07) | 3.36 | 7.63  | 12.92 | 19.36 | 26.92 | 24.29 | 27.17 | 29.59 | 31.14 | 32.24 |
| 25       | (0.45)       | (0.09) | 4.19 | 9.53  | 16.15 | 24.20 | 33.66 | 30.36 | 33.96 | 36.99 | 38.92 | 40.30 |
| 30       | (0.55)       | (0.11) | 5.03 | 11.44 | 19.38 | 29.04 | 40.39 | 36.43 | 40.76 | 44.39 | 46.71 | 48.36 |
| 35       | (0.64)       | (0.12) | 5.87 | 13.35 | 22.62 | 33.88 | 47.12 | 42.50 | 47.55 | 51.79 | 54.49 | 56.42 |

Source: Summers Value Partners Estimates

## Paths for shareholder value creation

- 1) Rybelsus **sales estimates increase** as physicians and patients appreciate the drug's unique profile
  - Direct-to-consumer advertising starting in the United States
  - More clinical studies underway evaluating new indications including weight loss (PK studies) and cardiovascular safety benefits (SOUL trial with 10,000 patients)
  - Additional country launches happening around the world
  
- 2) Emisphere becomes a **reporting company** and begins trading on a **national exchange**
  
- 3) Emisphere is **acquired** by Novo Nordisk or a royalty company (Royalty Pharma PLC, etc.)
  
- 4) Increasing **investor interest**
  - No Wall Street coverage currently
  - Low investor awareness today

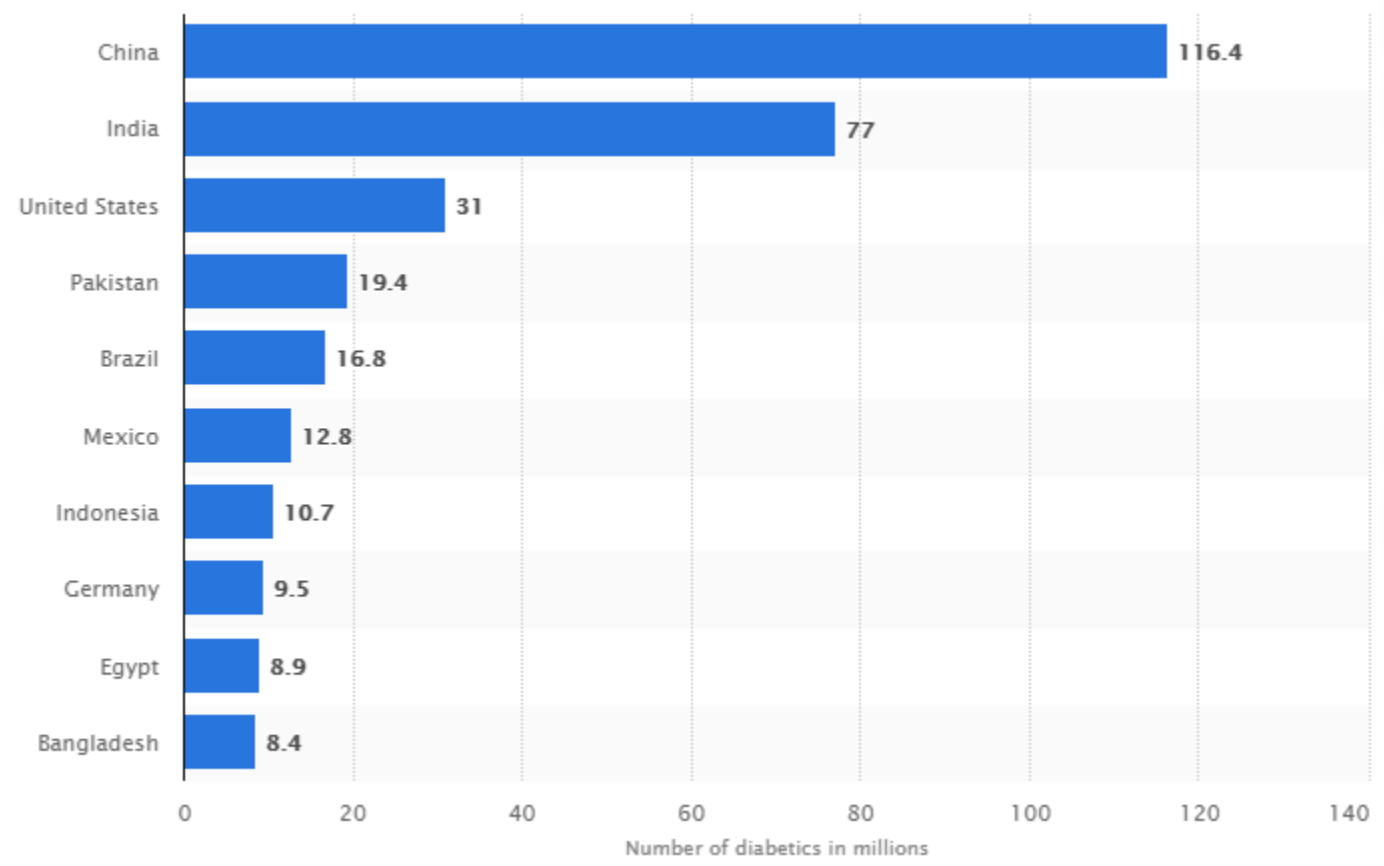
## Key Risks

- Emisphere is a non-reporting company subject to little SEC oversight with no updated financials
- Emisphere is effectively controlled by MHR Fund Management
- The company does not have a historical track record of sales or profits
- Emisphere is an illiquid security trading on the over-the-counter pink sheet exchange
- Rybelsus may not perform as expected
- Novo Nordisk could de-emphasize Rybelsus commercial activities
- Rybelsus is subject to FDA regulatory oversight

 Emisphere RYBELSUS  
semaglutide tablets

# Appendix

**Type 2 Diabetes is a growing epidemic around the world.**



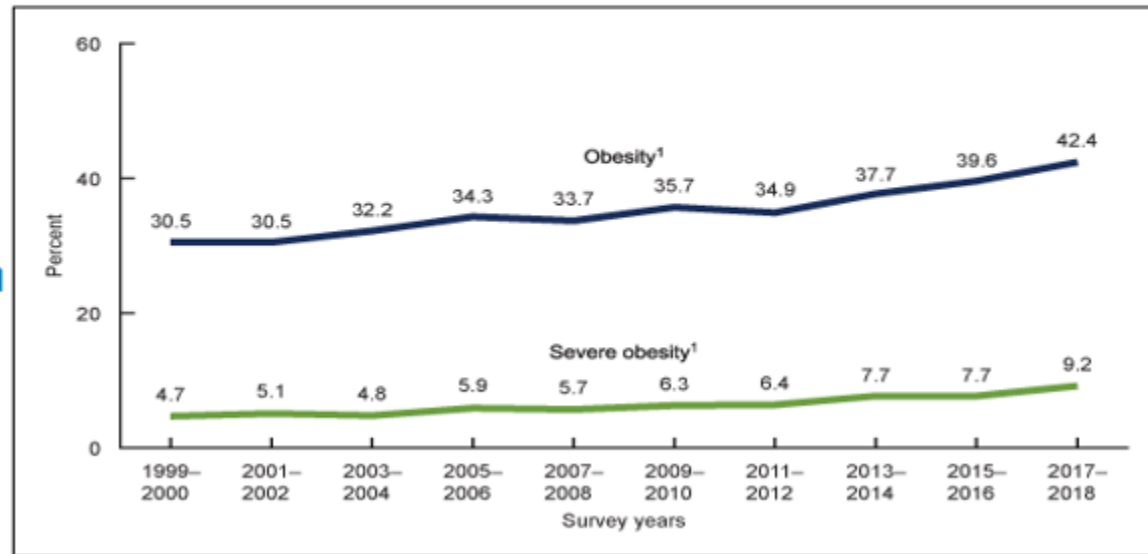
Source: www.statista.com

## Type 2 Diabetes in the United States (overall numbers).

- **Prevalence:** In 2018, 34.2 million Americans, or 10.5% of the population, had diabetes.
  - Nearly 1.6 million Americans have type 1 diabetes, including about 187,000 children and adolescents
- **Undiagnosed:** Of the 34.2 million adults with diabetes, 26.8 million were diagnosed, and 7.3 million were undiagnosed.
- **Prevalence in seniors:** The percentage of Americans age 65 and older remains high, at 26.8%, or 14.3 million seniors (diagnosed and undiagnosed).
- **New cases:** 1.5 million Americans are diagnosed with diabetes every year.
- **Prediabetes:** In 2015, 88 million Americans age 18 and older had prediabetes.

**It is estimated that 42% of adults (80 million people) are clinically obese in the United States. The trend is increasing over time.**

**Figure 4. Trends in age-adjusted obesity and severe obesity prevalence among adults aged 20 and over: United States, 1999–2000 through 2017–2018**



Source: www.cdc.gov

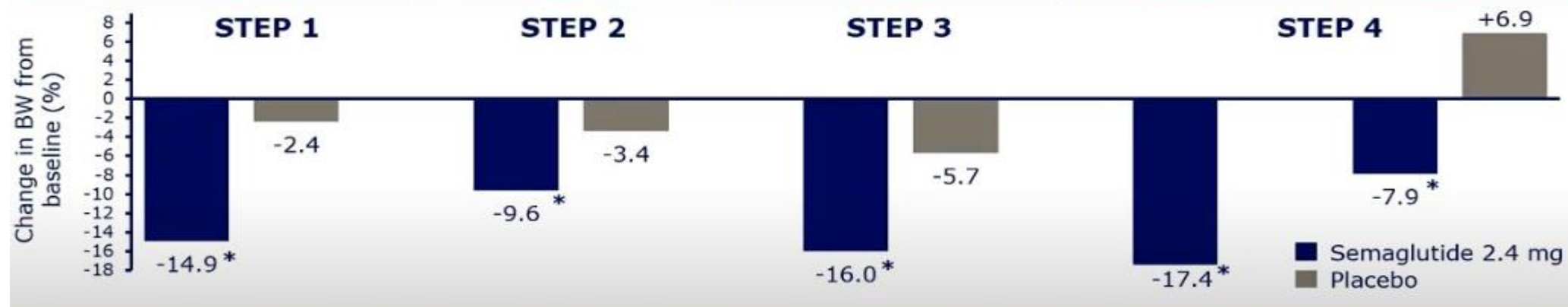


Ozempic showed a profound weight loss benefit in the Phase 3 STEP trials. Ozempic should file for a weight loss indication in 4Q20. Rybelsus phase 3 development in weight loss will begin in the near term.

# STEP programme: Phase 3a results

Effects of semaglutide 2.4 mg once-weekly in patients with obesity

|                                   | Weight management                                      | Weight management in T2D                            | Weight management with IBT   | Sustained weight management   |   |
|-----------------------------------|--|---|--|---|---|
| <b>Trial details</b>              | Adults with obesity or overweight without T2D (n=1961) | Adults with obesity or overweight with T2D (n=1210) | Adults with obesity or overweight, without diabetes adjunct to IBT (n=611) | Adults with obesity or overweight without diabetes reaching target dose during run-in (n=902) | Adults with obesity or overweight without diabetes after run-in (n=803) |
| <b>Duration &amp; Baseline BW</b> | 0-68 wks<br>105.3 kg                                   | 0-68 wks<br>99.8 kg                                 | 0-68 wks<br>105.8 kg   | 0-68 wks<br>107.2 kg  | 20-68 wks<br>96.1 kg  |



**Treatment policy estimand:** Evaluates the treatment effect regardless of trial product discontinuation and use of rescue medication

Source: EASD Virtual Meeting 2020

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