



# CORPORATE OVERVIEW

November 2022

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# AMRYT CORPORATE OVERVIEW

GLOBAL, COMMERCIAL-STAGE BIOPHARMACEUTICAL COMPANY DEDICATED TO ACQUIRING, DEVELOPING AND COMMERCIALIZING NOVEL TREATMENTS FOR RARE DISEASES

Four growing commercial products: metreleptin, Mycapssa®, Filsuvez® and lomitapide



Global commercial infrastructure, financial flexibility & experienced team in place to drive product growth



EBITDA positive driving strong operating cash flows



Significant development pipeline with multiple near and medium-term growth drivers



Track record of successful acquisition, integration, performance and growth



NASDAQ (AMYT); global HQ in Dublin, Ireland; US HQ in Boston MA



# CONSISTENT PERFORMANCE AND GROWTH

## Q3 2022 AND RECENT HIGHLIGHTS

8.2% YoY revenue growth in Q3 2022 to \$61.1M (Q3 2021: \$56.5M); 12.5% YoY revenue growth on a constant currency basis

Generated EBITDA\*\* of \$12.5M in Q3 2022 - 11<sup>th</sup> consecutive quarter of positive EBITDA generation

Operating cash flows of \$14.3M for Q3 2022

Cash of \$83.4M at September 30, 2022

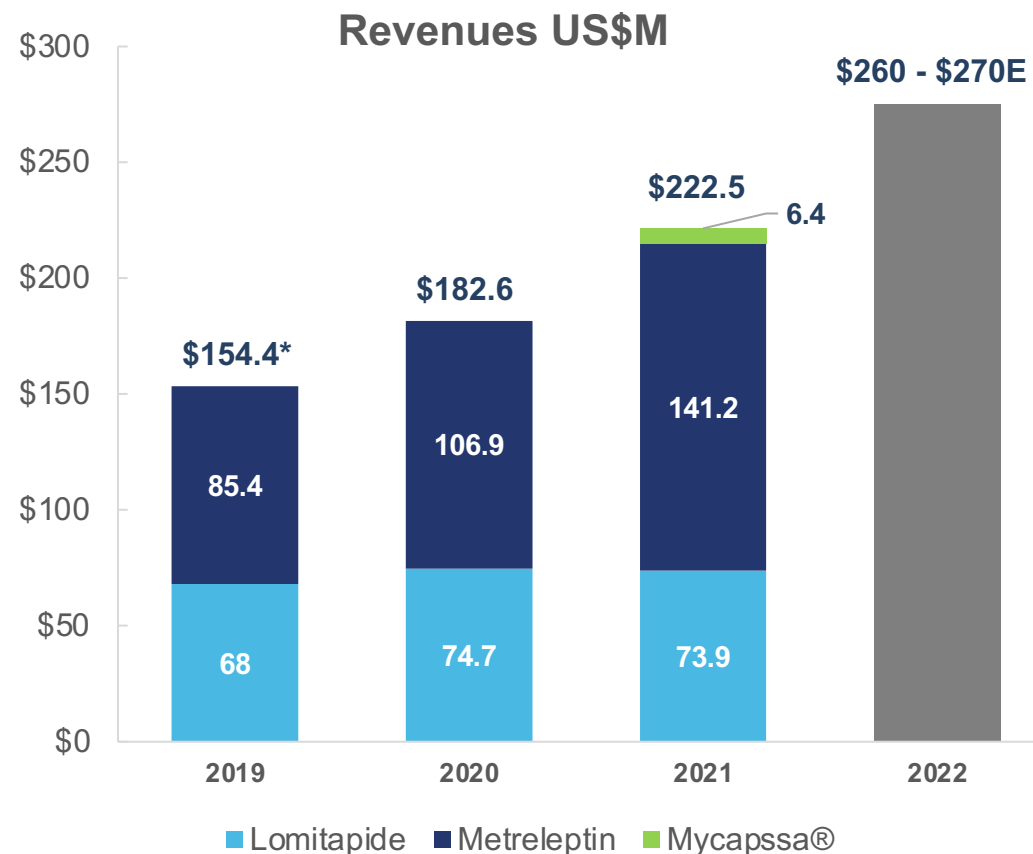
Mycapssa® revenues increased 26.9% QoQ to \$5.7M and 292.8% YoY

Pathway agreed with FDA to initiate a Phase 3 study for NET - expected Q1 2023

Filsuvez® European launch progressing well

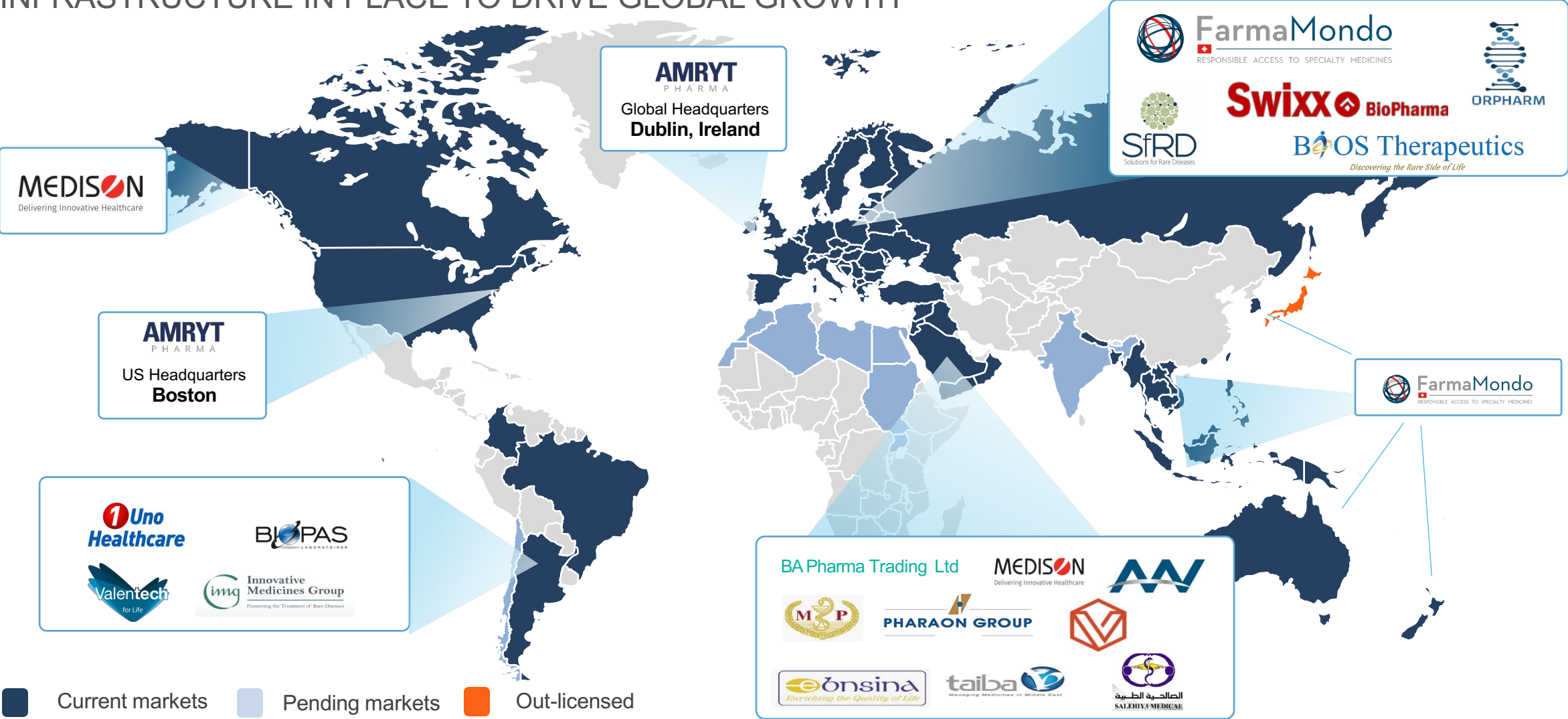
Significant metreleptin LATAM \$8.3M tender won - revenue expected to be recognized in Q4

Reaffirming FY 2022 revenue guidance to \$260M - \$270M, representing 17-21% YoY growth















































# GLOBAL INFRASTRUCTURE

## INFRASTRUCTURE IN PLACE TO DRIVE GLOBAL GROWTH



# INDUSTRY LEADERS IN RARE DISEASES

	 <div><b>DR JOE WILEY</b> CEO</div> <div></div>	
 <div><b>RORY NEALON</b> COO/CFO</div> <div></div>	 <div><b>STEPHEN JOYCE</b> Head of Marketing, Head of APAC</div> <div></div>	 <div><b>DR GERRY GILLIGAN</b> VP Manufacturing Supply Chain</div> <div></div>
 <div><b>DR TRACY CUNNINGHAM</b> Chief Medical Officer</div> <div></div>	 <div><b>FINN DOYLE</b> Head of Commercial Strategy</div> <div></div>	 <div><b>JOHN MC EVOY</b> General Counsel</div> <div></div>
 <div><b>DR HELEN PHILLIPS</b> Head of Medical Affairs</div> <div></div>	 <div><b>KIERAN ROONEY</b> Head of Business Development</div> <div></div>	 <div><b>JULIE EASTWOOD</b> Head of Human Resources</div> <div></div>
 <div><b>SHEILA FRAME</b> President Americas</div> <div></div>	 <div><b>JORDI CASALS</b> President of EMEA</div> <div></div>	 <div><b>ELIZABETH JOBES</b> Chief Compliance Officer</div> <div></div>



# GROWING COMMERCIAL PORTFOLIO & ENHANCED COMBINED DEVELOPMENT PIPELINE

EARLY AND LATE-STAGE PIPELINE WITH MULTIPLE VALUE INFLECTION POINTS

PROGRAM	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKETED	UPCOMING MILESTONES
Metreleptin (Myalept® / Myalepta®)	GL						
	PL <sup>(1)</sup>					EU	
					US		Phase 3 study initiated Q4 2021
Lomitapide (Juxtapid® / Lojuxta®)	HoFH (adults)						
	HoFH (Pediatrics) <sup>(2)</sup>				EU		Data expected Q4 2022
Mycapssa®	Acromegaly						Launched Sep '20 in US. CHMP positive opinion Q3 2022. EC approval expected Q4 2022
	Neuroendocrine tumors (NET) <sup>(3)</sup>						Phase 3 initiation anticipated Q1 2023
Oleogel-S10 (Filsuvez®)	EB (DEB / JEB)					EU	European Commission approval June 2022 Great Britain approval September 2022
					US		
	Radiation-Induced Dermatitis						Investigator- initiated study Q4 2021
AP103	EB (DEB)						Clinical development planned 2024

Definitions: Dystrophic EB ("DEB"); Junctional EB ("JEB")

(1) Global Phase 3 study to support US label expansion for metreleptin in the treatment of partial lipodystrophy (PL).

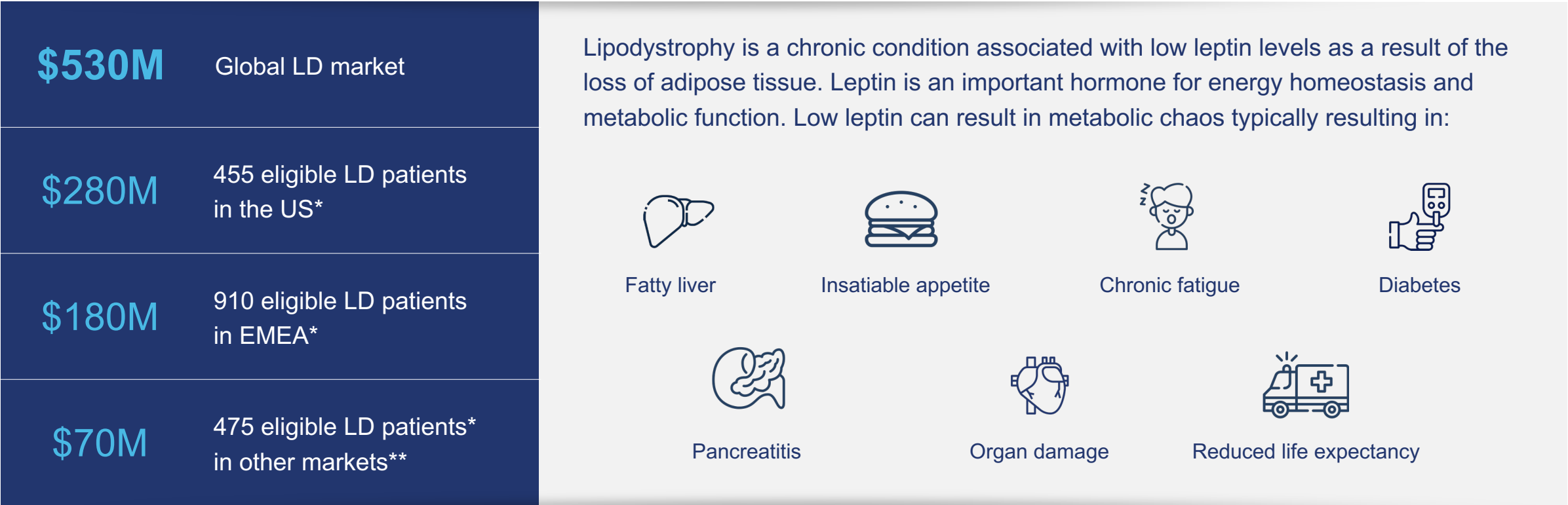
(2) We are conducting a Phase 3 study of homozygous familial hypercholesterolemia ("HoFH") in children and adolescents in Europe, the Middle East and Africa ("EMEA") as part of our European Medicines Agency ("EMA") pediatric investigation plan (PIP) commitment.

(3) 505(b)(2) pathway Phase 2 not required, Phase 3 initiation anticipated in Q1 2023 for the treatment of carcinoid symptoms in NET.



# METRELEPTIN - LIPODYSTROPHY MARKET OVERVIEW

Metreleptin is approved in the US (under the trade name Myalept®) as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy (GL) and in the EU (under the trade name Myalepta®) as an adjunct to diet for the treatment of leptin deficiency in patients with congenital or acquired GL in adults and children two years of age and above and familial or acquired partial lipodystrophy (PL) in adults and children 12 years of age and above for whom standard treatments have failed to achieve adequate metabolic control



\* Prevalence – 1.0 per million GL – 3.0 per million PL, discounted to 1.0 per million for severe cases.  
\*\* Includes key markets in which Amryt operates: Brazil, Argentina, Colombia and Canada.

# KEY BARRIERS TO DEVELOPMENT OF A METRELEPTIN BIOSIMILAR

~100+

- Reference biologics with **more attractive revenue opportunities** than metreleptin (peak global revenues above \$200M - \$500M)



- Orphan Drug Exclusivity in PL would further **reduce the mid-term opportunity for a biosimilar** with a 'skinny' label in GL

\$100 -  
300MM

- **High biosimilar development cost** and long timeline
  - Total development costs estimated to be in excess of \$100M<sup>1</sup>
  - Development time estimated at 5 to 9 years<sup>1</sup>



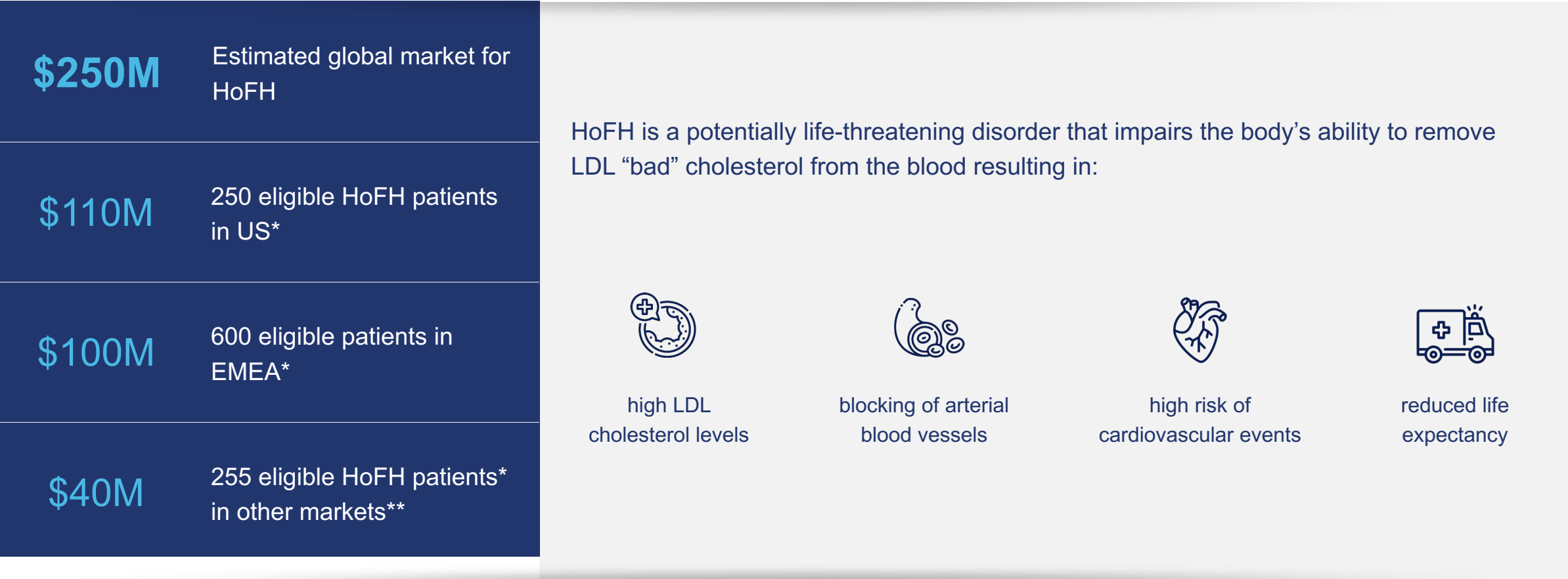
- 84% of all FDA approved biosimilars (32 out of 38) competed comparative Phase 3 studies<sup>2</sup>
- FDA and EMA similarly require comparative studies where there is uncertainty about whether there are clinically meaningful differences with the reference product<sup>3</sup>
- Metreleptin price is a major cost driver as the sponsor must purchase the reference drug for a comparative trial
- REMS program with an ETASU
- Ultra-rare disease assets – small number of patients<sup>4</sup>

Source: Health Advances analysis

1. Pfizer Biosimilars (accessed 9/16/22), McKinsey 2022 Three Imperatives for R&D in Biosimilars
2. Moore et al 2021 JAMA Intern Med
3. FDA 2015 Scientific Considerations in Demonstrating Biosimilarity to a Reference Product Guidance for Industry, EMA 2014 Revised Overarching Guideline on Biosimilar
4. Hoss A. Dowlatabat (2016) The opportunities and challenges of biosimilar orphans, Expert Opinion on Orphan Drugs, <https://doi.org/10.1517/21678707.2016.1171142>

# LOMITAPIDE - HOFH MARKET OVERVIEW

Lomitapide is approved as an adjunct to a low-fat diet and other lipid-lowering medicinal treatments for adults with the rare cholesterol disorder, Homozygous Familial Hypercholesterolaemia ("HoFH") in the US, Canada, Colombia, Argentina and Japan (under the trade name Juxtapid®) and in the EU, Israel and Brazil (under the trade name Lojuxta®).

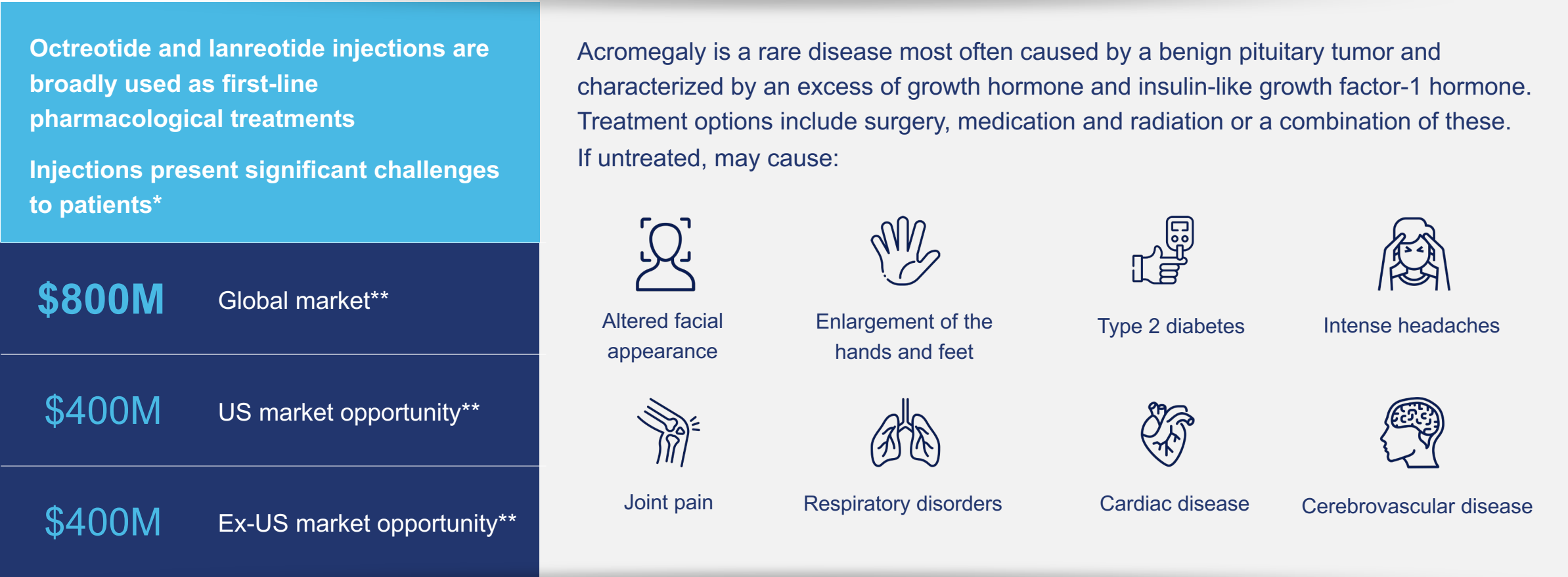


\* Includes Pediatric HoFH market opportunity. Prevalence – 3 per million EU, America, Australia; 6 per million – due to consanguinity, e.g. Middle East, Turkey and founder effects, e.g. Canada. 50% diagnosis rate based on phenotypic presentation of LDL-C levels. Approx. 50% eligible population after PCSK9 inhibitors address a portion of the unmet medical need. Excludes FCS.

\*\* Includes key markets in which Amryt operates: Brazil, Argentina, Colombia and Canada.

# MYCAPSSA® - ACROMEGALY - MARKET OVERVIEW

Mycapssa® is the first and only FDA-approved oral somatostatin analog (SSA) for appropriate patients with acromegaly, providing effective and consistent biochemical control while reducing the treatment burden associated with injectable therapies.



# MYCAPSSA® - NEUROENDOCRINE TUMOR (NET) - MARKET OVERVIEW

Amryt is advancing Mycapssa® into late-stage clinical development for the treatment of neuroendocrine tumors (NET) patients with carcinoid symptoms

Current standard of care is octreotide LAR and lanreotide depot injections


Potential addressable patient population on SSAs estimated at ~24,000 in the US\*\*

**\$1.9B** Global market\*\*\*


**\$1.0B** US market opportunity\*\*\*

**\$0.9B** Ex-US market opportunity\*\*\*


NETs are abnormal growths of neuroendocrine cells occurring throughout the body (most common in GI tract). NETs can metastasize and produce hormones that cause significant symptoms (“carcinoid syndrome” which includes diarrhea and flushing episodes)\*. NET Symptoms Include:




Diarrhea & Constipation




Flushing




Fatigue




Anxiety & Depression



GI Tract Malignancies



Pancreatic Malignancies



Lung Malignancies

13

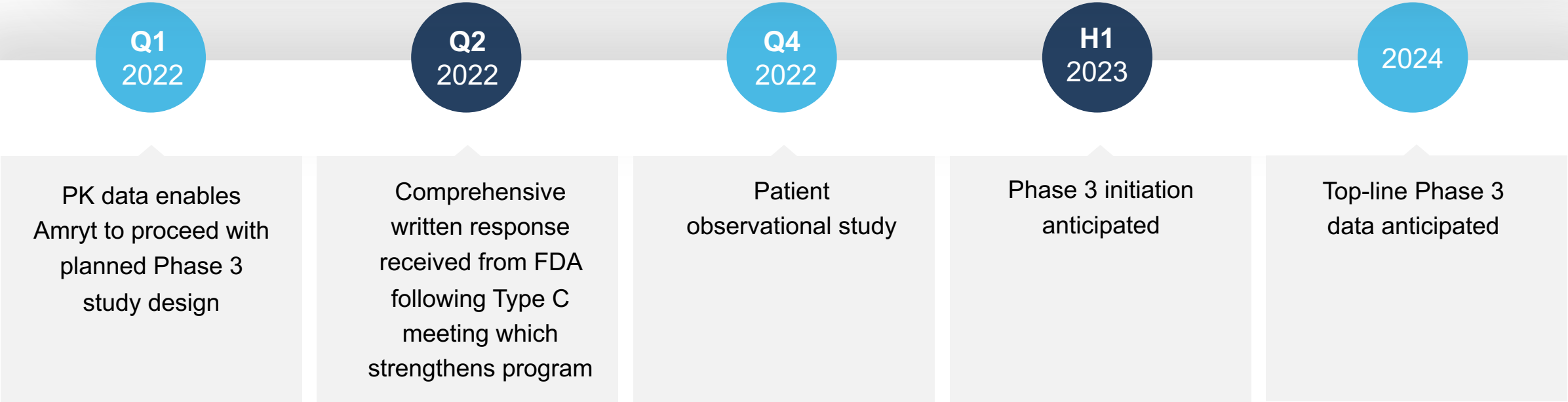
\*Hauso et al, Cancer, 2008; Cancer Research UK.  
\*\*National Cancer Institute SEER Database; Halperin et al. 2017 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6066284/>  
\*\*\*Based on management estimates.

AMRYT  
PHARMA

# MYCAPSSA® - DEVELOPMENT AND REGULATORY TIMELINE FOR NET PROGRAM

**Q3 2021** - FDA agreed that a single positive Phase 3 study would be sufficient for approval in neuroendocrine tumors (NET) patients with carcinoid symptoms, consistent with the 505(b)(2) regulatory pathway

The Agency recommended that the primary endpoint in a Phase 3 study should demonstrate that patients are able to maintain the baseline level of “stability” during treatment with Mycapssa®



# FILSUEZ® - FIRST APPROVED THERAPY FOR EB

European Commission and GB have approved Filsuvez® for the treatment of dystrophic and junctional EB in patients 6 months and older

Phase 3 EASE study investigating Filsuvez® was the largest ever global trial and first ever positive readout in EB

Primary endpoint was met demonstrating 44% increase in target wound closure with Filsuvez® versus control gel

Filsuvez® was shown to be well tolerated with a reassuring safety profile

> \$1.0B Estimated global EB market\*

EB is a rare and devastating group of hereditary disorders of the skin, mucous membranes, and internal epithelial linings characterized by extreme skin fragility and blister development. Patients with severe forms of EB suffer from:

- |                                                                                                          |                                                                                                                |                                                                                                             |                                                                                                             |
|----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| <br>chronic wounds    | <br>recurrent blistering    | <br>scarring             | <br>intolerable pain     |
| <br>limited mobility | <br>high risk of infection | <br>high risk of cancer | <br>risk of early death |

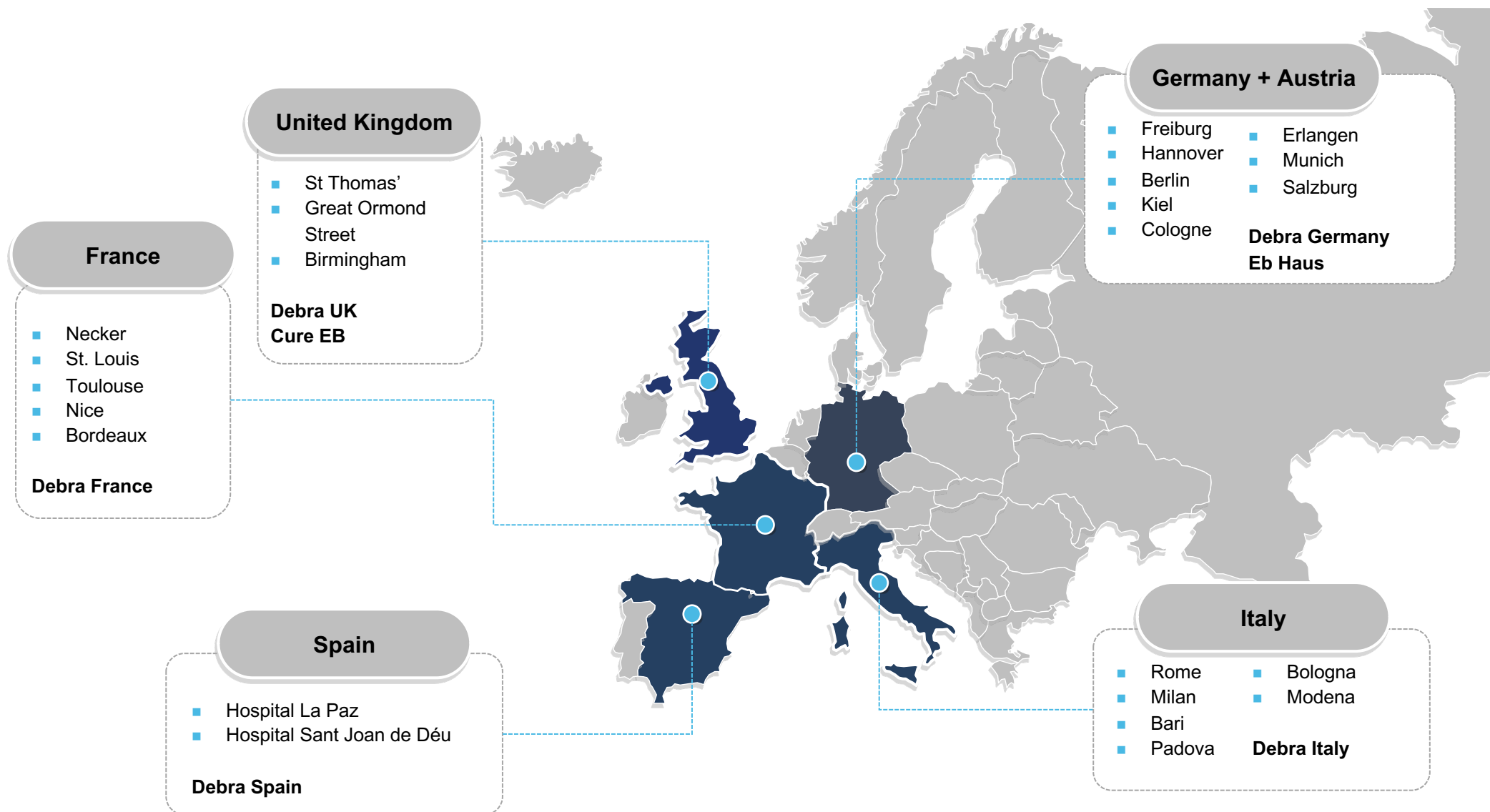


# FILSUEVZ® - EUROPEAN LAUNCH ON TRACK

POTENTIAL TO LEVERAGE EU APPROVAL ACROSS OTHER JURISDICTIONS



# SMALL NUMBER OF CENTERS TREATING MAJORITY OF EB PATIENTS IN EUROPE



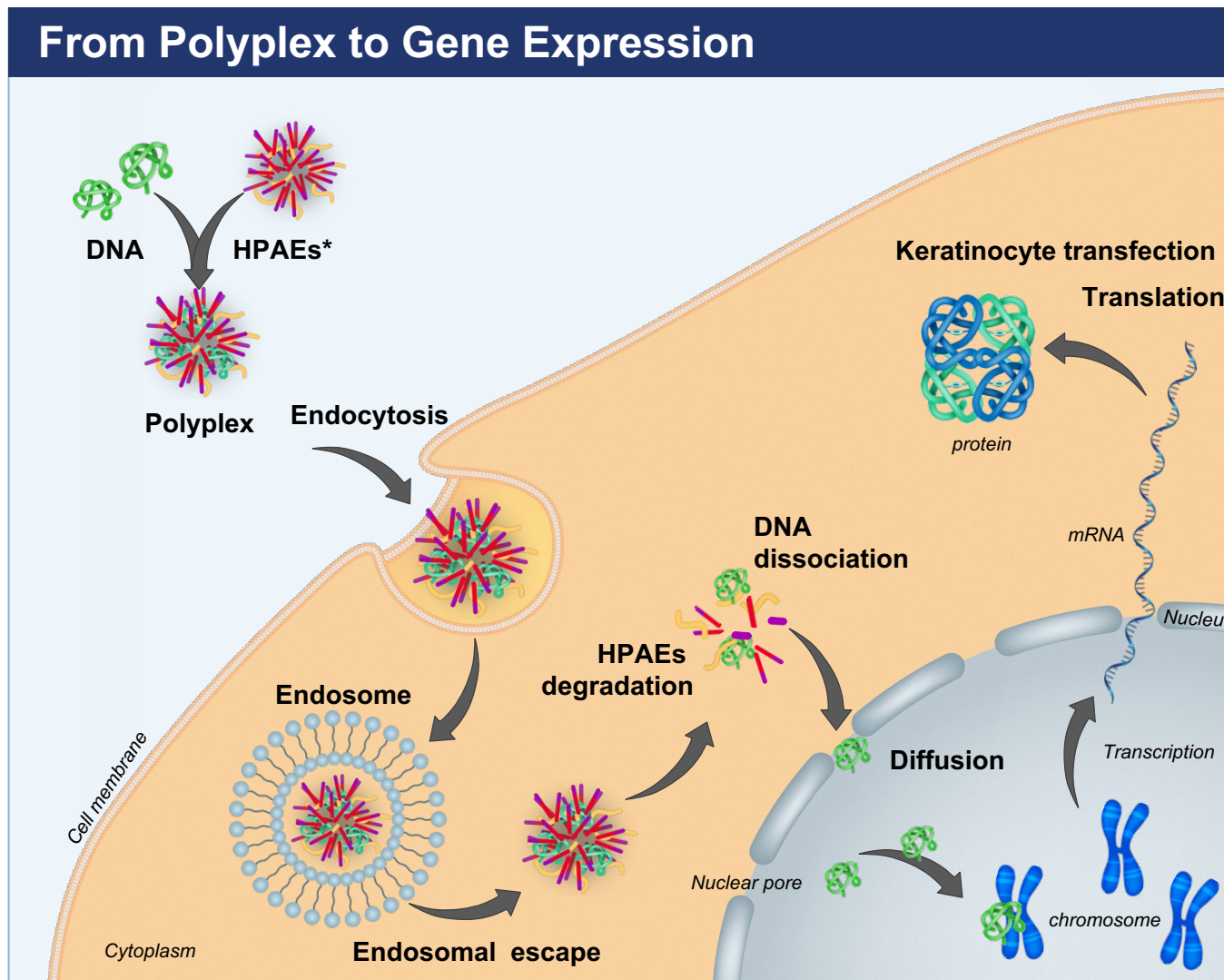
# AP103 - BUILDING AN EB FRANCHISE - GENE THERAPY PLATFORM

Novel polymer-based topical gene therapy delivery platform

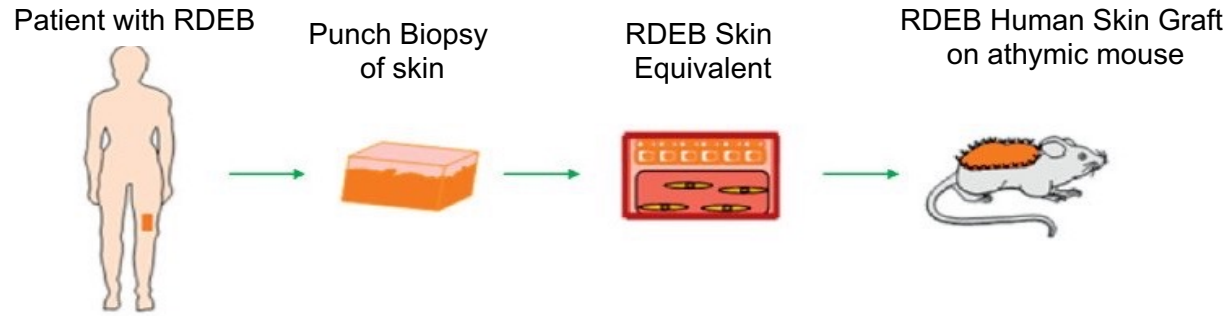
AP103, our first product candidate utilizing this platform, is being studied for DEB

Granted Orphan Drug Designation by FDA and EMA in 2020

Potential use for the treatment of other genetic diseases



# AP103 - PROOF OF CONCEPT IN A PRE-CLINICAL EB MODEL



Phase 1/2a clinical trial to begin in 2024

Epidermis

Dermis

Control RDEB Skin No C7

Images taken at 20x

1xHPAE-COL7A1 Topically

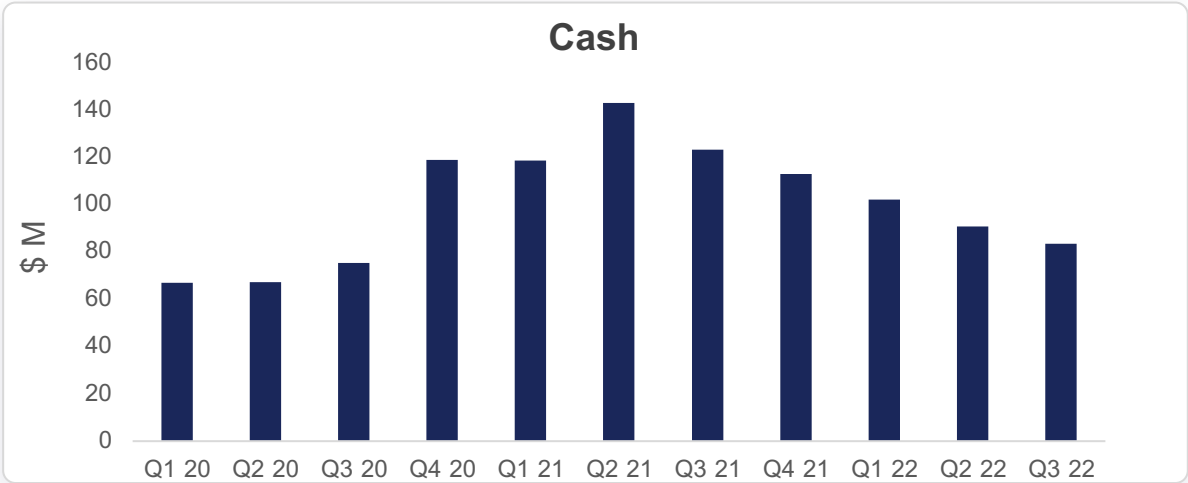
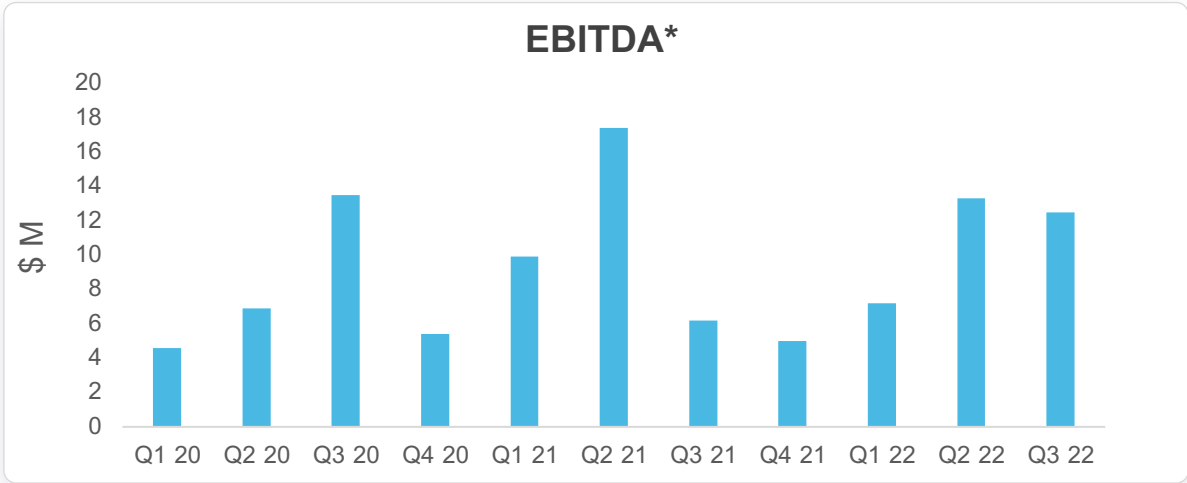
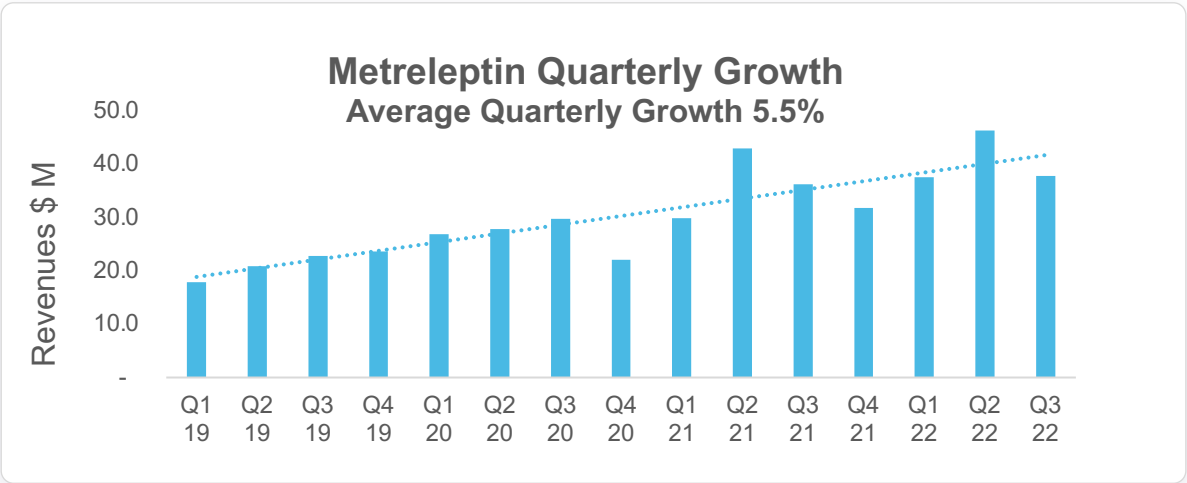
4 weeks

3xHPAE-COL7A1 Topically

10 weeks

# CONSISTENT FINANCIAL PERFORMANCE AND GROWTH

## BUILDING A GLOBAL LEADER IN RARE DISEASES



\*See Appendix: non-GAAP/IFRS reconciliation  
Note: All quarterly financials are unaudited

# STRONG FINANCIALS

## BUILDING A GLOBAL LEADER IN RARE DISEASES

### EBITDA AND CASH

\$41.9M EBITDA\* in FY 2021 excl. restructuring costs

\$12.5M EBITDA\* in Q3 2022 excl. restructuring costs

Cash \$83.4M\*\* at June 30, 2022

### REVENUE

FY 2021 revenues \$222.5M

FY 2022 revenue guidance \$260M - \$270M  
representing 17-21% growth YoY

### \$125M CONVERTIBLE DEBT FACILITY

5.5 year bullet, Apr 2025

Unsecured

Coupon: 5% cash

Convertible price: \$12.93 per ADS

### \$125M TERM DEBT FACILITY (\$105M DRAWN)

\$85M term loan - SOFR\*\*+6.75%

\$40M RCF (\$20M drawn) - SOFR\*\* +4.00%

5 year bullet, Feb 2027 (refinanced Feb '22)

Secured

# CONTACT & CORPORATE INFORMATION

## BUILDING A GLOBAL LEADER IN RARE DISEASES

### AMRYT CONTACT

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LISTING PARTICULARS	NASDAQ
TICKER	AMYT



# AMRYT - A GLOBAL LEADER IN RARE DISEASES



**Revenue generating commercial portfolio with four approved and growing products, driving positive EBITDA**



**Track record of successful acquisition, integration, performance and growth**



**Significant development pipeline with multiple near and medium-term growth drivers**



**Global commercial infrastructure, financial flexibility and experienced team in place to drive product growth**



# APPENDIX

# IFRS AND NON-GAAP ADJUSTED RESULTS – Q3 2022 EBITDA

US\$M	Q3 2022 (unaudited)	Q3 2022 Non-cash Items <sup>1</sup>	Q3 2022 Non-GAAP Adjusted
Revenue	61.1	-	61.1
Gross profit	27.4	19.7	47.1
R&D expenses	(8.0)	-	(8.0)
SG&A expenses	(27.0)	0.4	(26.6)
Share based compensation expenses	(2.9)	2.9	-
Operating (loss) / profit before finance expense	(10.5)	23.0	12.5 <sup>2</sup>

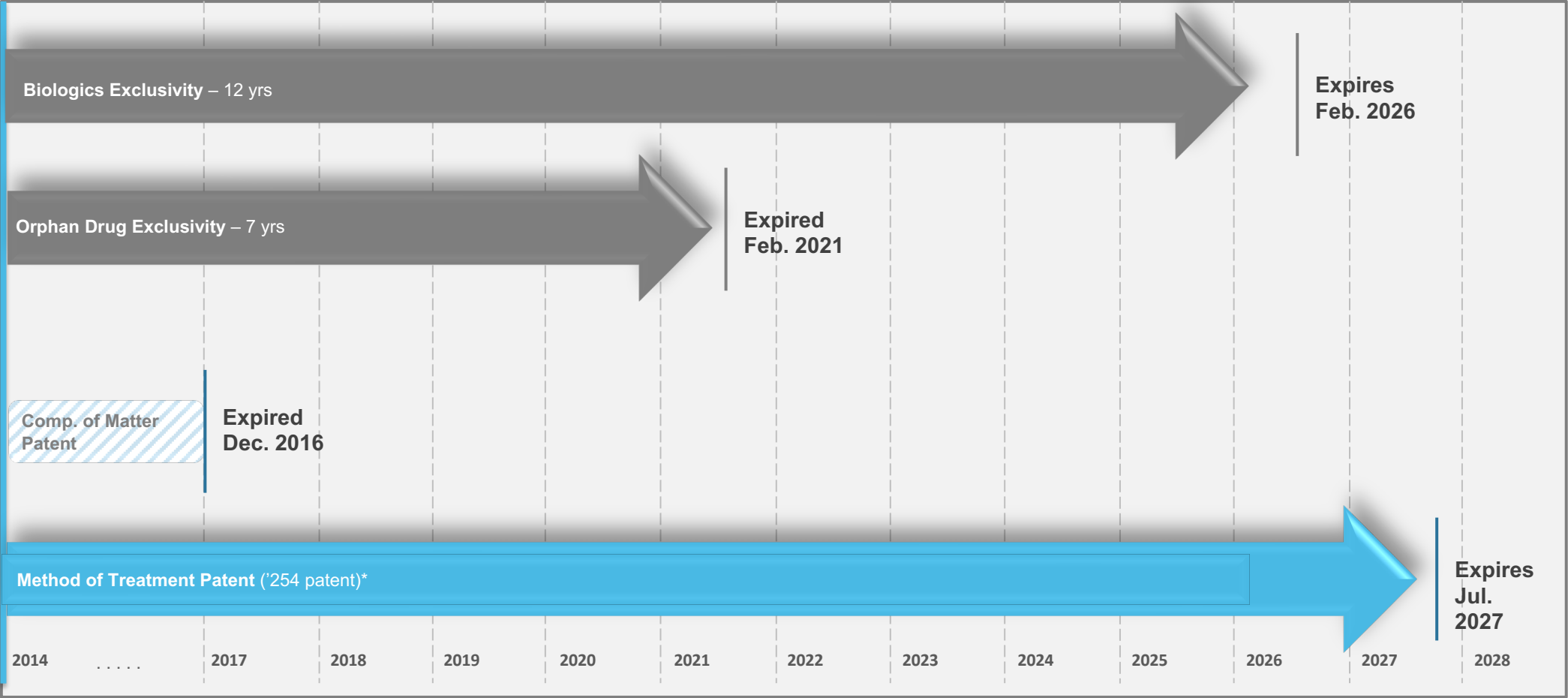
1. Non-cash items include amortisation of the acquired metreleptin, lomitapide, Mycapssa® and Filsuvez® intangible assets (\$16.6M), amortisation of the inventory fair value step-up related to the acquisition of Chiasma, Inc. (\$3.1M), depreciation and amortisation (\$0.4M) and share based compensation expenses (\$2.9M).
2. EBITDA is earnings before interest, tax, depreciation, amortisation and share based compensation expenses. To supplement Amryt's financial results presented in accordance with IFRS generally accepted accounting principles, the Company uses EBITDA as a key measure of company performance as the Company believes that this measure is most reflective of the operational profitability or loss of the Company and provides management and investors with useful supplementary information which can enhance their ability to evaluate the operating performance of the business. EBITDA, as measured by the Company, is not meant to be considered in isolation or as a substitute to operating profit / loss attributable to Amryt and should be read in conjunction with the Company's condensed consolidated financial statements prepared in accordance with IFRS.

# IFRS AND NON-GAAP ADJUSTED RESULTS - FY 2021 EBITDA<sup>2</sup>

US\$M	FY 2021 (unaudited)	FY 2021 Non-cash adjustments <sup>1</sup>	FY 2021 Non-GAAP Adjusted
Revenue	222.5	-	222.5
Cost of sales	(106.1)	53.4	(52.7)
Gross profit	116.4	53.4	169.8
R&D expenses	(37.7)	-	(37.7)
SG&A expenses	(92.0)	1.8	(90.2)
Acquisition & severance related costs	(16.9)	-	(16.9)
Share based compensation expenses	(8.3)	8.3	-
Impairment charge	(32.6)	32.6	-
Operating (loss) / profit before finance expense	(71.2)	96.1	25.0 <sup>2</sup>
Operating (loss) / profit before finance expense and restructuring and severance related costs (EBITDA <sup>1</sup> )	(54.3)	96.1	41.9 <sup>2</sup>

1. Non-cash items for FY21 include amortisation of the acquired metreleptin, lomitapide and Mycapssa® intangible assets (\$49.0M), amortisation of the inventory fair value step-up related to the acquisition of Chiasma and Aegerion (\$4.4M), depreciation and amortisation (\$1.8M), impairment charge (\$32.6M) and share based compensation expenses (\$8.3M).
2. EBITDA, as applied in the above table, is defined as earnings before interest, tax, depreciation, amortisation, impairment, restructuring and severance related costs and share based compensation expenses. To supplement Amryt's financial results presented in accordance with IFRS generally accepted accounting principles, the Company uses EBITDA as a key measure of company performance as the Company believes that this measure is most reflective of the operational profitability or loss of the Company and provides management and investors with useful supplementary information which can enhance their ability to evaluate the operating performance of the business. EBITDA, as measured by the Company, is not meant to be considered in isolation or as a substitute to operating profit / loss attributable to Amryt and should be read in conjunction with the Company's condensed consolidated financial statements prepared in accordance with IFRS.

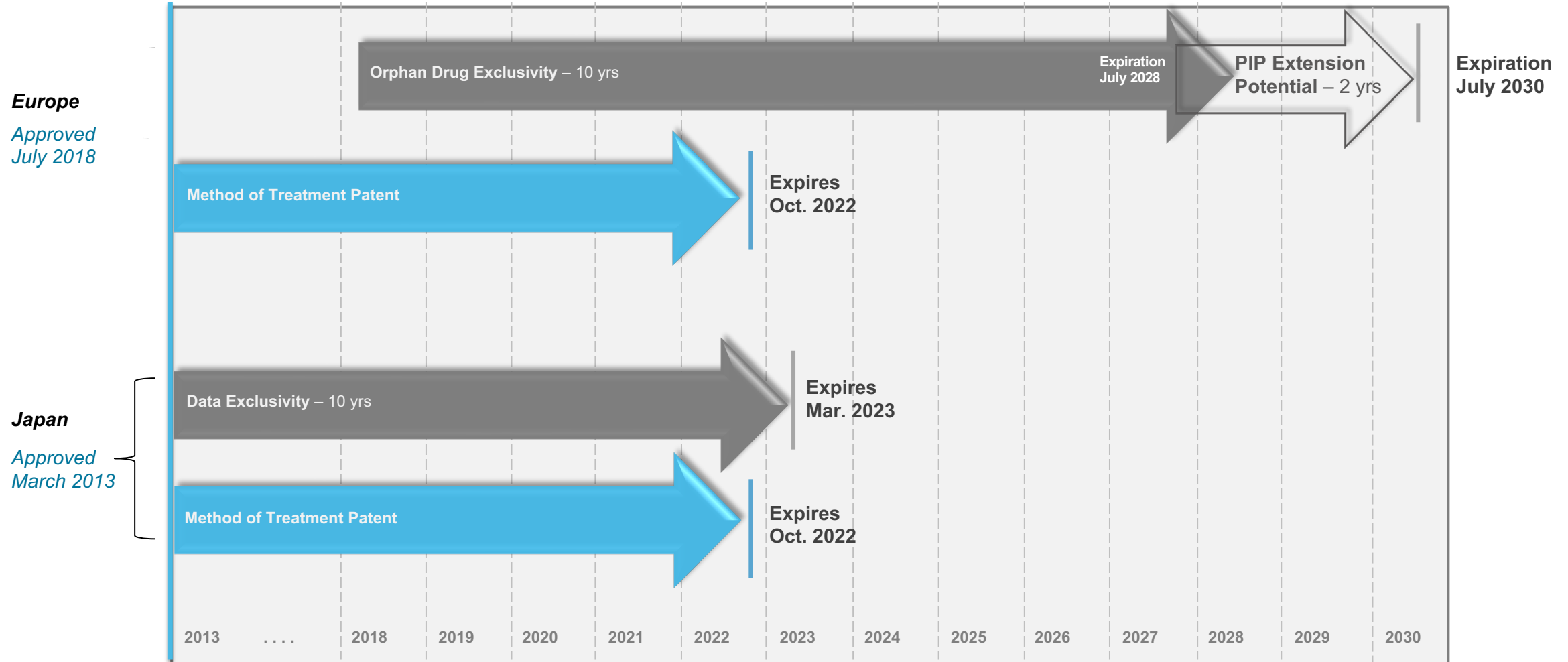
# MYALEPT® (US) REGULATORY EXCLUSIVITY / PATENT TIMELINE ASSUMES LOE JULY 2027



\* A PTE of 1,445 days was applied to the '254 patent, thus extending patent protection to July 17, 2027.

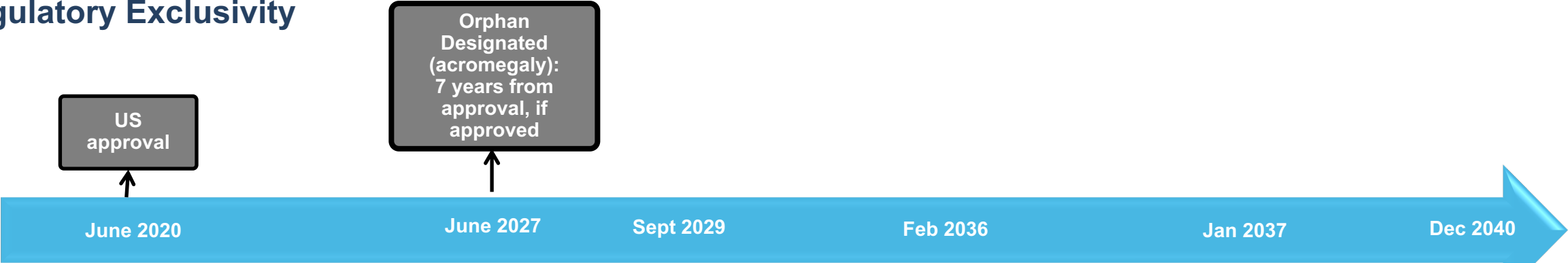
# MYALEPTA® (EX-US) REGULATORY EXCLUSIVITY / PATENT TIMELINE

## ASSUMES LOE JULY 2028 WITH POTENTIAL 2-YEAR EXTENSION

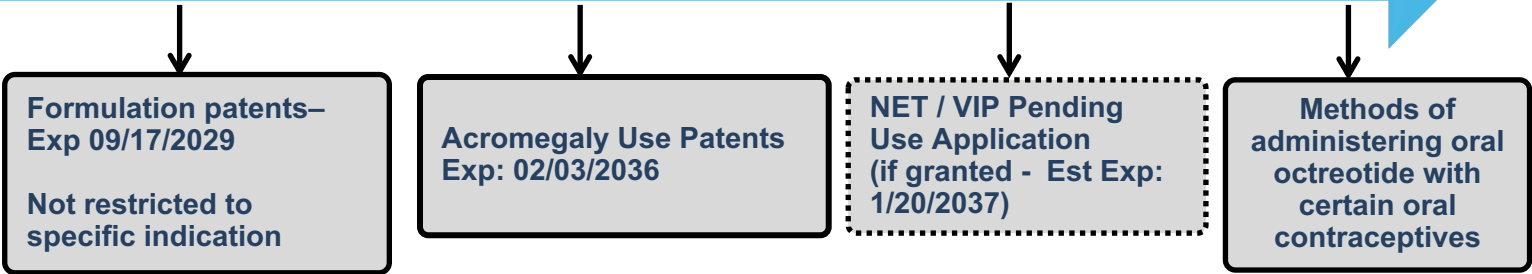


# MYCAPSSA® - US EXCLUSIVITY TIMELINE

## Regulatory Exclusivity



## Patent Exclusivity



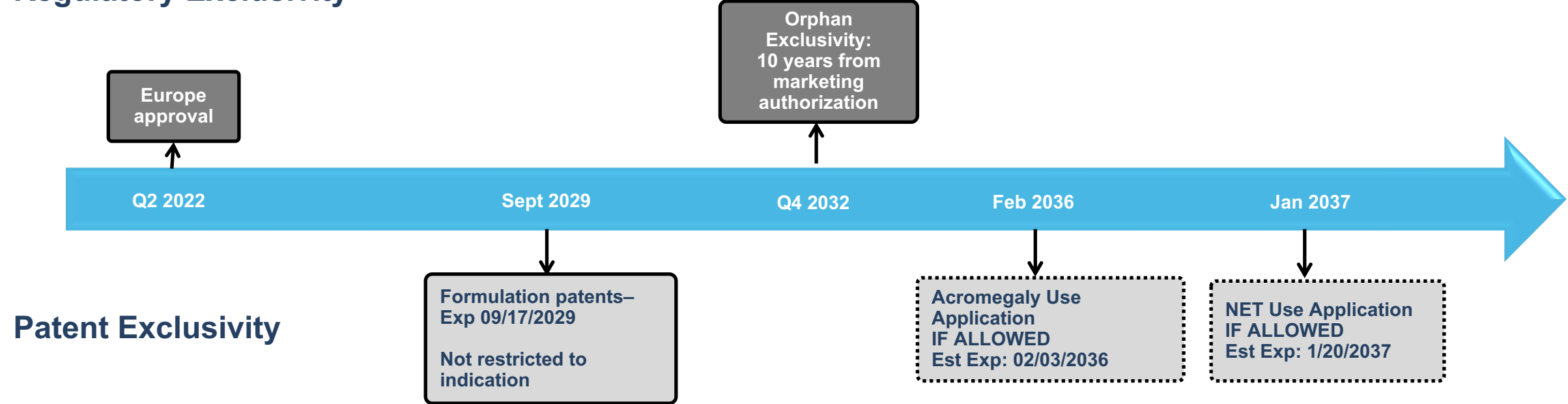
Patent Summary:

- 3 formulation and 1 acromegaly use patents expire Sept 2029
- 4 acromegaly use patents (acromegaly) expire February 2036
- 1 octreotide method of use patent expiring December 2040
- 1 pending application covers NET/VIP use est. expiration January 2037



# MYCAPSSA®- EUROPEAN EXCLUSIVITY TIMELINE

## Regulatory Exclusivity



**Regulatory Summary:**

- Orphan exclusivity prevents generic entry Q2 2032

**Patent Summary:**

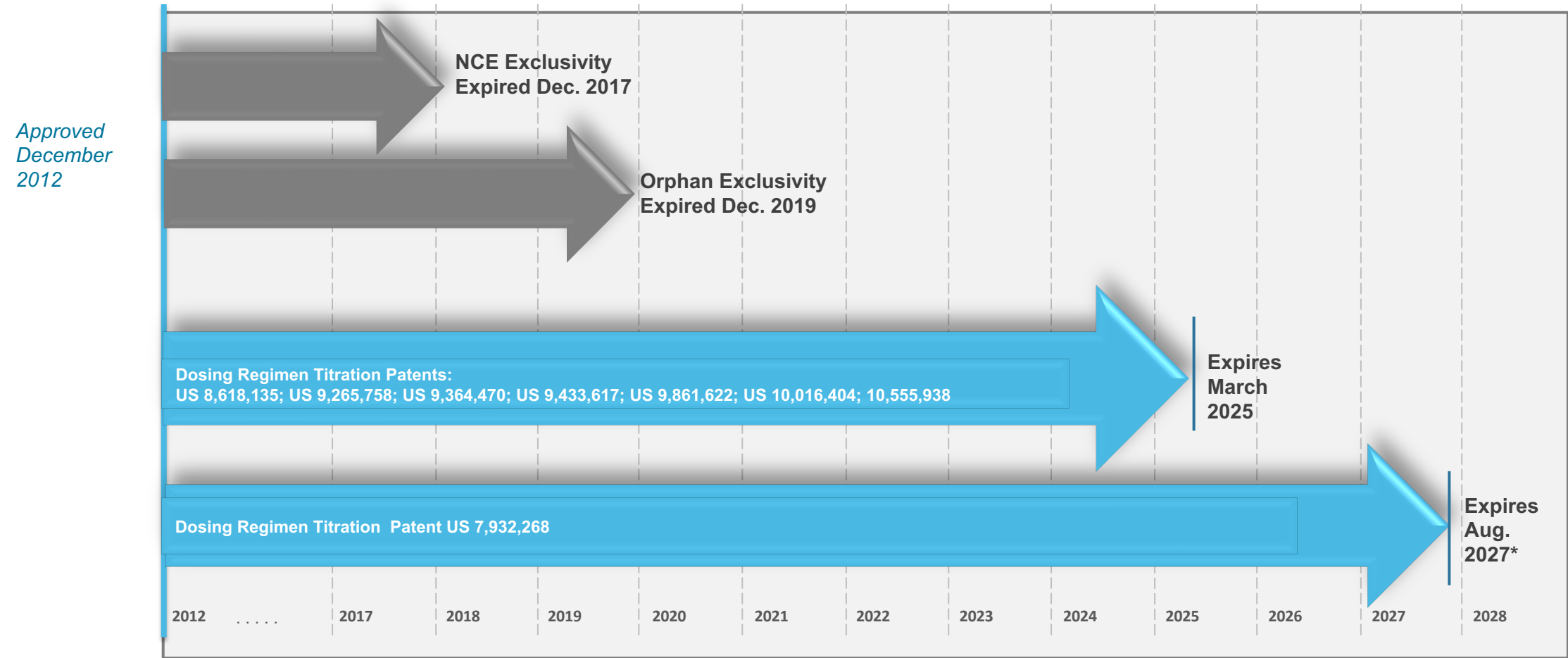
- Composition patent expires Sept 2029
- Acromegaly Use Application, if allowed would expire Feb 2036

**Label expansion to include NET:**

- Orphan exclusivity would NOT prevent approval of NET product

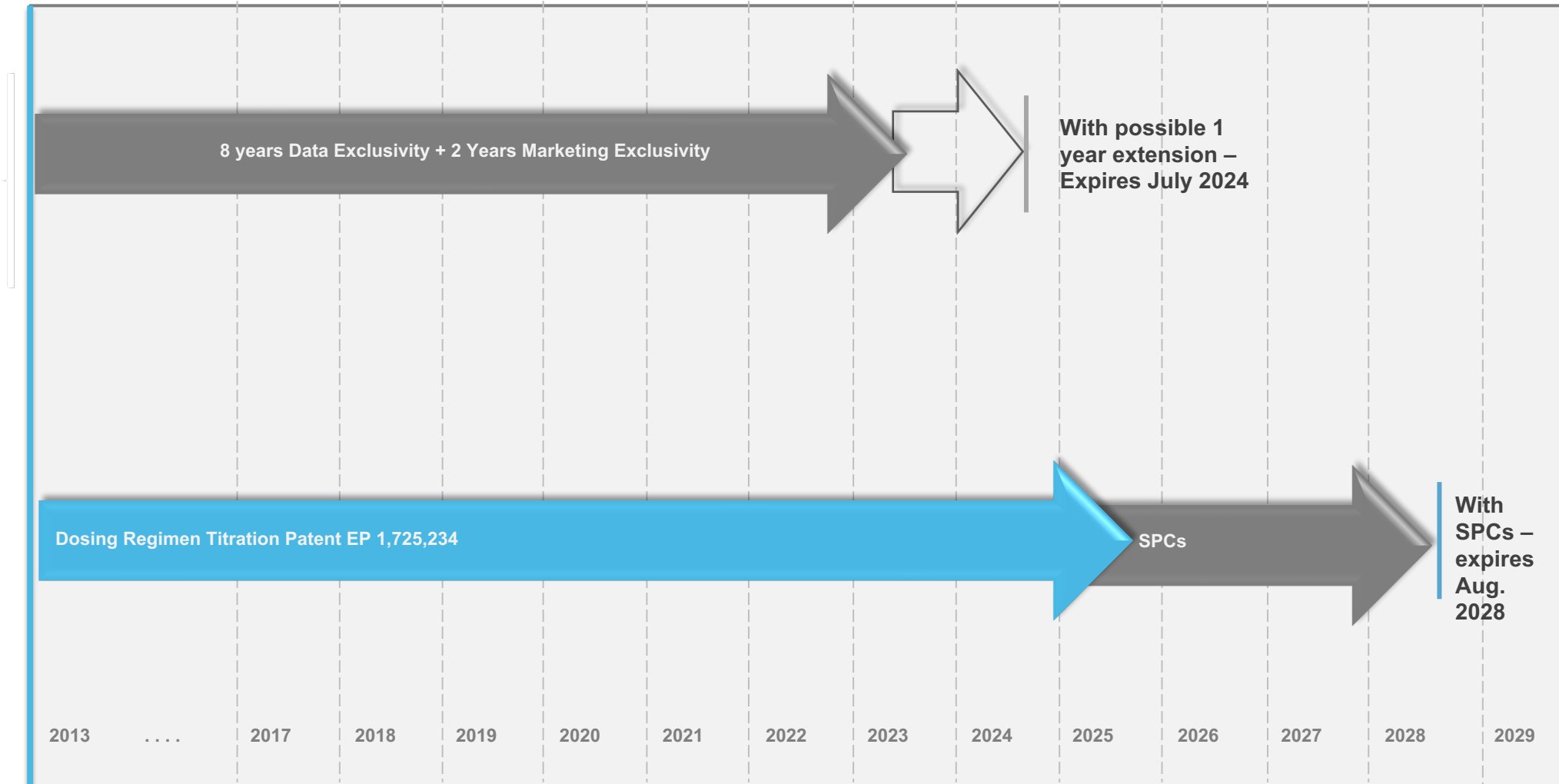
Assumptions:  
Product approval Q4 2022

# JUXTAPID® US REGULATORY EXCLUSIVITY / PATENT TIMELINE

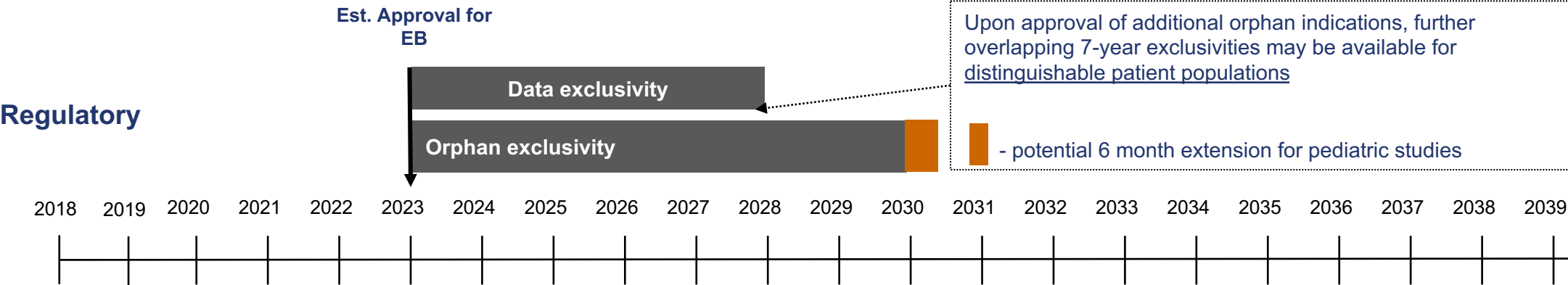


\*Patent Term Adjustment of 895 days was awarded due to Patent Office delays, extending term to 8/19/2027

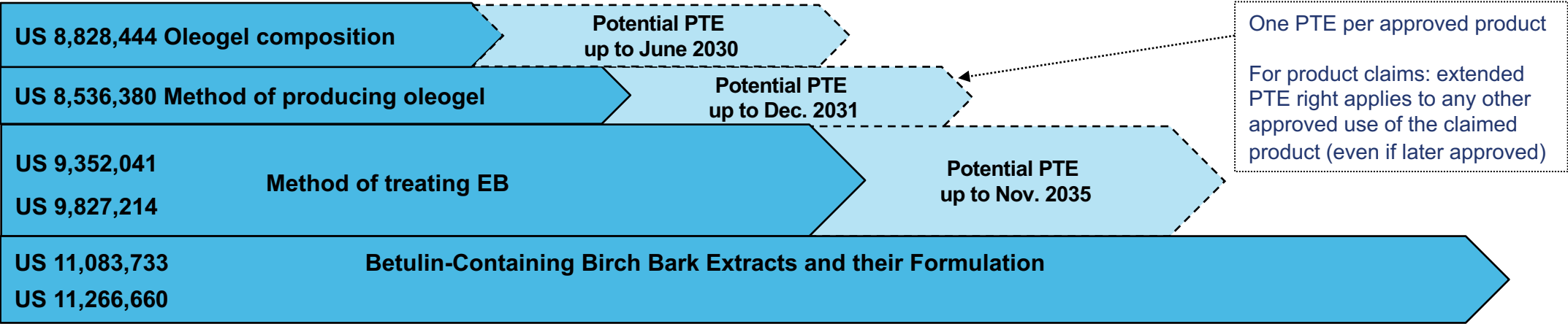
# LOJUXTA® EU REGULATORY EXCLUSIVITY/PATENT TIMELINE



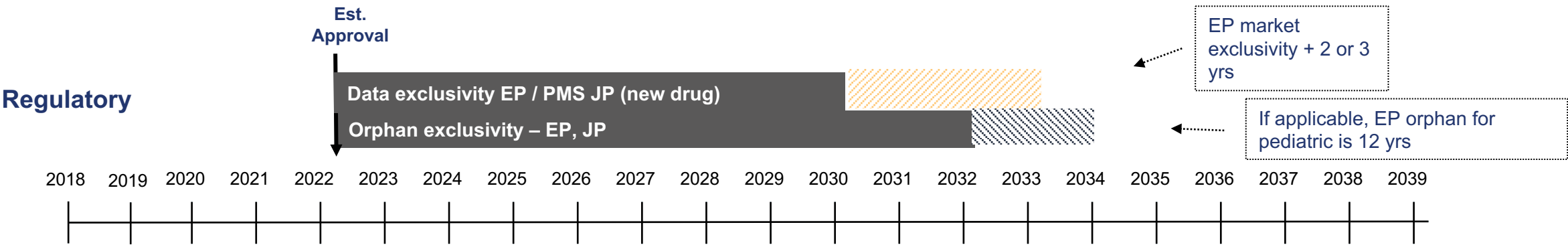
# FILSUEVZ® ANTICIPATED EXCLUSIVITY TIMELINE IN US



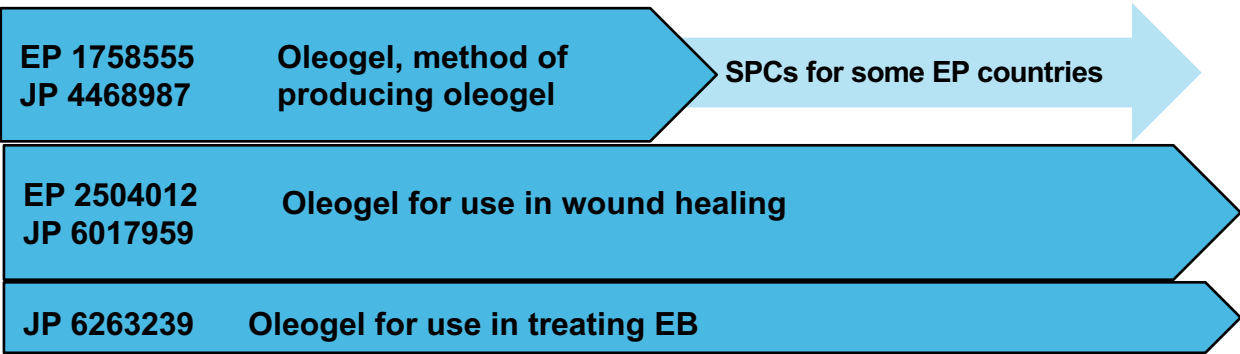
## Granted Patents



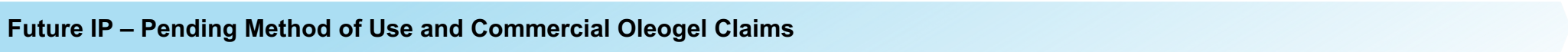
# FILSUEZ® ANTICIPATED EXCLUSIVITY IN EUROPE AND JAPAN



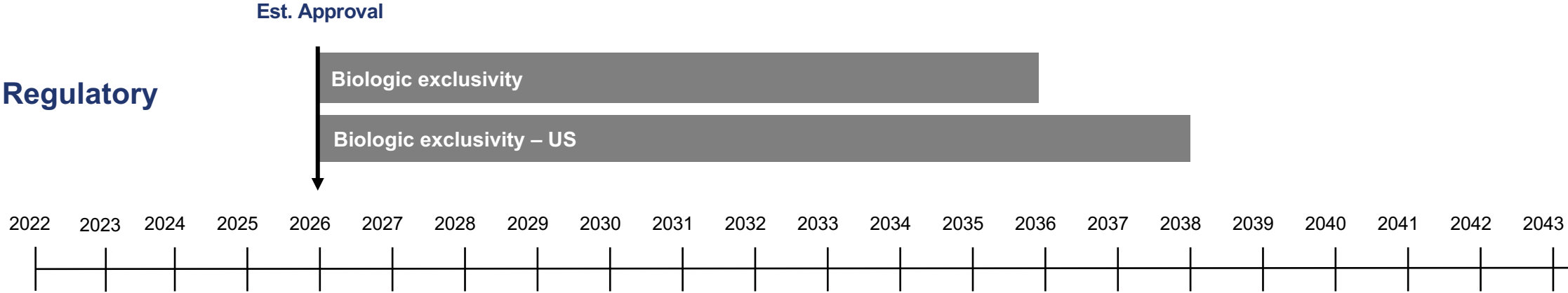
## Granted Patents



## Pending Claims



# AP103 REGULATORY AND PATENT EXCLUSIVITIES



## Patent Protection

