

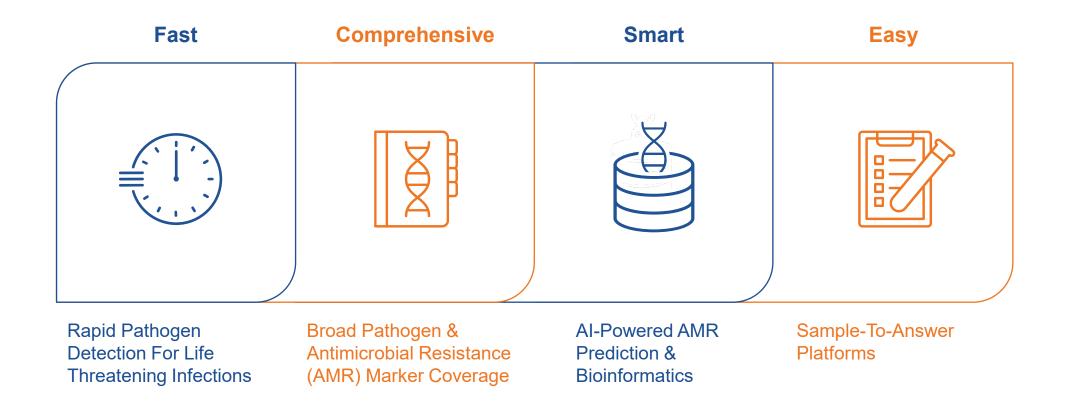
# Forward looking statements disclaimer

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 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 November 2020 private placement, 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 and its group companies: Striving to innovate molecular microbiology





# OpGen's combined portfolio: Synergistic products & capabilities

**Unyvero Platform** & Syndromic Tests

Acuitas Tests & Acuitas Lighthouse

Global Commercial Presence

Ares Genetics NGS & Bioinformatics









Unyvero FDA-cleared platform for lower respiratory tract infection (LRT & LRT BAL) as well as 5 CE IVD tests; Unyvero A30 RQ platform in development Acuitas AMR Gene Panel pending FDA clearance (isolates) to improve antibiotic decision making; Lighthouse knowledge base deployed for public health use Direct sales and marketing in the U.S.;

EMEA, APAC, LatAm and China distribution with partners:

Ares Technology for AI-powered AMR prediction combining ARESdb with NGS; Strategic partnerships with globally leading IVD & pharma companies



# OpGen's strategic rationale 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

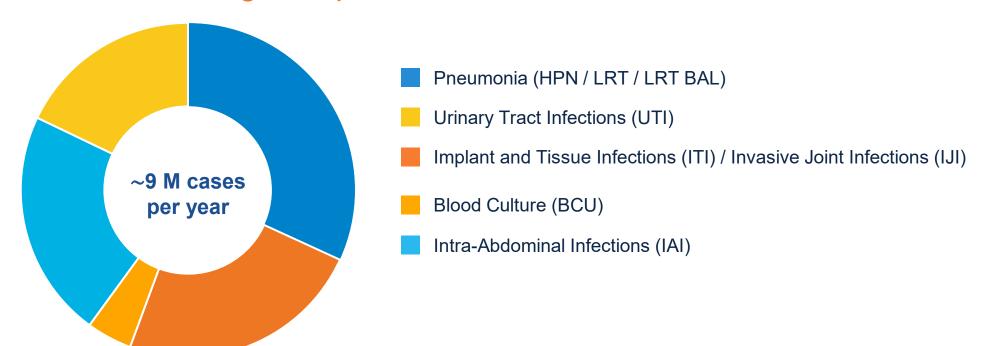


Financial leverage, operational synergies, and positive growth-driven business outlook



# OpGen to address unmet clinical needs and large available market opportunities

U.S. and European markets with ~9 million hospitalized patients annually 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.



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# We help fight the COVID-19 global pandemic

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

CE-IVD marked SARS CoV-2 Kit with PULB







- Time to result in ~1 hour
- Can be used with RNA isolated by performing standard RNA isolation processes, as well as with oropharyngeal or nasopharyngeal swabs collected in PCR compatible viral transport medium treated with PULB provided in the kit
- Runs on Real-Time PCR systems such as QuantStudio™ 5 and Bio-Rad CFX96™
- PCR-compatible Universal Lysis Buffer (PULB)

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



- Multiplex PCR system capable of detecting COVID-19 bacterial coinfections such as bacterial pneumonia
- HPN: Coverage of 29 pathogens and 19 resistance markers
- LRT (LRT BAL): Coverage of 36 (37) pathogens and 10 (10) antibiotic resistance markers
- Range of sample materials: sputum, bronchoalveolar lavage and tracheal aspirates
- Results in 4-5 hours



# Sample-to-answer high-throughput testing capabilities

Innovating molecular microbiology through proprietary platforms and content

Striving for molecular microbiology innovation

**MDx Platforms** 

**MDx Content** 







Unyvero A50 High-Plex PCR

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

Low- to high-plex PCR Broad range of sample types









ARESdb
MDx Content & NGS Applications

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

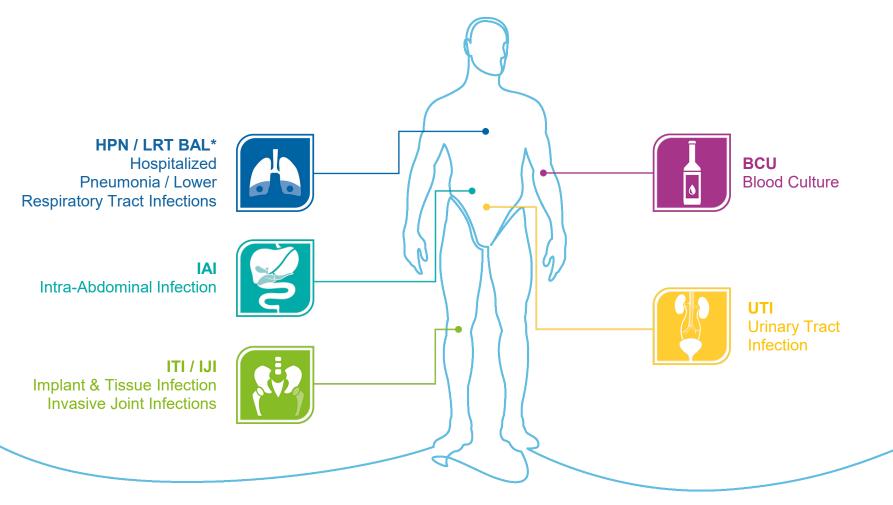
\*Unyvero A30 RQ Analyzer in development, latest design concept; final product may differ.

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



## **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	<b>!</b>	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
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
UTI		Severe cases of Urinary Tract Infections	103 targets, pathogens (88) and antibiotic resistance markers (15)	Midstream urine, suprapubic aspiration, tissue	CE-IVD marked

<sup>\*\*</sup>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



## **Providing Clear Direction**

- FDA-cleared, sample-to-answer, in less than 5 hours with just about 2 min hands-on time
- Direct from native specimen, FDA-cleared for bronchoalveolar lavage fluids and tracheal aspirates
- Multiplex PCR with array detection
- Detects the most clinically relevant pathogens (incl. atypicals) and antibiotic resistance markers associated with lower respiratory tract infections including pneumonia
- Broadest carbapenemase resistance coverage
- The only FDA-cleared LRT panel that detects Pneumocystis jirovecii
- Critical information for life-saving treatment decisions





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# 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 Such As...**

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



### Identifies...

a Broad Panel of Resistance Genes, Spanning 9 Antibiotic Classes



#### Tests...

Directly from Pure, Isolated Colonies (FDA Clearance Decision Pending), Multiplex PCR from Bacterial Isolates to results in under 3 hours



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



# Unyvero A30 RQ Rapid sample-to-answer testing platform in development



#### Platform available for partnering



### **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**

- 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



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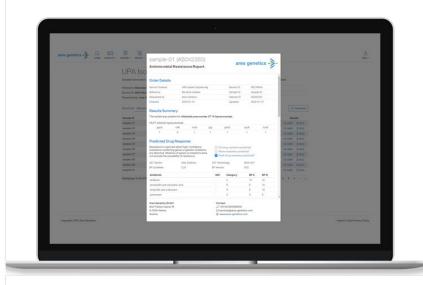


## **Ares Genetics & ARESdb\***



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





#### **Global ARESdb Database**

- Unique Knowledgebase on Antibiotic Resistance Markers building 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

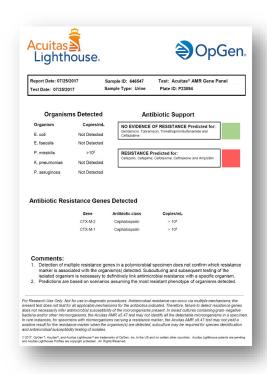
First RUO applications launched through NGS service laboratory and cloud platform

Partners and customers include globally leading IVD & pharma companies and national agency

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



# Acuitas Lighthouse®: Diagnostics data management platform for antibiotic resistant pathogens\*



Rapid molecular antibiotic resistance prediction



Cloud-based bioinformatics platform powers our ability to trace AMR in real-time with the potential to change the landscape of clinical infectious disease management and improve outcomes for patients



Successfully met all development milestones under 1st year contract Expanded the partnership for 2nd year contract term – Re-started testing post COVID-19 related pause at NY sites –
Ramp-up of testing volume in Q4-20 and 2021 to date

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



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## **Dual commercial model**

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



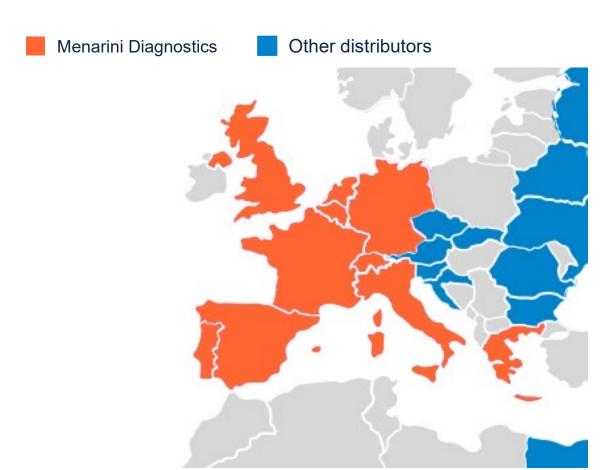
# Expanding global commercial reach though direct sales in U.S. and via global distributors

- Direct sales in the U.S.
- European distribution through Menarini Diagnostics
- China distribution through Beijing Clear Biotech
- 27 distributors covering 46 countries in EMEA, LATAM, and APAC
- 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 EMEA markets and additional product lines



# **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 EMFA countries

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## OpGen's strategic rationale and benefits



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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
- Cash raised via ATM and warrant exercises through 2020 \$25.3 million
- ATM gross capacity at end of 2020 \$5.4 million (paused for 90-day lock-up post PIPE closing)
- Access to additional EUR 5 million tranche in non-dilutive debt financing for COVID-19 related R&D from the European Investment Bank (EIB)

### **Capital Structure - Shares Outstanding**

- Common Stock ~25.1 million shares (as of December 31, 2020)
- Warrants ~5.2 million (warrants avg. exercise price \$2.00)
- Equity Awards ~1.5 million (includes grants of 1.3 million options granted to BoD and Executives in Sept 2020)
- Fully Diluted Shares Outstanding ~31.8 million shares



## **Operations**

#### **Facilities**

- 20,000 sq. ft. Corporate HQ and FDA registered R&D / manufacturing facility 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

### **Employee count:**

- Approximately 110 employees globally:
  - ~57 R&D, Operations, SW & Bioinformatics
  - ~20 Manufacturing, QM /QA /QC & RA
  - ~18 Sales & Marketing
  - ~15 General & Administration



# **OpGen Executive Leadership Team and Board**

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



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)

**Evan Jones** 

Mario Crovetto

Don Elsey

Prabhavathi (Prabha) Fernandes, Ph.D.

Oliver Schacht, Ph.D. (CEO)



## Recent newsflow

## OpGen has recently announced several key updates and milestones

- OpGen reports preliminary unaudited FY 2020 combined pro forma revenues of \$ 5.2 million and provides busines update
- OpGen subsidiary Curetis and Annar enter exclusive distribution agreement for Unyvero products in Colombia
- OpGen announces data from 1,400 patient sample multicenter publication showing Unyvero LRT BAL Panel provides accurate detection
  of common agents of bacterial pneumonia and of *Pneumocystis jirovecii* in bronchoalveolar lavage (BAL) fluid
- OpGen group company Ares Genetics extends collaboration with #1 global generics manufacturer Sandoz
- OpGen closes \$ 10 million PIPE financing with "at the market pricing"
- Ares Genetics commercially launches NGS-based antibiotic resistance testing service for native specimens and receives bulk order from public health agency
- Unyvero platform and product portfolio to be expanded beyond lower respiratory tract infections such as pneumonia (LRT / LRT BAL) to
  include complicated urinary tract infections (cUTI) and invasive joint infections (IJI) in the U.S.
- Product portfolio going forward to be centered around rapid, molecular diagnostic platform offerings and increased focus on value added bioinformatics solutions, including Ares Genetics' NGS-bases and AI-powered AMR and AST prediction capabilities.
- Focus on the pending Acuitas AMR Gene Panel (isolates) FDA clearance and subsequent U.S. commercial launch
- Discontinue Acuitas AMR Gene Panel (urine) clinical trial and discontinue FISH product line globally by mid-2021
- Curetis has successfully obtained CE IVD marking of its proprietary, rapid SARS CoV-2 PCR test kit



# Upcoming milestones, newsflow & catalysts

## **Unyvero & Acuitas® rapid molecular tests**

- U.S. FDA clearance decision Acuitas® AMR Gene Panel (isolates) once FDA resumes review of Al-letter response post COVID-19 related FDA staffing surge and timeline extension
- Commercial launch of Acuitas<sup>®</sup> AMR Gene Panel (isolates) in the U.S. upon obtaining FDA clearance
- Clinical data and publications
- Clinical trial updates and regulatory submissions for Unyvero UTI and IJI products
- China NMPA approval and subsequent commercial launch for Unyvero platform and pneumonia test
- Unyvero A30 RQ development milestones and partnering opportunities

#### **Ares Genetics**

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



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