



FY2016 Full Year Results, Ending March 31, 2017

Conference Call for investors and analysts

May 12, 2017
www.osei.com

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Presenters



Peter Bains
Chief Executive
Officer



Andrew J. Oakley
Chief Financial
Officer

Sosei – Building a global biopharmaceutical company

Today

- COPD product royalties
- Early stage 'Wave1' partnerships
- Emerging 'Wave2' pipeline
- StaR/SBDD platform refuels early pipeline

MID-STAGE DEVELOPMENT



























- W1 progress toward Ph2
- COPD product royalties
- W2 proprietary pipeline advances to Ph1
- StaR/SBDD platform refuels early pipeline
- MiNA Ph1/2a readout

EARLY STAGE DEVELOPMENT

- W2 proprietary product commercialization
- COPD+Asthma product royalties
- W1 product royalties
- Pipeline partnerships
- StaR/SBDD refuels early pipeline
- MiNA commercialization & licensing potential

LATE-STAGE DEVELOPMENT/ COMMERCIALIZATION

Expanding and advancing a broad pipeline

	Product/Programme	Indication	Partner	Discov.	Preclin.	Phase 1	Phase 2	Phase 3	Market	
Sosei	Products /Development Pipeline (Sosei)									
	Seebri®/Ultibro®	COPD	 NOVARTIS							
	QVM 149	Asthma	 NOVARTIS							
WAVE 1	Wave 1: Partnered Pipeline									
	M ₁ agonist	AD/Sz Cognition	 Allergan							
	M ₄ agonist	AD/Sz Psychosis	 Allergan							
	M ₁ M ₄ dual agonist	Sz/AD Psych / Cog	 Allergan							
	A _{2A} antagonist	Cancer I/O	 AstraZeneca							
	CGRP antagonist	Migraine	 TEVA							
	Not disclose	Pain	 Daiichi-Sankyo							
WAVE 2	Wave 2: Proprietary Pipeline									
	mGlu ₅ NAM	Neurology								
	Orexin OX ₁ antagonist	Addiction								
	Orexin OX ₂ agonists	Narcolepsy								
	Anti-PAR2 mAb	Atopic Dermatitis								
	GLP-1 antagonist	Hyperinsulinism								
	Not-disclosed	gastro-intestinal disorders	 Titsubo							
	Multiple targets (mAbs)	Immuno-oncology	 kymab							
Multiple targets (SMEs)	Multiple indications									

FY 2016 Operational and Financial Highlights

Strong revenue growth from multiple sources

- \$125m upfront from Allergan – key driver of headline performance
- \$10m from AZ for Ph1 initiation of immuno-oncology candidate
- \$4m – Collaboration with Daiichi Sankyo
- Solid growth in royalties from COPD products licensed to Novartis
- Sales milestone of \$5m from Novartis – COPD products

Robust pipeline progression

- Partnered pipeline (Wave 1) progressing as anticipated
 - 2 Collaborations in Phase 1
- Expanded proprietary pipeline (Wave 2) from Heptares platform progressing towards pre-clinical entry
- Strengthened our science and technology leadership (leadXpro, G7, ORBIT)
- Heptares Zurich (formerly G7 Therapeutics) acquisition to complement existing StaR technologies
- SO-1105 submission for oropharyngeal candidiasis in Japan

CONSOLIDATED EARLY STAGE BIOTECH PROFILE

Equity Stake and Acquisition Option Agreement with MiNA Therapeutics

*Significant subsequent event

- Strategic investment of GBP 35 million – 25.6% equity share
- Exclusive option to acquire the company
- Phased options will be based on clinical milestones of MiNA's Phase 1/2a OUTREACH study with MTL-CEBPA in advanced liver cancer
- MiNA will continue to develop and enhance its RNA activation platform

**POTENTIAL TO ACCELERATE AND EXPAND SOSEI PIPELINE
AND CREATE NEW COMPLEMENTARY PLATFORM**

Financial Highlights for FY2016

Strong year – dominated by Allergan upfront milestone

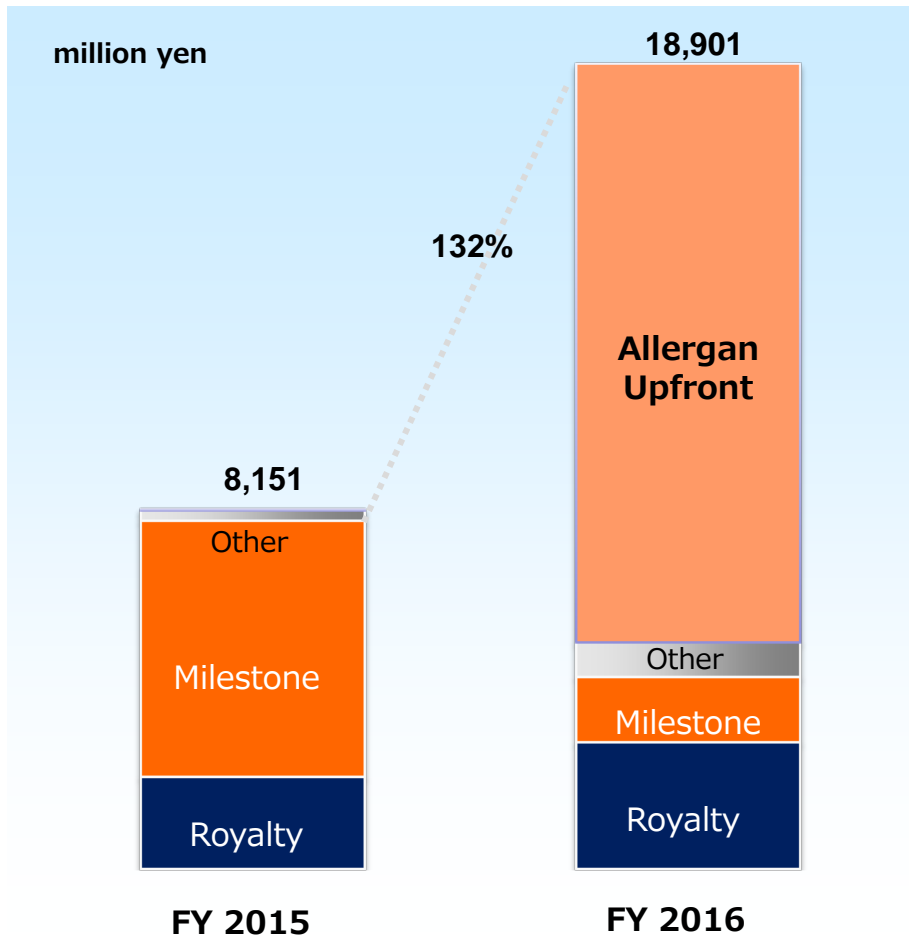
(million yen)	FY2015	FY2016	% change	% cc* change
Revenue	8,151	18,901	132%	143%
Operating income	1,075	12,389	1,052%	986%
Net Income	(1,547)	9,638	nm	nm
Earnings Per Share (EPS)	(93.60)	579.97	nm	nm
Cash & cash equivalents	10,068	13,899	na	na

(million USD)	FY2015	FY2016	% change	% cc* change
Revenue	67.8	174.4	157%	143%
Operating income	8.9	114.3	1,184%	986%
Net Income	(12.9)	88.9	nm	nm
Earnings Per Share (EPS)	(0.78)	5.35	nm	nm
Cash & cash equivalents	83.8	128.2	na	na

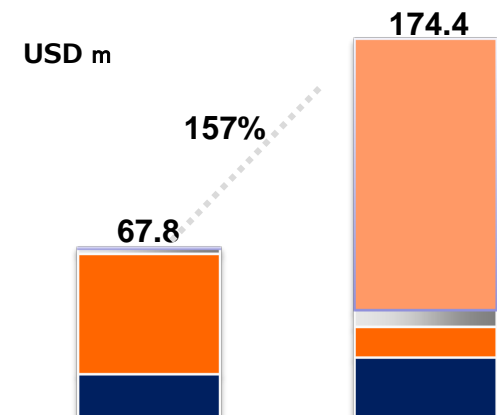
*cc (constant currency)

yen/USD FY2106 108.38 (FY2015 120.15)

Significant progress across partnered programs



- Allergan upfront \$125m
- \$10m from AZ for PhI initiation-A_{2A}
- \$4m Upfront - Daiichi Sankyo
- Growth in COPD royalties
- \$5m COPD sales milestone
- Constant currency growth 143%

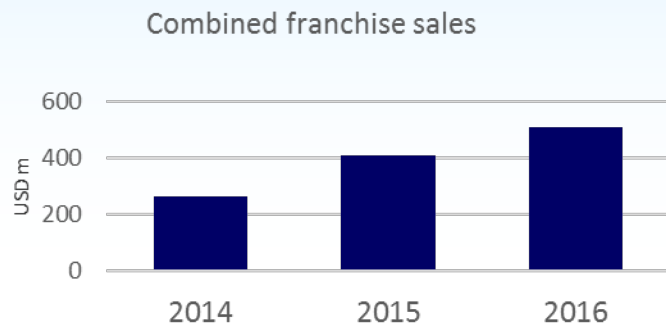


COPD franchise momentum continues

	FY 2016	FY 2015	% change	
	USD m	USD m	USD	cc
<i>Ultibro Breezhaler</i>	363	260	40	38
<i>Seebri Breezhaler</i>	149	150	-1	2

*Based on Novartis Annual Report 2016

*cc (constant currency)



Seebri[®] Breezhaler[®]

- Licensed to Novartis in 2005
- Seebri[™] Neohaler[®] was approved in the US October 2015
- Sunovion – US commercialization rights of Seebri[™] Neohaler[®]

Ultibro[®] Breezhaler[®]

- Approved in over 90 countries
- Approved in the US October 2015 – b.i.d
- FLAME data + GOLD guideline changes
- Utibron[™] Neohaler[®] was launched in US by Sunovion in April 2017
- Filed for approval in China

Royalties and Milestone

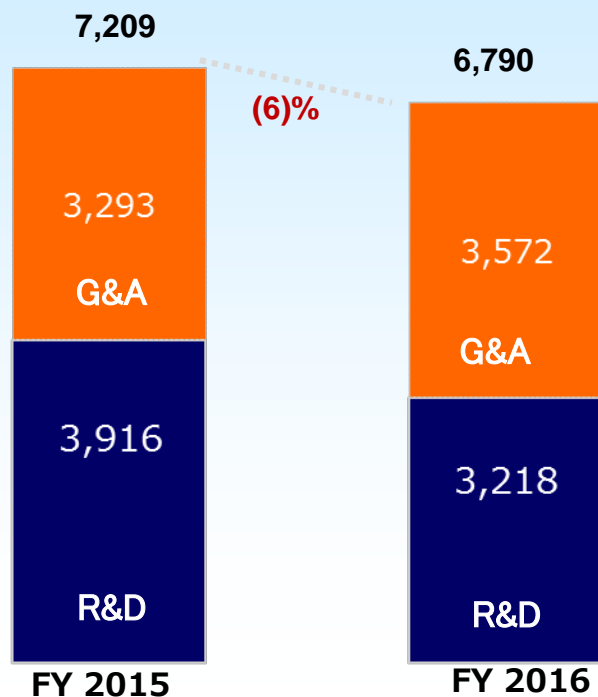
- USD 5m Sales Milestone – Sales >USD 500m

¹ Seebri[®], Ultibro[®], Breezhaler[®] and Neohaler[®] and Utibron[™] are registered trademarks of Novartis AG. Seebri[™], and Ultibro[™] are trademarks of Novartis AG.

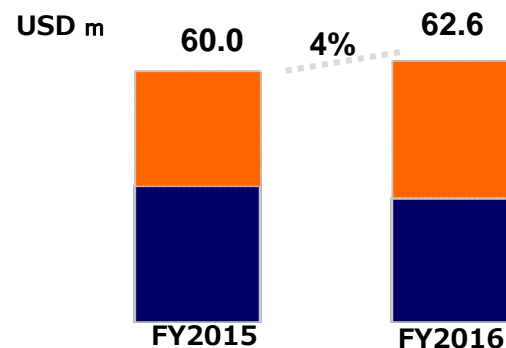
² Utibron[™] Breezhaler[®]

Currency masks underlying increase in operating expenses

million yen

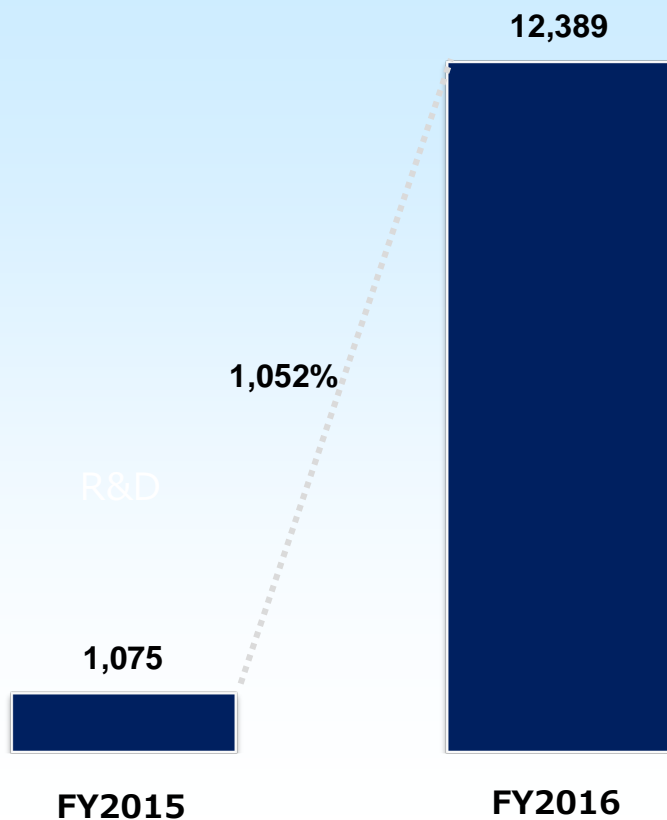


- Constant currency basis, + 12%
- 67% of current cost base in the UK
- Significant spend on muscarinics in PY
- Heptares Zurich costs for 3 months
- Scale up of StaR technology platform
- Investment to progress Wave 2

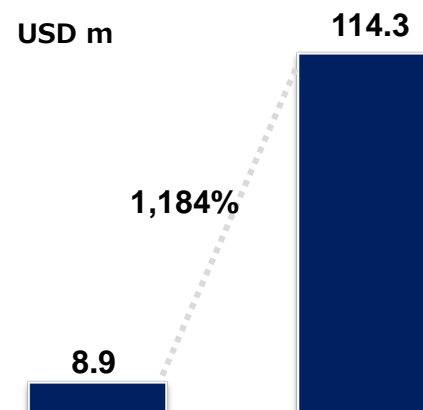


Impact from Allergan upfront and currency benefit

(Operating Income - million yen)



- Constant currency: + 907%
- Allergan upfront
- Currency benefit on operating expenses



Considerable variation below the operating line

(million yen)	FY2015	FY2016	% change
Net Interest Cost	438	193	(56)%
Foreign Exchange Loss (Gain)	123	(1,512)	nm
Contingent Consideration	3,816	277	(93)%
Income Tax (Benefit) Expense	(1,750)	2,844	nm

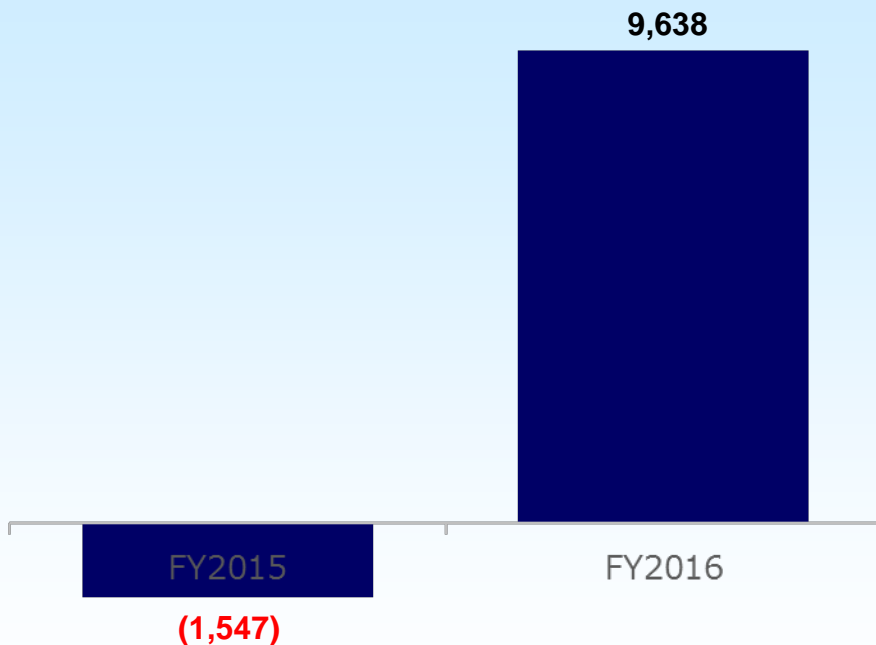
(million USD)	FY2015	FY2016	% change
Net Interest Cost	3.6	1.8	(50)%
Foreign Exchange Loss (Gain)	1.0	(14.0)	nm
Contingent Consideration	31.8	2.6	(92)%
Income Tax (Benefit) Expense	(14.6)	26.2	nm

*cc (constant currency)

yen/USD FY2106 108.33 (FY2015 120.15)

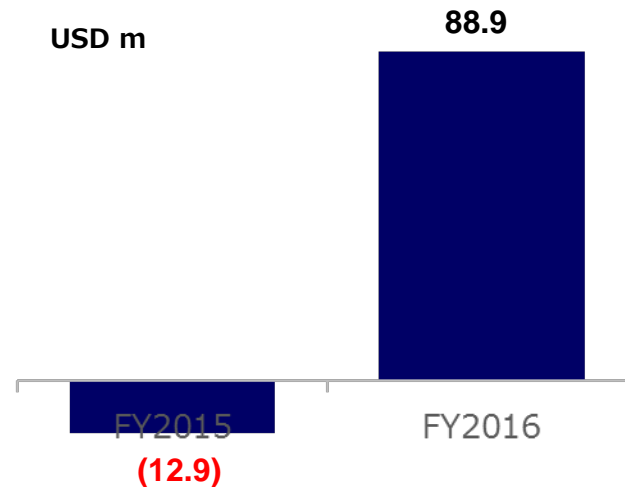
Strongly profitable – but one-off effects dominate

(Net Income - million yen)



- Allergan upfront drives top line
- Brexit FX benefit above and below Op Inc.
- Contingent Consideration for Allergan in FY15
- EPS 579.97 compared to (93.60)

USD m



FY March 2018 – profitable – but dependent on milestones

Revenues

- Several milestones expected from existing Wave 1 projects
- Materially lower due to effect of Allegan upfront in FY 16
- Royalty income boost from US launch of COPD portfolio



Operating Expenses

- Investment to progress Wave 2 portfolio
- Further scaling of discovery platform
- Stock compensation from new employee incentive plan



Profitability

- Materially lower and dependent on milestone delivery
- No repeat expected of currency benefit in 2016 year
- Contingent consideration in line with milestone receipt



Strategy Update and Outlook

Sosei Vision & Mission

Vision

- To become a leading global biopharmaceutical company, originating in Japan

Mission

- To discover, develop and deliver new and innovative medicines
- To make a significant contribution to improving the health and quality of life of people around the world
- To deliver superior, long-term shareholder value

Sosei – Building a global biopharmaceutical company

Outlook 12-18m

- W1 pipeline progresses toward Ph2
- COPD product royalties
- W2 proprietary pipeline advances to Ph1
- StaR/SBDD platform refuels early pipeline
- MiNA Ph1/2a readout

- COPD product royalties
- Early stage 'Wave1' partnerships
- Emerging 'Wave2' pipeline
- StaR/SBDD platform refuels early pipeline

- W2 proprietary product commercialization
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**EARLY STAGE
DEVELOPMENT**

**MID-STAGE
DEVELOPMENT**

**LATE-STAGE
DEVELOPMENT/
COMMERCIALIZATION**

Transition to mid-stage biotech – 12-18 months

Wave1

- M1 plan to progress into Phase 1b patient studies – H2 17
- M4 plan to progress into Phase 1 – H2 17
- M1/M4 Dual to progress post mono therapy data
- A_{2A} Phase 1a study read out H2 17
- CGRP – Potential to progress into P1 – H2 18

Moving to mid-stage development

Transition to mid-stage biotech – 12-18 months

Wave 2

- Up to 3 molecules to progress into full pre-clinical development
- At least one molecule progressing into Phase 1
- StaR/SBDD scaling and refueling–investment in discovery capability

Moving into early stage development
Building a balanced pipeline

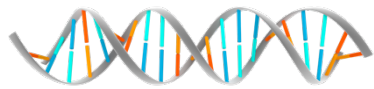
Transition to mid-stage biotech – 12-18 months

MiNA – Moving into mid-stage development

- MTL-CEBPA HCC Phase 1/2a data – potential to move to Phase 2b/3
- MTL-CEBPA Potential to start Phase 1/2a in other indications
- Advance other saRNA targets into full pre-clinical development

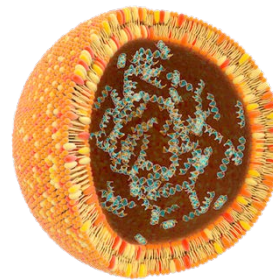
**Potential to accelerate and expand Sosei pipeline
and create complimentary scalable platform**

MiNA has developed MTL-CEBPA for the treatment of multiple liver diseases



**Small activating RNA
targeting CEBPA gene**

Active ingredient



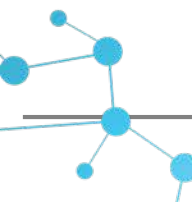
**NOV340 SMARTICLES®
liposome**

Formulation



MTL-CEBPA

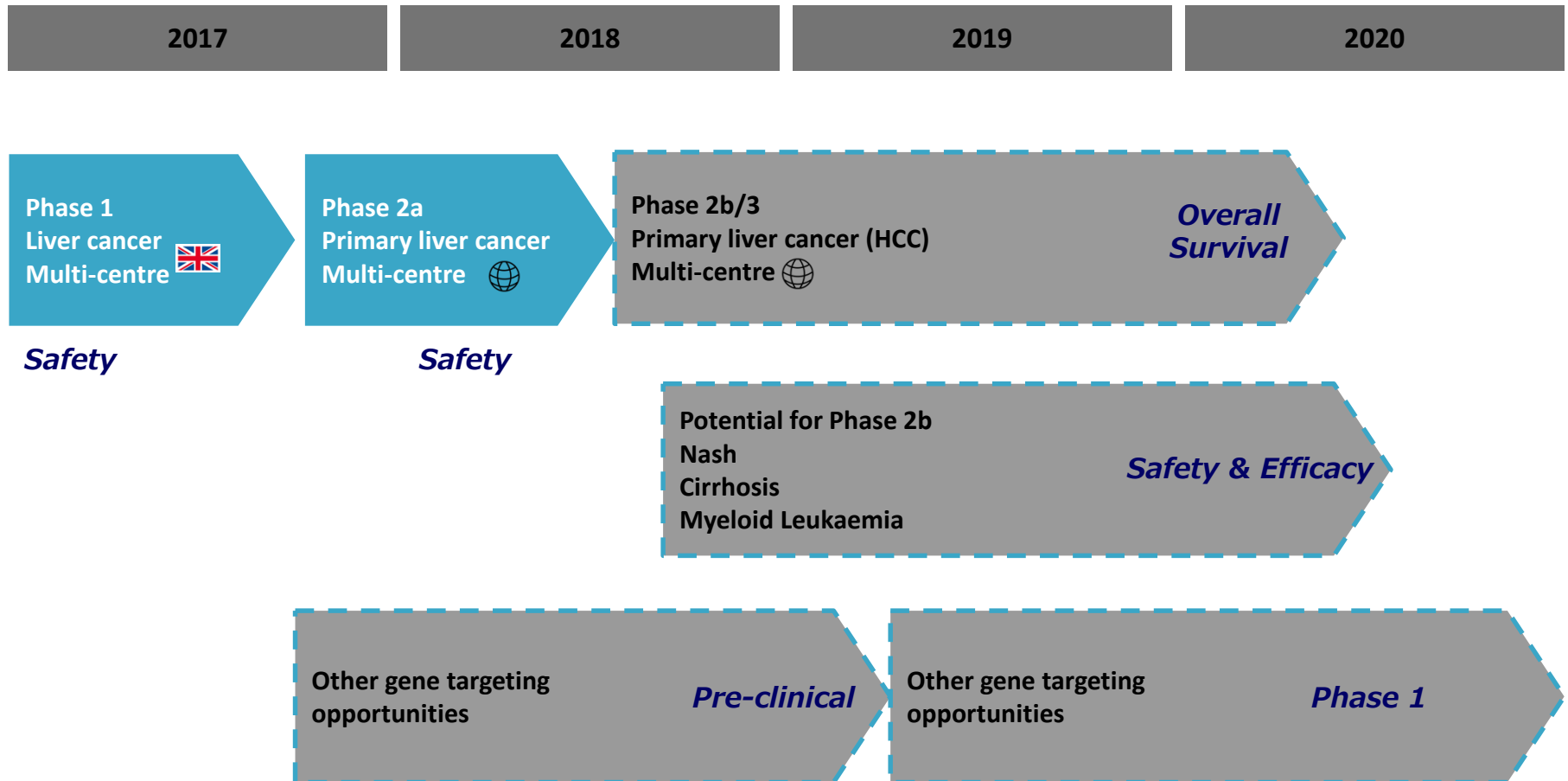
Drug Product



OUTREACH – The first-in-human clinical study of a saRNA therapeutic

- OUTREACH is a first-in-human Phase 1 clinical study of MTL-CEBPA, our lead saRNA therapeutic, in patients with liver cancer
 - Multiple centres in UK
 - Dose-escalation Phase 1 study
 - Assessing the safety and tolerability of MTL-CEBPA
 - In patients with advanced primary or metastatic liver cancer

MiNA pipeline – potential to move into mid-stage development



Outlook – Looking forward the next 12-18 months

Product/Programme	Indication	Partner	Discov.	Preclin.	Phase 1	Phase 2	Phase 3	Market
Products /Development Pipeline (Sosei)								
Seebri®/Ultibro®	COPD	NOVARTIS						
QVM 149	Asthma	NOVARTIS						
Wave 1: Partnered Pipeline								
M ₁ agonist	AD/Sz Cognition	Allergan						
M ₄ agonist	AD/Sz Psychosis	Allergan						
M ₁ M ₄ dual agonist	Sz/AD Psych / Cog	Allergan						
A _{2A} antagonist	Cancer I/O	AstraZeneca						
CGRP antagonist	Migraine	TEVA						
Not disclosed	Pain	Daiichi-Sankyo						
Wave 2: Proprietary Pipeline								
Multiple	Multiple							
MiNA: Proprietary Pipeline								
MTL-CEBPA	HCC							
MTL-CEBPA	Multiple							
MTL-Other	Multiple							



Thank you!

Q&A

Overview & Highlights for FY2016

Strong Revenue Growth from existing partnership

Allergan/Heptares agreement

April 2016: To develop & commercialize novel therapeutic drugs for Alzheimer's and other neurological diseases with Allergan

Allergan has received exclusive rights to develop and commercialize broad clinical and preclinical portfolio of M₁, M₄ and dual M₁/M₄ agonists for the treatment of major neurological diseases including Alzheimer's disease



**Heptares received upfront
payment of \$125m**

Overview & Highlights for FY2016

Strong Revenue Growth from existing partnership

Astra Zeneca: Initiation of Ph1

Aug 2015: Agreement with AstraZeneca to develop cancer treatments

Heptares has granted AstraZeneca exclusive global rights to develop, manufacture and commercialise the adenosine A2A receptor antagonist, HTL1071, a small molecule immuno-oncology candidate, and potential additional A2A receptor-blocking compounds.

Initiation of Phase 1 clinical study triggered a \$10 million milestone payment

Revenue stream from new collaboration

Daiichi Sankyo/Heptares collaboration

March 2017: A drug discovery and licensing agreement with Daiichi Sankyo Company, Limited ("Daiichi Sankyo") focused on a single G protein-coupled receptor (GPCR) nominated by Daiichi Sankyo that plays a crucial role in relieving pain

Heptares will receive an upfront payment of \$4 million, research funding of approximately \$8 million, and is eligible to receive additional research, development and commercialization milestone payments.

Heptares has received upfront payment of \$4 million