

# OpGen

## Corporate Overview

April 2021



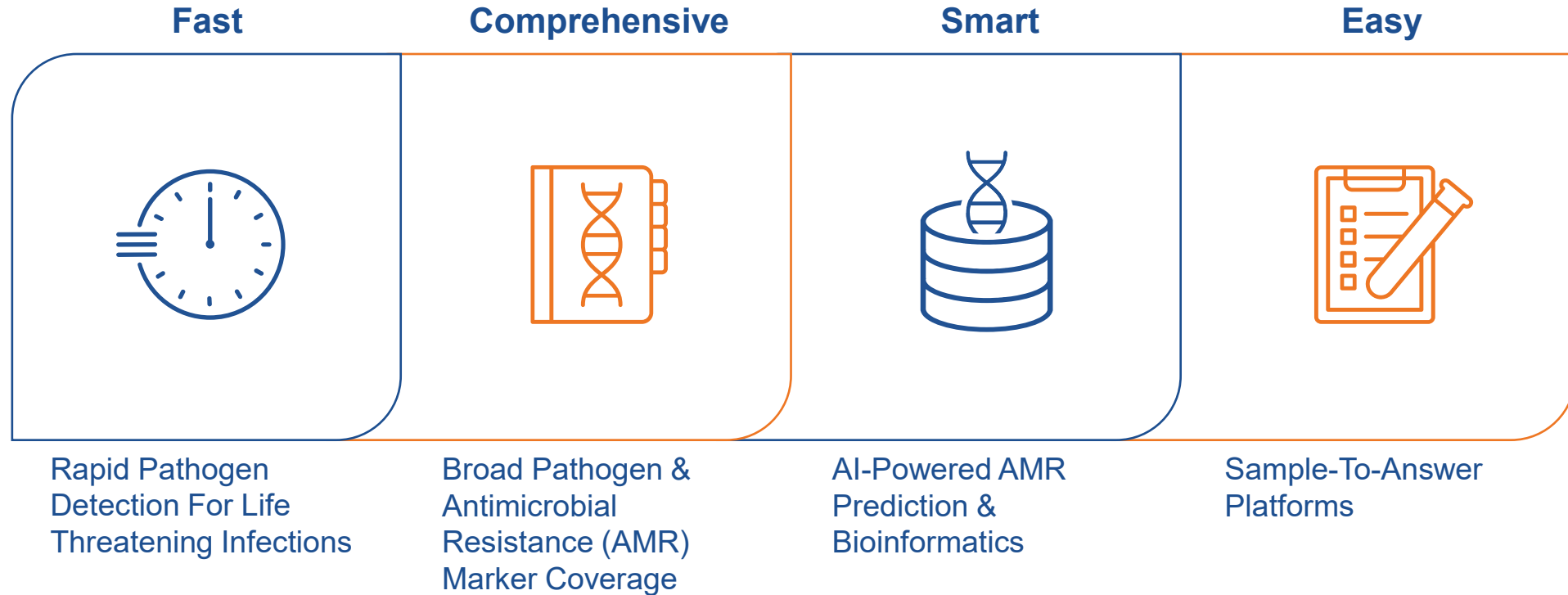
# Forward looking statements disclaimer

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 & Bioinformatics



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**



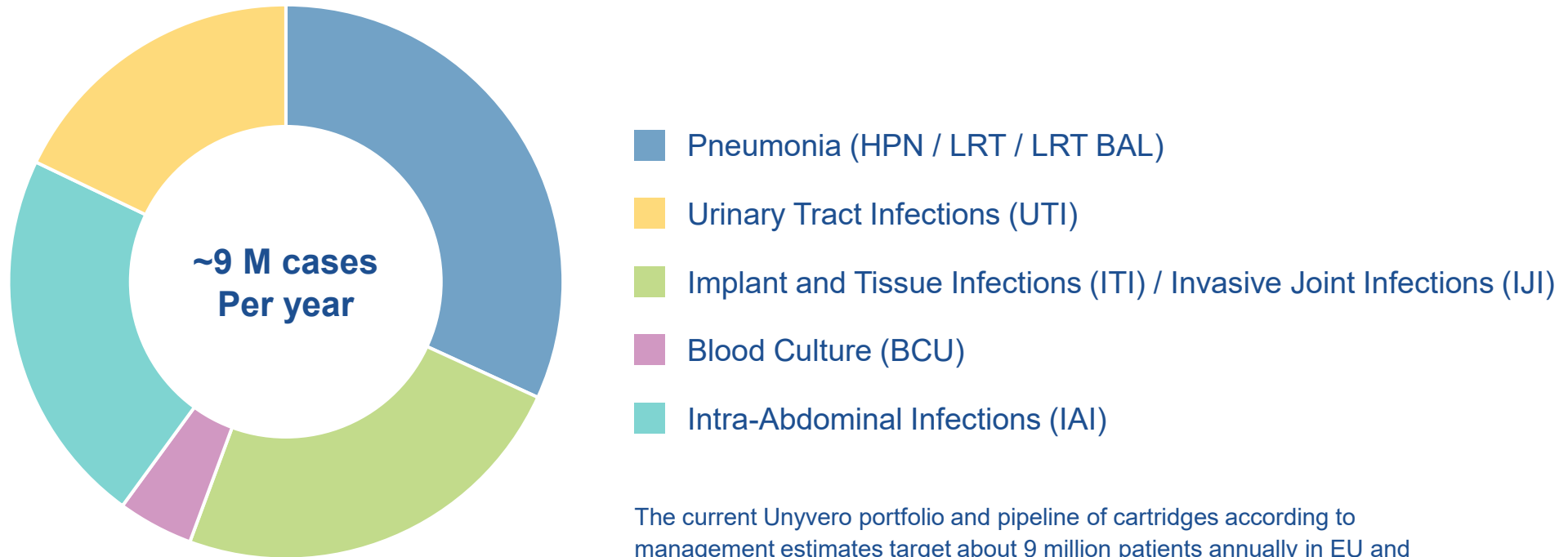
**Global commercial channel capabilities & partners**



**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



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



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



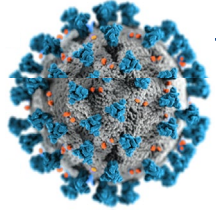
Global commercial channel capabilities & partners



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

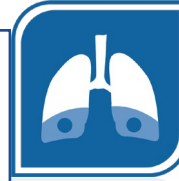
# We help fight the COVID-19 global pandemic

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™



unyvero

## 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

# Sample-to-answer high-throughput testing capabilities

Innovating molecular microbiology through proprietary platforms and content

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

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\*\*\*

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

Acuitas  
Lighthouse



Acuitas Lighthouse  
MDx Content

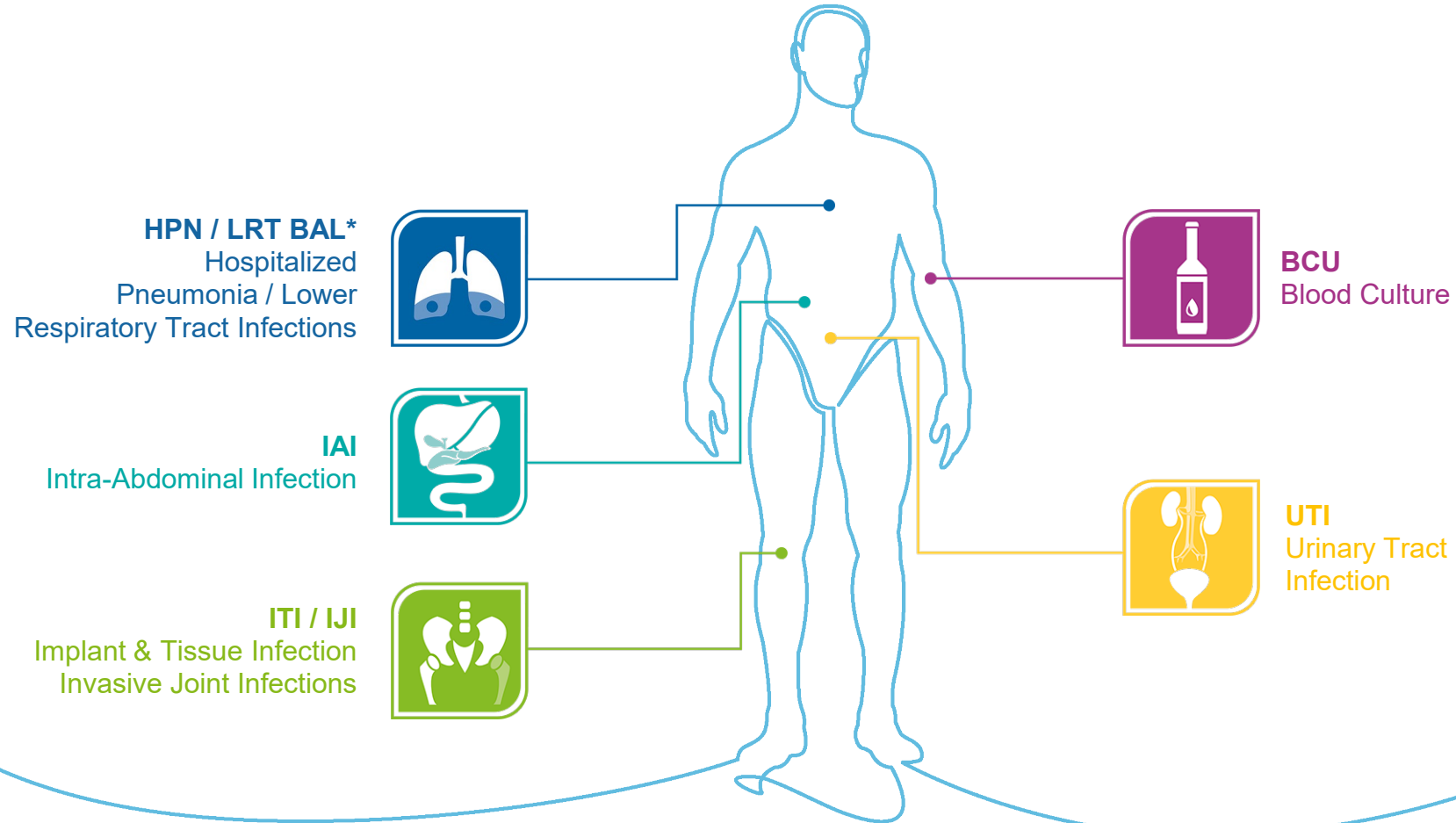
ares genetics









ARES Genetics  
ARESdb & NGS Applications

# Broad Unyvero cartridge portfolio

unyvero



# 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

# 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**



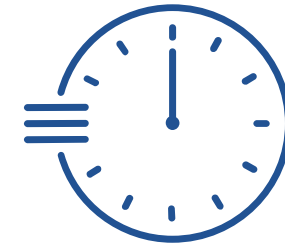
*E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *E. faecalis*, as well as in several others e.g. *C. freundii* complex, *C. koseri*, *E. cloacae* complex, *K. aerogenes*, *K. michiganensis*, *K. oxytoca*, *K. quasi-pneumoniae*, *K. variicola*, *M. morganii*, *P. rettgeri*, *P. stuartii*,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

**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 in advanced stages of development

### Key Design Features

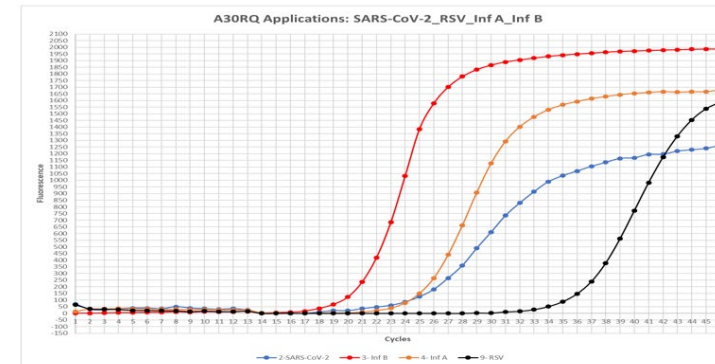
- Fully integrated, closed, sample-to-answer MDx platform
- Universal real-time PCR technology for low- to mid-plex testing
- Flexible cartridge fluidics for numerous chemistries and assay formats
- Fast turn-around time of 45-90 minutes
- Light-weight, stackable benchtop design with small footprint
- 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



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
- Expect V&V ready instrument series to become available by Q2-2021



red curve:  
Influenza B, Ct = 21

orange curve:  
Influenza A, Ct = 25.5

blue curve:  
SARS-CoV2, Ct = 25

black curve:  
RSV, Ct = 36

# 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**

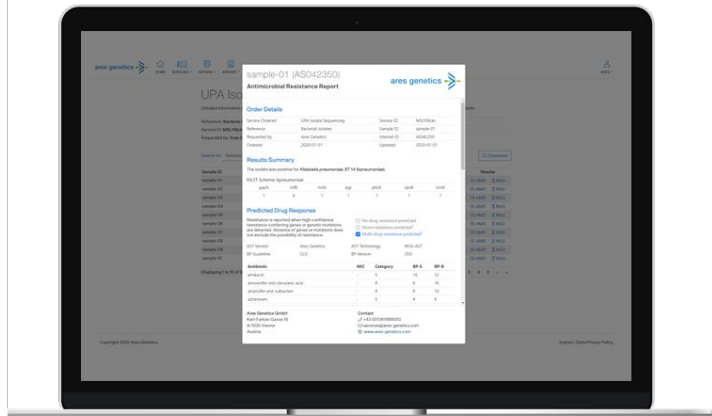


Global commercial channel capabilities & partners



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

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



### 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

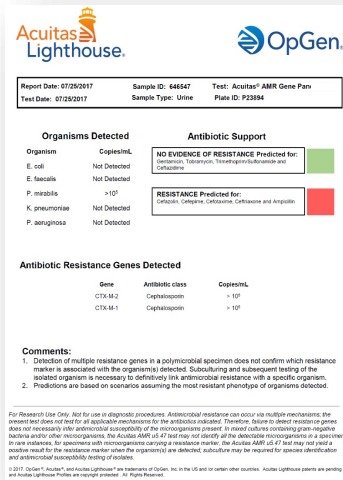
### Partners and customers include

- Globally leading IVD & pharma companies and national agency
- Recently further expanded the Sandoz collaboration

# Acuitas Lighthouse®

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

## Acuitas Test Result



Acuitas Lighthouse. OpGen.

Report Date: 07/25/2017 Sample ID: 646547 Test: Acuitas® AMR Gene Panel  
Test Date: 07/25/2017 Sample Type: Urine Plate ID: P23884

Organisms Detected		Antibiotic Support	
Organism	Copies/mL	NO EVIDENCE OF RESISTANCE Predicted for: Cephalosporins, Tetracyclines, Trimethoprim-sulfamethoxazole and Colistin	
E. coli	Not Detected	<b>RESISTANCE Predicted for:</b> Colistin, Cephalosporins, Carbapenems and Ampicillin	
E. faecalis	Not Detected		
P. mirabilis	>10 <sup>3</sup>		
K. pneumoniae	Not Detected		
P. aeruginosa	Not Detected		

Antibiotic Resistance Genes Detected		
Gene	Antibiotic class	Copies/mL
CTX-M-2	Cephalosporins	>10 <sup>3</sup>
CTX-M-1	Cephalosporins	>10 <sup>3</sup>

**Comments:**

1. Detection of multiple resistance genes in a polymicrobial specimen does not confirm which resistance marker is associated with the organism(s) detected. Subculturing and subsequent testing of the isolated organism is necessary to definitively link antimicrobial resistance with a specific organism.
2. 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 data will not test for all resistance mechanisms for the antibiotic classes. Therefore, failure to detect resistance genes does not necessarily rule out antimicrobial susceptibility of the microorganisms present. In related studies concerning gene-sequence based AMR, the Acuitas AMR v1.47 test may not identify all detectable microorganisms in a specimen. In rare instances, for specimens with microorganisms carrying a resistance marker, the Acuitas AMR v1.47 test may not yield a positive result for the resistance marker when the organism(s) are detected; subculture may be required for species identification and antimicrobial susceptibility testing of isolates.

© 2017 OpGen®. Acuitas® and Acuitas Lighthouse® are trademarks of OpGen, Inc. in the US and/or other countries. Acuitas Lighthouse patents are pending and Acuitas Lighthouse Platform is copyright protected. All Rights Reserved.

Rapid molecular antibiotic resistance prediction

## Acuitas Lighthouse Analysis

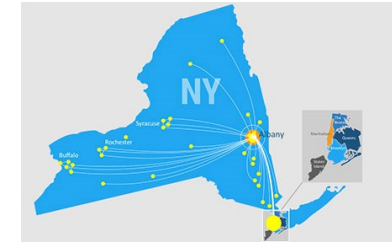


Cloud-based bioinformatics platform

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 post COVID-19 related pause at NY sites ramping-up significantly in 2021 to-date

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



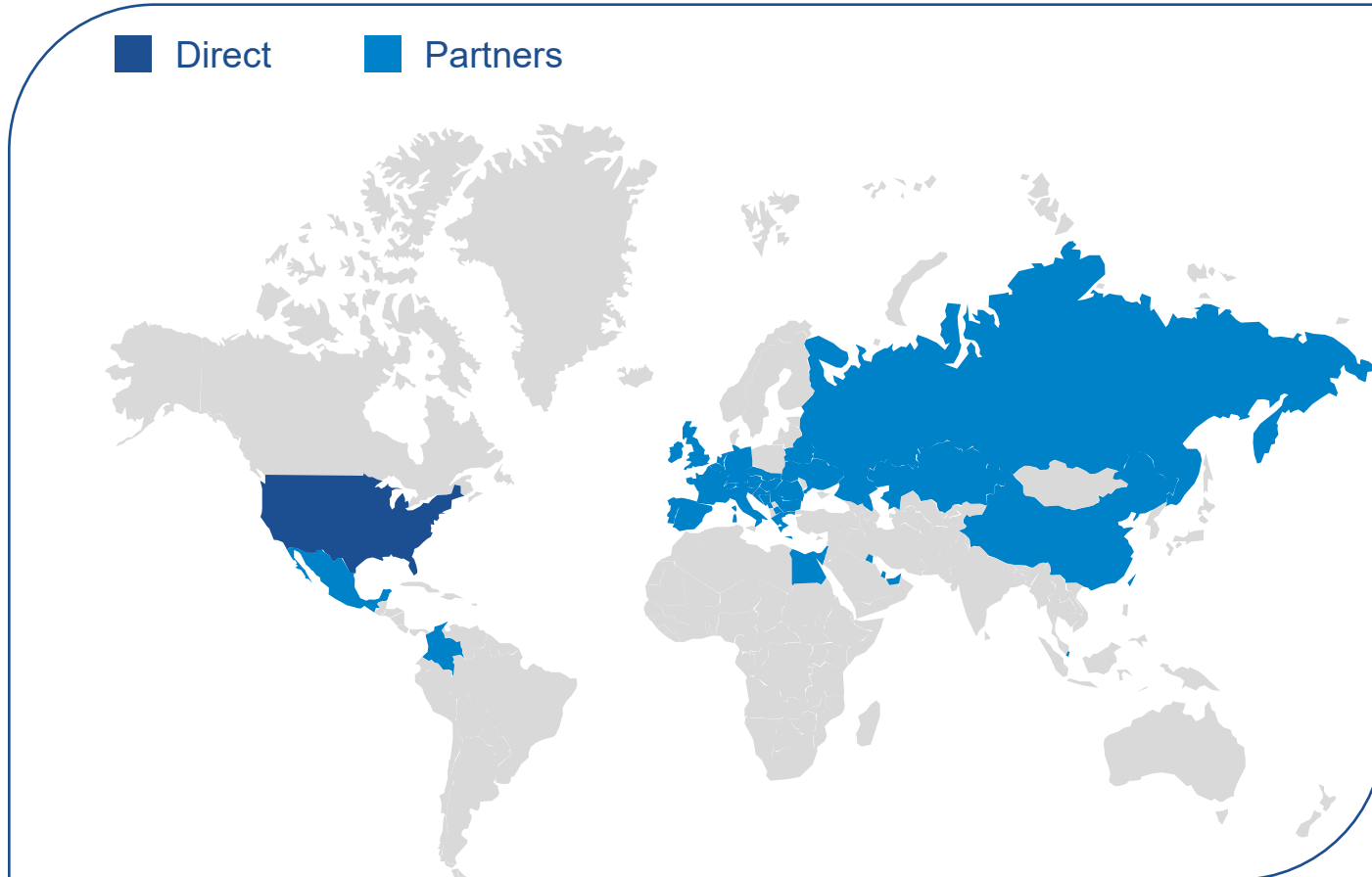
**Global commercial channel capabilities & partners**



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

# Dual commercial model

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

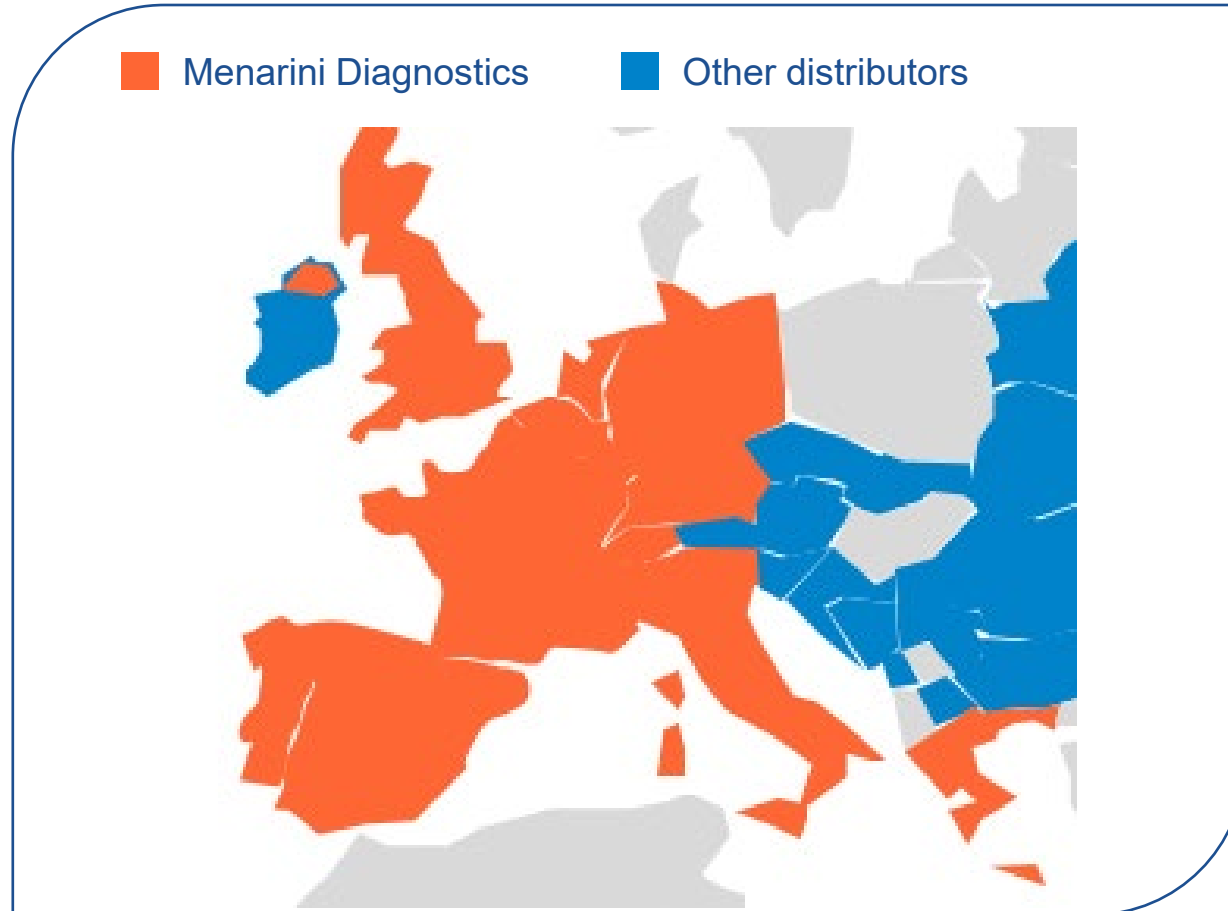


**Expanding global commercial reach though direct sales in U.S. and via global distributors**

- 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
- Expect 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



# 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

# 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

- Q4 2020 revenues of \$ 1.4 million and FT 2020 revenues of \$ 4.2 million (audited)
- No revenue guidance for 2021 at this time due to COVID-19 situation

## Cash position



- Maintained strong cash position:
  - \$ 13.4 million as of December 31, 2020
  - \$ 39 to \$ 40 million (projected) as of 3/31/2021
- Successfully closed \$10.0 million PIPE financing with single U.S. healthcare-focused institutional investor on November 2020
- Raised \$ 25.0 million in Registered Direct with single U.S. healthcare-focused institutional investor on February 2021
- Executed warrant exercise and exchange deal for \$ 9.7 million gross proceeds on 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 April 1, 2021)
- Common Warrants ~8.9 million (warrants have avg. exercise price of \$ 3.40)
- Equity Awards ~2.6 million
- Fully Diluted Shares Outstanding ~49.8 million shares

# Operations

Headquartered in the U.S. with global operations

## Our Facilities

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

- Reduction of U.S. facility size with move to new Rockville, MD facility in Q2-2021 to about 10,000 sq. ft.
- provides 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



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

## Board Members



William (Bill) Rhodes (Chairman)



Prabhavathi (Prabha) Fernandes, Ph.D.



Mario Crovetto



Evan Jones  
(until 6/2021)



Don Elsey



Oliver Schacht, Ph.D. (CEO)

# Recent news flow

## OpGen recently announced several key updates and milestones

- OpGen extends and expands partnership with NYS DOH to detect antimicrobial resistant infections
- OpGen announces Q4-2020 and FY-2020 earnings and provides business update
- 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 raised \$ 25 million in Registered Direct with single U.S. healthcare institutional investor
- OpGen subsidiary Curetis and Annar entered distribution agreement for Unyvero products in Colombia
- OpGen announced data from 1,400 patient sample multicenter publication for Unyvero LRT-BAL
- OpGen closed \$ 10 million PIPE financing with “at the market pricing”

# 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 approval for pneumonia cartridge and subsequent commercial launch
- Clinical data and publications.
- Clinical trial updates and regulatory submissions for Unyvero UTI and IJI products.
- Unyvero A30 RQ development milestones and partnering opportunities.

## Ares Genetics

- Potential partnering / licensing opportunities based on multiple non-exclusive discussions with interested parties
- Clinical data and publications

# Contact info

## **OpGen Inc. (Global HQ)**

708 Quince Orchard Road  
Gaithersburg, MD 20878 USA  
+1 301.869.9683

[InvestorRelations@opgen.com](mailto:InvestorRelations@opgen.com)

## **Curetis GmbH**

Max-Eyth-Str. 42  
71088 Holzgerlingen, Germany  
+49 (0)7031 49195-10

[contact@curetis.com](mailto:contact@curetis.com)

## **Ares Genetics GmbH**

Karl-Farkas-Gasse 18  
1030 Wien, Austria  
+43 (0)1 361 8880 10

[contact@ares-genetics.com](mailto:contact@ares-genetics.com)



# Thank You!