

# Forward looking statements disclaimer

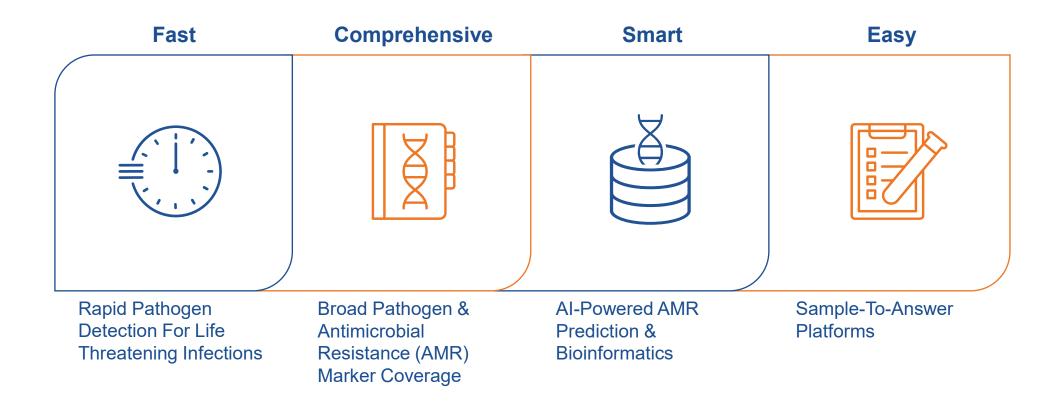
This presentation contains forward-looking statements that are subject to many risks and uncertainties. These statements, among other things, relate to our business strategy, goals and expectations concerning our products, future operations, prospects, plans and objectives of management. The words "anticipate," "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 1955. 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 costeffectively 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, 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**

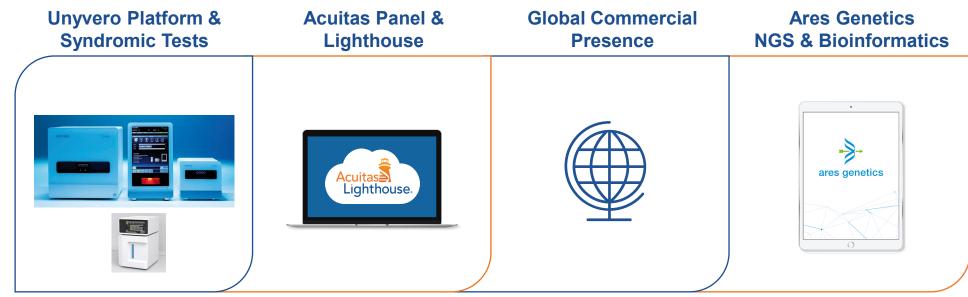
## Striving to innovate molecular microbiology





# **OpGen's combined portfolio**

## Synergistic products and capabilities



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

5 CE-IVD tests

Unyvero A30 *RQ* platform in advanced stages of development

Acuitas AMR Gene Panel for Isolates pending FDA clearance

Enhances targeted antibiotic decision making

Lighthouse knowledge base deployed for public health use

Direct sales and marketing in the U.S.

EMEA, APAC, Latin America and China distribution with partners

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



Global commercial channel capabilities & partners

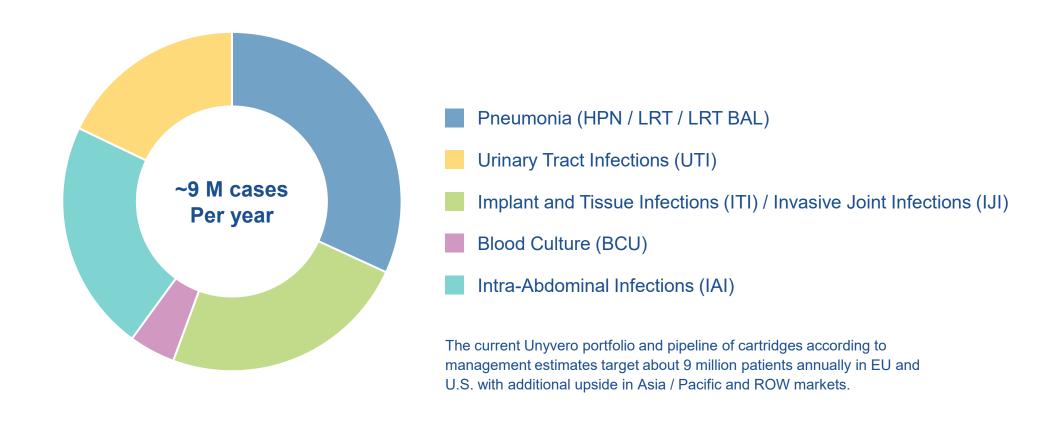


Financial leverage, operational synergies, and positive growth-driven business outlook



## Unmet clinical needs and large available market opportunities

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





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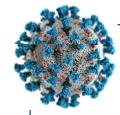


Financial leverage, operational synergies, and positive growth-driven business outlook



# 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™



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

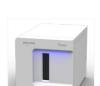
Innovating molecular microbiology through proprietary platforms and content

Rapid low- to high-plex MDx diagnostics Broad range of sample types and indications Proprietary PCR & NGS applications based on leading Al-powered AMR knowledgebases





Unyvero A50 High-Plex PCR



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





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





Acuitas Lighthouse MDx Content





ARES Genetics
ARESdb & NGS Applications



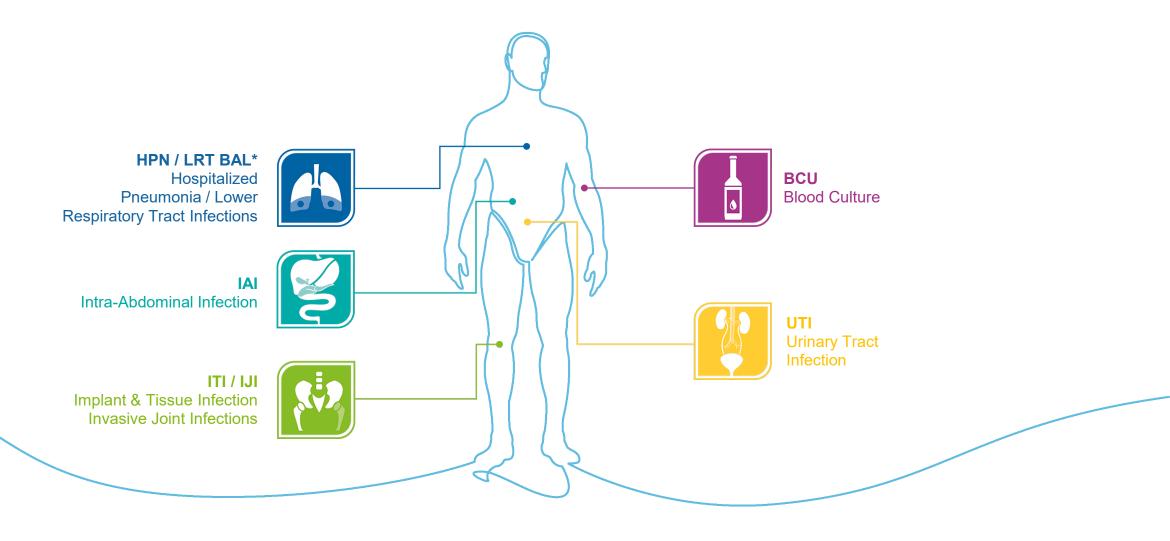
<sup>\*</sup>Unyvero A30 RQ Analyzer in development, latest design concept; final product may differ.

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

<sup>\*\*\*</sup>OpGen Qualified Applied Biosystems<sup>TM</sup> 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**







# 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***	İ	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

Critical results for life-saving treatment decisions



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* 



# **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



Identifies



Results under 3 hrs



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

Broad panel of resistance genes Spanning 9 antibiotic classes 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**

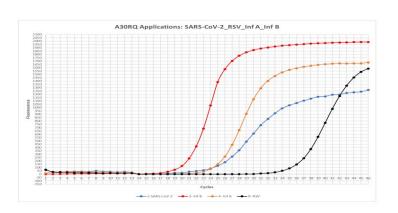
- Fully integrated, closed, sample-to-answer MDx platform
- Universal real-time PCR technology for low- to mid-plex testing
- Flexible cartridge fluidics for numerous chemistries and assay formats
- Fast turn-around time of 45-90 minutes
- Light-weight, stackable benchtop design with small footprint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



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Global commercial channel capabilities & partners



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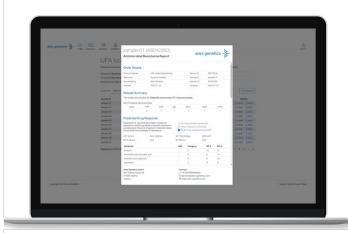


## **Ares Genetics and ARESdb\***



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



# **Acuitas Lighthouse**®

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

# Acuitas Test Result Acuitas Lighthouse Analysis Actionable AMR Tracing Committee Characteristic Section Committee 
Rapid molecular antibiotic resistance prediction

Cloud-based bioinformatics platform

Enables real-time AMR tracing

Potential to change the landscape of clinical infectious disease management and improve patient outcomes

Successfully met all development milestones under 1st year contract

Expanded partnership for 2<sup>nd</sup> year contract term; restarted testing post COVID-19 related pause at NY sites; ramp-up of testing volumes in Q4-20 and 2021 to-date



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## **Dual commercial model**

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



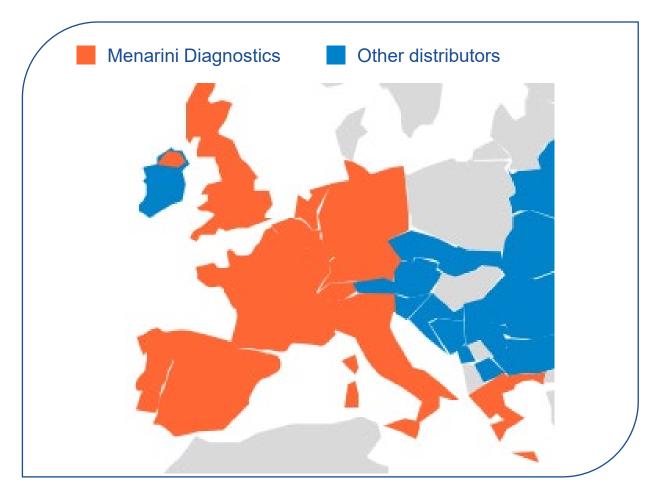
# Expanding global commercial reach though direct sales in U.S. and via global distributors

- 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
- Announced termination of FISH products distribution by June 30, 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





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## Financial considerations

#### Proforma combined revenue

- FY 2018 revenues of \$4.5
- FY 2019 revenues of \$6.0 million
- FY 2020 revenues of \$5.2 million (preliminary, unaudited)

## Reported revenue

- Q4 2020 revenues of \$1.3 million (preliminary, unaudited)
- No revenue guidance for 2021 at this time due to COVID-19 situation

## **Cash position**

- Maintained strong balance sheet with \$13.3 million cash as of December 31, 2020
- Successfully closed \$10.0 million PIPE financing with single U.S. healthcare-focused institutional investor on November 26, 2020
- Raised \$25.0 million in Registered Direct with single U.S. healthcare-focused institutional investor on February 9, 2021
- Total cash raised in FY 2020 and 2021 to date > \$60.3 million

## Capital structure – shares outstanding

- Common Stock ~ 30.4 million shares (as of March 1, 2021)
- Pre-funded Warrants ~ 3.0 million shares (as of March 1, 2021)
- Common Warrants ~10.4 million (warrants avg. exercise price \$2.67)
- Equity Awards ~1.7 million (includes grants of 1.3 million options granted to BoD and Executives in Sept 2020)
- Fully Diluted Shares Outstanding ~ 45.5 million shares



# **Operations**

## Headquartered in the U.S. with global operations

#### **Our Facilities**

#### **A Global Team**

**Corporate HQ** and FDA registered R&D / manufacturing facility (20,000 sq. ft.) in Gaithersburg, Maryland, USA

- planned reduction of U.S. facility size with move to new Rockville, MD facility in H1-2021 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





# **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** 



Don Elsey



Oliver Schacht, Ph.D. (CEO)



## Recent news flow

## OpGen recently announced several key updates and milestones

- OpGen Wins Chinese NMPA Approval for the Curetis Unyvero System
- OpGen's subsidiary Ares Genetics announces publication of study introducing best practice techniques for Al-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 reported preliminary unaudited FY 2020 combined pro forma revenues of \$5.2 million and provided busines update
- 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 group company Ares Genetics extended collaboration with #1 global generics manufacturer Sandoz
- 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 Alletter response amid COVID-19 related FDA staffing surge and timeline extension.
- 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**

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