





# FORWARD LOOKING STATEMENTS

#### OpGen, Inc.

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## **COMBINING TO BUILD A STRONGER FUTURE**

# **Strategic Rationale**

- Establish a leading antimicrobial resistance (AMR) precision medicine business
- Broad portfolio of high impact rapid diagnostics and best-in-class AMR bioinformatics
- Leverage combined sales, distribution, bioinformatics and operating infrastructure

## **Structure of Transaction**

OpGen acquisition of Curetis GmbH for 2.66 million new shares of OpGen common stock

## **Financial Considerations**

- Combined company positioned for strong growth profile and sustained value creation
- Estimated 2020 combined revenue of \$10-15 million, up from an anticipated \$5-6 million in 2019
- Targeting to significantly reduce net loss starting in 2020





Market leader positioned to capitalize on global opportunities in infectious disease and rapid AMR detection





Proprietary molecular diagnostic tests and platforms



Premier Al-powered bioinformatics solutions for multi-drug resistance diagnostics



Global commercial channel capabilities & partners

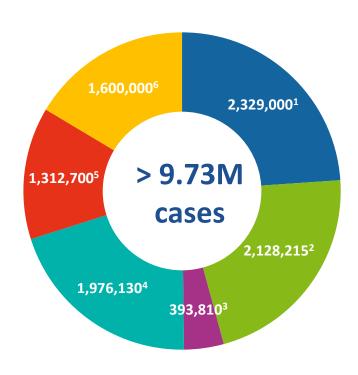






# COMBINED COMPANY ADDRESSES MULTIPLE HIGH IMPACT UNMET CLINICAL NEEDS AND LARGE AVAILABLE MARKET OPPORTUNITIES

U.S. and European market with high unmet medical need addressable through hospitalfocused sales channels



- Pneumonia (HPN/LRT)
- Implant and Tissue Infections (ITI)
- Blood Culture (BCU)
- Intra-Abdominal Infections (IAI)
- Sepsis Host Response (SHR)
- Urinary Tract Infections (UTI)

The current portfolio and pipeline of cartridges target almost 10 million patients annually in EU and U.S. with additional upside in Asia / Pacific and ROW markets





<sup>&</sup>lt;sup>1</sup> CDC (2010); ECDC (2008); Chalmers et al. (2014)

<sup>&</sup>lt;sup>2</sup> Margolis et al. (2011); American Diabetes Association (2014); Diabetes Deutschland (2012); Richard et al. (2011); Livesly and Chow (2002); Dorner et al. (2009); Deutsche Gesellschaft für Verbrennungsmedizin (2014); Mayhall (2003); Klevens et al. (2007) in Jhung (2009); Geffers (2001); Brun-Buisson (2011); Michelotti et al. (2012); Sunderlin (2006)

<sup>&</sup>lt;sup>3</sup> Martin (2012); Statista (2015); Dellinger et al. (2013)

<sup>&</sup>lt;sup>4</sup> HCUP (2013); CDC (2010)

<sup>&</sup>lt;sup>5</sup> Martin (2012); Statista (2015)

<sup>&</sup>lt;sup>6</sup> ECDC (2013), Klevens et al. (2002)

# COMBINED COMPANY'S PORTFOLIO OF COMMERCIAL STAGE **PRODUCTS & STRATEGIC RELATIONSHIPS**

# **Unyvero Platform & Tests**

**Unyvero FDA-cleared platform** and lower respiratory tract infection (LRT) test

## **Acuitas Tests**

Acuitas tests in development and pending FDA clearance to improve antibiotic decision making

## **Global Commercial Presence**

Direct sales in U.S., European distribution with A. Menarini Diagnostics, **China distribution with Beijing Clear Biotech** 

# **Strategic Fit**

Transformative Strategic Relationship in MDx and BioIT













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# SAMPLE-TO-ANSWER AND HIGH-THROUGHPUT TESTING CAPABILITIES

# Molecular microbiology leadership through proprietary platforms and content

## **Striving for Molecular Microbiology Leadership MDx Platforms MDx Content** ares genetics Acuitas \*\*\* **AMR Gene Panel Acuitas** Lighthouse. **Unyvero A50** Unyvero A30 RQ\* **ARESdb** High-Plex PCR Low- to Mid-Plex PCR MDx Content & NGS Applications Low- to High-Plex PCR Proprietary PCR & NGS Applications based on **Broad Sample Range** Leading AI-Powered AMR Knowledgebases





<sup>\*</sup> Unyvero A30 RQ Analyzer in development, latest design concept; final product may differ

<sup>\*\*</sup>Pending 510(k), not for diagnostic use.

# **CURRENT AND NEAR-TERM U.S. PRODUCT OFFERINGS**

## **Unyvero Pneumonia (LRT)**

#### **Description:**

- Sample-to-answer multiplex PCR from native specimen in about 5 hours with ~2min hands-on time
- 36 Pathogen ID, 10 resistance genes

#### Status:

FDA-cleared (De Novo 510(k)), launched June '18

#### **Differentiators:**

- Most comprehensive panel specifically tailored to bacterial pneumonia delivering unique clinically actionable insights
- Broadest coverage of carbapenem resistance
- Only molecular pneumonia panel to cover penicillin resistance

#### **Coming Next:**

- Unyvero LRT plus high sensitivity application for BAL samples (510(k) submitted)
- Unyvero Invasive Joint Infection (IJI) (partnering discussions ongoing)

## **Acuitas AMR Gene Panel**

#### **Description:**

- Sample-to-answer multiplex PCR from bacterial isolates in <3 hours
- Up to 47 resistance genes, accurate prediction of resistance for 12+ antibiotics
- Available now for Research Use Only (RUO)

#### Status:

FDA 510(k) submitted May '19

#### **Differentiators:**

- Rapid AMR prediction
- **CRE** infection control

#### **Coming Next:**

- Rapid urine test with sample-to-answer multiplex PCR from native specimen in <3 hours
- 5 pathogen ID/quantitation, up to 47 resistance genes, and accurate prediction of resistance for 12+ antibiotics
- Testing to support FDA De Novo submission in progress





# UNYVERO A30 RQ RAPID SAMPLE-TO-ANSWER TESTING PLATFORM



Platform open for partnering to rapidly create a broad menu of tests

In advanced discussions with first potential partner(s)

Anticipated transactions to include upfront & milestone payments, R&D funding, and royalties

# **Key Design Features**

- Fully integrated, closed, sample-to-answer MDx platform
- Universal real-time PCR technology for low- to mid-plex testing
- Flexible cartridge fluidics for numerous chemistries and assay formats
- Fast turn-around time of 45-90 minutes
- Light-weight, stackable benchtop design with small footprint
- Modular and scalable from 1 to 8 cartridge slots
- Designed for ease-of-use and flexible deployment in labs and near-patient settings
- Attractive COGS for instruments and reagents

# **Development Status**

- First multiplex PCR successfully demonstrated on fully functional prototypes in tech due diligence for potential partners
- Manufacturing aspects fully specified and in development or implementation phase
- Expect to progress development in 2019 for full V&V readiness for licensing partner's assays with possible CE-IVD launch in 2020







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Global commercial channel capabilities & partners







# **ARES GENETICS & ARESdb**



Bioinformatics subsidiary with globally leading proprietary AI-powered knowledgebase for AMR informing PCR & NGS-based diagnostics



#### Global ARESdb Database

- Leading Knowledgebase on quantitative Antibiotic Resistance Markers building on SIEMENS Microbiology Strain Collection
- Up to > 98% Accuracy for Antibiotic Resistance Detection
- Based on ~40,000 Pathogens and associated Resistance Data for > 100 Antibiotics

**Bio-IT AMR agreement with QIAGEN,** N.V

Pharma R&D agreement with Sandoz

Diagnostics R&D collaboration with global IVD player

**NGS Service Laboratory** 



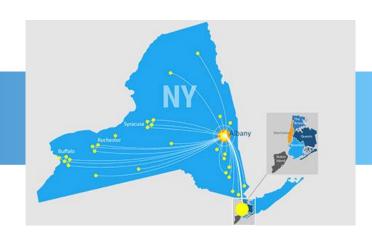
# **ACUITAS LIGHTHOUSE®: DIAGNOSTICS DATA MANAGEMENT PLATFORM** FOR ANTIBIOTIC RESISTANT PATHOGENS<sup>†</sup>

Rapid molecular antibiotic resistance prediction



Development contract for potential State-wide AMR surveillance network





Cloud-based bioinformatics platform powers our ability to rapidly generate meaningful results that have the potential to change the landscape of clinical management and improve outcomes for patients

<sup>†</sup>In development; For Research Use Only. Not for use in diagnostic procedures.







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Global commercial channel capabilities & partners









# **COMMERCIAL STRATEGY**

# OpGen and Curetis to realize synergies from a combined commercial effort

- Multiple products to same hospital call points via same sales channel to drive synergies and cost efficiencies
- Over 200 active customers with additional pipeline of accounts in evaluation phase



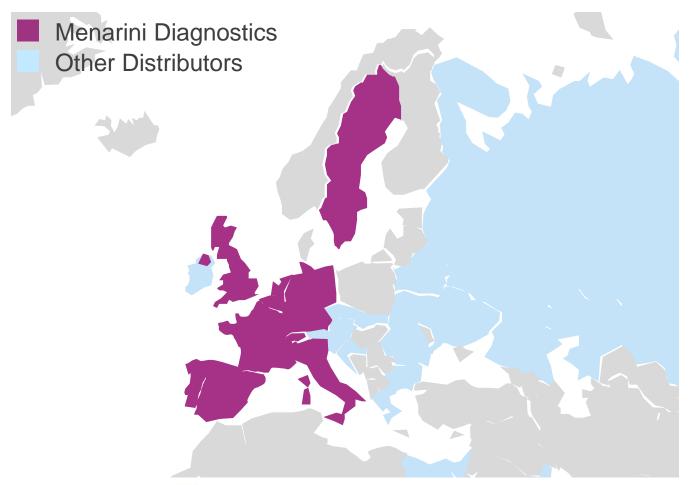
# Expanding global commercial reach though direct sales in U.S. and global distributors

- > Direct sales in the U.S. combined team of 12
- > European distribution through Menarini Diagnostics
- > China distribution through Beijing Clear Biotech
- > 17 distributors covering 40 countries in EU, ME, and Asia
- > Supported in EU / LatAM by Curetis Commercial ops team of 10



# PAN-EUROPEAN DISTRIBUTION BY MENARINI DIAGNOSTICS

Starting with 11 EU countries – option to expand relationship to further EMEA markets and additional product lines



# **Menarini Diagnostics Collaboration (Q1-2019)**

- > Covers entire Unyvero A50 product line
- > Initial countries: BE, CH, DE ES, FR, IT, LU, NL, PT, SE, UK
- > Option to expand relationship to further EMEA countries – Menarini to take over Greece from end of Jan 2020 onwards
- > Launch of collaboration at ECCMID 2019 (Amsterdam, April 13-19, 2019)









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## FINANCIAL CONSIDERATIONS

- Combined company positioned for strong growth profile and sustained value creation
  - FY2018 revenues of \$1.6 million (Curetis) and \$2.9 million (OpGen)
  - Estimated FY2019 combined revenue of \$5-6 million
  - Estimated 2020 combined revenue of \$10-15 million
- Net loss from operations and cash burn anticipated to decrease starting in 2020 due to operating synergies from combined corporate, manufacturing & distribution, R&D, and sales & marketing organizations
- Approximately 130 employees post-deal closing domestic and international
- Transaction close contingent on completing interim equity financing as well as debt holder and shareholder approvals from both existing companies
- OpGen has committed to raise interim capital of \$10 million in 2H 2019



# COMBINED COMPANY SENIOR MANAGEMENT TEAM

Combined team has decades of experience in precision medicine, molecular diagnostics and capital markets

**Chairman of the Board:** William Rhodes

**Chief Executive Officer:** Oliver Schacht, Ph.D.

**Chief Financial Officer:** Timothy C. Dec

Board Members: William Rhodes (Chairman)

Evan Jones (Non-executive role)

Oliver Schacht, Ph.D. (CEO)

Two Additional Curetis Appointees

One Additional OpGen Appointee



## TRANSACTION TIMELINE

# Subject to approval by OpGen's and Curetis' shareholders and debt financing providers

- Both companies' Boards of Directors have approved the implementation agreement
- Both companies will seek approval from their respective shareholders in meetings to be scheduled for the fourth quarter of this year
- Provided shareholders and debt holders for both OpGen and Curetis grant approval, the transaction is expected to be completed in early 2020







