



# OpGen Corporate Overview

August 13, 2021



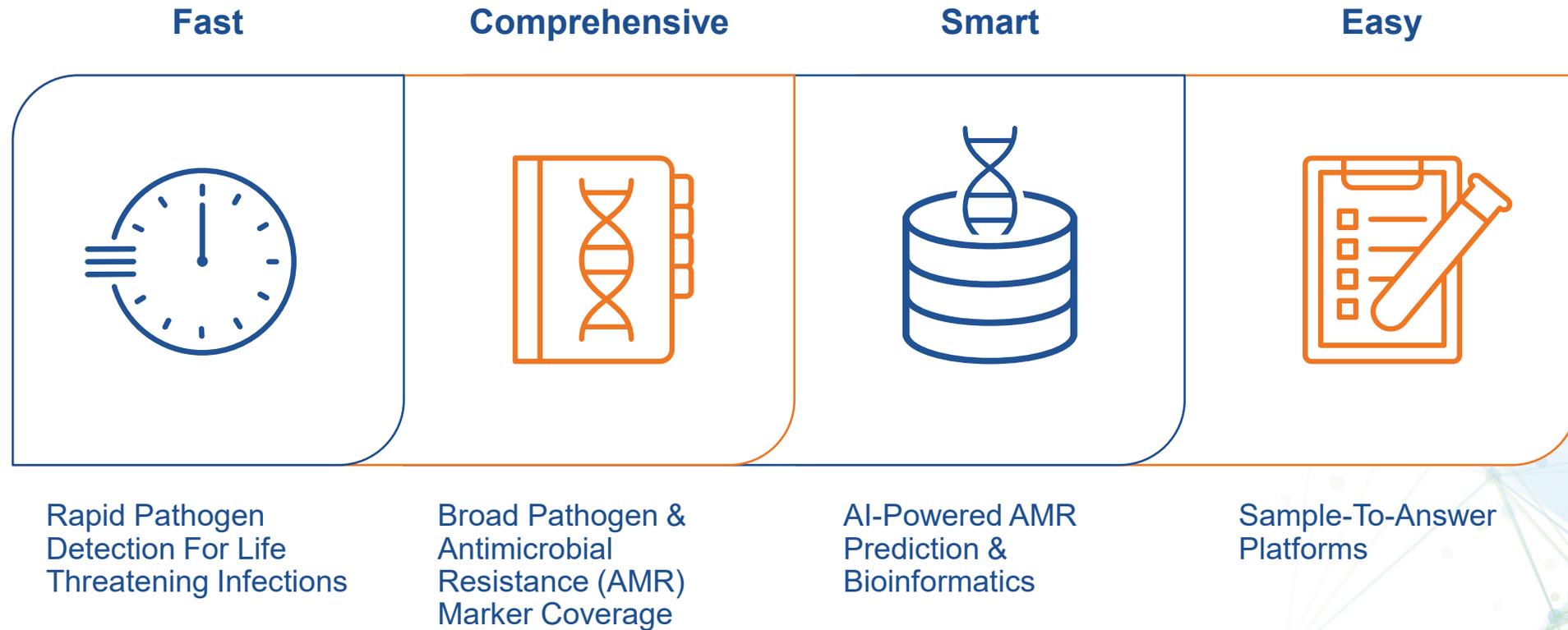
# Forward Looking Statements Disclaimer

This presentation contains forward-looking statements that are subject to many risks and uncertainties. These statements, among other things, relate to our business strategy, goals and expectations concerning our products, future operations, prospects, plans and objectives of management. The words “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will” and similar terms and phrases are used to identify forward-looking statements in this presentation. These statements and other statements regarding our future plans constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond OpGen’s control, and that may cause results to differ materially from expectations.

Factors that could cause results to differ materially from those described include, but are not limited to, our ability to successfully, timely and cost-effectively develop, seek and obtain regulatory clearance for and commercialize our product and service offerings, the rate of adoption of our products and services by hospitals and other healthcare providers, the fact that we may not effectively use proceeds from recent financings, including our February 2021 and November 2020 financings, and March 2021 warrant exercise and exchange, the realization of expected synergies from our business combination transaction with Curetis GmbH, the successful integration of our company with the operations and business of Curetis GmbH and its subsidiaries and the implementation of the combined company’s strategic and business goals and objectives, the impact of COVID-19 on our operations, financial results, and commercialization efforts as well as on capital markets and general economic conditions, the ability to comply with the complexities of operating a global business, the success of our commercialization efforts, the effect on our business of existing and new regulatory requirements, and other economic and competitive factors. For a discussion of the most significant risks and uncertainties associated with OpGen’s business, please review our filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which are based on our expectations as of the date of this presentation and speak only as of the date of this presentation. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

# OpGen Overview

Striving to innovate molecular microbiology



# OpGen's combined portfolio

## Synergistic products and capabilities

### Unyvero Platform & Syndromic Tests



FDA-cleared LRT & LRT BAL for lower respiratory tract infections

5 CE-IVD tests

Unyvero A30 RQ platform in advanced stages of development

### Acuitas Panel & Lighthouse



Acuitas AMR Gene Panel for Isolates pending FDA clearance

Enhances targeted antibiotic decision making

Lighthouse knowledge base deployed for public health use

### Global Commercial Presence



Direct sales and marketing in the U.S.

EMEA, APAC, Latin America and China distribution with partners

### Ares Genetics NGS & Bioninformatics



AI-powered AMR prediction combining ARESdb with NGS

Strategic partnerships and collaborations with globally leading IVD & pharma companies

# OpGen's strategic positioning and benefits



**Well positioned to capitalize on global opportunities in infectious disease and rapid AMR detection**



Proprietary molecular diagnostic tests and platforms



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



Global commercial channel capabilities & partners



Financial leverage, operational synergies, and positive growth-driven business outlook

# Unmet clinical needs and large available market opportunities

U.S. and European markets addressed through hospital-focused sales channels



- Pneumonia (HPN / LRT / LRT BAL)
- Urinary Tract Infections (UTI)
- Implant and Tissue Infections (ITI) / Invasive Joint Infections (IJI)
- Blood Culture (BCU)
- Intra-Abdominal Infections (IAI)

The current Unyvero portfolio and pipeline of cartridges according to management estimates target about 9 million patients annually in EU and U.S. with additional upside in Asia / Pacific and ROW markets.

# OpGen's strategic positioning and benefits



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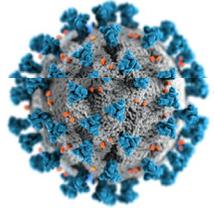
Global commercial channel capabilities & partners



Financial leverage, operational synergies, and positive growth-driven business outlook

# We help fight the COVID-19 global pandemic

SARS-CoV-2 kit with PCR-compatible universal lysis buffer (PULB), COVID-19 pneumonia co-infections



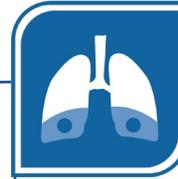
## SARS CoV-2 Kit with PULB CE-IVD marked\*

- Real-time RT-PCR kit for detecting SARS-CoV-2
- Developed by our team in Germany
- Time to result in ~1 hour
- Oropharyngeal (OP) and nasopharyngeal (NP) swab specimens
- Use with standard RNA isolation processes, and with OP/NP swabs collected in PCR compatible viral transport medium treated with PULB provided in the kit
- Runs on PCR systems such as QuantStudio™ 5 and Bio-Rad CFX96™

### Key Findings:

- A [study of clinical validation of the Curetis SARS-CoV-2 Kit with PULB using dry swabs](#) showed:
  - Performance of the *Curetis SARS-CoV-2 Kit with PULB* using dry swabs is comparable with that of GeneFinder COVID-19 Plus RealAmp Kit using isolated RNA
  - *Curetis SARS-CoV-2 Kit with PULB* using dry swabs can save time and money by eliminating the need for standard RNA isolation step

\*The Curetis SARS-CoV-2 Kit with PULB is CE IVD marked but it has not been authorized for emergency use by the U.S. FDA.



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## HPN/LRT cartridges CE-IVD & FDA-cleared for lower respiratory tract infections such as bacterial pneumonia

- Fully automated, cartridge-based, sample to answer multiplex PCR system
- Detects COVID-19 bacterial co-infections such as bacterial pneumonia
- HPN covers 29 pathogens and 19 resistance markers
- LRT and LRT BAL cover 36 and 37 clinically relevant pathogens, respectively; each detects 10 antibiotic resistance markers
- Native specimens: sputum, bronchoalveolar lavage and tracheal aspirates
- Results under 5 hours

### Key Findings:

- In a webinar titled "[Pneumonia Diagnosis: Bacterial Superinfection in COVID-19 Patients](#)", two infectious disease professionals presented their independent study results from the Unyvero HPN and Unyvero LRT BAL panels:
  - Distinguishing those COVID-19 patients with bacterial superinfection early and accurately is crucial for patient management and antibiotic stewardship
  - Unyvero detected bacterial pathogens up to 7 days earlier and would have enabled prompt and appropriate targeted antibiotics in 41.3% of cases and reduced time to appropriate therapy by 25.7 hours

# Sample-to-answer high-throughput testing capabilities

Innovating molecular microbiology through proprietary platforms and content

Rapid low-plex to high-plex MDx diagnostics  
Broad range of sample types and indications

Proprietary PCR & NGS applications based on  
leading AI-powered AMR knowledgebases

unyvero



Unyvero A50  
High-Plex PCR



Unyvero A30 RQ\*  
Low- to Mid-Plex qPCR

Acuitas  
AMR Gene Panel



Acuitas AMR Gene Panel\*\*  
Real-time PCR\*\*\*

Acuitas  
Lighthouse



Acuitas Lighthouse  
MDx Content

ares genetics



ARES Genetics  
ARESdb & NGS Applications

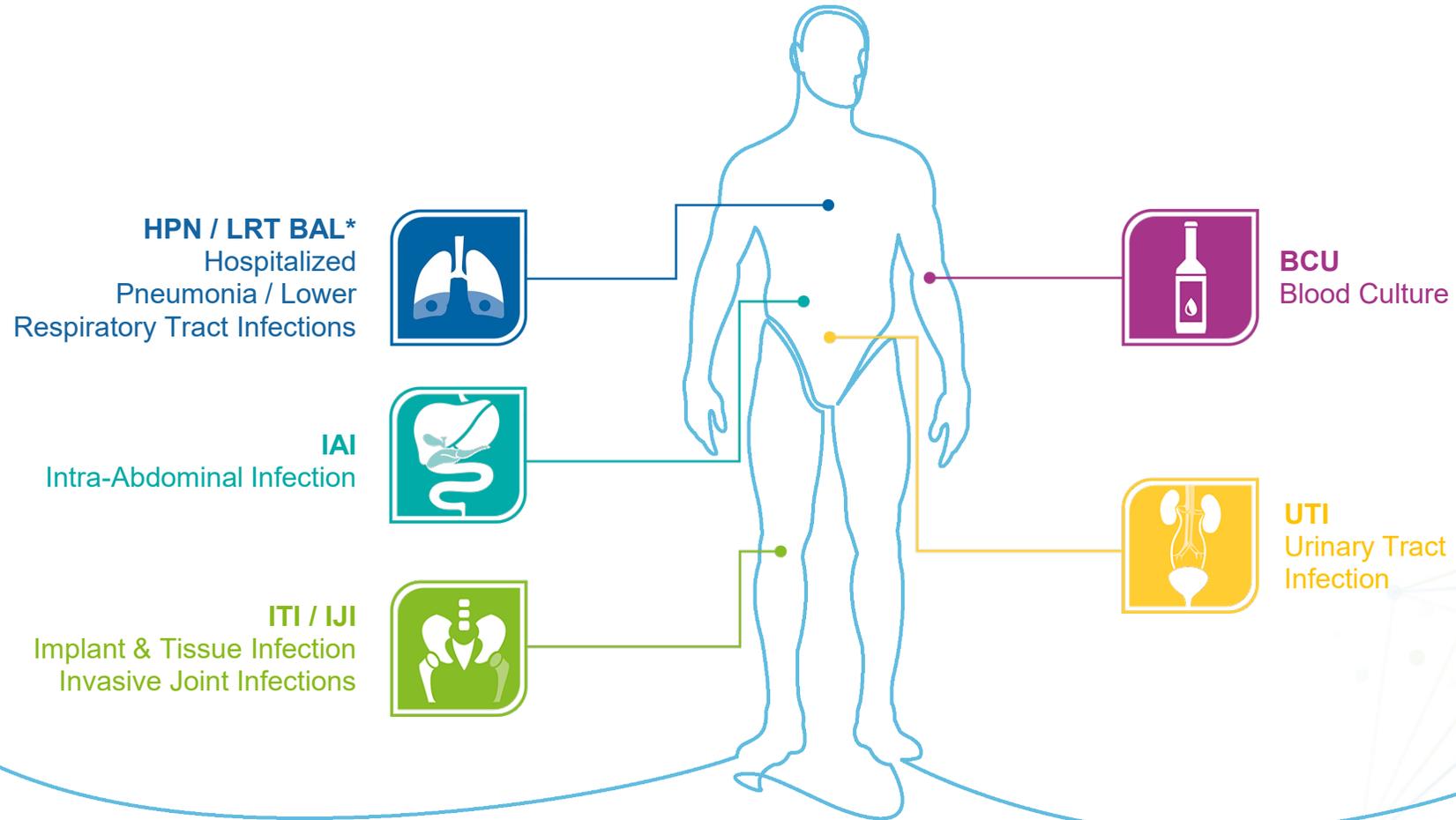
\*Unyvero A30 RQ Analyzer in development, latest design concept; final product may differ.

\*\*Pending 510(k), for Research Use Only, not for diagnostic use.

\*\*\*OpGen Qualified Applied Biosystems™ QuantStudio 5 Real-Time PCR System for use with the Acuitas AMR Gene Panel for real-time multiplex reaction and detection.

# Broad Unyvero cartridge portfolio

unyvero



\*Unyvero LRT / LRT BAL are FDA-cleared; all other products are CE-IVD marked or in development.

# Unique and differentiated syndromic panels



Cartridge	Indication area	Number of targets covered	Sample types	Clearance status
HPN** 	Severe cases of Pneumonia	48 targets**** pathogens (29) and antibiotic resistance markers (19)	Sputum, broncho-alveolar lavage, tracheal aspirate	CE-IVD marked Singapore (HAS) Thailand Malaysia
LRT & LRT BAL 	Lower Respiratory Tract Infections	LRT (LRT BAL): 46 (47) targets**** pathogens 36 (37) and antibiotic resistance markers 10 (10)	LRT: Tracheal aspirates LRT BAL: Bronchoalveolar Lavage (BAL)	LRT: FDA cleared (4/2018) LRT BAL: FDA cleared (12/2019)
ITI 	Severe cases of Implant and Tissue Infections	102 targets pathogens (85) and antibiotic resistance markers (17)	Sonication fluid, swabs, striche, tissue, pus, aspirate/exudate, etc.	CE-IVD marked
UTI 	Severe cases of Urinary Tract Infections	103 targets pathogens (88) and antibiotic resistance markers (15)	Midstream urine, suprapubic aspiration, tissue	CE-IVD marked
BCU*** 	Bloodstream infections	103 targets pathogens (86) and antibiotic resistance markers (17)	Positively flagged blood cultures	CE-IVD marked Singapore (HAS) Thailand
IAI 	Severe Intra-Abdominal Infections	130 targets pathogens (105), toxins (3) and antibiotic resistance markers (22)	Paracentesis fluids, biliary fluids, peritoneal fluids, drainage fluids, retroperitoneal fluids, pus, swabs, samples from positively flagged blood culture bottles inoculated with other fluids than blood (IAI fluids such as ascites)	CE-IVD marked

\*\*HPN: Hospitalized Pneumonia \*\*\*BCU: Blood Culture Application  
\*\*\*\*Difference between HPN and LRT (BAL) due to different reporting requirements between CE-IVD and U.S. FDA-cleared products.

# Current U.S. product offerings



## Unyvero LRT & LRT BAL



Sample-to-answer  
Results under 5 hrs  
2 min hands-on time



Direct from native specimen  
FDA-cleared for bronchoalveolar lavage (BAL, mini-BAL) and tracheal aspirates  
Multiplex PCR with array detection



Detects the most clinically relevant pathogens (incl. atypicals) &  
antibiotic resistance markers associated with lower respiratory tract infections  
including pneumonia



Broadest carbapenemase resistance coverage  
The only FDA-cleared panel that detects *Pneumocystis jirovecii*  
Identifies difficult to culture *Mycoplasma pneumoniae*, *Chlamydia pneumoniae*, *Legionella pneumophila*

**Critical results for  
life-saving treatment  
decisions**

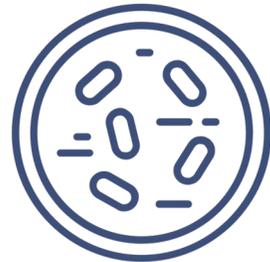


# Current U.S. product offerings: Acuitas AMR Gene Panel\*

Panel available for RUO in outbreak monitoring and epidemiology settings  
AMR Gene Panel for isolates: FDA clearance decision pending



Detects AMR Genes in Most  
Deadly Superbugs



*E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*,  
*E. faecalis*, as well as in several others e.g.  
*C. freundii* complex, *C. koseri*, *E. cloacae* complex,  
*K. aerogenes*, *K. michiganensis*, *K. oxytoca*,  
*K. quasi-pneumoniae*, *K. variicola*, *M. morgani*,  
*P. rettgeri*, *P. stuartii*, *R. ornithinolytica*,  
*R. planticola*, *S. marcescens*

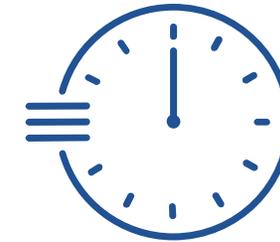
\* In development; For Research Use Only.  
Not for use in diagnostic procedures.

Identifies



Broad panel of resistance genes  
Spanning 9 antibiotic classes

Results under 3 hrs



Directly from pure isolated colonies  
FDA clearance decision pending  
Multiplex PCR results in under 3 hours

# Unyvero A30 RQ

Rapid sample-to-answer testing platform: batch of pre-series release analyzers now in final V&V testing following achievement of key milestone

## Key Design Features

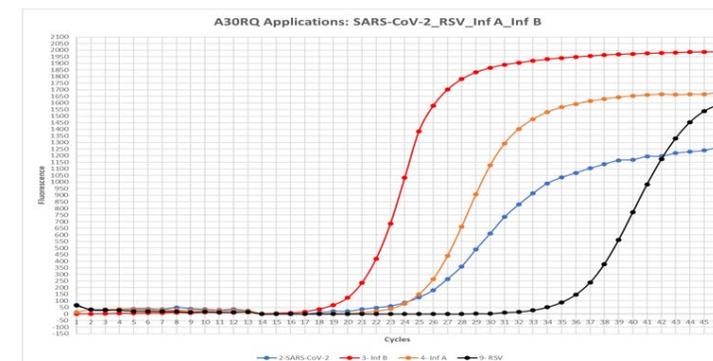
- Fully integrated, closed, sample-to-answer MDx platform
- Universal real-time PCR technology for low- to mid-plex testing
- Flexible cartridge fluidics for numerous chemistries and assay formats
- Fast turn-around time from ~30 to ~90 minutes
- Light-weight, stackable benchtop design with small footprint
- 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



Platform available for partnering

## Development Status

- Demonstrated clinical proof of concept from sample to answer with various assays including SARS CoV-2, Flu-A / Flu-B and RSV
- Manufacturing aspects fully specified and in development or implementation phase
- Curetis makes Unyvero A30 RQ platform available for partnering
- V&V testing for mechanical and electrical aspects as well as life-time testing ongoing



red curve:  
Influenza B, Ct = 21

orange curve:  
Influenza A, Ct = 25.5

blue curve:  
SARS-CoV2, Ct = 25

black curve:  
RSV, Ct = 36

\* Unyvero A30 RQ Analyzer in development, latest design concept; final product may differ.

# OpGen's strategic positioning and benefits



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Proprietary molecular diagnostic tests and platforms



**Premier AI-powered bioinformatics solutions for multi-drug resistance diagnostics**



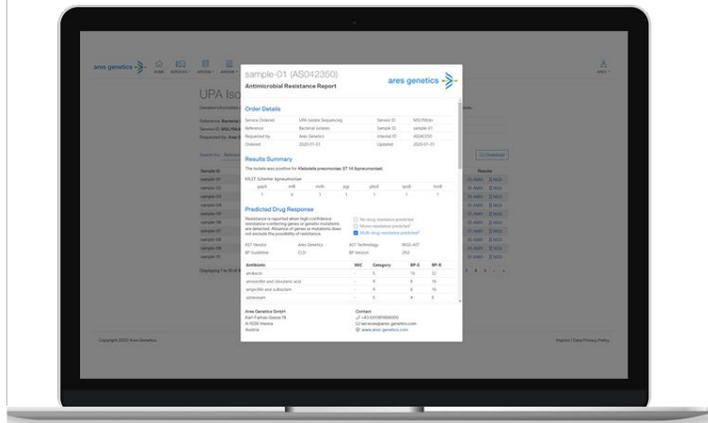
Global commercial channel capabilities & partners



Financial leverage, operational synergies, and positive growth-driven business outlook

# Ares Genetics and ARESdb\*

Bioinformatics powerhouse with industry-leading proprietary AI-powered AMR knowledgebase for molecular microbiology



\* In development; For Research Use Only.  
Not for use in diagnostic procedures.

## Global ARESdb

- Unique knowledgebase on antibiotic resistance markers building partly on Siemens microbiology strain collection
- Demonstrated up to > 99% accuracy for antibiotic susceptibility prediction in evaluation studies
- Based on > 55,000 pathogens and associated resistance data for > 100 antibiotics

## First RUO applications launched

- Through NGS service laboratory and cloud platform

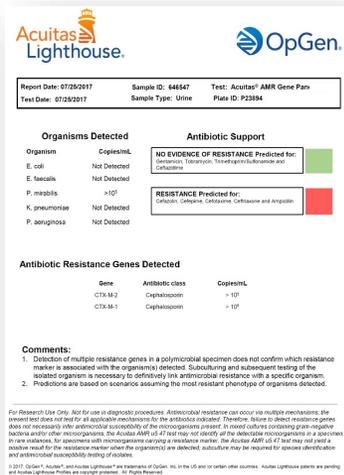
## Partners and customers include

- Globally leading IVD & pharma companies and national agency
- Amended Qiagen RUO partnership to global non-exclusive
- Recently further expanded the Sandoz collaboration
- Recently added partnerships with UPMC as well as a major U.S. CRO and CLIA lab

# Acuitas Lighthouse<sup>®</sup>

Cloud-based diagnostics data management platform for antibiotic resistant pathogens\*

## Acuitas Test Result



Acuitas Lighthouse. OpGen.

Report Date: 07/26/2017 Sample ID: 648547 Test: Acuitas<sup>®</sup> AMR Gene Pan  
Test Date: 07/26/2017 Sample Type: Urine Plate ID: P2394

Organisms Detected		Antibiotic Support	
Organism	Copies/mL	NO EVIDENCE OF RESISTANCE Predicted for:	RESISTANCE Predicted for:
E. coli	Not Detected	Cephalosporins, Tetracyclins, Streptogramins/Linkosamides and	
E. faecalis	Not Detected		
P. mirabilis	>10 <sup>7</sup>		Ceftriaxone, Cefotaxime, Cefuroxime and Ampicillin
K. pneumoniae	Not Detected		
P. aeruginosa	Not Detected		

Antibiotic Resistance Genes Detected		
Gene	Antibiotic class	Copies/mL
CTX-M2	Cephalosporin	> 10 <sup>7</sup>
CTX-M1	Cephalosporin	> 10 <sup>7</sup>

**Comments:**

- Detection of multiple resistance genes in a polymicrobial specimen does not confirm which resistance marker is associated with the organism(s) isolated. Subculturing and subsequent testing of the isolated organism is necessary to definitively link antimicrobial resistance with a specific organism.
- Predictions are based on scenarios assuming the most resistant phenotype of organisms detected.

For Research Use Only. Not for use in diagnostic procedures. Antimicrobial resistance can occur via multiple mechanisms, the reported test does not test for all applicable mechanisms for the antibiotic subclass. Therefore, failure to detect resistance genes does not necessarily infer antimicrobial susceptibility of the microorganisms present. In mixed cultures containing gram-negative bacteria and/or other microorganisms, the Acuitas AMR v1.0 test may not identify all detectable microorganisms in a specimen. In rare instances, for specimens with microorganisms carrying a resistance marker, the Acuitas AMR v1.0 test may not yield a positive result for the resistance marker when the organism(s) are detected. Additional data may be required for species identification and antimicrobial susceptibility testing of isolates.

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Rapid molecular antibiotic resistance prediction

\* In development; For Research Use Only.  
Not for use in diagnostic procedures.

## Acuitas Lighthouse Analysis



Cloud-based bioinformatics platform  
Enables real-time AMR tracing  
Potential to change the landscape of clinical infectious disease management and improve patient outcomes

## Actionable AMR Tracing



Signed contract extending and expanding partnership beyond 2<sup>nd</sup> year contract term by 6 months until Sept 30, 2021

Testing volumes at NY sites ramped up significantly in H1-2021

Retainer plus per test fees could add up to \$ 540k for Q2-Q3 2021

# OpGen's strategic positioning and benefits



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



Proprietary molecular diagnostic tests and platforms



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



**Global commercial channel capabilities & partners**



Financial leverage, operational synergies, and positive growth-driven business outlook

# Dual commercial model

Direct in USA – Distribution in EMEA, China and Rest of World

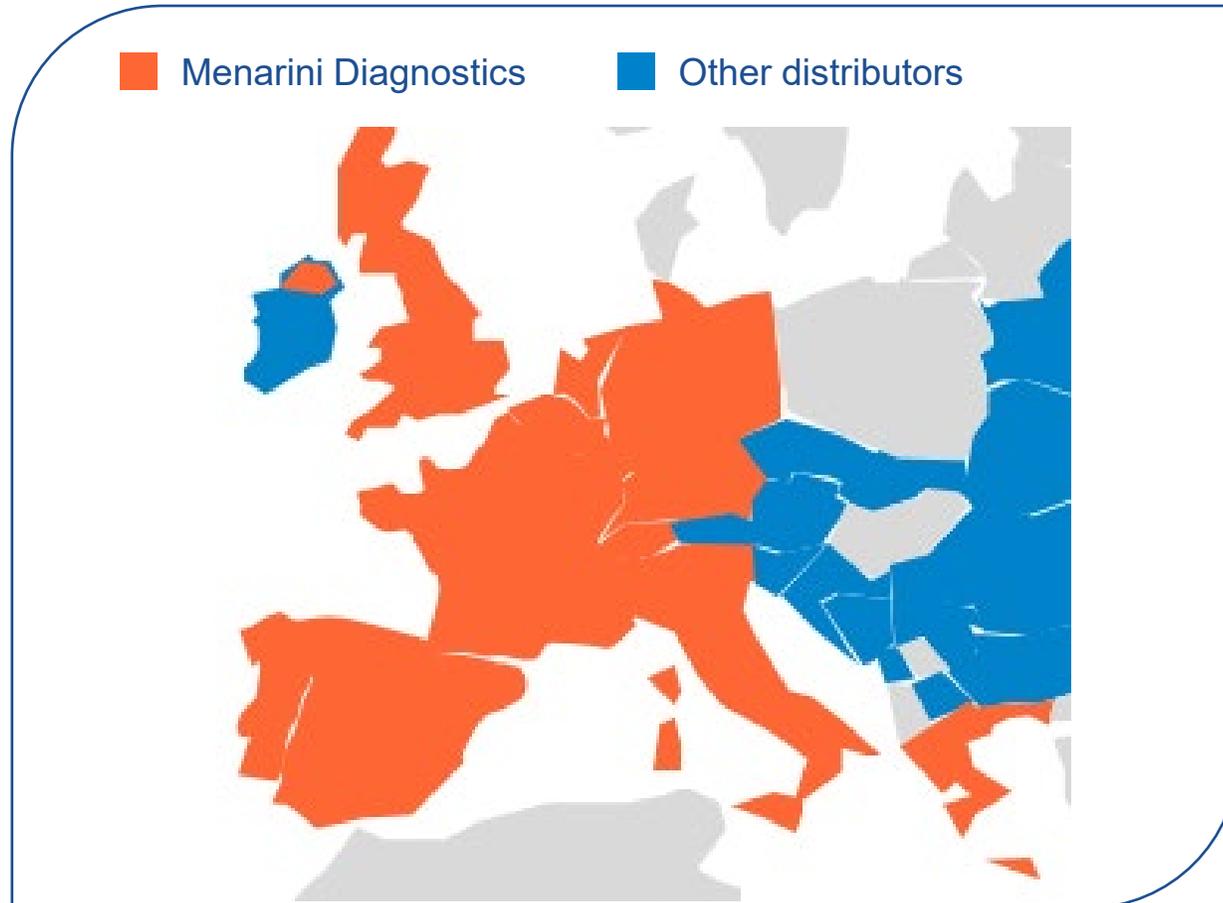


**Expanding global commercial reach through direct sales in U.S. and via global distributors**

- Direct sales in the U.S.
- European distribution through Menarini Diagnostics
- China distribution through Beijing Clear Biotech
- Distributors covering ~40 countries in EU, ME, LATAM, and Asia
- Exited our FISH products business ahead of schedule by end of Q1-2021
- Reduced number of distributors post FISH business exit in 2021

# Pan-European distribution via Menarini

Currently 11 EU countries; option to expand relationship to further markets



## Menarini Diagnostics & Curetis Collaboration

- Covers entire Unyvero A50 product line
- Currently covered countries: **BE, CH, DE, ES, FR, IT, LU, NL, PT, UK, GR**
- Option to expand relationship to further countries



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# Financial considerations



## Proforma combined revenue

- FY 2018 revenues of \$ 4.5 million
- FY 2019 revenues of \$ 6.0 million
- FY 2020 revenues of \$ 5.2 million



## Reported revenue

- H1 2021 revenues of \$ 1.6 million
- Exit from FISH business and non-recurring IVD partnering revenue from Ares completed R&D project in 2020 as well as growing Unyvero products and lab services testing revenues
- No revenue guidance for 2021 at this time due to COVID-19 situation



## Cash position

- Strong cash position:
  - \$ 31.2 million as of 6/30/2021
- Raised \$ 25.0 million in Registered Direct with single U.S. healthcare-focused institutional investor in February 2021
- Executed warrant exercise and exchange deal for \$ 9.7 million gross proceeds in March 2021
- Total cash raised in FY 2020 and 2021 to date approximately \$ 70 million



## Capital structure – shares outstanding

- Common Stock ~38.3 million shares (as of July 1, 2021)
- Common Warrants ~8.7 million (warrants have avg. exercise price of \$ 3.40)
- Equity Awards ~2.3 million
- Fully Diluted Shares Outstanding ~49.3 million shares

# Operations

Headquartered in the U.S. with global operations

## Our Facilities

**Corporate HQ** and FDA registered R&D / manufacturing facility in Rockville, Maryland, USA

- Moved to new Rockville, MD facility in Q2-2021 (~ **10,000 sq. ft.**)
- Optimized layout and operating efficiency at > \$600k p.a. net savings

**17,000 sq. ft.** FDA registered R&D, operations and G&A facility in Holzgerlingen, southern Germany

**17,000 sq. ft.** FDA registered manufacturing facility in Bodelshausen, southern Germany

**7,000 sq. ft.** Bioinformatics and NGS lab facility in Vienna, Austria

## A Global Team



# OpGen Executive Leadership Team and Board

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

## Leadership Team



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



**Timothy (Tim) C. Dec**  
Chief Financial Officer  
(until 8/20/2021)



**Johannes (Jan) Bacher**  
Chief Operating Officer

## Board Members



William (Bill) Rhodes (Chairman)



Prabhavathi (Prabha) Fernandes, Ph.D.



Mario Crovetto



Don Elsey



Oliver Schacht, Ph.D. (CEO)

# Recent news flow

## OpGen recently announced several key updates and milestones

- OpGen reports Q2-2021 earnings
- OpGen files S-3 universal shelf for up to \$ 150 million
- OpGen achieves key milestone in Unyvero A30 RQ development program
- OpGen cancels partially adjourned shareholder meeting
- OpGen announces prospective clinical data from Unyvero LRT BAL and data on Acuitas AMR Gene Panel for Isolates
- OpGen subsidiary Ares Genetics presents R&D pipeline update with robust performance on nanopore sequencing
- OpGen extends and expands partnership with NYS DOH to detect antimicrobial resistant infections
- OpGen group company Ares Genetics further extends collaboration with Sandoz
- OpGen raises \$ 9.7 million gross proceeds in warrant exercise and exchange
- OpGen announces publication of final study results of Unyvero HPN Panel for diagnosis of bacterial co-infections in ICU patients with COVID-19 pneumonia
- OpGen wins Chinese NMPA approval for the Curetis Unyvero System
- OpGen's subsidiary Ares Genetics announces publication of study introducing best practice techniques for AI-powered prediction of antibiotic susceptibility testing by next-generation sequencing
- OpGen raises \$ 25 million in Registered Direct with single U.S. healthcare institutional investor

# Upcoming milestones, news flow & catalysts

## Unyvero & Acuitas rapid molecular tests

- U.S. FDA clearance decision for Acuitas AMR Gene Panel (isolates) with FDA having resumed its review of AI-letter response at the end of January 2021 as soon as practicable given FDA staffing resource constraints
- Commercial launch of Acuitas AMR Gene Panel (isolates) in the U.S. upon obtaining FDA clearance
- China NMPA requesting supplementary clinical data to be generated in China (est. 600 samples) for submission and potential future approval for pneumonia cartridge and subsequent commercial launch
- Clinical data and publications: several scientific contributions illustrating the benefits of the Unyvero Lower Respiratory panels and the utility of the Acuitas AMR Gene Panel will be presented at the World Microbe Forum, June 20-24, 2021
- Clinical trial updates and regulatory submissions for Unyvero UTI and IJI products
- Unyvero A30 RQ further development milestones and partnering opportunities

## Ares Genetics

- Several upcoming commercial launches of services and solutions
- Potential partnering / licensing opportunities based on multiple non-exclusive discussions with interested parties
- Clinical data and publications

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**Thank You!**

