Highly Anticipated Drug Launches in 2017

Herspiegel Consulting LLC

Before we begin…

Inclusion criteria

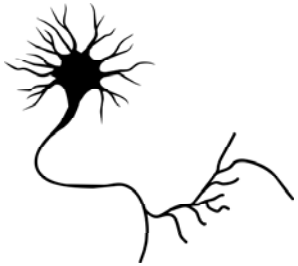
- High sales forecasts
- First-in-class MOA
- Breakthrough and fast track designations
- Qualitative opinions of analysts (investment banks specializing in pharma)

Key themes

1. Pricing is inescapable
2. Brace for a shakeup with President Trump
    a) Promises to decrease high drug prices in exchange for lax regulations
    b) Repeal / replace ACA

Herspiegel Consulting

1. Ocrelizumab (Ocrevus)



Roche
Manufacturer

Multiple Sclerosis
Indication

$4.1bn
2022 Sales Forecast

Why It Has Potential

- **First-ever** medicine to show ability to delay disability in patients with **PPMS** (existing treatments only delay RRMS)
- Designated a **breakthrough therapy** (Feb 2016)
- **Outperformed** Merck KGaA's top standard therapy, **Rebif**

Cautions

- **FDA pushed PDUFA** date from 12/28/16 to 3/28/17, citing questions about its commercial manufacturing process
- Generic Copaxone
- Will likely ramp up **payer pressure** on the entire MS market, which is already experiencing a cooldown

Other Commentary

- Payer pressure is attributable to clear industry trends in addition to formulary management

2. Dupilumab (Dupixent)

Sanofi / Regeneron
Manufacturer

Severe Atopic Dermatitis
Indication

$4.1bn
2022 Sales Forecast

Why It Has Potential

- Wealth of **solid clinical data**
- Unparalleled **efficacy**
- **Dearth** of solid atopic dermatitis **treatments**
- Examples: allergy-related disorders including Asthma

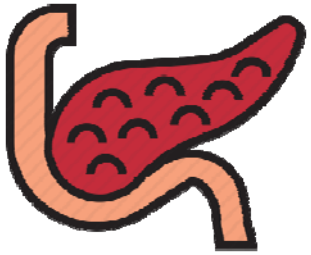
Cautions

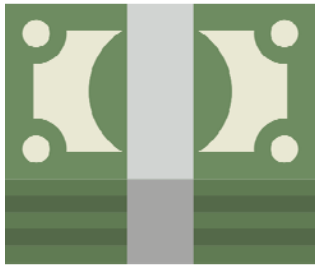
- **Payer obstacles have stalled recent launches of other specialty therapeutics** approved for chronic uses
- Examples: PCSK9 therapies Praulent (Sanofi / Regeneron) and Repatha (Amgen)
- Only **1.6M patients qualify for on-label treatment**, a small piece of the Eczema pie

Other Commentary

- Like many other drugs launching in 2017, all eyes will be on the price tag
- March 29, 2017 – FDA decision date

3. Semaglutide





Novo Nordisk
Manufacturer

Type 2 Diabetes
Indication

$2.2bn
2022 Sales Forecast

Why It Has Potential

- "Victoza is the strongest GLP-1 daily and **Semaglutide is the strongest GLP-1 weekly**"
- Outperformed AZ's weekly Bydureon (GLP-1), Merck's Januvia (DPP-4), and Sanofi's Lantus (basal)
- Also developing an **oral** Semaglutide, which will be the **first in the GLP-1 class**
- Wealth of positive clinical data, including, very **positive cardiovascular outcomes**

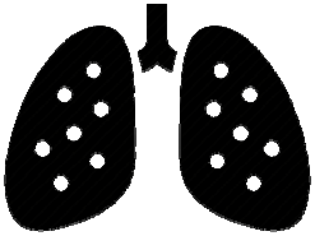
Cautions

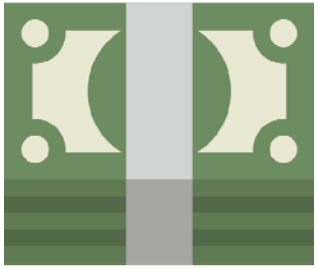
- Will have to face Lilly's weekly **Trulicity**, which is **quickly stealing market share** since its launch last year
- Pricing will be a challenge as the **GLP-1 class is crowded**

Other Commentary

- Novo will need to expand its outcomes research and build on its list of head-to-head studies
  - Example: currently recruiting for head-to-head study vs. Jardiance
- 12/5/2016 – NDA filed
- Phase III trials for oral Semaglutide are set to wrap up in late 2018 / early 2019

4. Durvalumab





AstraZeneca
Manufacturer

NSCLC
Indication

$1.9bn
2022 Sales Forecast

Why It Has Potential

- May snag a **first-line monotherapy** nod in combination with tremelimumab
- **NSCLC market is very lucrative**, as lung cancer is very aggressive
- Can exploit the **void** left by **BMS's Opdivo**, which flopped its own first-line monotherapy trial last August (BMS tanked 20%, making it a takeover target)

Cautions

- Efforts to snag **first line monotherapy** nod pushed back estimated completion date
- Opdivo (BMS), Keytruda (Merck), and Tecentriq (Roche) are all jockeying for position
- Regulators may not be in a rush to approve checkpoint drugs since **Keytruda has been on the market since 2015** and won a first-line monotherapy indication last October

Other Commentary

- 2/17/16 – won **breakthrough therapy status for bladder cancer**, where it will battle Tecentriq
- 12/9/16 – **BLA application accepted** for bladder cancer

5. Baricitinib

Eli Lilly / Incyte
Manufacturer

Rheumatoid Arthritis
Indication

$1.8bn
2022 Sales Forecast

Why It Has Potential

- Differentiators: **oral**; long-term extension study determined positive effects can be maintained for **at least 48 weeks**
- Will follow Pfizer's **Xeljanz**, which recently failed to match Humira in head-to-head trials
- Wealth of **positive data**

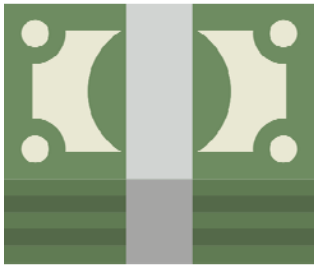
Cautions

- Waiting **longer than expected** due to FDA's request for additional data analyses in mid Jan.
- The biosimilars are coming!!
  - Amjevita (biosimilar of Humira)
  - Erelzi (biosimilar of Enbrel)
- **Robust RA pipeline** (all Ph III):
  - GSK / JNJ (Sirukumab)
  - Sanofi / Regeneron (Sarilumab)
  - Gilead / Galapagos (Filgotinib)

Other Commentary

- FDA decision date – mid-April

6. Valbenazine (Ingrezza)



Neurocrine	**Tardive Dyskinesia**	**$1.3bn**
Manufacturer	Indication	2022 Sales Forecast

Why It Has Potential

- Both **fast track** and **breakthrough designations** (plus pediatrics)
- Wealth of robust data for TD indication
- "Take on TD" market development campaign
- Also pursing indication for **Tourette Syndrome**
- Scheduled to be reviewed for approval before **Teva's SD-809**; can be first-ever FDA-approved medicine for TD

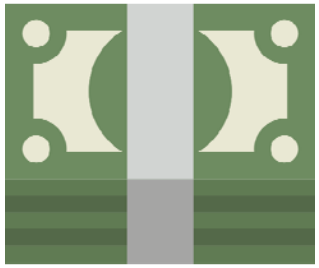
Cautions

- While it significantly improved overall symptoms, Valbenazine **missed primary endpoint** in TS study last January
- TS is the bigger market
- **Black box warning** for potential depression and suicidal ideation

Other Commentary

- 4/11/17 – FDA decision date
- Pediatric Tourette Syndrome data is expected in late March or early April

7. Axicabtagene Ciloleucel (KTE-C19)



Kite Pharma
Manufacturer

NHL / ALL
Indication

$1.4bn
2022 Sales Forecast

Why It Has Potential

- KTE-C19 pulled ahead of the race after series of **deaths in Juno's CAR-T trial**
- Novartis **cut much of its gene and cell therapy team** in 2016
- **PRIME designation from EMA**

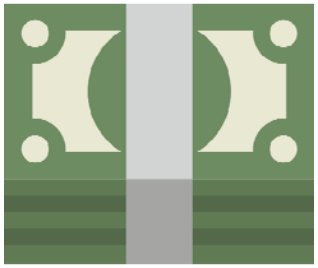
Cautions

- **Novartis** is also very strong in the CAR-T space
  - Very strong clinical data
  - Received **PRIME designation from EMA**

Other Commentary

- 12/4/16 – BLA submission date
- Ability to hit revenue targets depends on ability to **expand into other indications**
  - Example: solid tumors
- Analysts have predicted a price tag of **$300K per course**

8. Nusinersen (Spinraza)



Biogen
Manufacturer

Spinal Muscular Atrophy
Indication

$1.3bn
2022 Sales Forecast

Why It Has Potential

- **First-ever medicine** for spinal muscular atrophy (rare disease)
- Regardless of price, the **data illustrating unmet need and efficacy are overwhelming**
- SMA is the leading genetic cause of death for infants

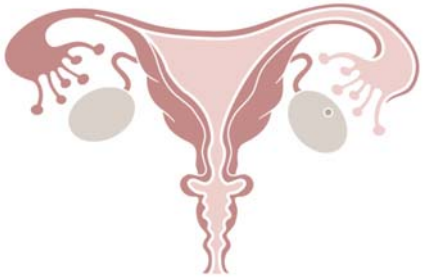
Cautions

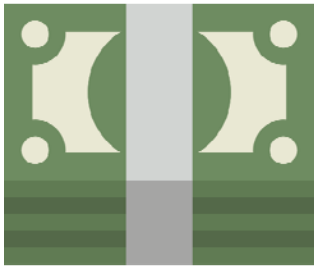
- "Price can be the straw that breaks the camel's back in terms of the U.S. market's tolerance for rare disease drug pricing."
- Price is $750K for the first year plus $375K per year after

Other Commentary

- Stock price dropped and attracted negative PR when price was announced
- Incidence: affects 1 / 10,000 babies and is often fatal
- 12/23/2016 – **FDA approved**

9. Niraparib





Tesaro	**Ovarian Cancer**	**$1.9bn**
Manufacturer	Indication	2022 Sales Forecast

Why It Has Potential

- Differentiator: showed efficacy in women with **BRCA gene mutation,** which is very hard to treat
- **Robust clinical data**: "we have never seen such large benefits in progression-free survival in recurrent ovarian cancer"
- Already won FDA's **priority review status**
- Massive potential patient population: **70%** of all ovarian cancer patients
- High expectations for a **broad label** (breast cancer)

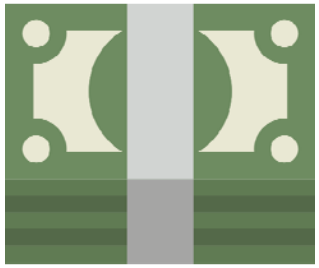
Cautions

- Not the first (or second) PARP-inhibiting drug on the market
- Examples: AZ's Lynparza and Clovis' Rubraca (also approved for BRCA gene mutation)

Other Commentary

- Jan 2017 – expanded access program (EAP) opened in the U.S.
- 6/30/17 – FDA decision date

10. Ribociclib



Novartis
Manufacturer

Breast Cancer
Indication

$1.6bn
2022 Sales Forecast

Why It Has Potential

- Snagged **FDA priority review** tag in Nov. 2016
- Differentiator: looking to collect pivotal data in **pre-menopausal women**
- **Strong phase III data**

Cautions

- Will need to challenge **Pfizer's Ibrance** in the CDK 4/6 field
- May have a **black box warning** for drug induced liver damage and mild cardiac arrhythmias

Other Commentary

- "Oncologists are used to monitoring the use of agents in these patients"
- Novartis doesn't view the "relatively routine" monitoring "as an undue burden"

Ending Notes

- All medicines in this list have the potential to be gamechangers, but **Ocrevus** is a standout favorite
- The pricing issue is here to stay
- The pharma sector is hurting