

Generics & Biosimilars

David Ridley

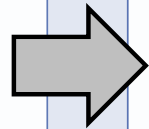
DUKE
FUQUA

Agenda

1. Where should Teva focus?
2. How is Teva?
3. How is the biosimilar market?
4. What are lessons and what is next?

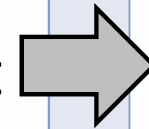
Developing

- Pipelines
- Licensing
- Patents



Commercializing

- Launching
- Reimbursement
- Pricing



Competing

- Lifecycle
- Biosimilars
- Generics

Teva's Strategic Focus

Product	Pro	Con
Innovative		
Biosimilars		
Global generics		
US generics		

Agenda

1. Where should Teva focus?
- 2. How is Teva?**
3. How is the biosimilar market?
4. What are lessons and what is next?

Teva has a branded migraine drug



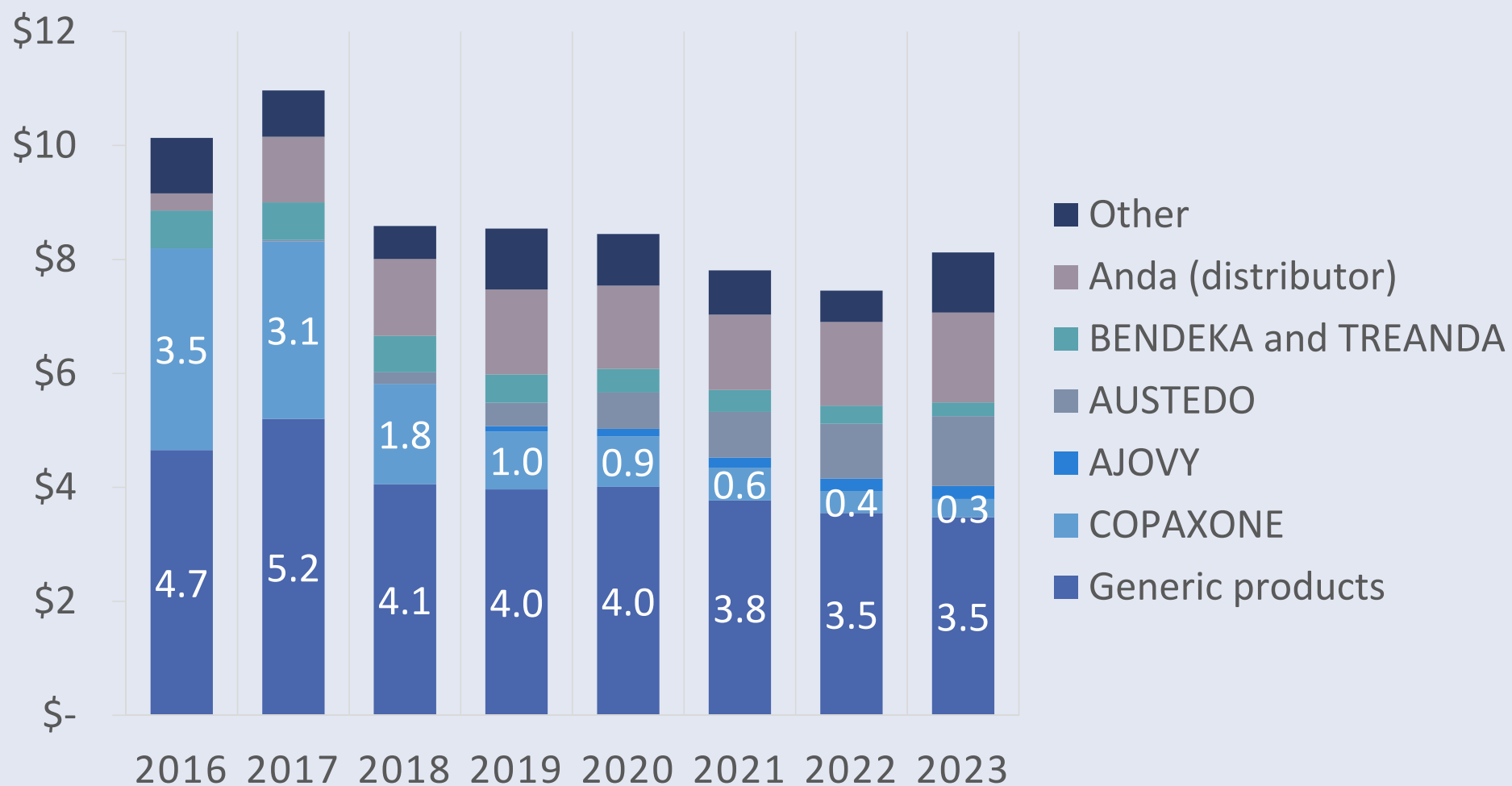
- Competition: migraine drugs in 2018
 - Amgen
 - Eli Lilly
 - Teva (“AJOVY”) – syringe, no autoinjector until 2020
- Competition: old migraine drugs (Triptans)
- Aggressive payers. Initially:
 - Express Scripts: excluded from formulary
 - Anthem: required step therapy (fail on 2 generic triptans)
 - BCBS: paid if from specialist, not primary care

Teva has branded multiple sclerosis drug

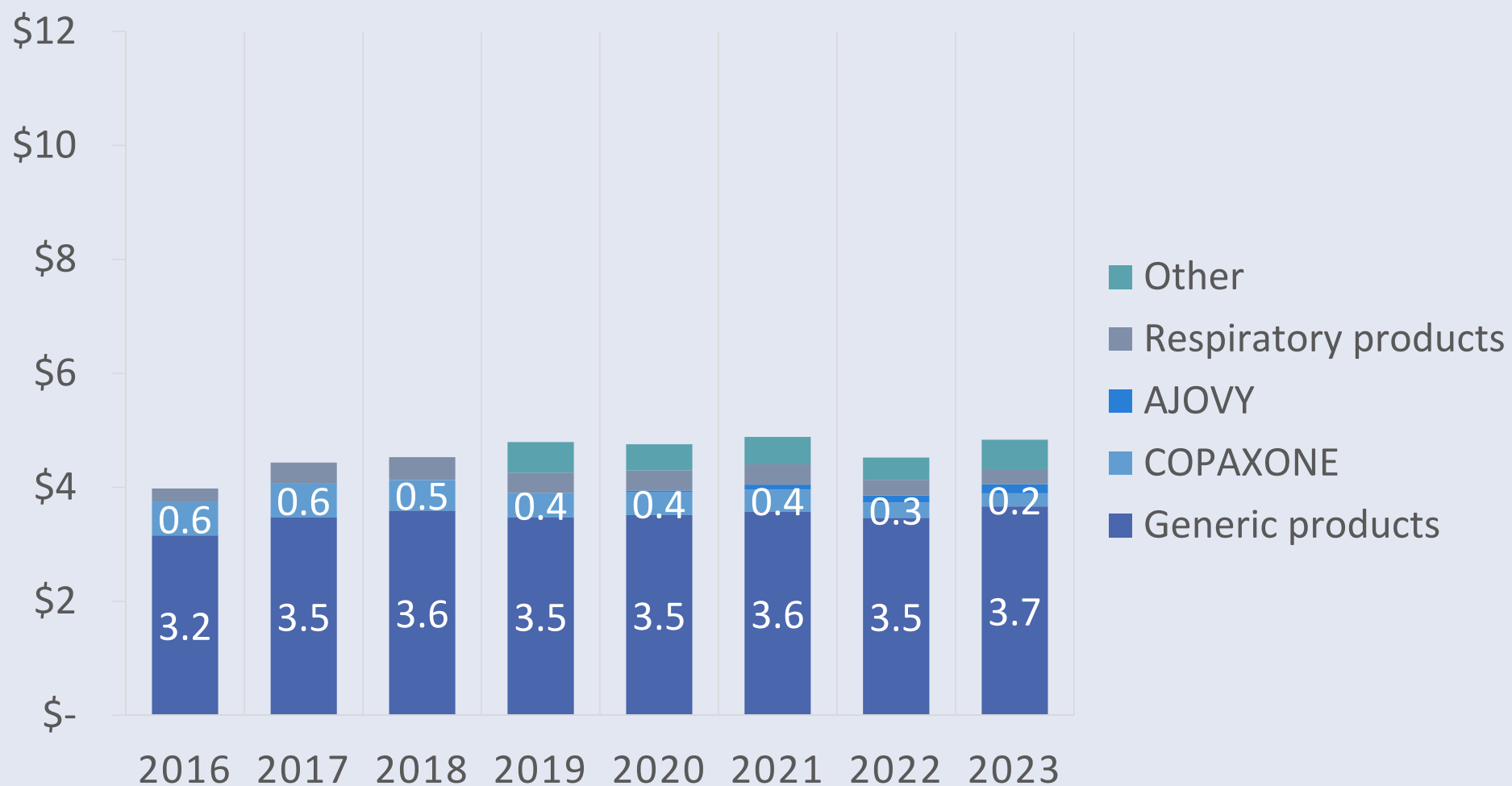


- Copaxone
- \$4 billion annual revenue at peak
- 20 mg (daily), 2014 expiration
- 40 mg (3x per week), 2018 exp.

TEVA NORTH AMERICAN REVENUE (BILLIONS)



TEVA EUROPEAN REVENUE (BILLIONS)



TEVA INTERNATIONAL REVENUE (BILLIONS)



TEVA

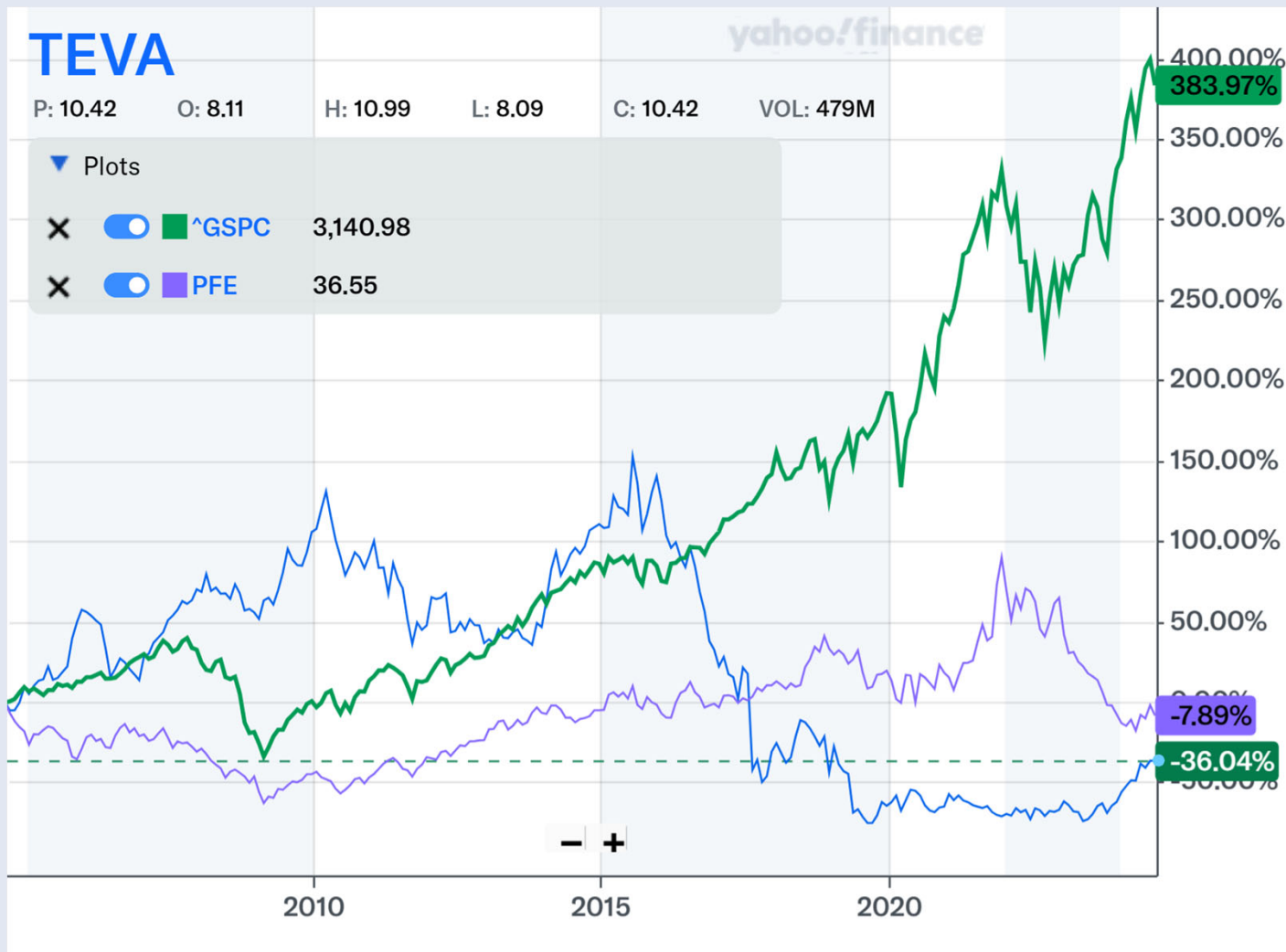
yahoo!finance

P: 10.42 O: 8.11 H: 10.99 L: 8.09 C: 10.42 VOL: 479M

▼ Plots

X ☒ ☒ ^GSPC 3,140.98

X ☒ ☒ PFE 36.55



S&P 500

Pfizer

TEVA

Teva's headaches

- New brand drug is in crowded class with aggressive payers
- Expired patent on blockbuster
- Core competency is in commodities
- New ventures limited by debt
 - Acquired Cephalon for \$7B
 - Acquired Allergan generics for \$40B
- Opioid litigation
- Price fixing litigation



Teva's Strategic Focus

Product	Pro	Con
Innovative	Israeli scientists favor Teva	But large phase 3 trials require global populations
Biosimilars	Expert in both brand and generic	But do they understand provider reimbursement ("buy & bill")
Global generics	Global market has branded generics	But Teva/P&G partnership ended
US generics	Scale and patent attorneys	But will buyers pay more than a few cents for one-stop shopping?

Lessons from Teva

- Don't go into massive debt expanding in a commodity business
- Even in a commodity business, try to differentiate
 - 180 days of exclusivity for successful patent challenge
 - Branded generics in many countries
 - Complex generics, such as drugs+devices, such as EpiPen & Advair
 - Biosimilars

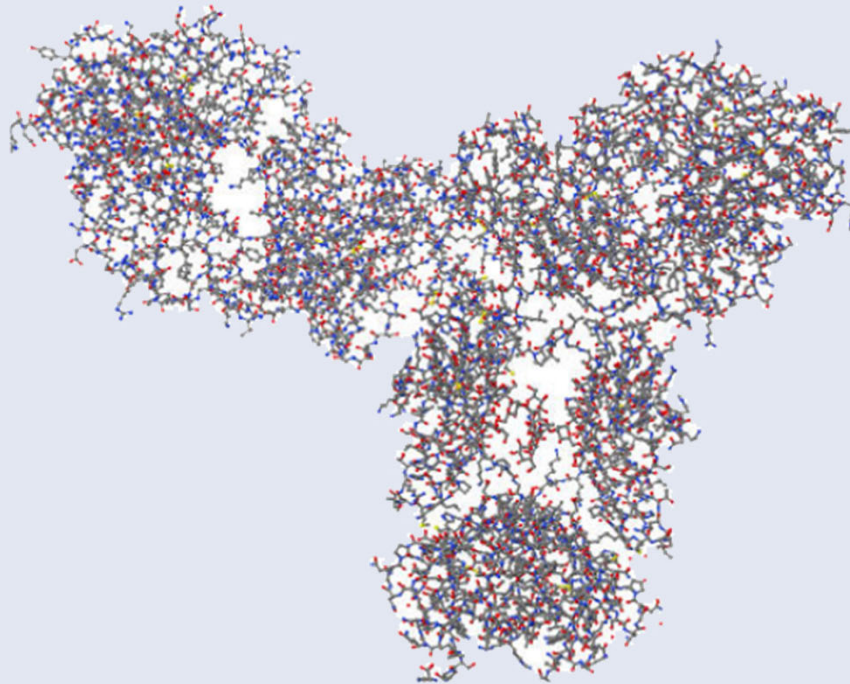
Agenda

1. Where should Teva focus?
2. How is Teva?
- 3. How is the biosimilar market?**
4. What are lessons and what is next?

Generics versus biosimilars



Aspirin

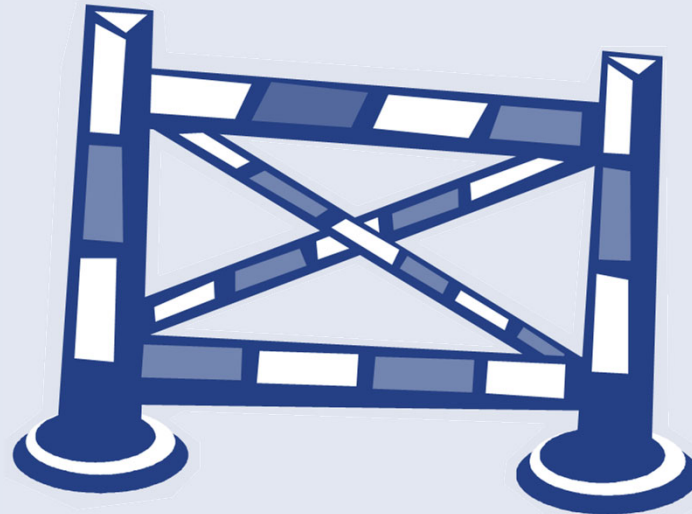


Monoclonal Antibody

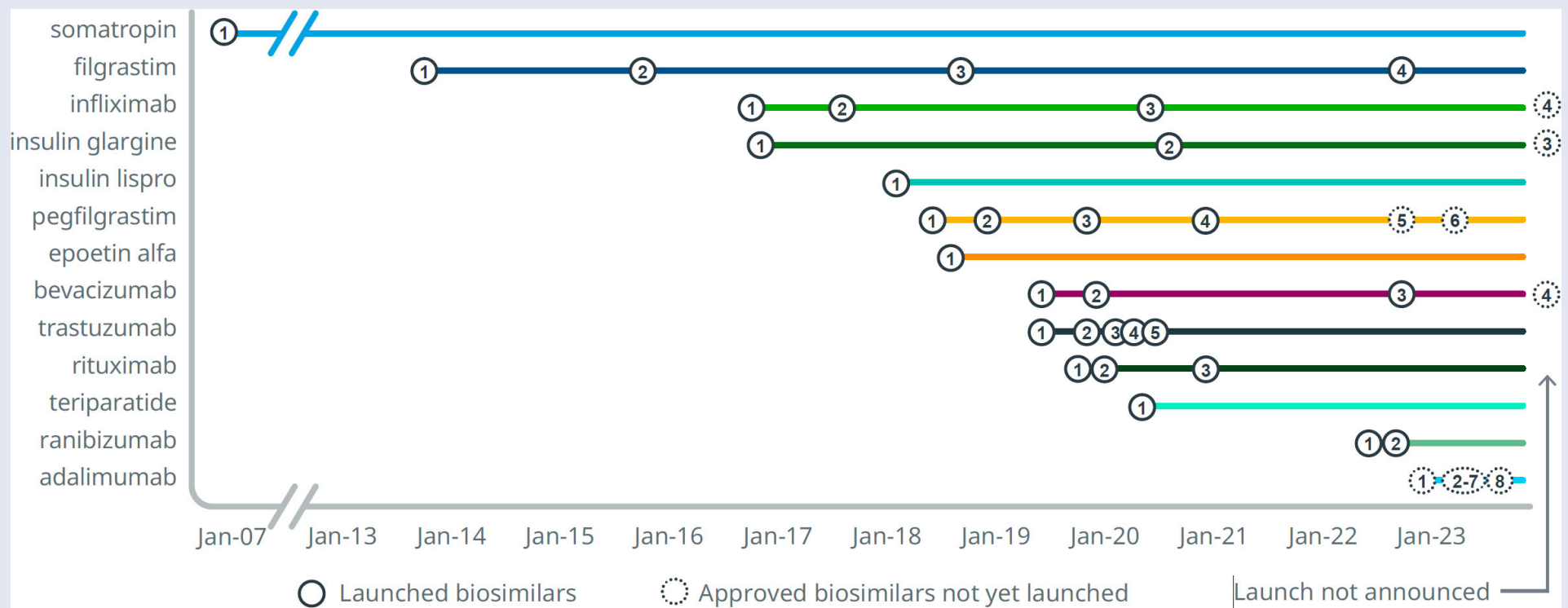
Source: FDA

Regulatory hurdles for biosimilars

- Intellectual property
- Clinical testing



Biosimilar launches in United States



Source: IQVIA 2023

Adalimumab (Humira) formulary coverage, 2024

Product name	Manufacturer	WAC (2023)	WAC vs. Humira	Express Scripts	CVS Caremark	OptumRx
Humira	AbbVie	\$6,922	n.a.	✓	✓ ⁴	✓
Humira ⁴	AbbVie/Cordavis	TBD	-0%	-	- ⁴	-
Amjevita (High WAC)	Amgen	\$6,576	-5%	-	-	✓
Amjevita (Low WAC)	Amgen	\$3,115	-55%	-	-	✓
Hulio	Biocon Biologics	\$6,576	-5%	-	- ³	-
adalimumab-fkjp	Biocon Biologics	\$995	-86%	-	- ³	-
Cyltezo ¹	Boehringer Ingelheim	\$6,576	-5%	✓	- ³	✓
adalimumab-adbm ¹	Boehringer Ingelheim	\$1,315	-81%	✓	- ³	✓
Yuflyma ²	Celltrion	\$6,576	-5%	-	- ³	-
Yusimry	Coherus	\$995	-86%	-	- ³	-
Idacio	Fresenius Kabi	\$6,576	-5%	-	- ³	-
Abrilada ¹	Pfizer	\$6,576	-5%	-	- ³	- ³
Hadlima ²	Samsung Bioepis/Organon	\$1,038	-85%	-	- ³	-
Hyrimoz ²	Sandoz	\$6,576	-5%	✓	✓	✓
Hyrimoz ²	Sandoz/Cordavis	\$1,315	-81%	-	✓	-
adalimumab-adaz ²	Sandoz	\$1,315	-81%	✓	✓	✓

WAC = list price. Source: Drug Channels

Adalimumab (Humira) biosimilars in US

FDA approval	Applicant	Proper name	Proprietary name	Interchangeable
2016	Amgen	adalimumab-atto	Amjevita	
2017	Boehringer	adalimumab-adbm	Cyltezo	✓
2018	Sandoz	adalimumab-adaz	Hyrimoz	
2019	Pfizer	adalimumab-afzb	Abrilada	
2019	Samsung	adalimumab-bwwd	Hadlima	
2020	Mylan	adalimumab-fkjp	Hulio	
2021	Coherus	adalimumab-aqvh	Yusimry	
2022	Fresenius	adalimumab-aacf	Idacio	

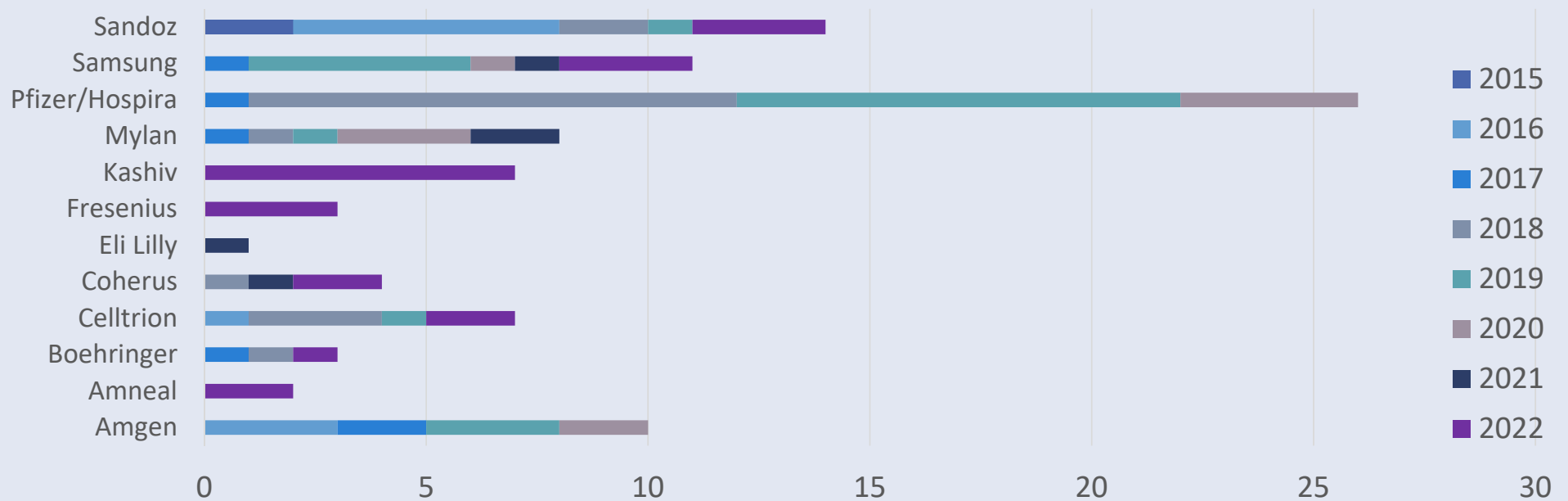
Source: Ridley using FDA Purple Book Data

Interchangeable

- Manufacturer must demonstrate
 - in trials
 - patients can switch back and forth
- Important in retail, because
 - allows pharmacist to substitute
 - without asking prescribing doctor

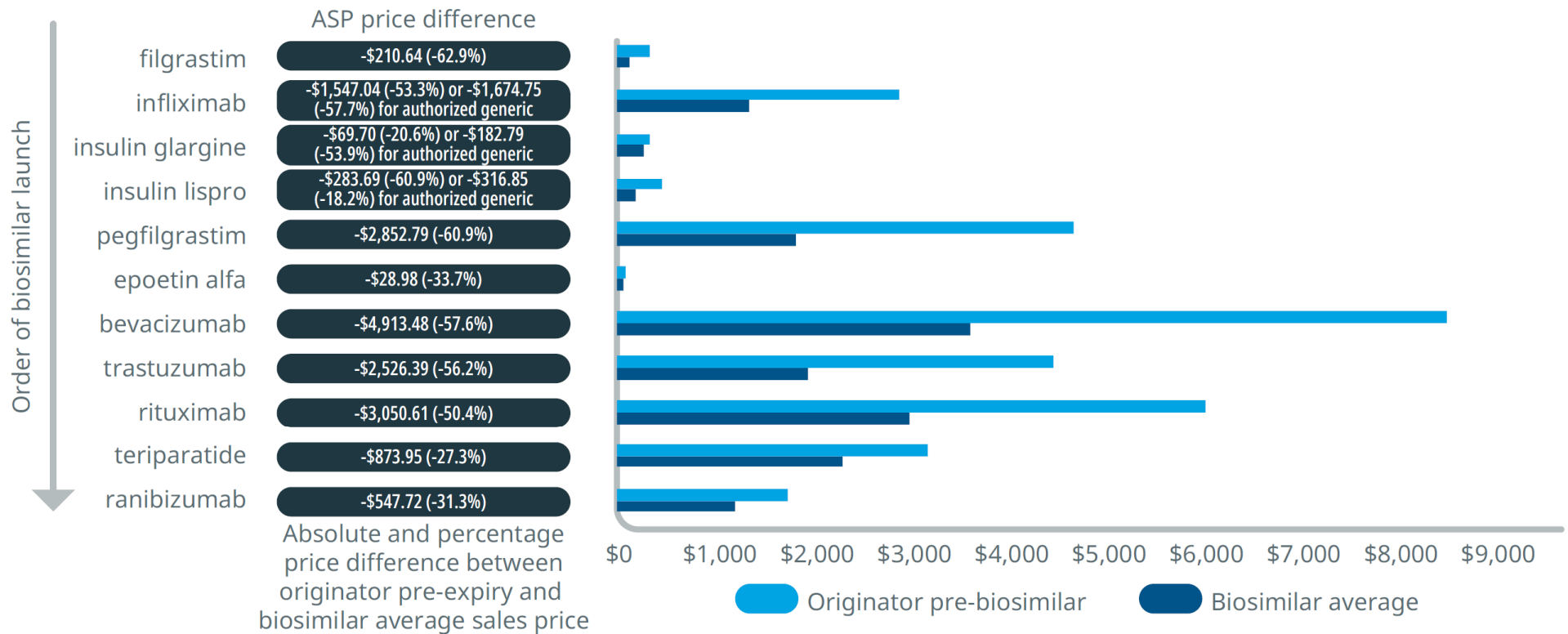
Product	Biosimilar maker
adalimumab	Boehringer
insulin glargine	Eli Lilly Mylan
ranibizumab	Coherus

FDA biosimilar applicants



By molecule/strength; there are fewer molecules
Source: Ridley using FDA Purple Book Data

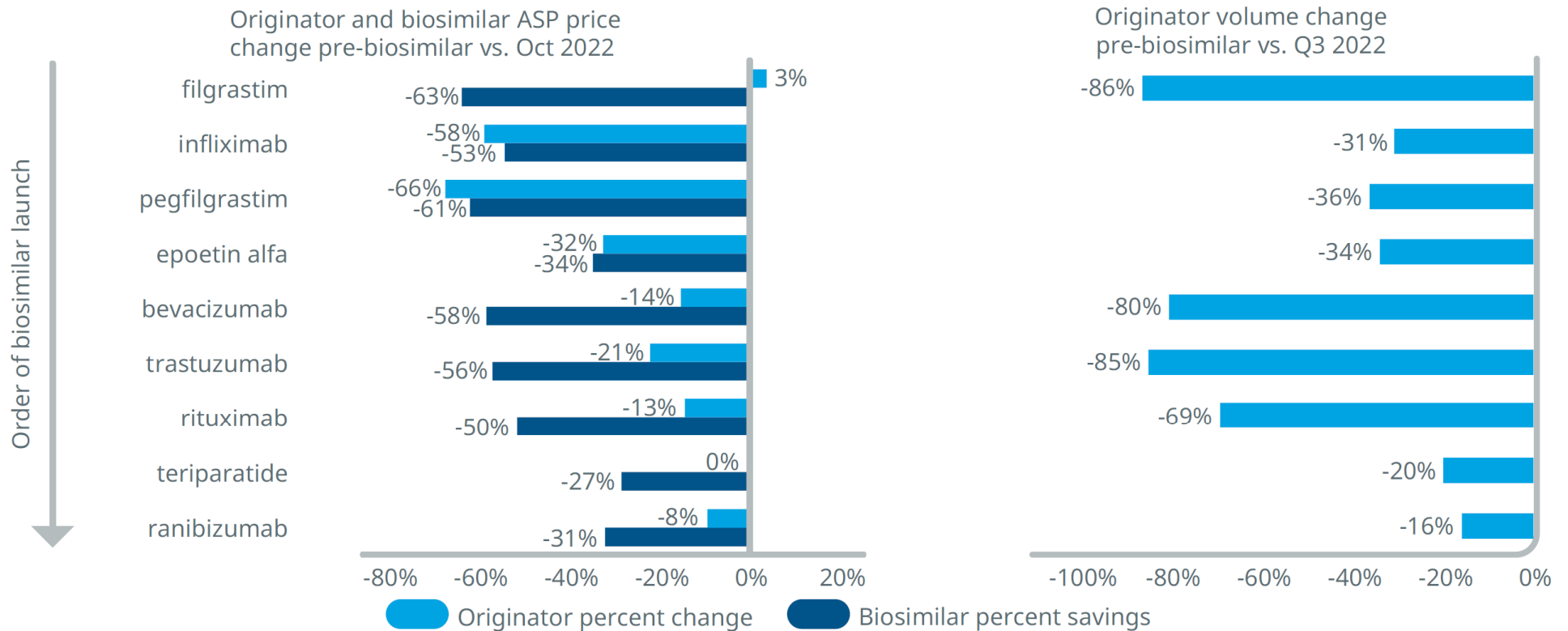
Originator and biosimilar prices



ASP=average sales price

Source: IQVIA 2023

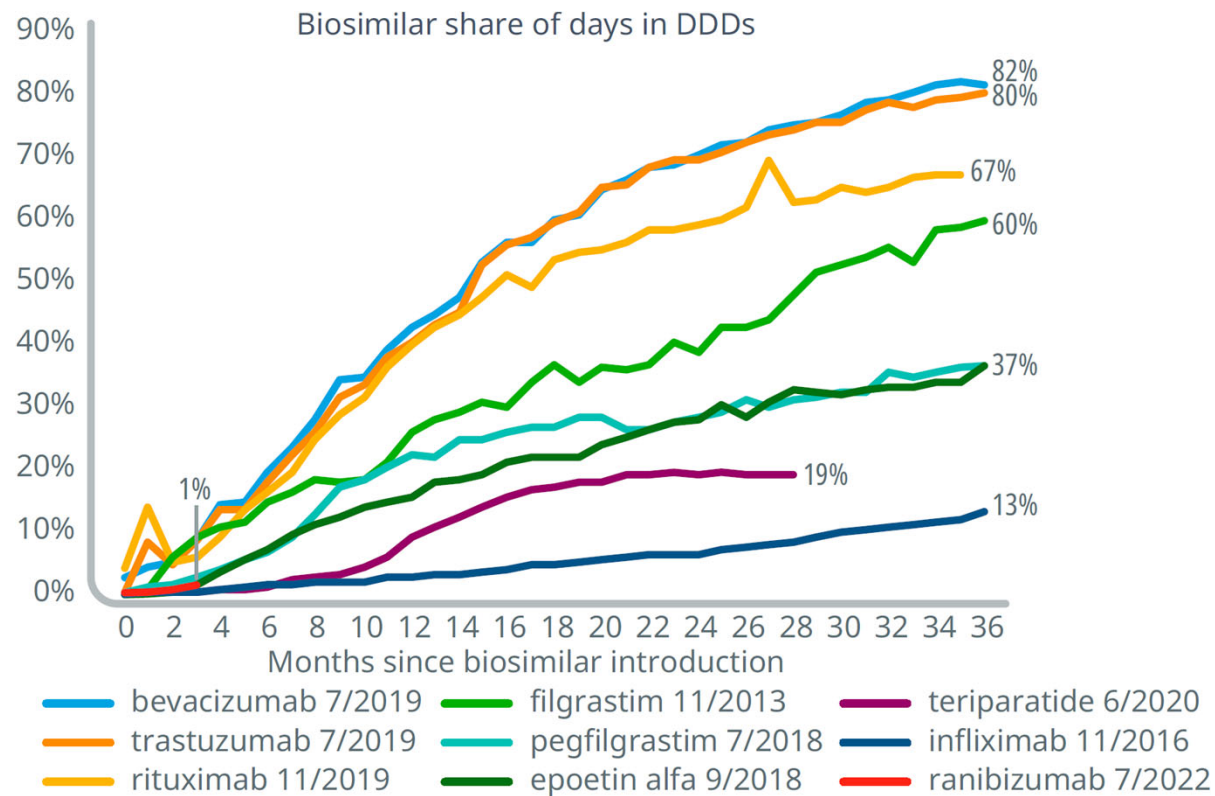
Originator and biosimilar prices



ASP=average sales price

Source: IQVIA 2023

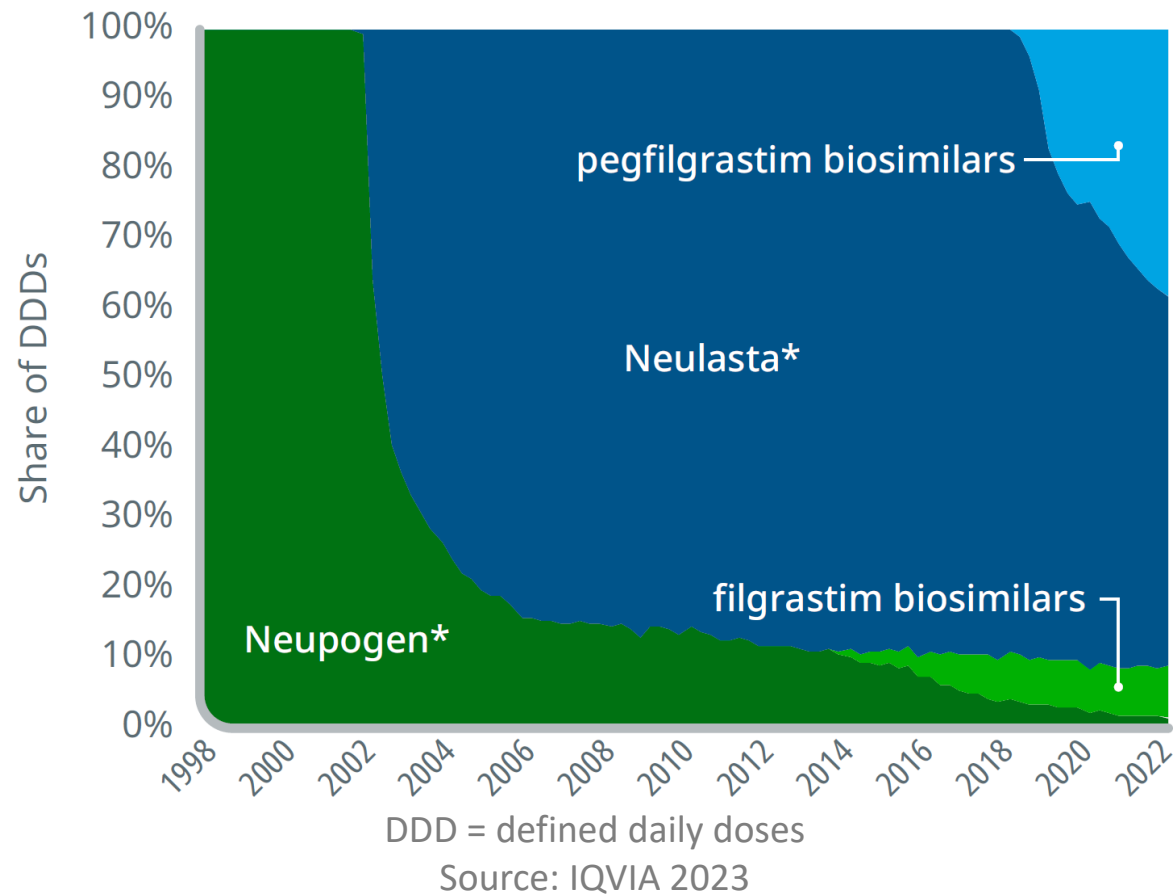
Biosimilar shares



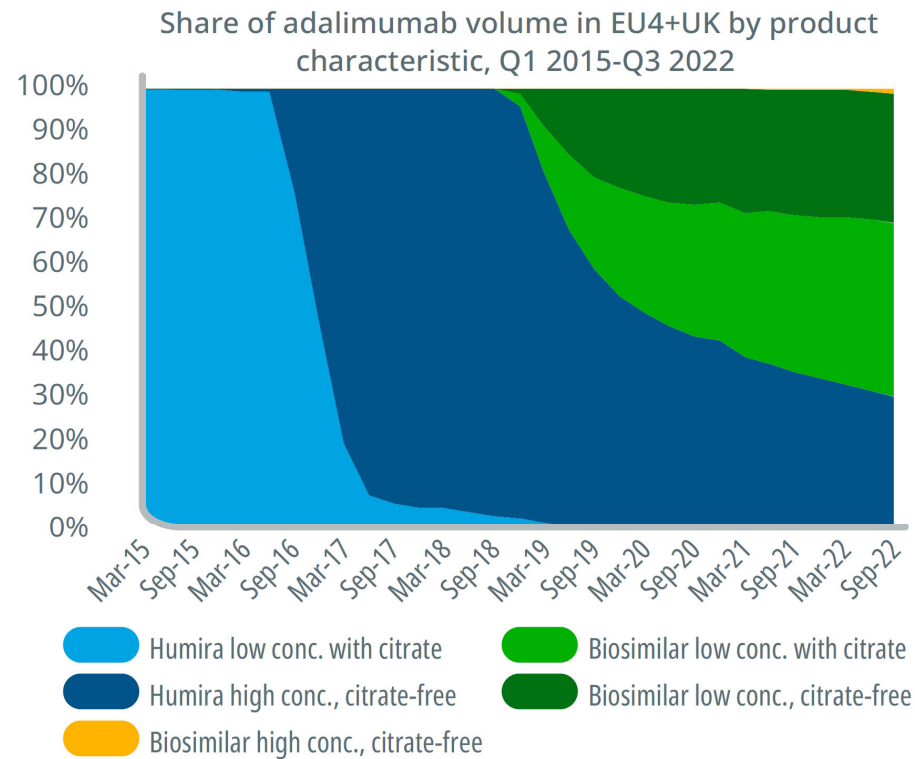
DDD = defined daily doses

Source: IQVIA 2023

Filgrastim and followers



Adalimumab and followers in Europe



Adalimumab = Humira; DDD = defined daily doses

Source: IQVIA 2023

Inflation Reduction Act

- Pharmaceuticals (small): 9 years to price controls
- Biologics (large): 13 years to price controls

Agenda

1. Where should Teva focus?
2. How is Teva?
3. How is the biosimilar market?
4. **What are lessons and what is next?**

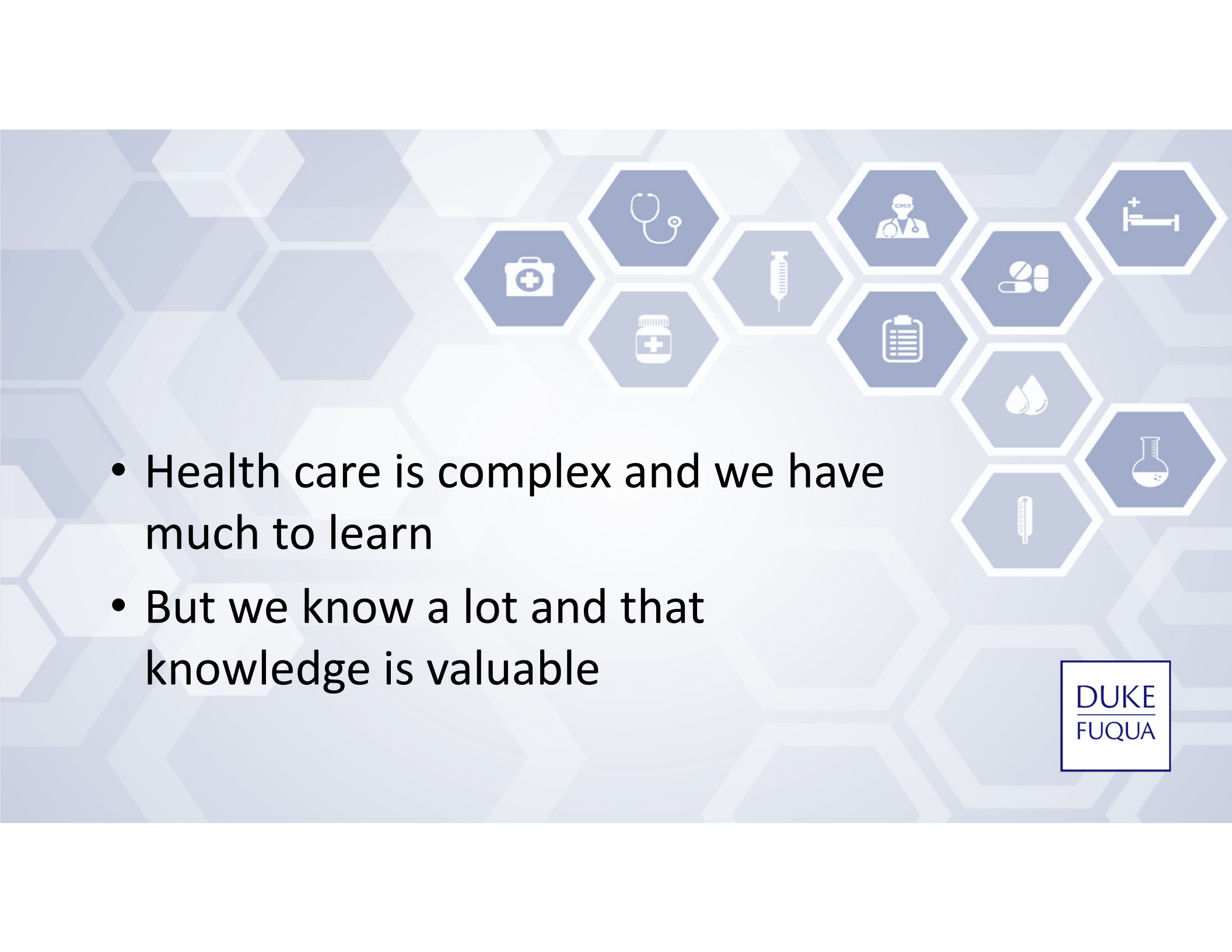
3 Conclusions

1. The branded drug business is great, if you have few competitors and patent protection.
2. The generic drug business is great, if you have 180 days of exclusivity and you are lean.
3. The biosimilars (and complex generics) business might be great, but it will depend on reimbursement.

Evaluations & exam

- Evaluations
 - Help improve the course
- Exam
 - ~40 multiple choice questions
 - comprehensive
 - closed book, notes, ...

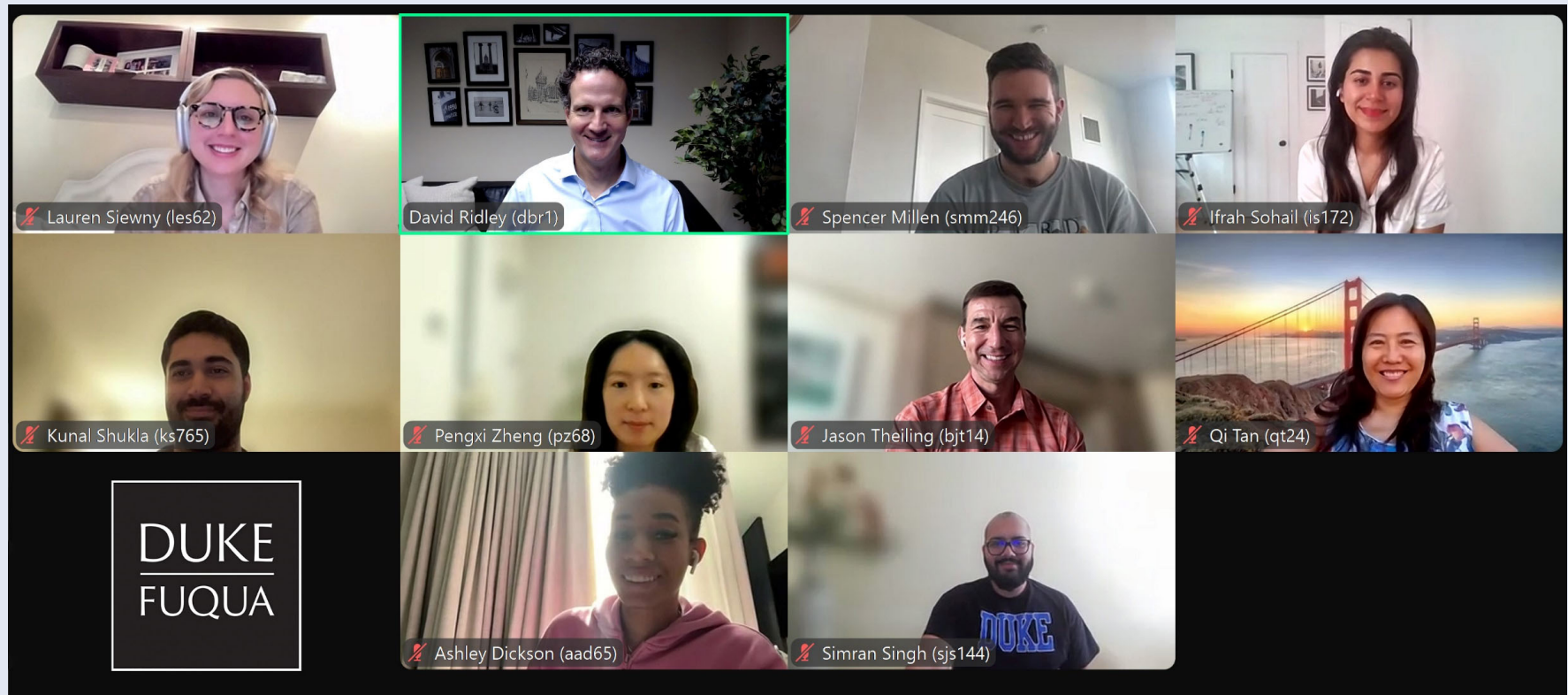


- 
- The background features a light blue hexagonal pattern. Overlaid on this are several white hexagons, each containing a different medical icon: a first aid kit, a stethoscope, a syringe, a doctor, a hospital bed, a pill bottle, a clipboard, a pill, a water drop, a flask, and a thermometer.
- Health care is complex and we have much to learn
 - But we know a lot and that knowledge is valuable

You are ready

- Message from a recent grad:
- “The knowledge I learned about the reimbursement landscape and regulatory compliance propelled my promotion from a senior manager to associate director within 12 months! People were amazed how fast I ramped up and how I was able to have an intelligent conversation with all the key stakeholders.”

Class photo



Please stay in touch

