# OpGen
# Corporate Overview

January 10, 2022

# 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 our 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 services 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, the continued realization of expected benefits of our business combination transaction with Curetis GmbH, the success of our commercialization efforts, the continued impact of COVID-19 on the Company’s operations, financial results, and commercialization efforts as well as on capital markets and general economic conditions, 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 press release and speak only as of the date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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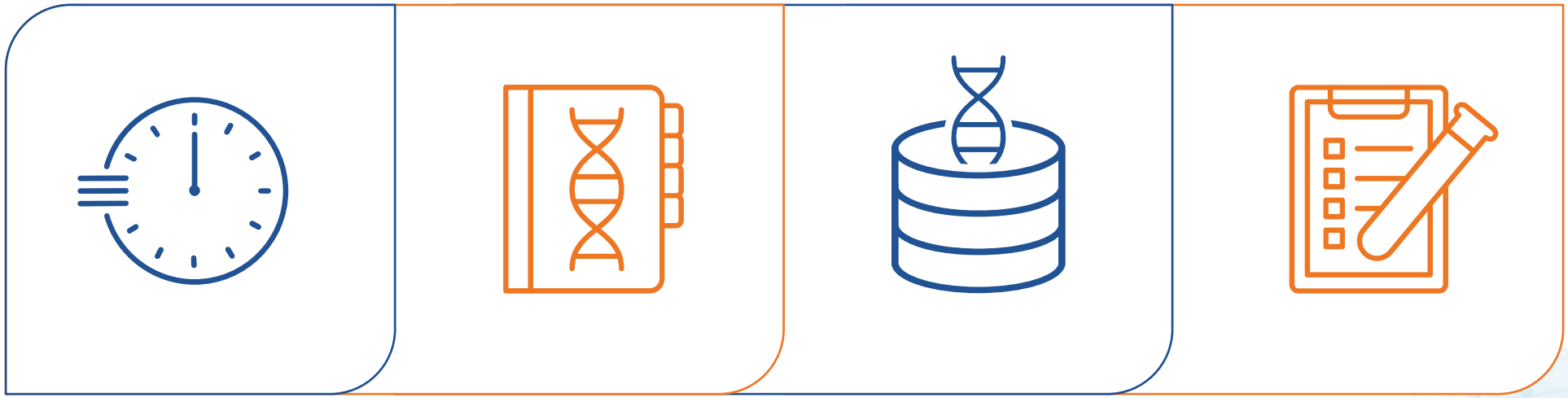
# OpGen Overview

## Striving to innovate molecular microbiology




Rapid Pathogen Detection For Life Threatening Infections

Broad Pathogen & Antimicrobial Resistance (AMR) Marker Coverage

AI-Powered AMR Prediction & Bioinformatics

Sample-To-Answer Platforms

# 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 AMR Gene Panel


- FDA-cleared Acuitas AMR Gene Panel for isolates
- Supports targeted antibiotic decision making & ASP program
- Enhances diagnostic capabilities to manage patients with AMR days earlier than conventional AST

### 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 microbiology, IVD & pharma companies, as well as U.S. based CLIA Lab / CRO

# 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.

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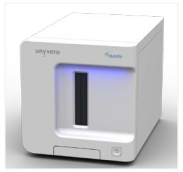
# Sample-to-answer high-throughput testing capabilities

## Innovating molecular microbiology through proprietary platforms and content

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

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 knowledge-bases**

Acuitas AMR Gene Panel


**Acuitas**
**MDx Content**

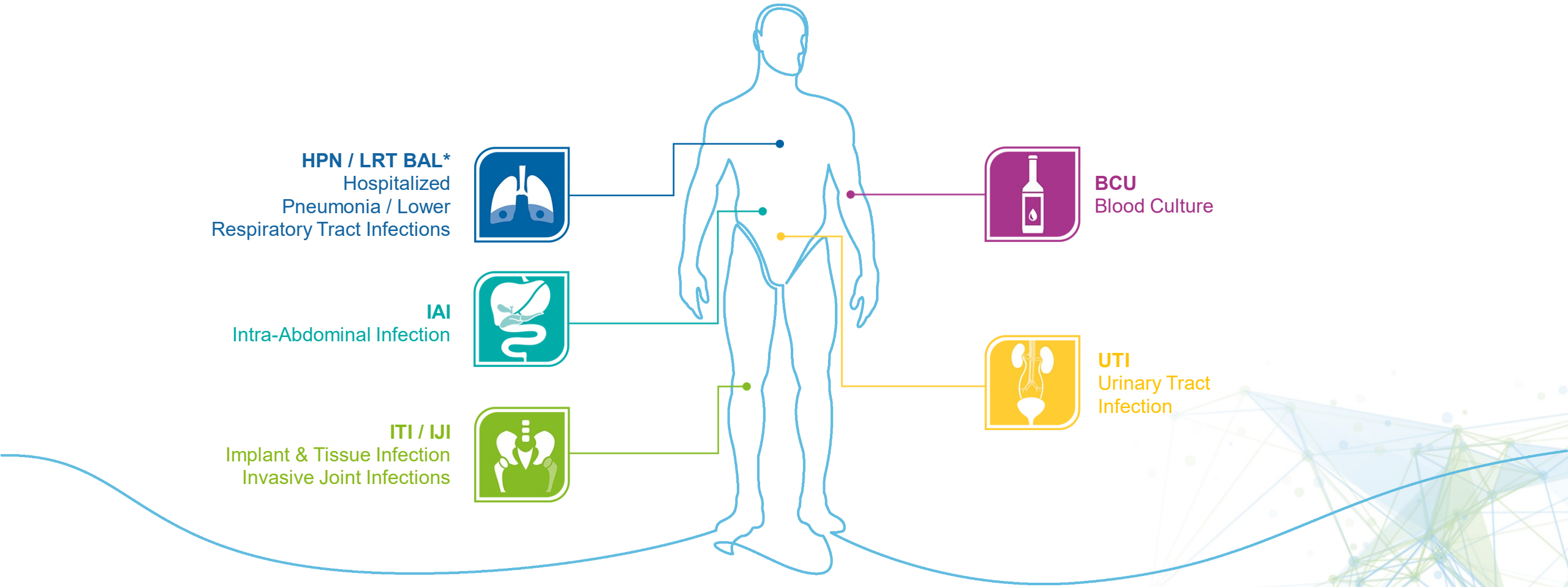
ares genetics
an OpGen group company


**ARES Genetics**
**ARESdb & NGS Applications**

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

unyvero

| Cartridge | Indication area | Number of targets covered | Sample types | Clearance status |
|---|---|---|---|---|
| HPN* | Severe cases of Pneumonia | 48 targets***<br>pathogens (29) and<br>antibiotic resistance markers (19) | Sputum, broncho-alveolar lavage, tracheal aspirate | CE-IVD marked<br>Singapore (HAS)<br>Thailand<br>Malaysia |
| LRT &<br>LRT BAL | Lower Respiratory Tract Infections | LRT (LRT BAL): 46 (47) targets****<br>pathogens 36 (37) and<br>antibiotic resistance markers 10 (10) | LRT: Tracheal aspirates<br>LRT BAL: Bronchoalveolar Lavage (BAL) | LRT: FDA cleared (4/2018)<br>LRT BAL: FDA cleared (12/2019) |
| ITI | Severe cases of Implant and Tissue Infections | 102 targets<br>pathogens (85) and<br>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<br>pathogens (88) and<br>antibiotic resistance markers (15) | Midstream urine, suprapubic aspiration, tissue | CE-IVD marked |
| BCU** | Bloodstream infections | 103 targets<br>pathogens (86) and<br>antibiotic resistance markers (17) | Positively flagged blood cultures | CE-IVD marked<br>Singapore (HAS)<br>Thailand |
| IAI | Severe Intra-Abdominal Infections | 130 targets<br>pathogens (105), toxins (3) and<br>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

## FDA-cleared AMR Gene Panel allows testing for a comprehensive panel of 28 genetic AMR markers in isolated bacterial colonies from 26 different pathogens

### Detects AMR Genes in Most Deadly Superbugs

*E. coli, K. pneumoniae, P. mirabilis, P. aeruginosa, E. faecalis*, as well as in several others:
*C. freundii* complex, *C. braakii, C. freundii, C. koseri, C. werkmanii, C. youngae, E. cloacae* complex, *E. asburiae, C. cloacae, E. hormaechei, E. kobei, E. ludwigii, K. aerogenes, K. michiganensis, K. oxytoca, K. quasi-pneumoniae, K. variicola, M. morganii, P. rettgeri, P. stuartii, R. ornithinolytica, R. planticola, S. marcescens*

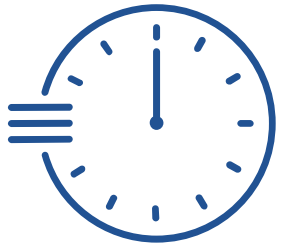
### Identifies

Broad panel of resistance genes

Spanning 9 antibiotic classes

Valuable diagnostic tool that informs about potential AMR patterns early and supports appropriate antibiotic treatment decisions

### Results under 3 hrs



Directly from pure isolated colonies

Multiplex PCR results in under 3 hours

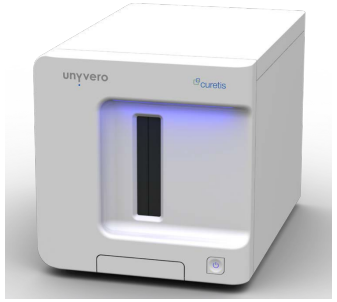
FDA cleared

# Unyvero A30 *RQ*

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

### Key Design Features

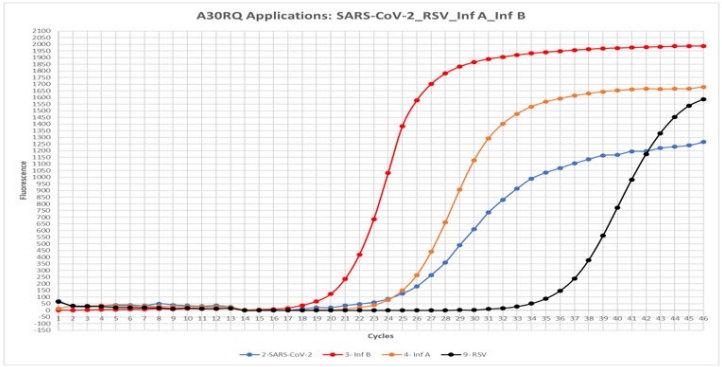
- Fully integrated, closed, sample-to-answer MDx platform
- Universal real-time PCR technology for low- to mid-plex testing
- Flexible cartridge fluidics for numerous chemistries and assay formats
- Fast turn-around time from ~30 to ~90 minutes
- Light-weight, stackable benchtop design with small footprint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

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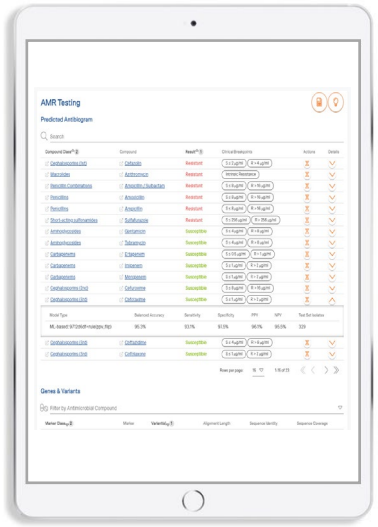
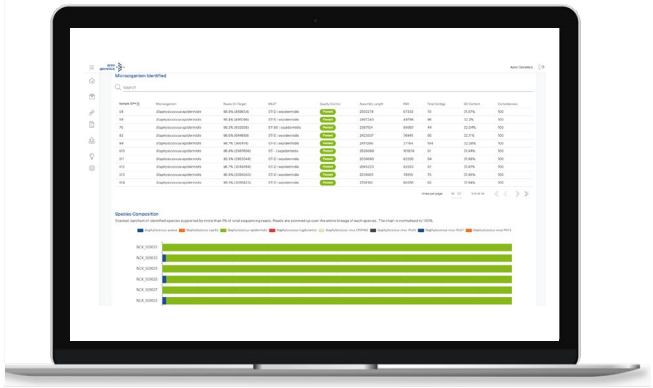
# Ares Genetics: AI-powered bioinformatics capabilities and services

**ARESdb*** proprietary AI-powered AMR knowledge base for molecular microbiology, **AREScloud** commercial web application that offers an advanced solution for infection prevention and infection control, and **NGS laboratory service**



## 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 > 78,000 pathogens and associated resistance data for > 100 antibiotics

## ARESCloud

- An accurate and user-friendly bioinformatics portal for genomic surveillance of pathogens and AMR
- Automatically converts isolate bacterial genome data from short read and long read NGS platforms into actionable intelligence on pathogens, reporting pathogen ID, AMR, antibiogram prediction, and other information relevant for infection prevention and control
- The highly accurate prediction of antibiograms directly from bacterial genome data can transform how we control healthcare-associated infections

## First RUO applications launched

- Through NGS service laboratory and cloud platform

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

# Ares Genetics: Strategic collaborations and partnerships

## Further increasing the value of ARESdb* and growing its proprietary contents

### Global network of partners and customers include

- Globally leading microbiology, IVD & pharma companies and national agencies
- Recently closed strategic database access transaction
- Qiagen RUO partnership is global and non-exclusive
- Sandoz master service agreement extended to January 2025 and expanding AMR collaboration
- Recently added partnerships with UPMC as well as a major U.S. CRO and CLIA lab

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# OpGen's strategic positioning and benefits

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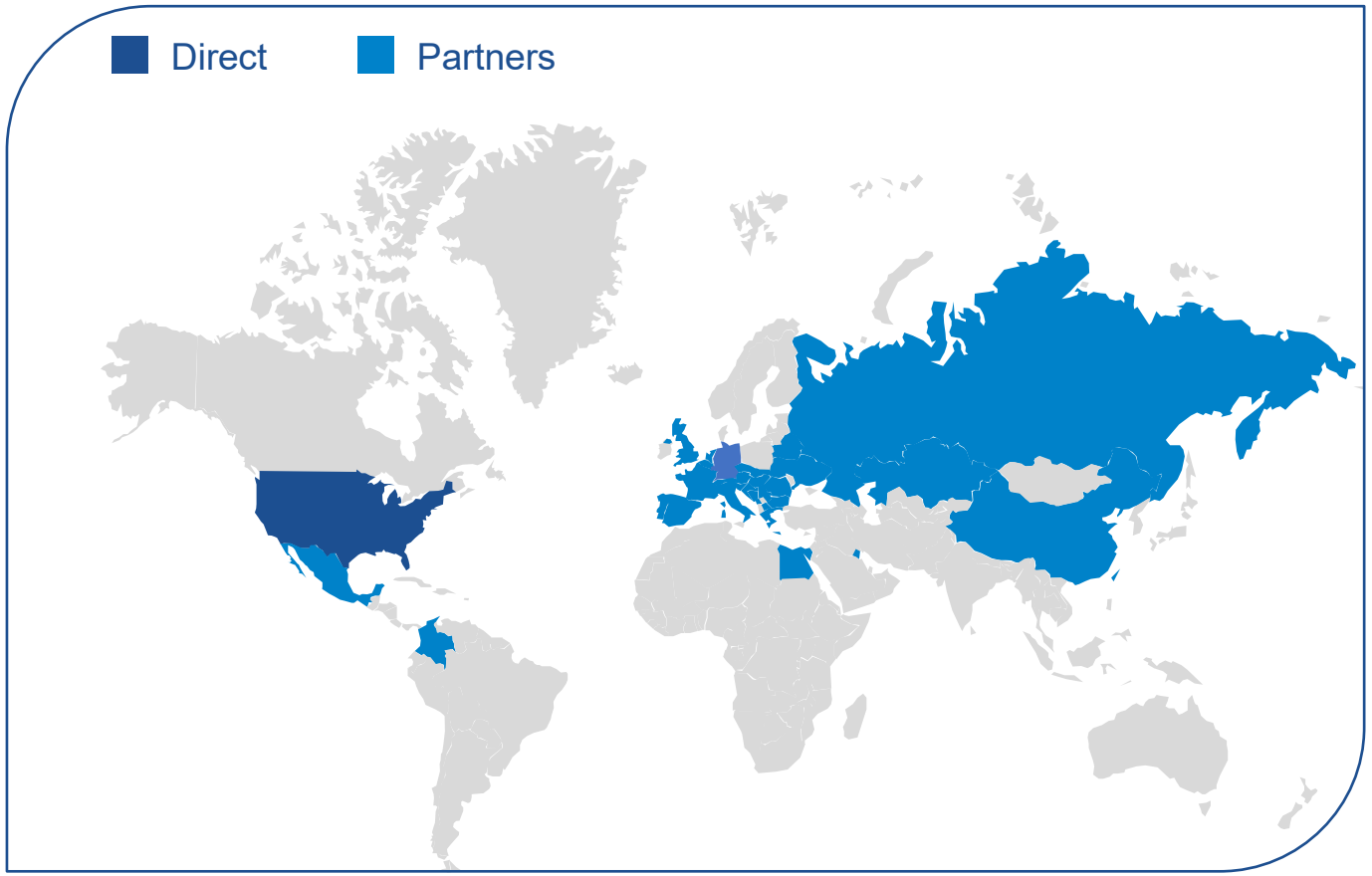
# Dual commercial model

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

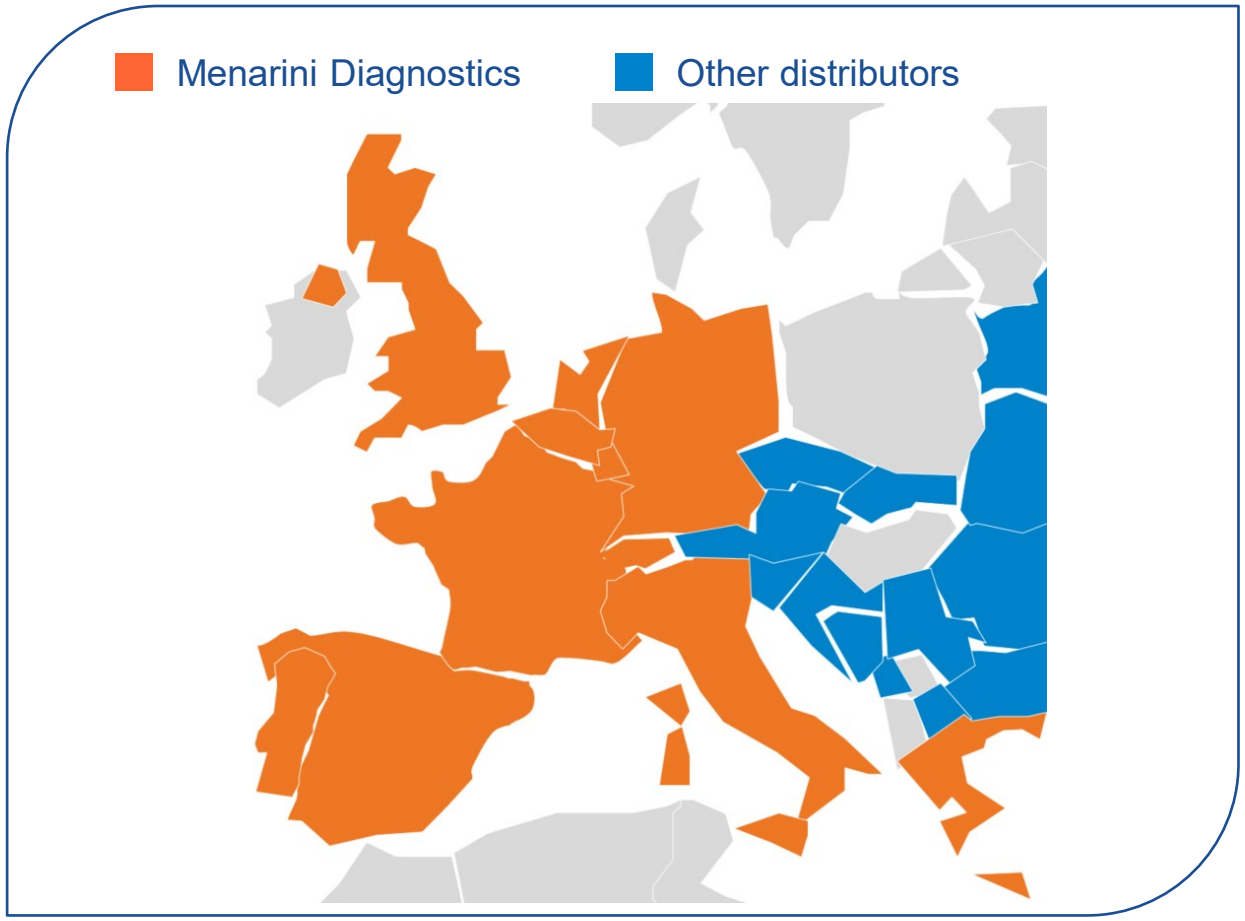



**Expanding global commercial reach though direct sales in U.S. and via global distributors**

- Direct sales in the U.S.
- European distribution through Menarini Diagnostics
- China distribution through Beijing Clear Biotech post NMPA clearance of pneumonia cartridge (pending)
- Distributors covering many countries in EU, ME, LATAM, and Asia
- Recently obtained full regulatory clearance for Unyvero system and several cartridges in Colombia

# 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

A.MENARINI diagnostics

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# Financial considerations

## Revenue (preliminary, unaudited)

- FY 2021 revenues of approx. $ 4.3 million
- Q4-2021 revenues of approx. $ 1.4 million

## Cash position

- Strong cash position: approximately $ 36.1 million as of 12/31/2021
- Raised $ 15 million in Registered Direct offering of preferred stock with single U.S. healthcare-focused institutional investor in October 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 2021 approximately $ 51.2 million
- S-3 universal shelf filed and effective for up to $ 150 million

## Capital structure – shares outstanding

- Common Stock ~46.5 million shares (as of 12/31/2021) – following conversion of all preferred stock into common shares in December 2021
- Common Warrants ~16.2 million (of which 7.5 million at $ 2.05 per share are from October 2021 financing)
- Equity Awards ~2.0 million (as of 12/31/2021)
- Fully Diluted Shares Outstanding ~64.7 million

# 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

Albert Weber joined as new CFO of OpGen

## Leadership Team

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

**Johannes (Jan) Bacher**
Chief Operating Officer,
Managing Director, Curetis

**Albert Weber**
Chief Financial Officer,
Managing Director, Curetis

**Arne Materna**
Managing Director & CEO,
Ares Genetics

**Faranak Atrzadeh**
Chief Marketing & Scientific Affairs Officer

## Board Members

William (Bill) Rhodes (Chairman)

Prabhavathi (Prabha) Fernandes, Ph.D.

Don Elsey

Mario Crovetto

Oliver Schacht, Ph.D. (President & CEO)

# Recent news flow

## OpGen recently announced several key updates and milestones

- Albert Weber joins as OpGen's new CFO
- Theo deVos joins as SVP Corporate Development and Operations for Ares Genetics in the U.S.
- OpGen subsidiary Ares Genetics and Sandoz extend their services frame agreement until January 2025
- OpGen's partner BCB achieves IRB approval for all 3 clinical trial sites in China
- OpGen's Unyvero platform and several cartridges (incl. HPN, ITI, IAI) receive full regulatory approval in Colombia and first commercial sales are made to distribution partner Annar Dx
- OpGen announces preliminary unaudited FY 2021 financials with $ 4.3 million revenue and $ 36.1 million cash at 12/31/2021
- OpGen subsidiary Ares Genetics announces strategic database access transaction
- OpGen subsidiary Ares Genetics launches AREScloud
- OpGen announces closing of $15 Million registered direct offering
- OpGen receives FDA 510(k) clearance for Acuitas AMR Gene Panel
- OpGen initiates clinical trial for Unyvero Urinary Tract Infection Panel
- OpGen announces data from prospective randomized controlled multicenter clinical study using the Unyvero HPN panel for hospitalized patients with suspicion of pneumonia
- OpGen wins Chinese NMPA approval for the Curetis Unyvero System

# Upcoming milestones, news flow & catalysts

## Unyvero & Acuitas rapid molecular tests

- Commercial roll-out of Acuitas AMR Gene Panel in the U.S.
- China NMPA: 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 trial updates and regulatory submissions for Unyvero UTI and IJI products
  - UTI: interim analysis of clinical trial data
  - UTI: completion of clinical trial and full data read out towards FDA submission
  - IJI: initiate clinical trial and update on design
- Unyvero A30 *RQ* further development milestones and partnering / licensing opportunities

## Ares Genetics

- Several upcoming commercial launches of services and solutions
- Further partnering / licensing opportunities
- Clinical data and publications

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# Thank You!