

14 March 2016

#### Australian Securities Exchange

#### Seqirus Presentation to Investors/Analysts

Please see attached presentation to investors/analysts given by:

- Gordon Naylor, President, Seqirus
- Russell Basser, SVP R&D, Seqirus
- Brent MacGregor, SVP Commercial Operations, Seqirus

during a site tour of the Seqirus influenza vaccine manufacturing facility at Liverpool, England on Friday, 11 March 2016. An investor/analyst visit to the Seqirus influenza vaccine manufacturing facility at Holly Springs, USA will also take place on Monday, 14 March 2016.

Edward Bailey Company Secretary





#### **INVESTOR / ANALYST SITE TOUR**

11<sup>th</sup> March 2016 LIVERPOOL

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#### **INTRODUCTION**

Gordon Naylor, President



#### The global burden of seasonal influenza remains high

Each year, influenza related illness:

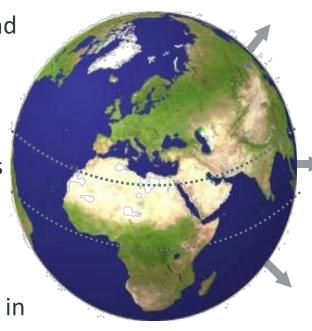
 Attacks 5%–10% of adults and 20-30% of children globally<sup>1</sup>

 Causes 3 million – 5 million cases of severe illness<sup>1</sup>

 Causes up to 500,000 deaths annually<sup>1</sup>

All countries are affected

 Significant economic costs:
 Medical care and lost labour in the US alone costs up to USD \$17bn annually



### Northern hemisphere

Influenza peak: November–March

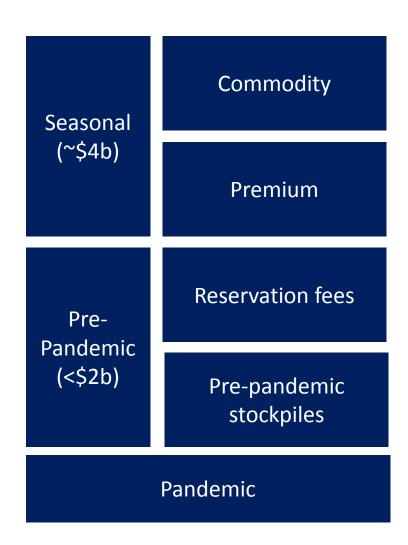
### **Tropics**Year-round activity

# Southern hemisphere Influenza peak: April–September



#### **Industry Overview**

- ~\$6b global market including prepandemic
- Seasonal market growing at low single-digits pa
- Distinct but related segments, with different competitive and growth characteristics





#### **Seqirus Today**



**CORPORATE FUNCTION** 

**OPERATIONAL BUSINESSES** 

#### **GLOBAL**

Influenza

**CSL R&D** 





#### **AUSTRALIA/NZ**

- In-licensing
- **Contract logistics**
- **Immunohaematology**
- Products of national significance: Q-fever vaccine and anti-venoms





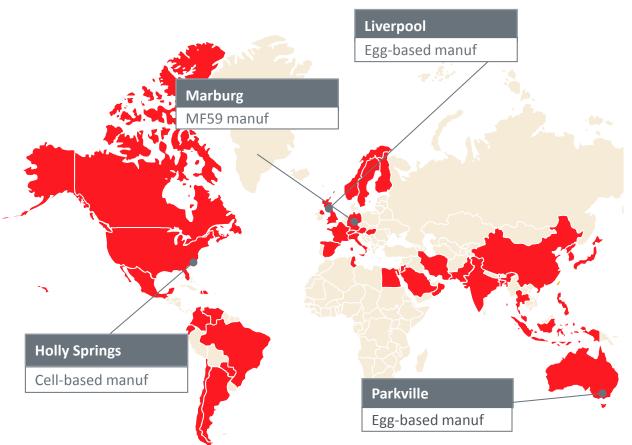






### Seqirus Manufacturing Sites & Commercial presence

- □ ~1900 employees
- Capacity Northern Hemisphere ~130mds\*(projected QIV)
- \*Assumption is QIV, ~34 weeks of NH campaign (@ 7 day / week operation)



#### **Highlights**

World's no. 2 influenza vaccine provider in sales with operations in more than 20 countries.

#### State-of-the art manufacturing

**Liverpool:** Manufacture of eggbased influenza vaccine

Holly Springs: Largest cell culture derived flu vaccine facility in the world, incl MF59 (adjuvant) production & pre-filled syringe capacity

Marburg: MF59 production

**Parkville:** Manufacturing of eggbased influenza vaccine

World's only manufacturer of Q-Fever vaccine, and a manufacturer of antivenoms for human use since the 1930s.



#### Leadership Team





SVP Commercial
Operations
BRENT
MACGREGOR



SVP Business Services KEN LIM



**SVP Operations STEVE MARLOW** 



VP Human Resources TANYA KENNEDY



SVP R&D RUSSELL BASSER



VP Quality VAS MAVROGENIS



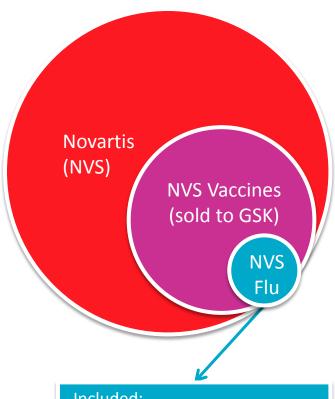
VP Finance
HELEN GEARING



Global Head Legal JOHN MINARDO



#### **Integration & Turnaround Update**



#### Included:

Most manufacturing assets, commercial footprint & people

#### Not included:

IT systems & infrastructure

- Acquisition was a carve out from a carve out
- Integration progressing well:
  - Transaction closed on 31 July 2015
  - Combined leadership team and organisation re-design
  - New global headquarters in Maidenhead, UK
- Major project underway to establish IT platform, including greenfield SAP



#### Success Plan

Complete integration

Improved focus / efficiency

Step down in R&D

Launch new products

Innovation

- Remaining elements of organisational design
- IT
- COGS, speed to market, quality, customers,
   Government
- Reduction in spend as complete clinical development programs
- Bring pipeline to market
- Shift to differentiated products
- Enhanced profitability facilitates margin expansion while funding innovation



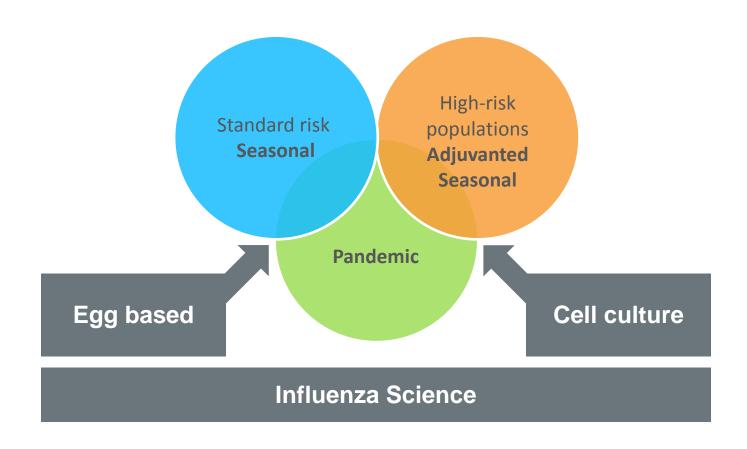


### SEQIRUS RESEARCH & DEVELOPMENT

Russell Basser, SVP R&D



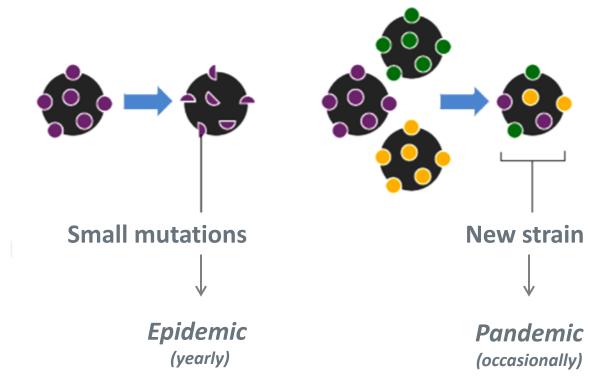
#### Seqirus Influenza Vaccine Platform





#### The difference between epidemic vs pandemic influenza

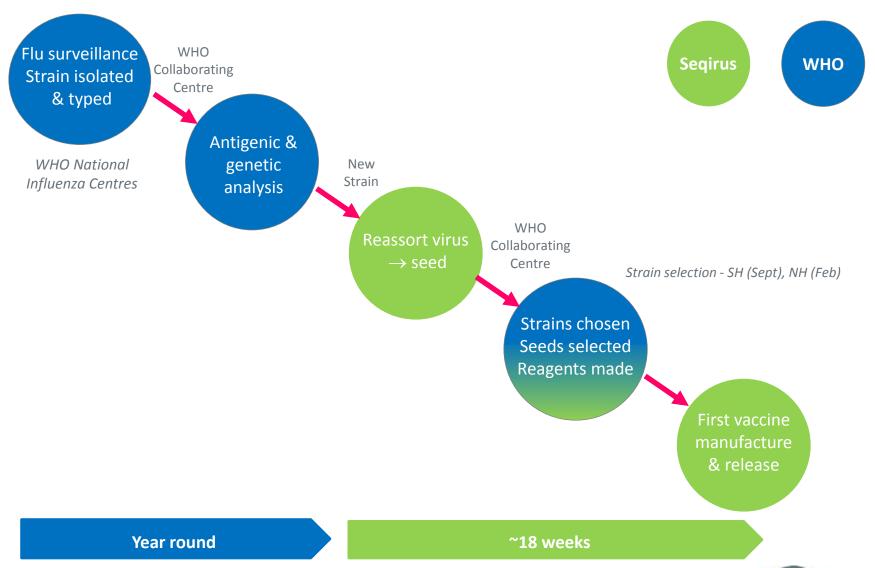
#### ANTIGENIC DRIFT ANTIGENIC SHIFT



May vary season to season SH vs NH

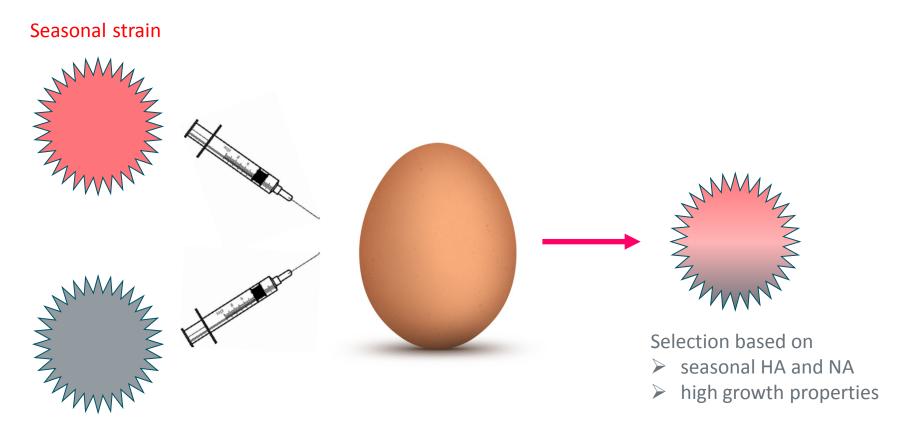


#### Identification and preparation of seasonal influenza vaccine strains (1)





Identification and preparation of seasonal influenza vaccine strains (2) Adaptation of virus for growth in eggs (reassortment)



High growth donor strain



#### The difference between Trivalent (TIV) & Quadrivalent (QIV) Influenza Vaccine

**Trivalent vaccine** = two A strains + "dominant" B strain **Quadrivalent vaccine** = two A strains + two B strains

#### WHO Influenza Collaborating Centres

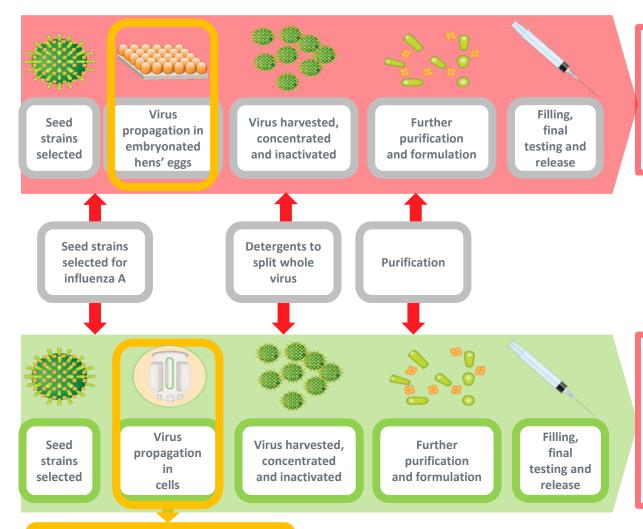
- select strains for vaccine twice per year SH (Sept), NH (Feb)
- determine likely dominant B strains

Type A influenza	Type B influenza
2 circulating strains (H1N1, H3N2) One maybe dominant	2 circulating strains (B/Victoria, B/Yamagata) One tends to be dominant
Can cause significant clinical disease	Tends to cause milder disease
Infects humans, other species (birds, pigs, etc)	Limited to humans



#### Egg vs cell culture manufacturing of influenza vaccine





#### **EGG-DERIVED**

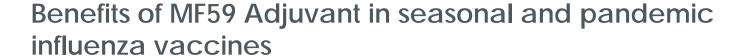
- Process well established & understood
- Long track record of safety & efficacy
- Efficient

#### **CELL CULTURE**

- Closed system, antibiotic-free
- Remove reliance on eggs
- Potential efficiency gains
- Potentially greater scalability
- Potentially faster from start
- Potentially better strain match

Sterile closed-system bioreactors, antibiotic-free vaccine production







FLUAD™	MF59			
Improved efficacy	Antigen Sparing	Cross-reactivity		
Pediatrics - efficacy 86% vs 43% non-adj. <sup>1</sup> Elderly - $\downarrow$ hospitalization by 25% <sup>2</sup>	Especially pandemic vaccine	Improved breadth of immune response		

#### **Extensive Safety Data**

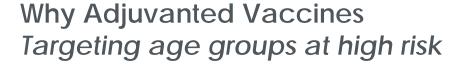
- Fluad™ licensed in 30 countries (1st approved Italy 1997)
- >100 million doses of MF59 adjuvanted vaccines distributed
  - 76 million seasonal Fluad™ (elderly)
  - ~25 million H1N1 pandemic (incl pregnant women / young children)
- Data in ~120,000 subjects from clinical studies
- 1. Vesikari et al, N Engl J Med. 2011;365:1406-16.
- 2. Iob et al, Epidemiol Infect. 2005;133:687-693; Mannino et al, Am J Epidemiol. 2012;176:527-53; Van Buynder et al, Vaccine 2013;31:6122-8.



#### Key R&D Influenza Vaccine Programs

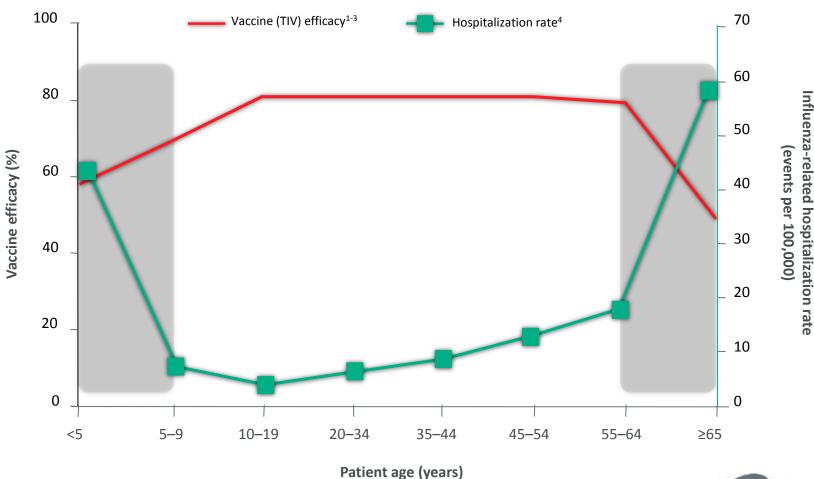
FLUCELVAX.	TIV	4+ under review in US	Currently <b>approved for 18+ yrs in US</b> Paediatric (4+yrs) under review Link to QIV program
Cell culture	QIV	Under review in US	Target 4+ years
Fluad™	TIV	Approved	Long standing approval in EU Approved 6M-2 yrs, 65+ yrs Canada Approved 65+ yrs US 2015
Adjuvanted (	QIV	Phase III completed	Age 6M to ≤6yrs – filing Q1 2017
		Phase III	Age ≥65yrs – pivotal study to commence 2016
afluria.	QIV	Under review in US & AUS	Age ≥18yrs
Fluvax®	QIV	Phase III completed	Age ≥ 5yrs – 18yrs
	QIV	Phase III	Age ≥ 6mo - <5yrs – pivotal study to commence 2016







#### Age-related hospitalizations and TIV efficacy rates



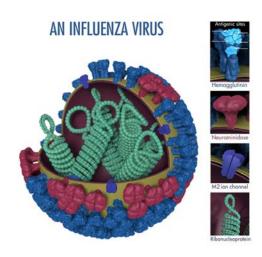
Segirus A CSL Company

#### Future directions for influenza vaccine innovation

#### Alternate routes of delivery



#### Universal vaccine

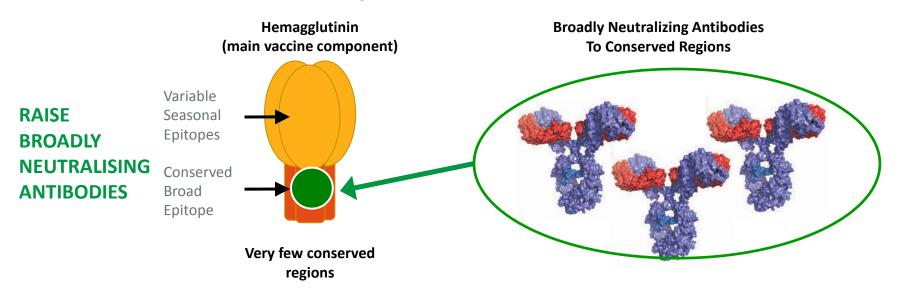


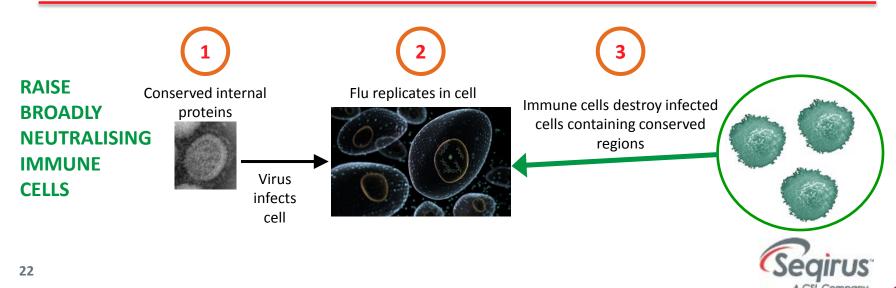
#### **Novel sources of antigens**





### Universal flu vaccine - target conserved parts of virus Goal to find 'Achilles heel/s' present in all flu viruses







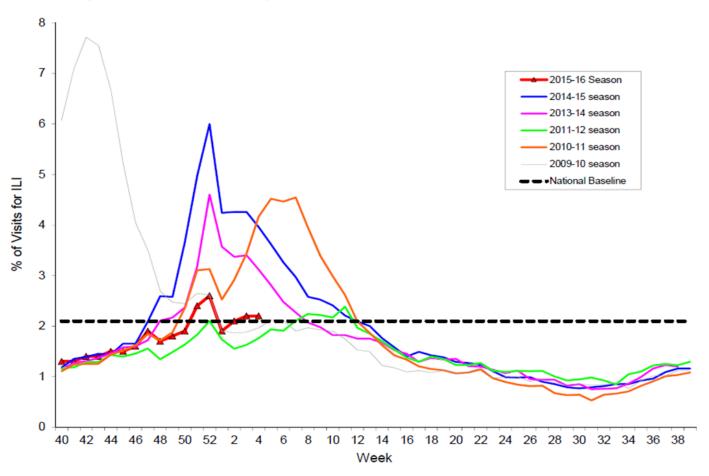
#### **SEQIRUS COMMERCIAL**

Brent MacGregor, SVP Commercial Operations



#### Influenza causes significant hospitalizations each year

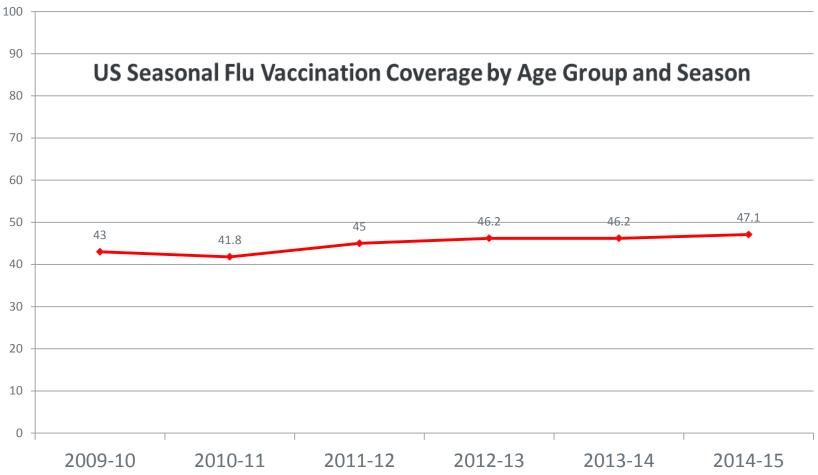
Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2015-2016 and Selected Previous Seasons







### In the US there has been modest growth of vaccination rates despite 2010 universal recommendation



Source: National Immunization Survey-Flu (NIS-Flu) and Behavioral Risk Factor Surveillance System (BRFSS), http://www.cdc.gov/flu/fluvaxview/coverage-1415estimates.htm. Accessed November 19, 2015.



### Our commercial focus for the coming years will be around five key drivers of growth

1		Launch Fluad 65+ in the US market in the elderly segment first, followed by the pediatric segment
2	11	Maintain our TIV offer in the near-term while launching our QIV offer
3		Grow our Rapivab business as a convenient intravenous offer in the hospital-setting emergency department
4		Focus our efforts on our key markets in the near-term: US, Europe, Australia
5		Optimise our pandemic and pre-pandemic enterprise to reinforce our reputation as a partner-of-choice in pandemic preparedness



### Seqirus provides a differentiated portfolio of vaccines and treatment for influenza that we will continue to improve

Brand	Age Indication Today	Planned Future Age Indication	Target Offer
F L U A D influenza vaccine, adjuvanted	65+ years	6 mths-6 years 65+years	QIV
FLUCELVAX. Influenza Vaccine	18+ years	4+ years	QIV
afluria.	18+ years	6mths+	QIV
Rapivab peramivir injection	18+ years	5+ years	I.V.
Influenza Virus Vaccine Fluvirin®	4+ years	4+ years	TIV
AGRIPPAL° INFLUENZA VACCINE (SURFACE ANTIGEN, INACTIVAT	6mths+	6mths+	TIV





# Our product strategy: adjuvanted QIV product in Pediatric and Elderly and egg or cell-based QIV for the general population



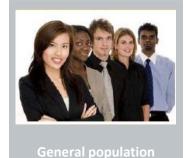
Fluad Pediatric (aQIV)

Expected greater efficacy in <u>vulnerable</u> populations compared to non-adjuvanted influenza vaccines





Fluad (aQIV)



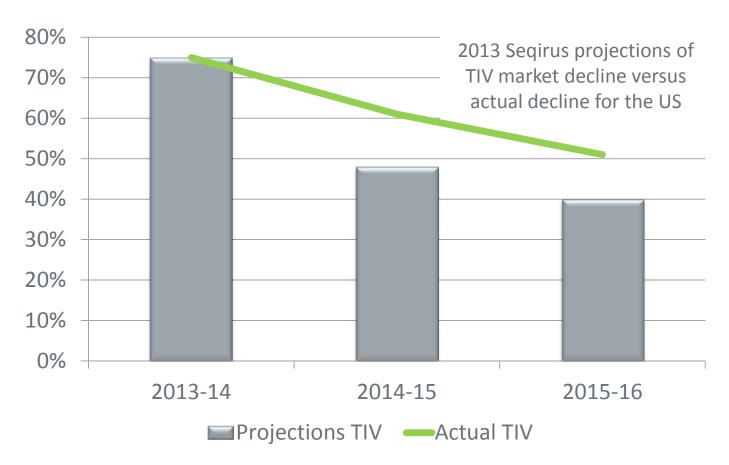
Afluria QIV *Flucelvax QIV* 

Flexibility of manufacturing platforms in US and Australia





# While the US and European markets are transitioning to QIV, this transition has taken longer than originally expected



Seqirus volume market share stable in 2015/16





### Rapivab™ (peramivir injection) is an effective complement to our Flu vaccines portfolio



- Approved in the US Dec 2014
- Niche indication for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than 48 hrs
- Single, rapid IV administration
- Stable at room temp. for 5 years

Treatment of adults patients with influenza	Day 1		Day 2		Day 3		Day 4		Day 5	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Tamiflu (75mg twice daily)	i	ě	ě	Ü	ě	Ü	ě	Ü	ě	ě
Rapivab (600mg IV)	Post and a second secon		No fu	urther i	njectio	ns requ	uired		-	





### In pandemic preparedness, Seqirus is a leading global player with a strong track record

Leading pandemic assets and capabilities

Pre-Pandemic (<\$2b) Reservation fees

Pre-pandemic stockpiles

**Pandemic** 

**Production capabilities** with global manufacturing network with different technologies. Holly Springs specifically designed for rapid scale-up of production in a pandemic situation

**Strong worldwide reputation and track record** built through fast response and significant value

capture in the 2009 flu pandemic and, more recently, in the H7N9 threat

**Unique product offering** due to MF59 adjuvant, enhances efficacy and production efficiency, which maximizes population coverage and has made us a preferred pandemic supplier to governments

Key government contracts around the world



### In Australia and NZ, Seqirus augments its core flu vaccine with a comprehensive In-Licensed Vaccine & Pharmaceutical Portfolio

Vaccine Partners	Products	Pharma Partners	Products
MERCK	Gardasil, RotaTeq, Varivax, Vaqta, Pneumovax23, Zostavax, MMRII, H-B-VaxII	GRÜNENTHAL  CUMBERLAND	Palexia Tramal Caldolor Versatis
<b>™</b> valneva	Rabipur Menjugate Jespect	A healthy decision	Fuicidin BenPen Burinex
PaxVax	Vivotif Oral Dukoral	VALEANT Pharmacaucians international	Tetrabenazine
STATENS SERUM INSTITUT	ADT Booster	Allergy therapeutics ABELLÓ	Grazax Mitizax Jext





#### **IN SUMMARY**

**Gordon Naylor** 

### On track to meet our growth targets over the next few years

- Integration is going well
- Fluad will drive a material increase in defensible value in our primary market
- Migration to QIV in key markets will increase value per dose across much of the sales volume
- Deep operational and scientific capabilities will deliver a nimble, efficient supply chain
- Rapivab is a useful complementary product
- The proven cell culture platform provides strategic optionality
- We see interesting potential Innovation pathways for the future





Holly Springs



Liverpool



Parkville

