

### **CORPORATE OVERVIEW**

September 2021

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### AMRYT CORPORATE OVERVIEW

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

#### **Corporate Overview**

EBITDA positive and growing commercial business with three commercial products (metreleptin, oral octreotide and lomitapide) and a significant development pipeline

Founded in 2015 - Global HQ in Dublin, Ireland; US HQ in Boston, MA

Positive Phase 3 EASE trial results in EB. Regulatory submissions for Oleogel-S10 submitted and accepted by the FDA and EMA with a target PDUFA date set for Nov 30, 2021. AP103 pre-clinical gene therapy asset.

Acquisition of Chiasma Inc. closed Aug 5, 2021

#### **Financials**



Nasdaq: AMYT (trades ADSs, 5 Ordinary Shares per ADS)

LSE/AIM: AMYT (trades Ordinary Shares)

Revenues: \$62.8M in Q2 2021 (Q2 2020: \$46.2M); \$182.6M in FY 2020 (2019: \$154.1M\*)

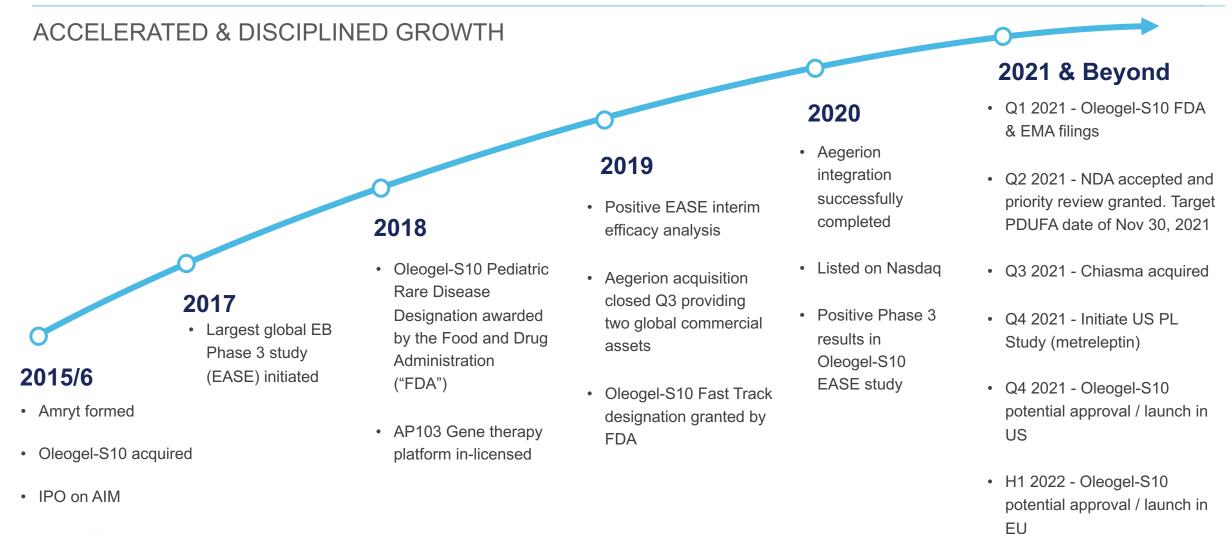
Guidance increased from \$210M-\$215M to \$220M-\$225M for FY2021 representing 20%-23% growth YoY

EBITDA: \$17.4M Q2 2021 (Q2 2020: \$6.9M); \$30.4M FY 2020\*\*

Cash of \$142.9M at June 30, 2021 (March 31, \$118.6M)



### **MOMENTUM BUILDING**



• Lojuxta® in-licensed

### **GLOBAL INFRASTRUCTURE**





### **EXPERIENCED MANAGEMENT TEAM**

#### COMPRISED OF INDUSTRY LEADERS IN RARE DISEASES



**DR JOE WILEY** CEO SOFINNOVA VENTURES





**RORY NEALON** COO/CFO AIB Trinity Biotech



DR MARK SUMERAY **Chief Medical Officer** Aegerion<sup>®</sup> Histol Myers Squibb









Head Of Medical Affairs Aegerion<sup>®</sup> AstraZeneca gsk

**DR HELEN PHILLIPS** 



**ELIZABETH JOBES Chief Compliance Officer** Spark. AUXILIUM



SHEILA FRAME **President Americas** AstraZeneca NOVARTIS



**DR TRACY CUNNINGHAM** VP Head of Development AstraZeneca SANOFI



**DR GERRY GILLIGAN** VP Manufacturing Supply Chain



\*



Aegerion<sup>®</sup> AMGEN

Hospira



JOHN MC EVOY **General Counsel** HERBERT SMITH EREFHILLS ARTHUR COX



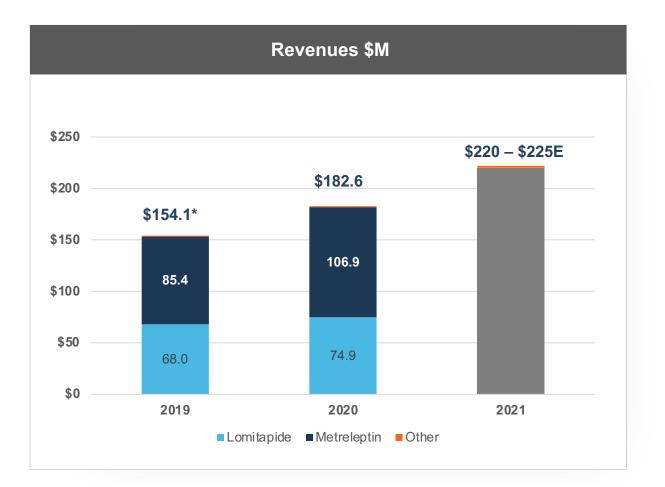
JULIE EASTWOOD Head of Human Resources TRICASTLE Totalmobile



### **CONSISTENT PERFORMANCE AND GROWTH**

#### **GROWING GLOBAL REVENUES**

- Three growing commercial products: metreleptin (Myalept<sup>®</sup> / Myalepta<sup>®</sup>), oral octreotide (Mycapssa<sup>®</sup>) and lomitapide (Juxtapid<sup>®</sup> / Lojuxta<sup>®</sup>)
- FY 2020 revenues increased 18.5% YoY to \$182.6M
- 35.9% revenue growth in Q2 2021 to \$62.8M (Q2 2020: \$46.2M)
- 54.3% YoY increase in metreleptin revenues to \$43.1M in Q2 2021 (Q2 2020: \$27.9M): 7.7% YoY increase in lomitapide revenues to \$19.5M in Q2 2021 (Q2 2020: \$18.1M)
- Increasing FY 2021 revenue guidance to \$220M \$225M representing 20 - 23% growth on FY 2020





#### **GROWING COMMERCIAL PORTFOLIO & ENHANCED COMBINED DEVELOPMENT PIPELINE**

#### EARLY AND LATE-STAGE PIPELINE WITH MULTIPLE VALUE INFECTION POINTS

PROGRAM	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKETED	UPCOMING MILESTONES* / RECENT DATA	
Metreleptin	GL							
(Myalept® / Myalepta®)	<b>PL</b> <sup>(1)</sup>					EU		
				US			Phase 3 study planned Q4 2021	
Lomitapide	HoFH (adults)							
(Juxtapid® /	HoFH (Pediatrics) <sup>(2)</sup>				EU		Data Expected - 2022	
Lojuxta®)	juxta®) FCS <sup>(3)</sup>						Positive POC study, development path under review	
	Acromegaly						Launched Sep '20 in US, EMA submission Q2 2021	
<b>Mycapssa</b> ®	Neuroendocrine tumors (NET) <sup>(4)</sup>						IND Submitted – Phase 3 planned in 2022	
	EB (DEB / JEB)						Positive Top Line Data Readout (Primary endpoint value=0.013)	
Oleogel-S10 <sup>(5)</sup>	Radiation-Induced Dermatitis (6)			Investigator- initiated study planned H2 2021				
AP103	EB (DEB)						Clinical Development Planned - H2 2022	

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

\* Upcoming clinical milestones are subject to the impact of COVID-19 on our business.

(1) We have not yet commenced any clinical trials in the United States for metreleptin for the treatment of 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") post-approval commitments.

(3) An investigator-led open-label Phase 2 trial studying lomitapide in patients with FCS is ongoing and we announced encouraging topline data on efficacy and safety on March 30 2021.

(4) 505(b)(2) pathway Phase 2 not required, Phase 3 planned in 2022.

(5) Oleogel-S10 was approved in 2016 by the EMA for the treatment of partial thickness wounds in adults but has not been commercially launched.

(6) We have not yet commenced any clinical trials for radiation-induced dermatitis. This planned radiation-induced dermatitis Phase 2 trial is an investigator-initiated study.



#### **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.

Lipodystrophy is a chronic condition associated with low leptin levels as a result of the loss of adipose tissue. Leptin is an important hormone for energy homeostasis and metabolic function. Low leptin can result in metabolic chaos typically resulting in:

Fatty liver	Insatiable appetite	Chronic fatigue	Diabetes	Pancreatitis	Organ damage	Reduced life expectancy
455 eligible	LD patients* in the US <b>\$280M</b>		910 eligible LD patients* in <b>\$180M</b>		\$	ents* in other markets** 70M

The global market LD market is estimated at \$530 million with US estimated at ~\$280 million

\* Prevalence – 1.0 per million GL – 3.0 per million PL, discounted to 1.0 per million for severe cases – ~70% blended diagnosis & eligibility rate \*\* Includes key markets in which Amryt operates: Brazil, Argentina, Colombia & Canada



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®).

HoFH is a potentially life-threatening disorder that impairs the body's ability to remove LDL "bad" cholesterol from the blood. Typically results in extremely high blood LDL cholesterol levels leading to aggressive and premature blocking of arterial blood vessels. HoFH patients are at a high risk of experiencing life-threatening cardiovascular events and have a substantially reduced life expectancy. The effect of lomitapide on cardiovascular morbidity and mortality has not been determined.

250 eligible HoFH patients* in US	600 eligible patients* in EMEA	255 eligible HoFH patients* in other markets**
\$ <b>110M</b>	~\$100M	\$ <b>40M</b>

The global market for HoFH is estimated at ~\$250 million with US estimated at ~\$110 million

\* 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 & Canada.

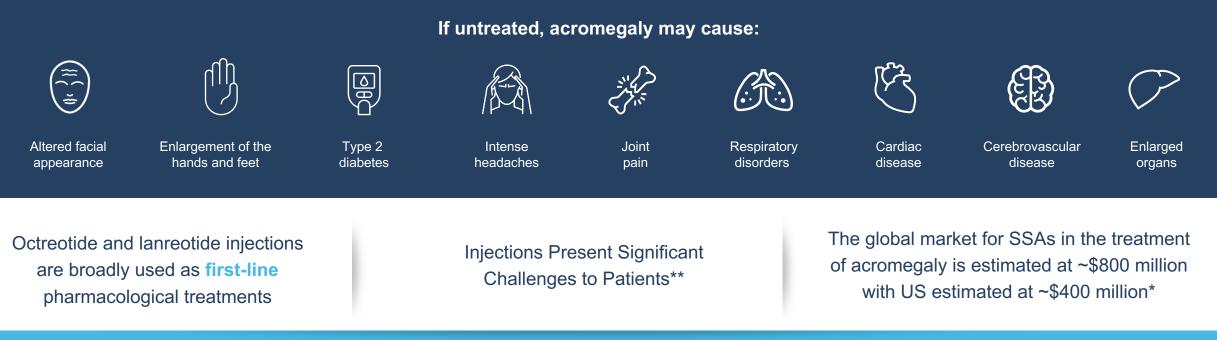


				Combined
	<b>Commercial Products</b>	2 marketed products with multiple lifecycle extension opportunities	1 marketed product in first full year of launch	3 marketed products with strong IP protection
	Infrastructure	Global medical + commercial	US medical + commercial	Enhanced US plus global medical + commercial
ĊĊĊ ĊĊĊ	Call points	Endocrinology + cardiology	Endocrinology	Endocrinology overlap + cardio
	Development Pipeline	Oleogel-S10: NDA and MAA submitted in US and EU AP103 gene therapy	NET pipeline opportunity TPE platform technology	Strengthened development pipeline and potential to leverage TPE and other Amryt products
	Financial	High revenue growth EBITDA positive	Revenue generating with high growth potential	Revenue accretive immediately Approx. \$50M cost synergies Expected to be EBITDA positive and cash generative in 1 <sup>st</sup> calendar year



### **MYCAPSSA<sup>®</sup> - ACROMEGALY - MARKET OVERVIEW**

Acromegaly is a rare disease most often caused by a *benign pituitary tumor* and characterized by an excess of growth hormone and insulin-like growth factor-1 hormone. Treatment options include surgery, medication and radiation or a combination of these.



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**

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 diarrhoea and flushing episodes)<sup>\*</sup>.



used as first-line pharmacological treatments

otential addressable patient population on SSA estimated at **~24,000 in the US**\*\*

The global NET market opportunity is currently estimated to be \$1.9 billion\*\*\* with the US accounting for approx. \$1billion\*\*\*



### **OLEOGEL-S10 - POTENTIAL FIRST IN MARKET THERAPY FOR EB**

- Phase 3 EASE study investigating Oleogel-S10 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 Oleogel-S10 versus control gel
- Favorable trends observed among secondary endpoints including procedural pain, change in EBDASI score and BSAP
- Oleogel-S10 was shown to have an acceptable safety profile

**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 severe, chronic blistering, ulceration and scarring of the skin, mutilating scarring of the hands and feet, joint contractures, strictures of the esophagus and mucous membranes, a high risk of developing aggressive squamous cell carcinomas, infections and risk of premature death.

**Received Fast Track Designation** 

Granted Rare Pediatric Disease Designation by FDA Regulatory submissions accepted by FDA and EMA. NDA submission granted priority review. Target PDUFA date of Nov 30, 2021

The global market is estimated to be in excess of \$1 billion\*

### BIRCH TRITERPENES IMPACT ON WOUND HEALING<sup>1</sup>

	Wound healing <sup>2</sup>	
In hours …	In days …	In weeks …
Inflammation	New tissue formation	New epidermal barrier formation
Begins immediately Clot formation occurs Cellular activity stimulated by PDGF, TGFb and VEGF	Cellular migration to wound site (fibroblast, endothelial cells and keratinocytes) to fill the defect Changes in cytoskeleton network and cell surface receptors enable cellular migration	Skin cells differentiate from the basal layer into epidermal skin cells and form the epidermal barrier
Transient modulation of inflammatory mediators e.g. COX-2, IL-6, IL-8 <sup>3</sup>	Stimulation of keratinocyte cytoskeleton and migration via effects on filipodia, lamelipodia <sup>3</sup> stress fibres and actin	Enhancement of keratinocyte differentiation, partly via upregulation of TRPC6 <sup>4</sup>
	Effects of birch triterpenes	
Anti-inflammatory activity shown for betulin, oleanolic acid, erythrodiol, betulinic acid and lupeol <sup>6</sup>	Birch triterpenes may also have anti- tumoural, antiviral and antibacterial effects <sup>5,6</sup>	



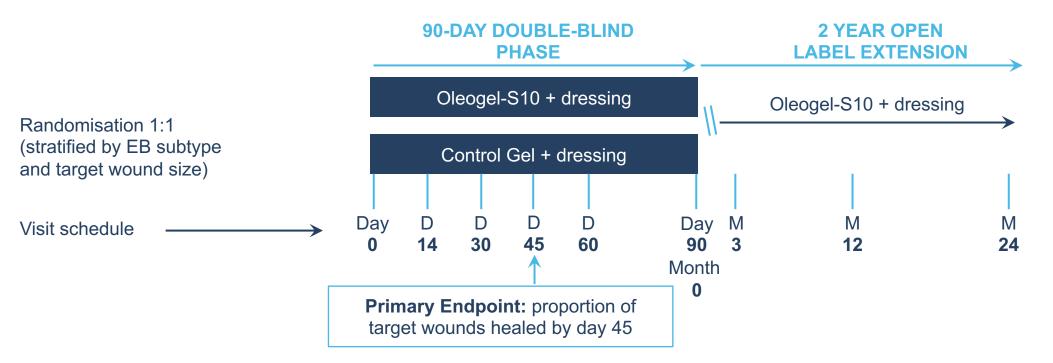


### **OLEOGEL-S10 EASE PHASE 3 STUDY IN EB**

✓ Primary endpoint met, September 2020

✓ p-value = 0.013

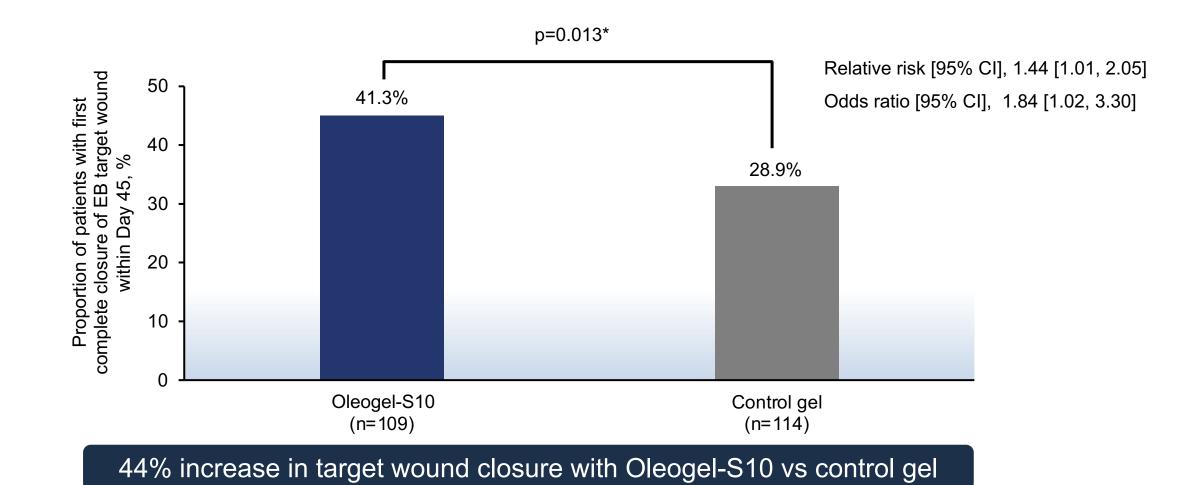
#### LARGEST EVER GLOBAL PHASE 3 STUDY IN EB



#### DOUBLE BLIND, RANDOMIZED, PLACEBO CONTROLLED, PHASE 3, EFFICACY AND SAFETY STUDY OF OLEOGEL-S10 IN PATIENTS WITH JUNCTIONAL AND DYSTROPHIC EB

ease

#### EASE TRIAL MET ITS PRIMARY ENDPOINT

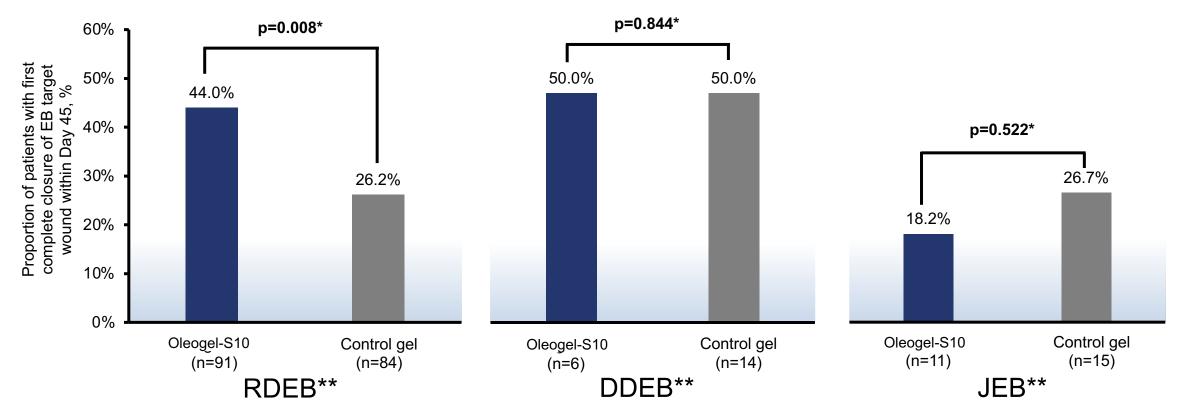




#### RDEB SUBGROUP DRIVES PRIMARY ENDPOINT TREATMENT EFFECT

Relative risk [95% CI], 1.72 [1.14, 2.59]

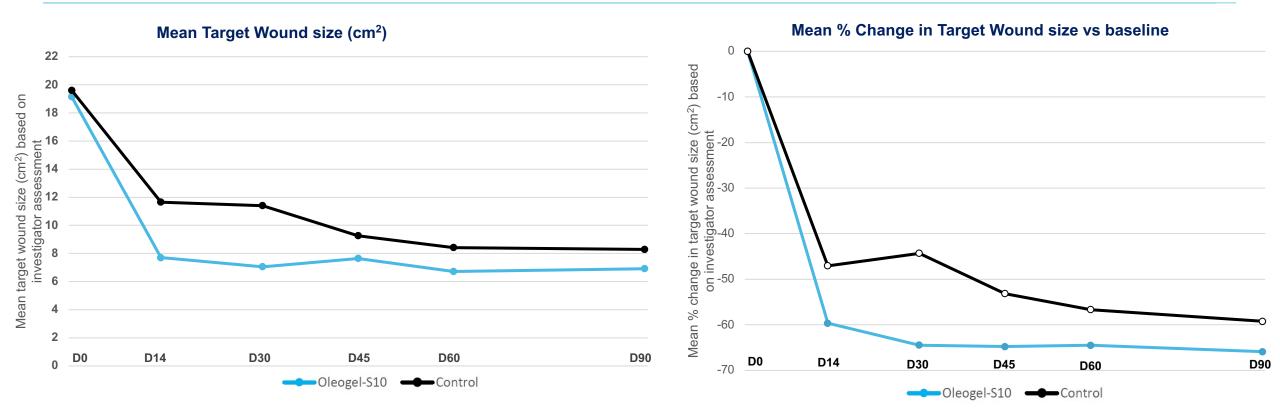




#### 72% increase in target wound closure in RDEB patients with Oleogel-S10 vs control gel



### **REDUCTION IN TARGET WOUND SURFACE AREA**



Oleogel-S10 (all patients): 65.9% reduction in mean surface area over 90 days treatment

Substantial early reduction from day 14 which was then maintained

No. Patients	Day 0	Day 14	Day 30	Day 45	Day 60	Day 90
Oleogel-S10	107	102	98	87	91	79
Control gel	111	107	101	97	95	84

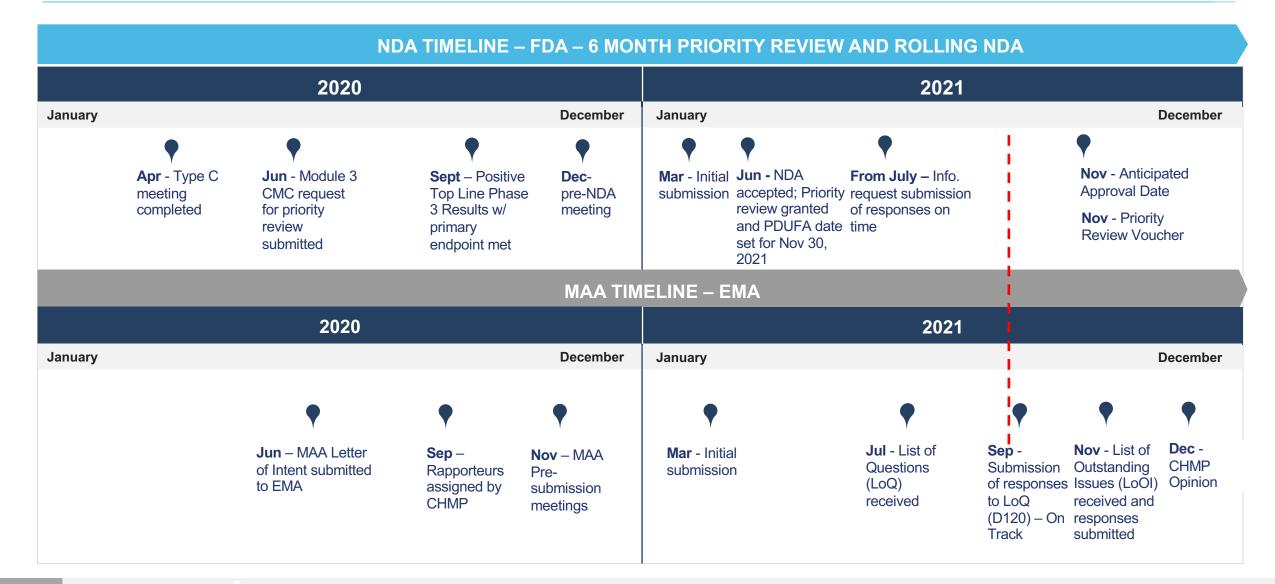


# TIME TO FIRST COMPLETE CLOSURE OF EB TARGET WOUND WITHIN D90 – BY EB SUBTYPE

	RDEB		DDEB		JEB	
	Oleogel-S10 (N=91)	Control Gel (N=84)	Oleogel-S10 (N=6)	Control Gel (N=14)	Oleogel-S10 (N=11)	Control Gel (N=15)
Closure	52.7%	44.0%	66.7%	57.1%	18.2%	33.3%
<b>Time to first complete closure (days)</b> Mean (SD)	<b>37.9</b> (20.76)	<b>46.9</b> (27.31)	<b>28.8</b> (19.75)	<b>31.0</b> (14.68)	<b>24.0</b> (15.56)	<b>48.0</b> (29.18)
95% CI Mean	(31.9, 44.0)	(37.8, 56.1)	(-2.7, 60.2)	(18.7, 43.3)	(-115.8, 163.8)	(11.8, 84.2)
Minimum - maximum	14 - 95	15 - 96	10 - 56	15 - 58	13 - 35	15 - 94
Median	33.5	45.0	24.5	29.5	24.0	47.0
Log-rank Test						
p-value	0.175		0.890		0.382	

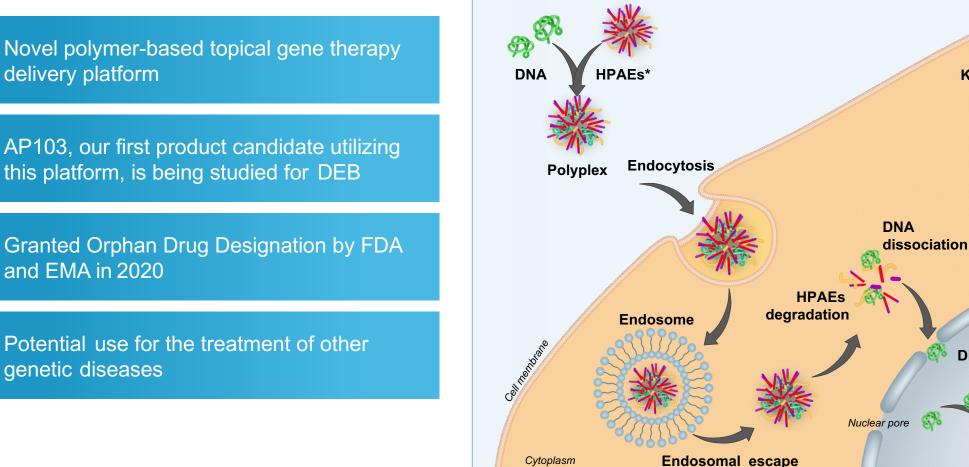


### **OLEOGEL-S10 - US & EUROPEAN ANTICIPATED REGULATORY TIMELINES**





#### **AP103 - BUILDING AN EB FRANCHISE - GENE THERAPY PLATFORM**



#### From Polyplex to Gene Expression

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



Nucleus

Transcription

Keratinocyte transfection

mRNA

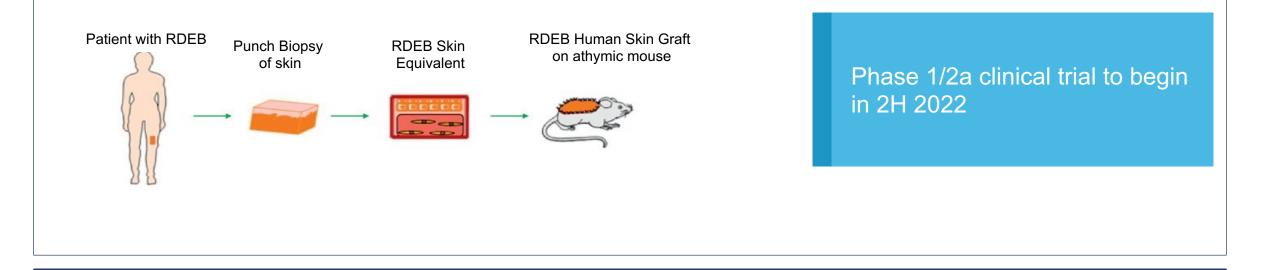
chromosome

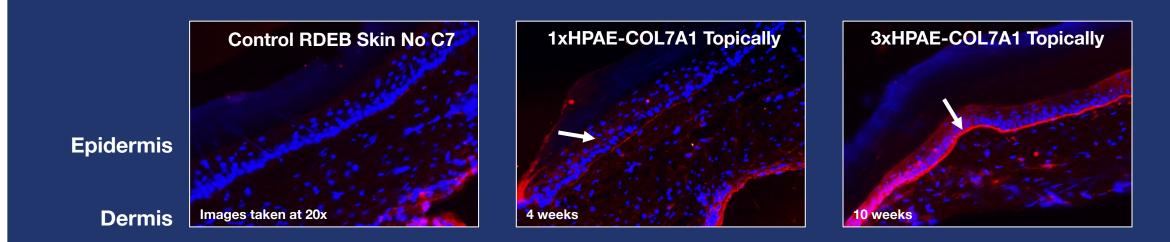
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Diffusion

Translation

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

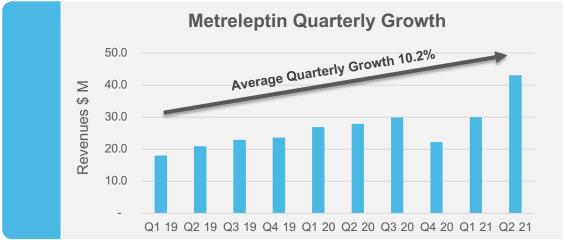


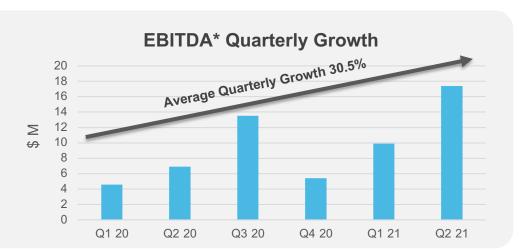


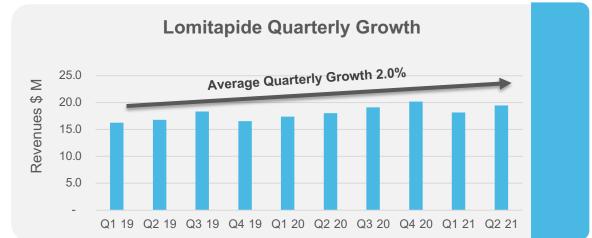


### **CONSISTENT FINANCIAL PERFORMANCE AND GROWTH**

#### 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

\$30.4M EBITDA\* in FY 2020 \$27.4M EBITDA\* in H1 2021 Cash \$142.9M\*\* at 30 June, 2021 (\$118.6M at 31 March, 2021) FY 2020 revenues \$182.6M FY 2021 revenue guidance \$220M - \$225M representing 20-23% growth YoY

#### \$125M Convertible Debt Facility

- ▲ 5.5 year bullet, Apr 2025
- ▲ Unsecured
- ▲ Coupon: 5% cash
- ▲ Convertible price: \$12.95 per ADS; \$2.59 per Ord Share

#### \$90M Term Debt

Facility

- ▲ 5 year bullet, Sep 2024
- ▲ Secured
- ▲ Coupon: 6.5% cash & 6.5% PIK

Chiasma deal estimated to deliver annualized cost synergies of approx. \$50M post integration



### **CONTACT & CORPORATE INFORMATION**

#### BUILDING A GLOBAL LEADER IN RARE DISEASES

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TICKER	AMYT	AMYT



Revenue generating commercial portfolio with three approved commercial products

Robust clinical pipeline with Oleogel-S10 potential near-term approval in a potential \$1BN\* global market and Phase 3 ready Mycapssa® in a potential \$1.9BN\* NET global market opportunity





Financial flexibility to execute on growth plans

Global commercial infrastructure and experienced team in place to drive product launches and growth









### **TPE - VALIDATED DELIVERY TECHNOLOGY PLATFORM**

## With the approval of Mycapssa<sup>®</sup>, the TPE\* represents a validated technology delivery platform for potential new development opportunities







Capsules with TPE technology have an enteric coating to protect against degradation in the stomach.

>

Once in the small intestine, the capsule is designed to dissolve and release the TPE formulation.





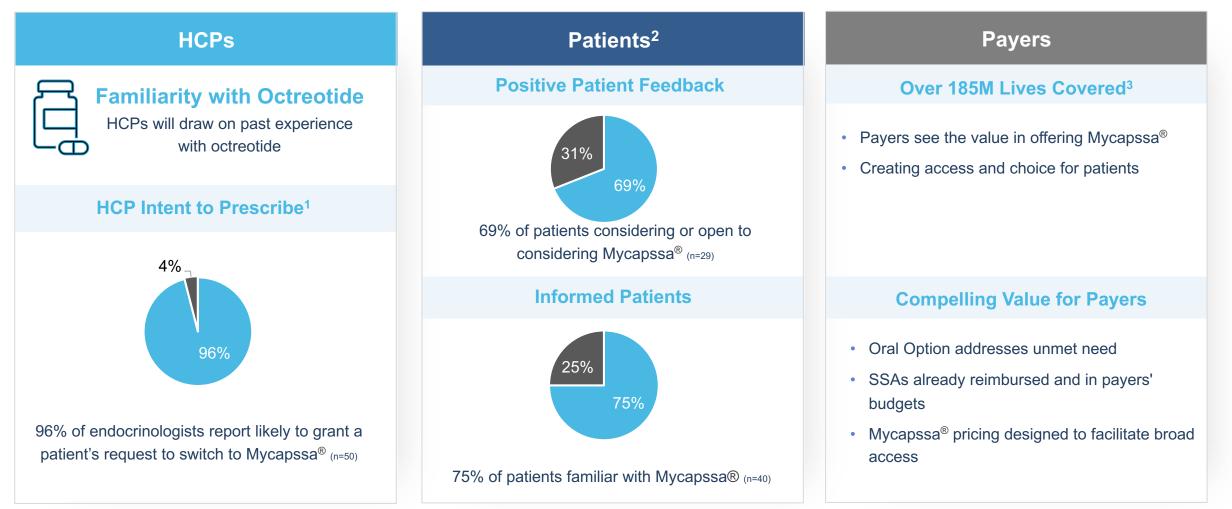
TPE technology induces the reversible expansion of tight junctions between intestinal epithelial cells, a natural process to absorb nutrients.

Capsules containing TPE can allow drug therapies to enter systemic circulation while excluding toxins, bacteria and viruses.



### **MYCAPSSA® - STANDARD OF CARE IMPACT**

#### THE FOUNDATION IS IN PLACE





### **EPIDERMOLYSIS BULLOSA ("EB")**

#### ADDRESSING A HIGH UNMET MEDICAL NEED



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 severe, chronic blistering, ulceration and scarring of the skin, mutilating scarring of the hands and feet, joint contractures, strictures of the esophagus and mucous membranes, a high risk of developing aggressive squamous cell carcinomas, infections and risk of premature death.

CauseMost types of EB are inherited. A mutation in the genes encoding structural proteins in the skin causes<br/>loss of mechanical integrity, extreme fragility and vulnerability to trauma.



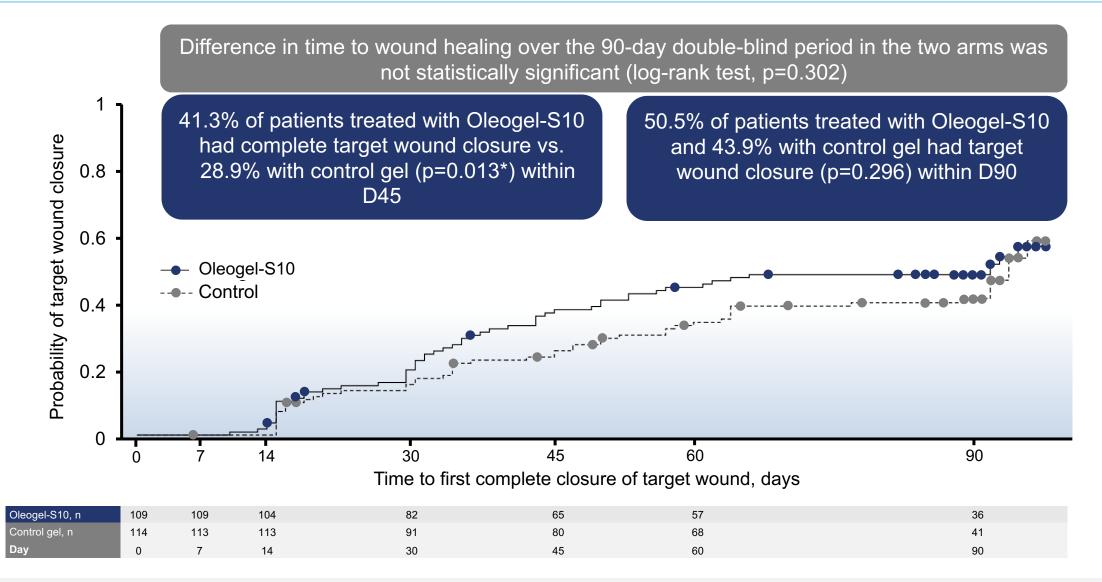
Incidence among live births 1:20,000<sup>1</sup>, multiplied by life expectancy per EB sub-type, generates an estimated total EB prevalence of 30/million in the general population of which ~31% are DEB & JEB patients<sup>2</sup> - Resulting prevalence of ~14,100 for DEB & JEB<sup>3</sup>

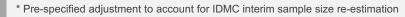
#### ন্ট্রি নার্হন্ট্রের

Current Standard of Care There are no approved pharmaceutical treatments. Disease management is mostly supportive and involves wound care, pain control, controlling infections, nutritional support, and prevention and treatment of complications.



### KAPLAN-MEIER SURVIVAL CURVE SHOWING SEPARATION IN TARGET WOUND CLOSURE AROUND DAY 30 AND DIFFERENCE NARROWING AROUND DAY 90



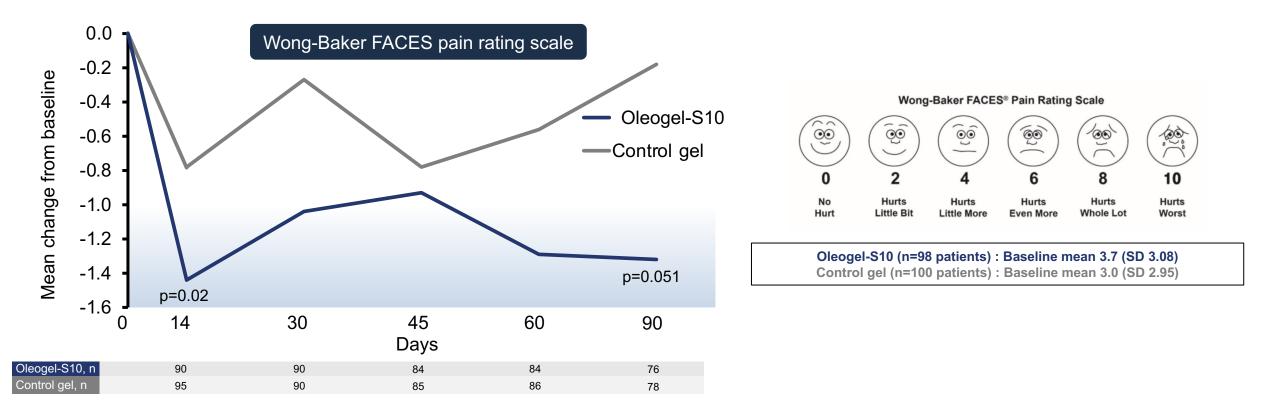


TIME TO FIRST CLOSURE (DAYS)	Oleogel-S10 (N=109)	Control Gel (N=114)
Mean (SD)	<b>37.7 days</b> (21.65)	<b>44.5 days</b> (26.15)
95% Cl	[31.9, 43.6]	[37.1, 51.9]
Median	33.0 days	39.0 days
Minimum-Maximum	10-95 days	15-96 days

#### In wounds that achieved complete closure, Oleogel-S10 did so in a shorter number of days



### PROCEDURAL PAIN REDUCTION WAS OBSERVED WITH OLEOGEL-S10 (PATIENTS ≥ 4 YEARS OF AGE)

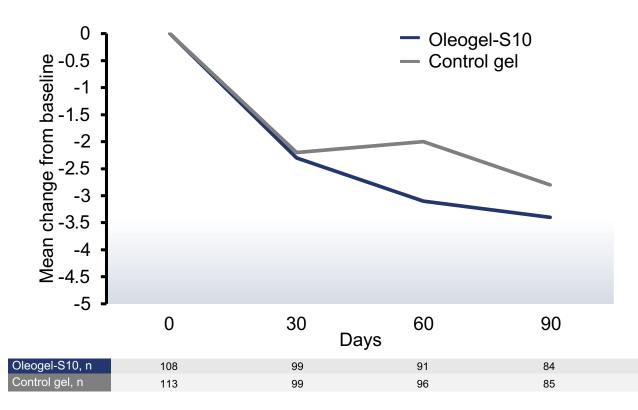


206 patients ≥ 4 years of age used Wong-Baker FACES pain rating scale to assess the degree of pain experienced during their dressing change. Improvement observed was greater with Oleogel-S10 treatment.



#### **REDUCTION IN TOTAL BODY WOUND BURDEN (EBDASI) WITH OLEOGEL-S10**





Assessment of Total Body Wound Burden based on the 'EB Disease Activity and Scarring Index' (EBDASI)

Section I: Skin Activity

Anatomical Location	Erosi	ons/Blisters/Crusting	Number of lesions if <3
	0	absent	
	1	1-3 lesions, none ≥2 cm in any diameter	
	2	1-3 lesions, at least one lesion ≥2 cm in any diameter, none >6 cm	
	3	>3 lesions, none >6 cm in diameter	
	5	>3 lesions, and/or at least one lesion ≥6 cm in diameter	
	7	>3 lesions, and/or at least one lesion ≥16 cm in diameter almost entire area involved	
	8 10	almost entire area involved entire area involved	
	10	entire area involved	
Ears			
Face			
Neck			
Chest			
Abdomen			
Back			
Arms			
Hands			
Legs			
Feet			

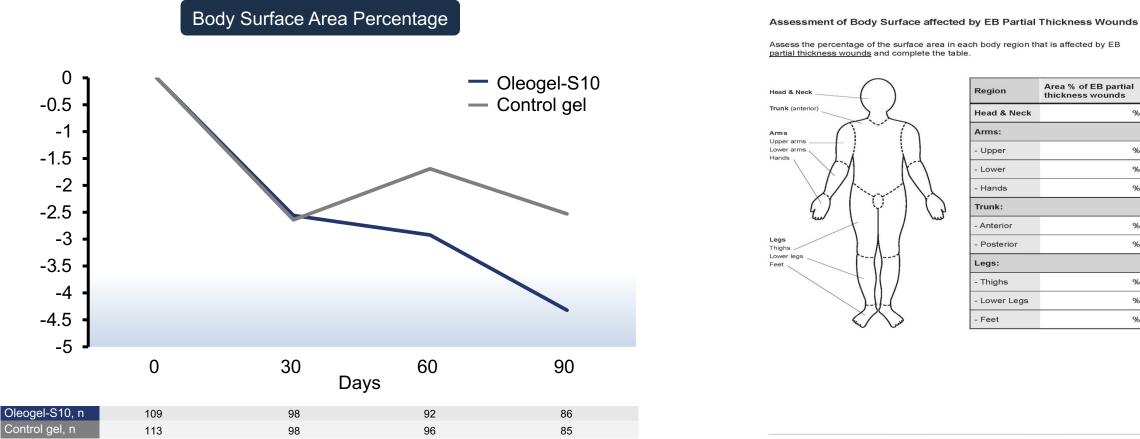
Epidermolysis Bullosa Disease Activity and Scarring Index (EBDASI), Section I: Skin, Activity Used with Permission of Professor Dedee Murrell and the Australasian Blistering Diseases Foundation

EBDASI Section I: Skin, Activity	Patients of all age groups	EASE Study BEB-13
Visit: D0 D30 D60 D90 M3 M12	□ M24	ENG v2
Date (DD MM YYYY):	Patient No.: E 3 0	

Total body wound burden based on EBDASI (skin index activity) demonstrated an improvement with Oleogel-S10



## **REDUCTION IN TOTAL BODY SURFACE AREA OF EB PARTIAL THICKNESS WOUNDS** WITH OLEOGEL-S10



BSAP (Investigator assessment)	Patients of all age groups	EASE Study BEB-13		
Visit: D0 D30 D60 D90 M3 M12	2 🗆 M24	ENG v2		
	Patient No.:	3 0		

The percentage of the total body surface with partial thickness wounds reduced (BSAP using Lund and Browder)



%

%

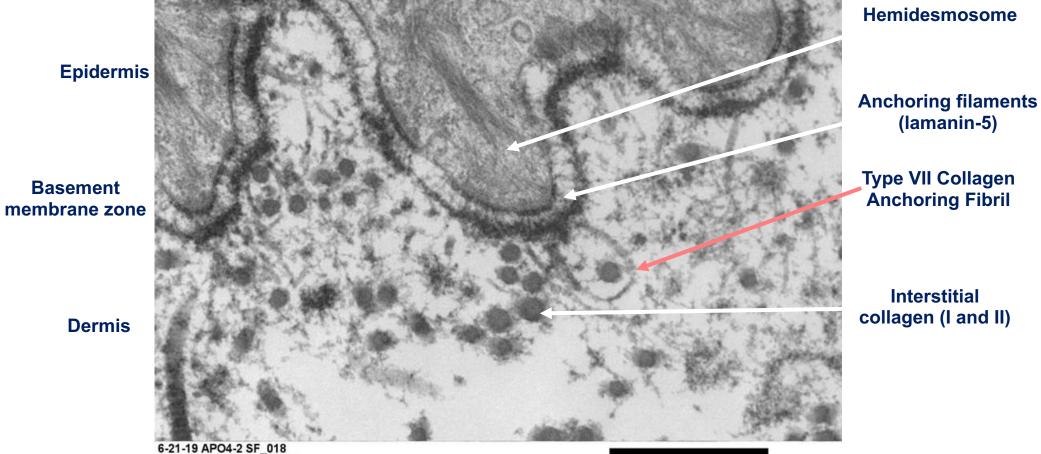
%

### EASE SAFETY SUMMARY DOUBLE BLIND PERIOD: OLEOGEL-S10 WELL TOLERATED

Adverse event category	Oleogel-S10 (n=109) n (%)	Control gel (n=114) n (%)	All Patients (n=223) n (%)	
Patients with any adverse events (AEs*)	89 (81.7)	92 (80.7)	181 (81.2)	
Mild AEs (grade 1)	46 (42.2)	41 (36.0)	87 (39.0)	
Moderate AEs (grade 2)	30 (27.5)	45 (39.5)	75 (33.6)	
Severe AEs (grade 3/4)	13 (11.9)	6 (5.3)	19 (8.5)	
Any related AEs	27 (24.8)	26 (22.8)	53 (23.8)	
Any AE leading to study withdrawal	3 (2.8)	2 (1.8)	5 (2.2)	

The most frequently reported AEs\* were wound complication (61.5% vs 53.5%), pyrexia (8.3% vs 13.2%), wound infection (7.3% vs 8.8%), pruritus (7.3% vs 5.3%) and anaemia (7.3% vs 3.5%)

## **AP103 - ELECTRON MICROSCOPY IMAGE SHOWING ANCHORING FIBRILS**

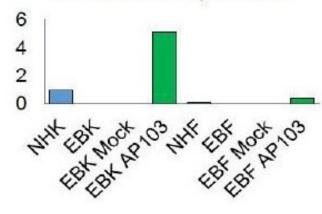


6-21-19 APO4-2 SF\_018 Print Mag: 94000x @ 8.0 in

500 nm Direct Mag: 50000x



### Protein Production from RDEB Cells Treated with AP103\*



### C7 relative expression

- Approximately 5-fold more hCol7 protein is expressed in RDEB keratinocytes after a single AP103 delivery compared with normal keratinocyte endogenous levels of hCol7 protein. <u>These levels are comparable to those delivered by</u> <u>viral methods</u>
- RDEB fibroblasts express approximately 3.5-fold more hCol7 protein compared with normal fibroblast levels

### **Confirmation of Expression & Delivery of HCOL7**

AP103 application produced type VII collagen at levels exceeding previously tested non-viral methods, and similar to those following delivery using viral vectors

Treated RDEB cells produced much higher amounts of type VII collagen than seen in healthy cells

No indication of cellular toxicity was seen after treatment with AP103



## **IFRS AND NON-GAAP ADJUSTED RESULTS - Q2 2021 EBITDA**

US\$M	Q2 2021 (unaudited)	Q2 2021 Non- cash Items <sup>1</sup>	Q2 2021 Non-GAAP Adjusted	
Revenue	62.8	-	62.8	
Cost of sales	(26.2)	11.0	(15.2)	
Gross profit	36.6	11.0	47.6	
R&D expenses	(8.5)	-	(8.5)	
SG&A expenses	(22.0)	0.3	(21.7)	
Share based compensation expenses	(2.0)	2.0	-	
Operating (loss) / profit before finance expense	4.1	13.3	<b>17.4</b> <sup>2</sup>	

1. Non-cash items include amortisation of the acquired metreleptin and lomitapide intangible assets (\$10.7M), amortisation of the inventory fair value step-up that was acquired at the acquisition date (\$0.3M), depreciation & amortization (\$0.3M) and share based compensation expenses (\$2.0M).

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 2020 EBITDA**

US\$M	FY 2020 (unaudited)	FY 2020 Non-cash Items <sup>1</sup>	FY 2020 Non-GAAP Adjusted
Revenue	182.6	-	182.6
Cost of sales	(119.0)	70.6	(48.4)
Gross profit	63.6	70.6	134.2
R&D expenses	(27.6)	-	(27.6)
SG&A expenses	(76.7)	1.5	(75.2)
Acquisition & severance related costs	(1.0)	-	(1.0)
Share based compensation expenses	(4.7)	4.7	-
Operating (loss) / profit before finance expense	(46.4)	76.8	<b>30.4</b> <sup>2</sup>

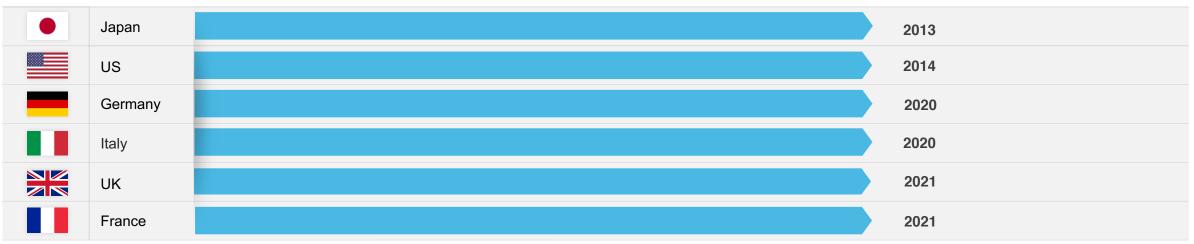
1. Non-cash items include amortisation of the acquired metreleptin and lomitapide intangible assets (\$43.0M), amortisation of the inventory fair value step-up that was acquired at the acquisition date (\$27.6M), depreciation & amortization (\$1.5M) and share based compensation expenses (\$4.7M).

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.



# **EXPANDING PATIENT ACCESS TO METRELEPTIN**

### **Reimbursement achieved**

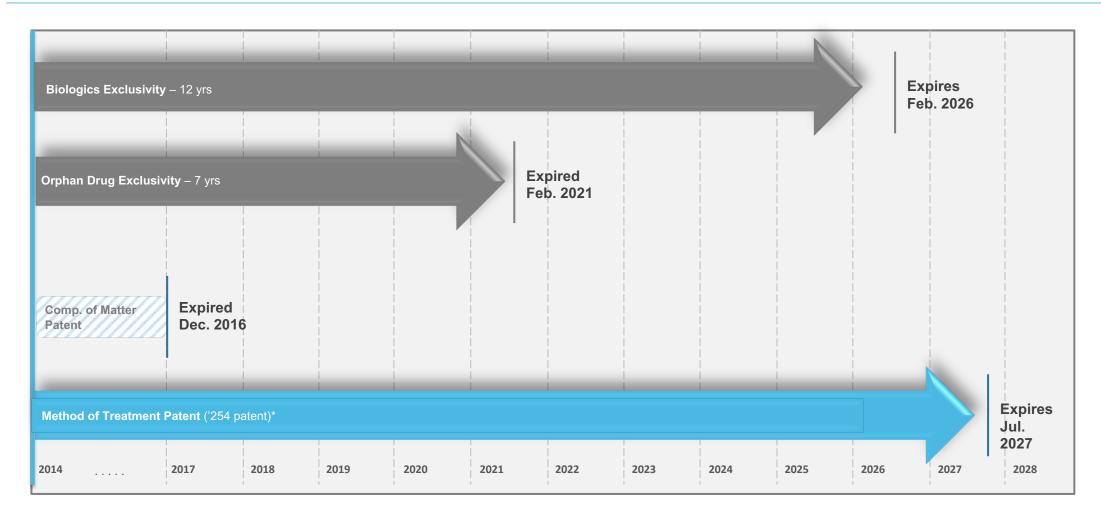


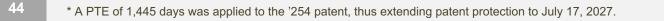
### National reimbursement processes ongoing

Spain	AEMPS dossier submission								
Norway	NOMA dossier submission								
Portugal	INFARMED dossier submission								
Netherlands	ZIN dossier submission pending								
Poland	AHTAPol dossier submission pending								
Paid Named Patient Supply	Denmark Switzerland	Serbia Turkey	Portugal Spain	Austria Oman	UAE Greece	Israel Brazil	Argentina Colombia	Qatar Bahrain	Saudi Arabia



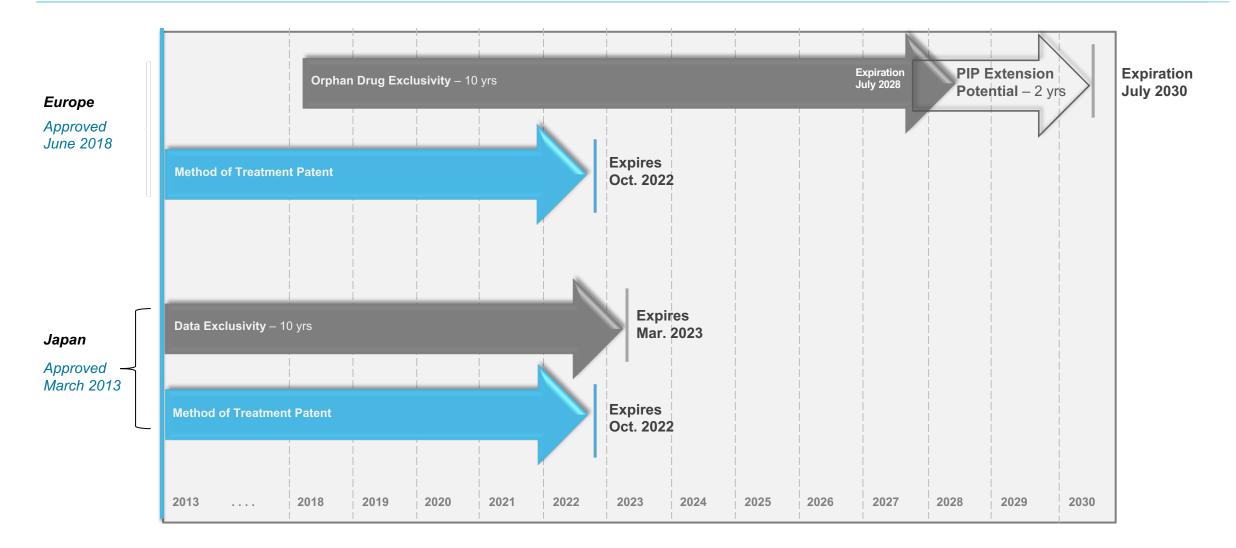
# MYALEPT® (US) REGULATORY EXCLUSIVITY / PATENT TIMELINE ASSUMES LOE JULY 2027





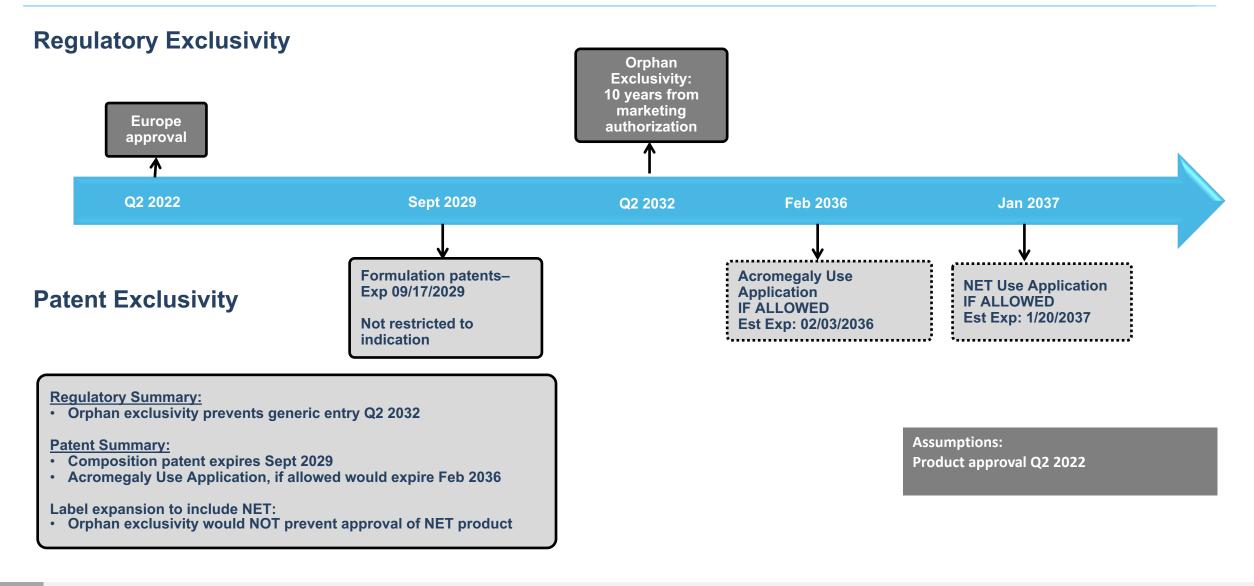


# MYALEPTA® (EX-US) REGULATORY EXCLUSIVITY / PATENT TIMELINE ASSUMES LOE JULY 2028 WITH POTENTIAL 2-YEAR EXTENSION



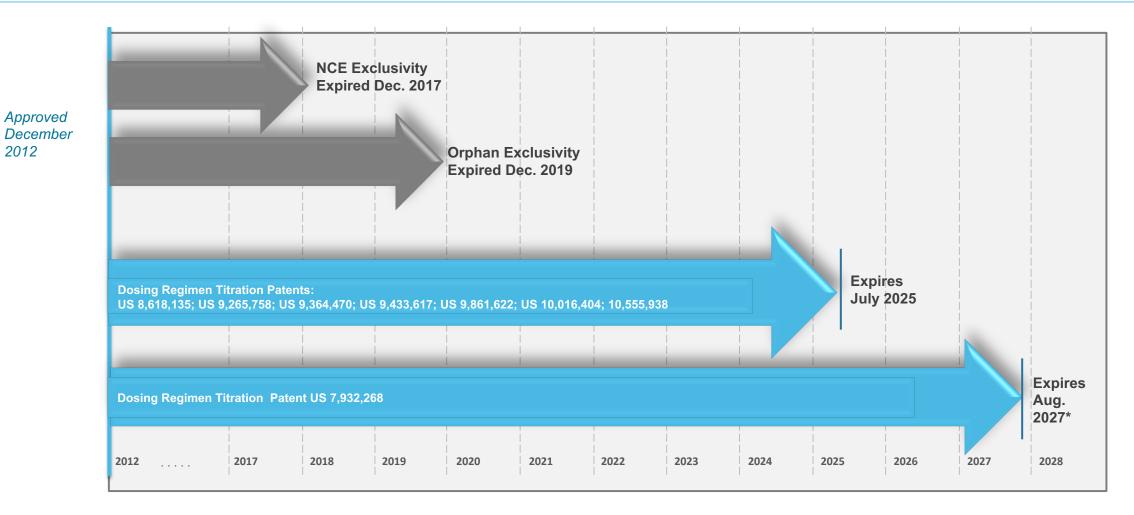


## **MYCAPSSA®- EUROPEAN EXCLUSIVITY TIMELINE**



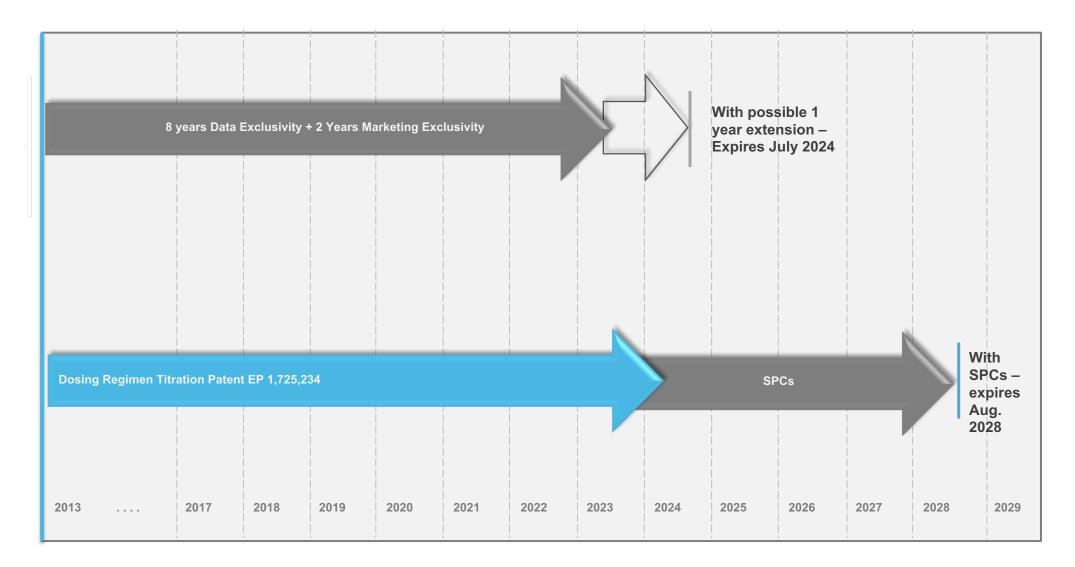


## JUXTAPID® US REGULATORY EXCLUSIVITY / PATENT TIMELINE



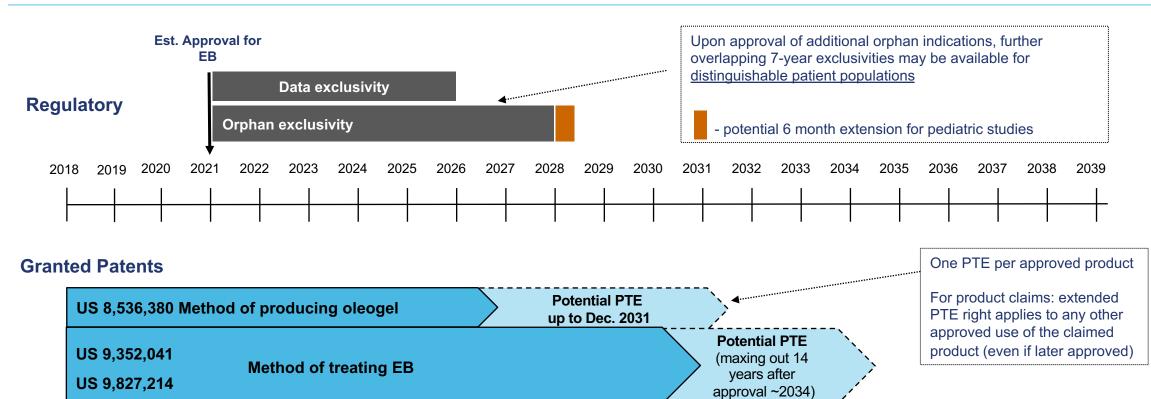


## LOJUXTA® EU REGULATORY EXCLUSIVITY/PATENT TIMELINE





## **OLEOGEL-S10 ANTICIPATED EXCLUSIVITY TIMELINE IN US**



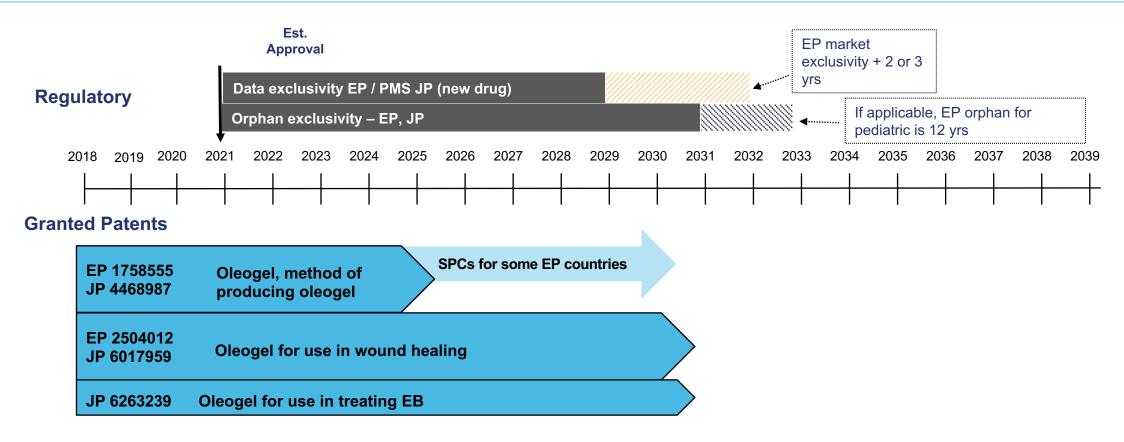
### **Pending applications**

#### US 62/613,646 – Pending provisional (AMRT-005)

• Non-provisional PCT filed in Jan. 2019 – patent term on any patents that issue to 2039



### **OLEOGEL-S10 ANTICIPATED EXCLUSIVITY IN EUROPE AND JAPAN**



### **Pending applications**

#### US 62/613,646 – Pending provisional (AMRT-005)

• Non-provisional PCT filed in Jan. 2019, nationalizes in 2020 – patent term on any patents that issue to 2039



## **AP103 REGULATORY AND PATENT EXCLUSIVITIES**

