## Aytu BioScience (NASDAQ: AYTU)

Corporate Overview – December 2019



### **Corporate Overview**

- AYTU is a specialty pharmaceutical company commercializing best-inclass therapeutics.
- AYTU's strategy is to build a commercial portfolio of products competing in large therapeutic areas through licensing and acquisition.
- AYTU operates an efficient commercial model with a nationwide 100person sales force leveraging co-promotion partners.

Two recent pivotal transactions that are expected to: (1) expand commercial critical mass, (2) multiply revenue run-rate, (3) accelerate time to + EBITDA

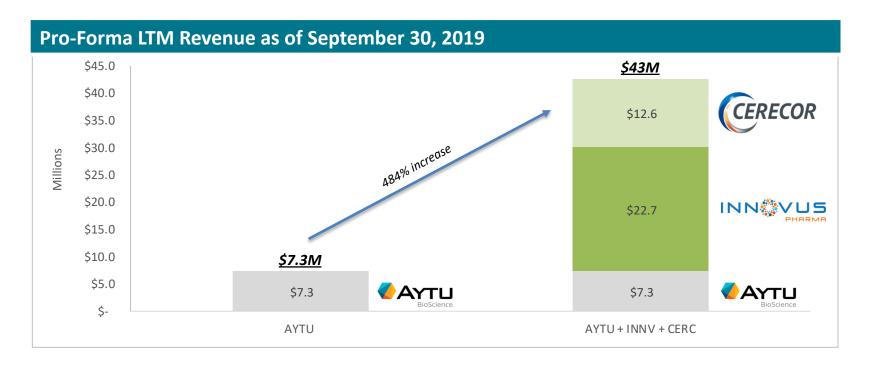


Pro-forma LTM revenue of \$43M (as of September 30, 2019)



### 5X Revenue Increase Over FY19

Two acquisitions result in a 484% increase in revenue as of September 30, 2019.



- Prescription Portfolio 9 Rx products competing in large therapeutic markets
- Consumer Health Portfolio >30 products competing in the \$40B consumer segment



# Commercially-Focused Management Team with a History of Growing Commercial Organizations

#### Josh Disbrow - Chairman & CEO

- Former VP of Commercial Operations at Arbor Pharmaceuticals where revenues grew from zero to over \$127MM in < 5 years;</li>
   Acquired by KKR
- Previous COO of Ampio Pharmaceuticals (NYSE: AMPE) and head of Business Unit
- Progressive commercial roles at LipoScience, Cyberonics, and GlaxoSmithKline

#### David Green, CPA – Chief Financial Officer

- Former CFO of Specialized Health Products International and Catheter Connections, acquired by CR Bard and Merit Medical
- Former Chief Accounting Officer of Intarcia Therapeutics
- Previous Managing Director of Duff & Phelps and Director of E&Y Capital Markets

#### Jarrett Disbrow – EVP, Marketing & Market Access

- Founder and original President/CEO of Arbor Pharmaceuticals where revenues grew from zero to over \$127MM in <5 years;</li>
   Acquired by KKR
- Former CEO of Vyrix Pharmaceuticals, a specialty pharmaceutical company focused on male sexual dysfunction
- Progressive commercial roles at Accentia Pharmaceuticals, GlaxoSmithKline

#### Matthew Phillips – EVP, Commercial Operations

- Former CCO of Cerecor, Inc. and President & COO of Zylera Pharmaceuticals, specialty pediatric company acquired by Cerecor
- Former Executive Director of Managed Markets and Corporate Accounts at Victory Pharmaceuticals
- Progressive commercial roles at Dura Pharmaceuticals and Eisai, Inc.



## **Recent Pivotal Acquisitions**

Innovus Pharmaceuticals (announced 9/12/19)
Cerecor Commercial Rx Portfolio (closed 11/1/19)



# Innovus Acquisition: Novel Consumer Health Products Competing in Large Markets - \$23M in LTM Revenue

Well-positioned brands competing in the \$40B consumer health market

**Diabetes Care** 

Sexual & Urological Health

Respiratory & Allergy











Products commercialized through Innovus' proprietary Beyond Human platform





# Cerecor Acquisition: Established Rx Brands in Large Therapeutic Markets - \$12.6M in LTM Revenue

Established pediatric and primary care brands competing in ~19\$B addressable markets

<u>Cerecor Prescription</u> <u>Therapeutic Portfolio</u>



AcipHexSprinkle

rabeprazole sodium delayed release capsules, for oral use; 5mg & 10mg

Granule formulated proton pump inhibitor

<u>Cerecor Prescription</u> <u>Vitamin Portfolio</u>





Fluoride-based pediatric supplements



Second-generation cephalosporin suspension



# Diverse Portfolio Filling Unmet Needs in Large Therapeutic Categories (~\$66B TAM)

\$6.5B TAM

<b>AYTU Products</b>	Addressing Everyday Conditions in Primary Care		
"Natesto"	Only nasally-administered testosterone		
Zolpi <b>MiST</b>	Only oral spray sleep aid		
Tuzistra XR@	Only twelve-hour codeine cough syrup		

\$19B TAM

CERC Products	Addressing Large Pediatric Primary Care Markets		
Karbinal ER (carbinoxamine maleate)	Extended-release liquid antihistamine		
AcipHexSprinkle rabeprazole sodium delayed release capsules, for oral use; 5mg & 10mg	Granule formulation proton pump inhibitor		
CEFACLOR For Oral Suspension, USP ——250 mg/s m.	Second generation cephalosporin suspension		
Poly-Vi-Flor Tri-Vi-Flor	7 SKU Rx fluoride-based dietary supplement line		

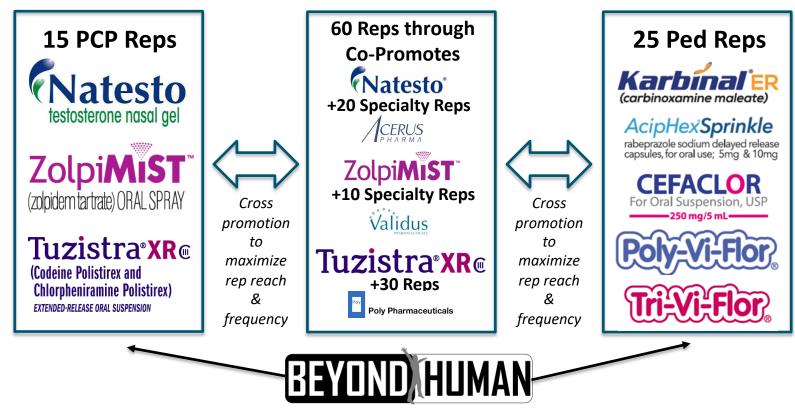
\$40B TAM

	Competing in Large OTC Categories			
Novel, niche OTC medicines and supplements	FlutiCare Zestia UriVArx DIABASENS			



## **Leveraging Cross-Selling & Co-Promotes**

• National sales footprint with 100 sales representatives, co-promote partners, cross selling opportunities and direct-to-consumer support.



Innovus' Direct-to-Consumer Marketing Platform



### **Overview of Product Growth Drivers**



Natesto®: The Only FDA-Approved, Nasally-Administered Testosterone Replacement Therapy



## Natesto : The Only Nasally Delivered Low T Therapy

#### The Only FDA-Approved Intranasal Testosterone



- Fast, clean application
- Easy to use and transport
- Rapid T<sub>max</sub> < 1 hour</li>

- Uniquely-delivered, patented TRT with multiple advantages over existing treatment options
- Only nasally-administered: rapid, pulsatile drug delivery
- Delivers the <u>lowest dose</u> among topical testosterones (5.5 mg/dose)

#### **No BLACK BOX Warning**

- Natesto is the *only* topical TRT without a BLACK BOX warning
- All others carry a "BLACK BOX warning" due to the risk of transference

#### ↓ AndroGel BLACK BOX Warning ↓

AndroGel® (testosterone gel) 1.62% for topical use CIII Initial U.S. Approval: 1953

#### WARNING: SECONDARY EXPOSURE TO TESTOSTERONE

See full prescribing information for complete boxed warning.

- Virilization has been reported in children who were secondarily exposed to testosterone gel (5.2, 6.2).
- Children should avoid contact with unwashed or unclothed application sites in men using testosterone gel (2.2, 5.2).
- Healthcare providers should advise patients to strictly adhere to recommended instructions for use (2.2, 5.2, 17).



### **Natesto Growth Plan**

### Natesto commercial expansion effective 12/1/19

- Natesto sales efforts will be expanded through enhanced commercial partnership with Acerus Pharmaceuticals ("Acerus")
  - Natesto licensor Acerus will fully fund and launch a U.S.-based specialty sales force in support of Natesto growth.
  - Expansion nearly doubles U.S. sales footprint to 60 representatives
- Aytu continues to book all top line revenue from Natesto sales to wholesalers/retailers
  - Aytu remains exclusive supplier in U.S.
- All revenue milestones removed
  - Milestone payments of up to \$75M removed
- Regulatory responsibilities and clinical trial expenses assumed by Acerus
- Revised, favorable new commission structure
  - Aytu will pay Acerus commissions on sales generated through specialists' prescriptions
  - Previously paid royalties removed in favor of paying Acerus commission on Natesto revenue upside
- Deal economics remain essentially unchanged on current level of Natesto sales;
   Acerus committed to minimum sales level (make whole provision)



# Natesto Spermatogenesis Study Findings Drive Significant Clinical Value

"Currently, <u>there are no FDA-approved therapies</u> to treat men with low testosterone who wish to preserve their fertility.

About 20% of men with Low T deal with these decisions, and Natesto could be an alternative for simultaneously increasing testosterone while preserving sperm production."

Ranjith Ramasamy, MD

**Director of Reproductive Urology** 

Miller School of Medicine
University of Miami



# Study Completed Demonstrating No Impact of Natesto on Male Fertility

- Natesto Effects on Testosterone, Luteinizing Hormone, Follicle Stimulating Hormone and Semen Parameters
  - First study ever to demonstrate minimal, or no impact of a TRT on sperm concentration, motility, and motile sperm count
  - Data released at ASRM conference October 16, 2019
  - Prospective, open-label study investigating Natesto's impact on patients' semen parameters, endogenous testosterone production, and LH/FSH levels
  - Assessed 50 patients with confirmed hypogonadism (testosterone (T) < 350 on</li>
     2 consecutive samples collected more than 1.5 hours apart in the morning
  - 2 complete sperm cycles ~ 24 weeks; 6 study visits
- Principal Investigator: Ranjith Ramasamy, MD
  - Director of Male Reproductive Medicine and Surgery;
     Associate Professor; Department of Urology University of Miami
- Primary endpoint: Change in Testosterone, Semen Parameters,
   Follicle Stimulating Hormone, Luteinizing Hormone, and Estradiol

ZolpiMist™: The Only FDA-Approved, oral spray Zolpidem Tartrate



# ZolpiMiST: Sleep, Delivered, Fast

- Novel, rapid-acting oral spray formulation of most prescribed prescription sleep aid, zolpidem tartrate
- Significant patient advantages over Ambien® including:
  - Rapid onset of action to deliver faster sleep onset than
     Ambien
    - Significantly more patients achieved therapeutic blood levels in 15 minutes with ZolpiMist oral spray than with Ambien tablets
  - Effective for patients with difficulty swallowing
- Large market <u>1% TRx market share</u> = ~\$50M
- Co-promotion with Validus Pharmaceuticals in psychiatry



# Tuzistra® XR: The Only FDA-approved, 12-hour Codeine Suspension



## Tuzistra XR : All-Day, All-Night Cough Relief

- Only FDA-approved codeine-based antitussive suspension with 12-hour dosing
  - Current codeine syrups are dosed every 4-6 hours
- Patented, extended-release oral suspension codeine polistirex and chlorpheniramine polistirex oral
  - Two Orange Book-listed patents; others pending
- Co-promotion with Poly Pharmaceuticals
  - Nearly doubles sales footprint (promotion started 9/3/2019)

\$3B U.S. Market

30-35 million Rxs annually



## **AYTU Current & Pro Forma Cap Table**

	Current	Estimated Pending Innovus	Post- Innovus
Total common stock	17,981,904	4,000,000	21,981,904
Total preferred stock, as converted	20,205,845	1,000,000	21,205,845
Total common stock equivalents	38,187,749	5,000,000	43,187,749
Options and warrants "nearly in the money"			
October warrants 2019 PIPE (WA \$1.25)	10,000,000	-	10,000,000
October warrants 2018 (WA \$1.50)	10,173,593	-	10,173,593
Armistice warrants (WA \$1.00)	4,403,409		4,403,409
	24,577,002	-	24,577,002
Options and Warrants "out of the money"	1,884,217	-	1,884,217
Fully diluted shares outstanding	64,648,968	5,000,000	69,648,968



### **Aytu BioScience Summary**

#### Recently transformed, revenue generating specialty pharmaceutical company

- Doubled organic 'Aytu heritage product' revenue from FY18 to FY19
- Innovus and Cerecor acquisitions accelerate revenue growth >\$43M LTM revenue

#### Two transformational transactions announced in past two months

- INNV: Acquisition of \$23M revenue-generating company
- CERC: Acquisition of ~\$12.6M revenue-generating commercial business

#### Growing product portfolio addressing large markets

- Aytu Rx Products (~6.5B TAM)
- Innovus Consumer Products (~\$40B TAM)
- Cerecor Rx Products (>\$19B TAM)

#### Expanded nationwide sales force

- Expanded U.S.-based, specialty sales force with national footprint
- Leveraging co-promotion partnerships to increase reach without ↑ in SG&A
- Sales deployment in large, overlapping therapeutic areas

#### Upcoming and ongoing catalysts:

- Reporting combined revenue for AYTU + CERC for quarter-ending 12/31/19 2/2020
- Closing of Innovus transaction (combined LTM revenue of \$31M) Q1 2020
- Reporting combined revenue for AYTU + CERC + INNV for quarter-ending 3/21/20 5/2020

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