Disruptive Technology to Guide Precision Antibiotic Therapy

NASDQ: OPGN

June 2019

Forward Looking Statement

This presentation includes statements relating to the company's Acuitas® AMR Gene Panel products, Acuitas Lighthouse® Software, FDA cleared QuickFISH® products, and commercialization plans for these products and services. These statements and other statements regarding our future plans and goals constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, 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 our control, and which 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 successful development of new products and services, our ability to obtain regulatory clearances and approvals for our products and services, the rate of adoption of our products and services by hospitals and other healthcare providers, 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 (SEC). 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.

Corporate Overview

Precision medicine company focused on combatting the global antibiotic resistance crisis by leveraging molecular diagnostics, informatics, and genomic analysis

Provider of rapid and actionable information about life threatening drug resistant infections

Building global network of customers and partners to improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs

Key product Acuitas® AMR Gene Panel can detect five pathogens and 47 resistance genes, predicting resistance for 9 classes of antibiotics
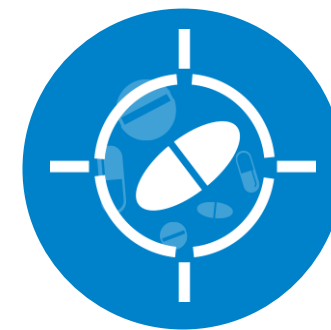
Collaborations with industry leaders to support the execution of our commercialization strategy as we work to address a $2 billion potential market for precision medicine MDRO solutions

OpGen and the Investment Opportunity

VALIDATED, DISRUPTIVE TECHNOLOGY

Collaborations with NY Dept. of Health, Merck, QIAGEN and Thermo Fisher

SIGNIFICANT MARKET OPPORTUNITY

Working to address a $2B global market in need of novel solutions

ADDRESSING MAJOR GLOBAL CRISIS

Multi-drug resistance causes $20B in excess direct healthcare costs and 700,000 deaths annually[1]

BUILDING COMMERCIAL MOMENTUM

Key commercial milestones throughout 2019, including two anticipated regulatory approvals

EXPERIENCED TEAM

Management has proven track record of value creation for diagnostic, genomic and pharma companies

Addressing the Significant and Growing Global Challenge of Multi-drug Resistance

Antibiotic resistance is one of the biggest public health challenges and leads to a significant number of patient infections, hospitalizations and deaths. It is often caused by antibiotics use or the spread of the resistant strains of bacteria

700,000

Deaths each year from antimicrobial resistance[1]

50,000

Deaths annually in the US and Europe from drug-resistant infections[1]

$20 Billion

Excess direct healthcare costs in the US from drug-resistant infections[2]

1. O'Neill, Jim. "Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations." *Review on Antimicrobial Resistance* (December 2014)
2. "Antibiotic Resistance Threats in the United States." Prepared by the CDC (2013)
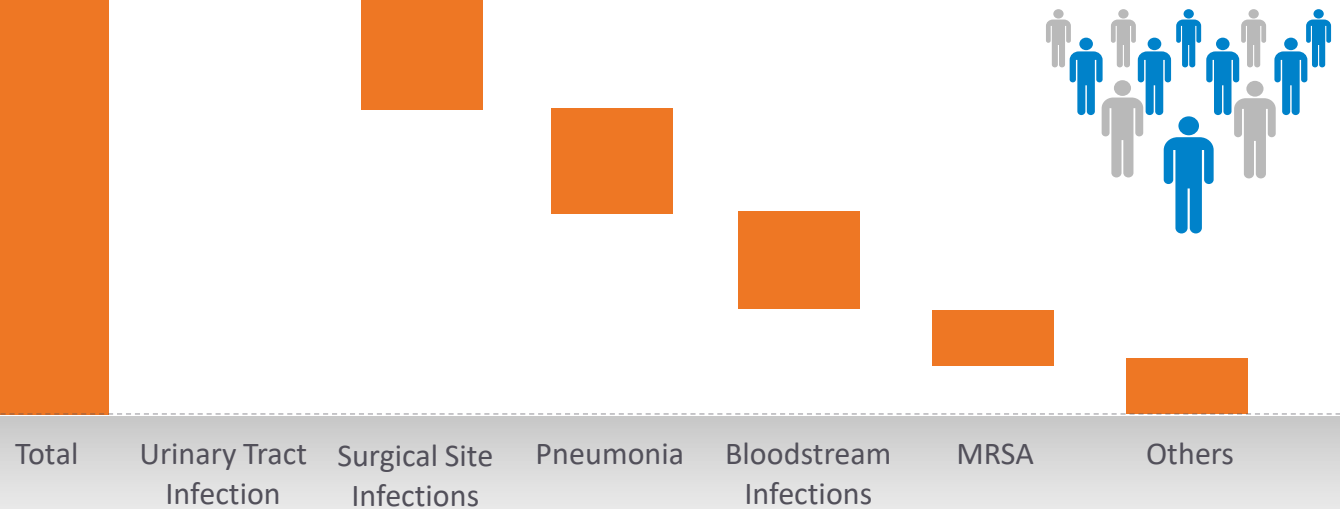
Large Market for Precision Medicine MDRO Solutions

Lead Product: Complicated urinary tract infections (cUTI), Clinical Isolates.
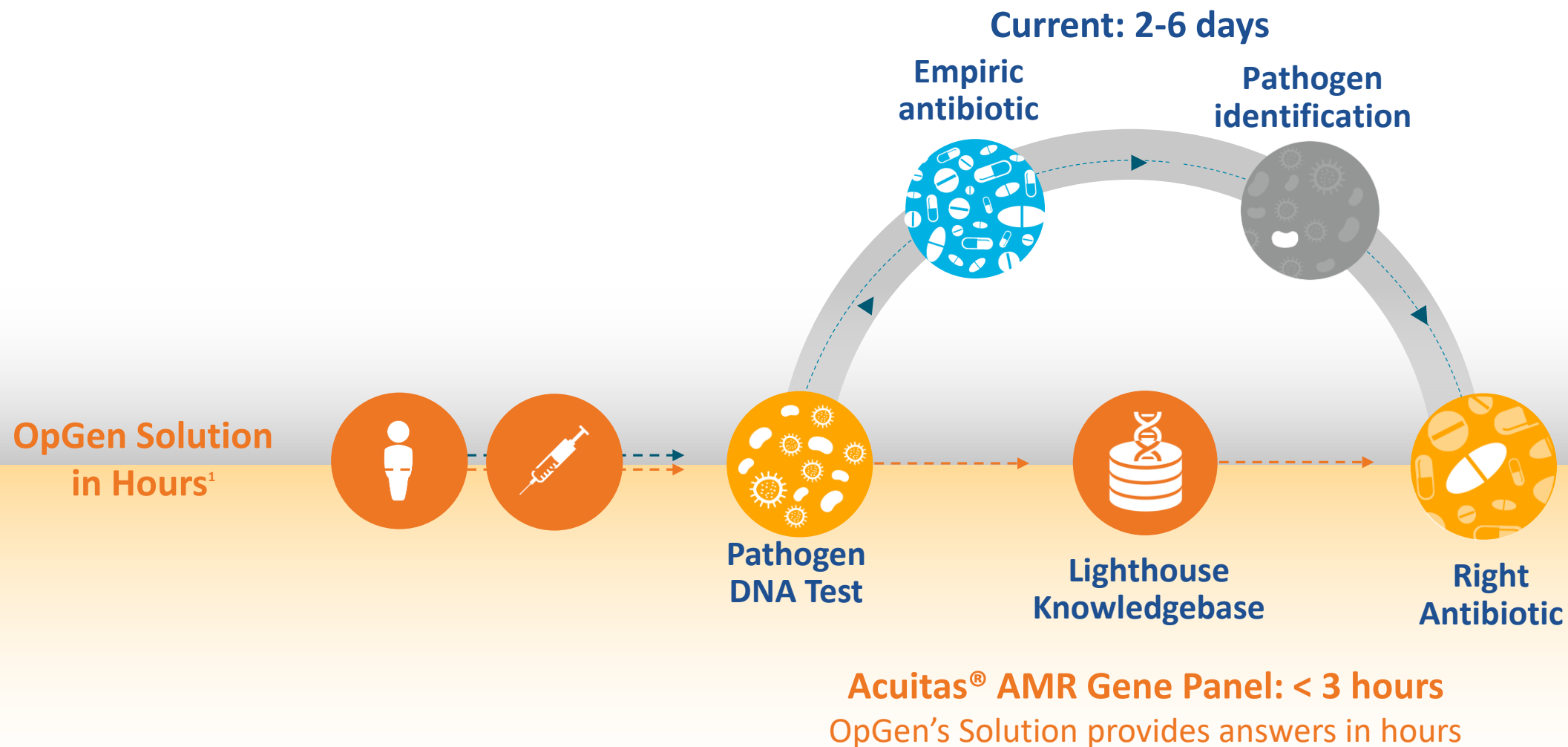*Second Product Target: Lower Respiratory Infection*

- $2B Global Market[1]

- 19% CAGR: One of the fastest growing U.S. molecular diagnostic segments[1]

- Multiple high-acuity patient types

Global Hospital Acquired Infection Testing Revenue 2012[1]

$2.2 Billion

| Total | Urinary Tract Infection | Surgical Site Infections | Pneumonia | Bloodstream Infections | MRSA | Others |

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Our Solution: Rapid, Precision Medicine Antibiotic Decision Making

Current: 2-6 days

Empiric antibiotic

Pathogen identification

OpGen Solution in Hours[1]

Pathogen DNA Test

Lighthouse Knowledgebase

Right Antibiotic

Acuitas® AMR Gene Panel: < 3 hours
OpGen's Solution provides answers in hours

1. For Research Use Only. Not for use in diagnostic procedures.

A Proprietary, Curated MDRO Genomic Knowledgebase

Data Sources *feed the* **OpGen Analytics Models** *which power the* **Commercial Applications**

Merck SMART Pathogen Archive (>250,000 samples)

Thousands of pathogens from hospitals worldwide

Drug susceptibility testing

Genomic analysis, DNA sequencing

Patient hospital data

Lighthouse Knowledgebase

Insights to power rapid diagnostics and optimized patient–specific interventions

Healthcare management information

Pharma insights

15,000 clinical isolates including results from 10,000 SMART isolates
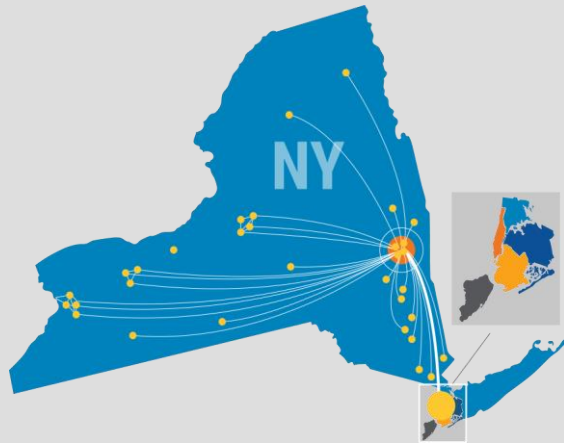
Productive Industry Relationships for Precision Medicine MDRO Solutions

Activities with top industry players provide validation for technology and bolster commercialization strategy

NY State Department of Health and ILÚM (Merck)

New York State funding for OpGen and ILÚM to build a sustainable, flexible infectious diseases reporting, tracking and surveillance tool for antimicrobial resistance that can be applied across the State. The goal is to improve patient outcomes and save healthcare dollars

QIAGEN

Use EZ1 instruments and reagent kits from QIAGEN and sell or place them with customers in the United States for use with the Acuitas® AMR Gene Panel

ThermoFisher SCIENTIFIC

Combine Thermo Fisher's real-time PCR solutions with OpGen's genomic analysis and bioinformatics technology to help healthcare providers rapidly and accurately identify bacterial antibiotic susceptibility using resistance gene profiles

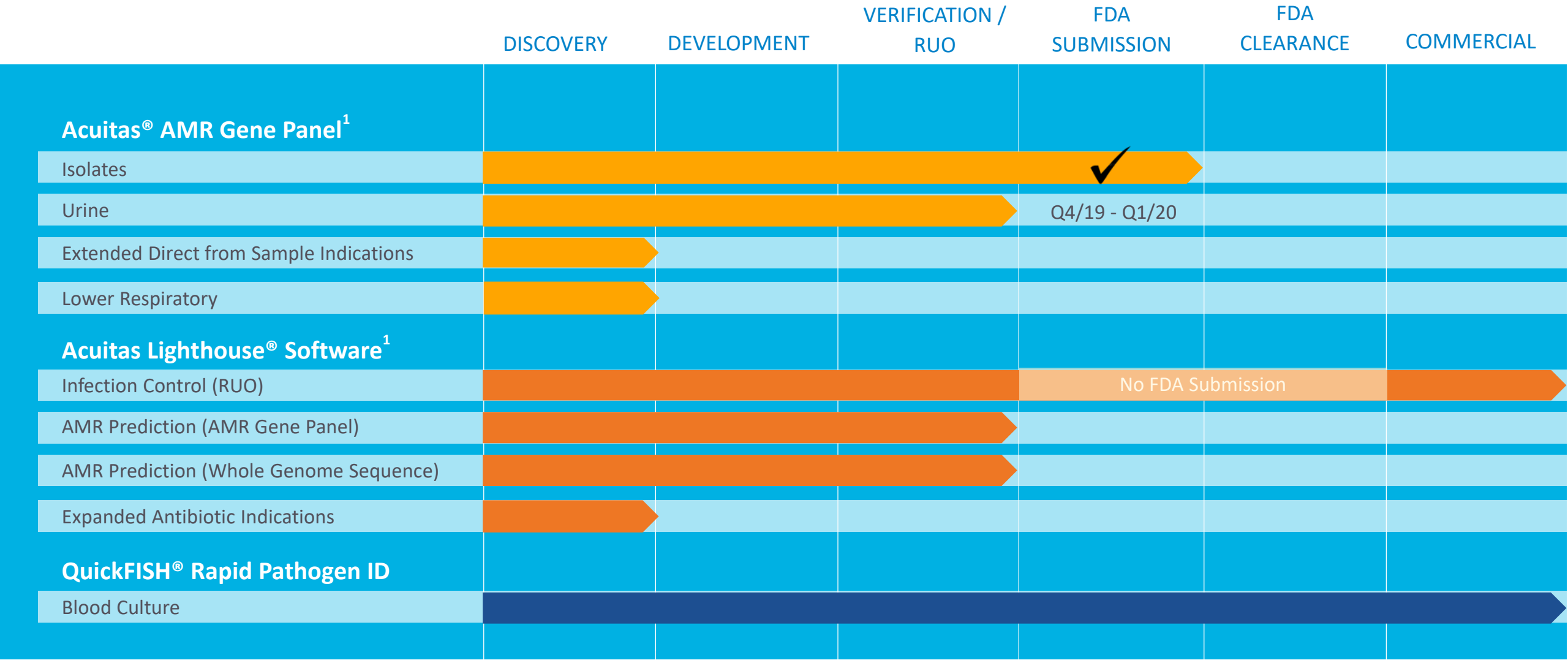**ilúm™ HEALTH SOLUTIONS**
Powering Better Outcomes

Provides mobile precision medicine and Antimicrobial Stewardship solutions that accelerate definitive therapy selection and optimize clinical decision support
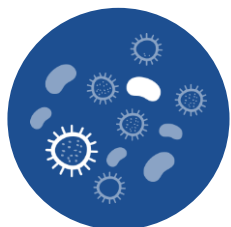
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Products and Pipeline

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Novel Product Pipeline

	DISCOVERY	DEVELOPMENT	VERIFICATION / RUO	FDA SUBMISSION	FDA CLEARANCE	COMMERCIAL
Acuitas® AMR Gene Panel[1]						
Isolates				✓		
Urine				Q4/19 - Q1/20		
Extended Direct from Sample Indications						
Lower Respiratory						
Acuitas Lighthouse® Software[1]						
Infection Control (RUO)				No FDA Submission		
AMR Prediction (AMR Gene Panel)						
AMR Prediction (Whole Genome Sequence)						
Expanded Antibiotic Indications						
QuickFISH® Rapid Pathogen ID						
Blood Culture						

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Insights Powered by Rapid Diagnostics & Bioinformatics[1]

RESULTS
< 3 hours

DETECTS
5 pathogens
47 resistance genes & mutations
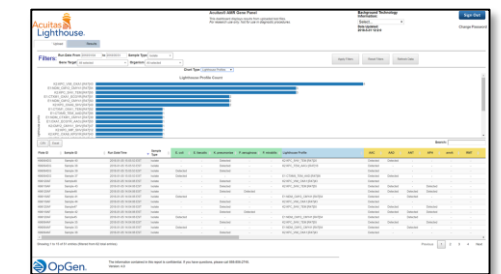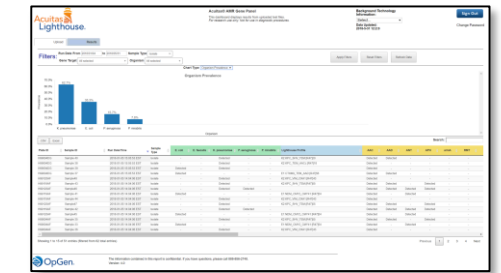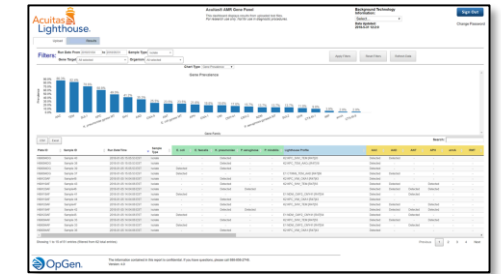
PREDICTS RESISTANCE FOR
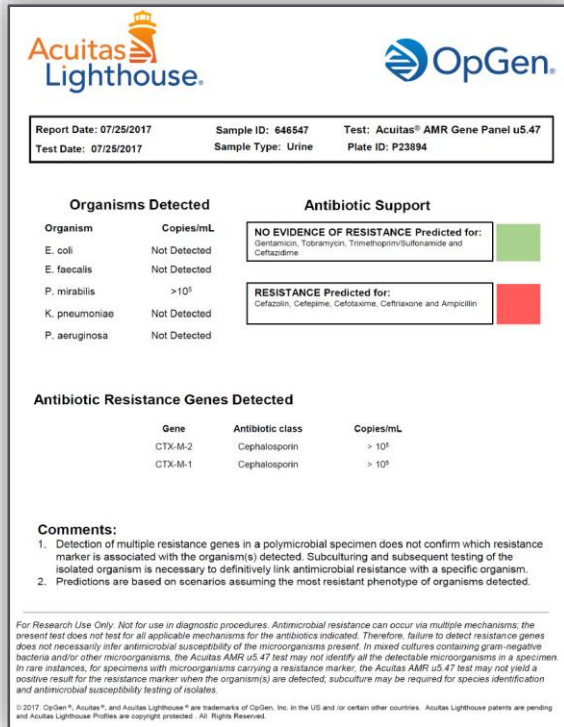12 antibiotics

SPECIMEN TYPES
Urine
Isolates

Predict Antibiotic Resistance[1] · Know Local AMR Ecosystem

Proprietary, cloud-based bioinformatics platform powers our ability to rapidly generate meaningful results that can change the landscape of clinical management and improves outcomes for patients

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Initial Focus on High Risk Patient Bacterial Isolate Testing

Blood
Respiratory
Urine
Intra Abdominal
Skin & Soft Tissue
Other

Positive Samples

MDR Confirmatory & Dx Testing

Antibiotic Therapy Decisions

Infection Control

1 million U.S. bacterial isolate potential testing opportunity[1]
90,000 estimated U.S. CRE samples annually[2]

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1. Company estimates
2. Achaogen, Inc. Estimate

Management of Complicated Urinary Tract Infections

Complicated urinary tract infections (cUTI) are increasingly difficult to treat due to rising antibiotic resistance rates. 34% annual ESBL resistance increase 2010-2014

cUTI Resistance Profile

1.3 million[1]
complicated UTIs (cUTI) per year

14%	35%	3-14%
ESBL (Extended-spectrum b-lactamase-resistant)	Fluoroquinolone Resistant	Cephalosporin or Penicillin/ b-lactamase inhibitor resistant
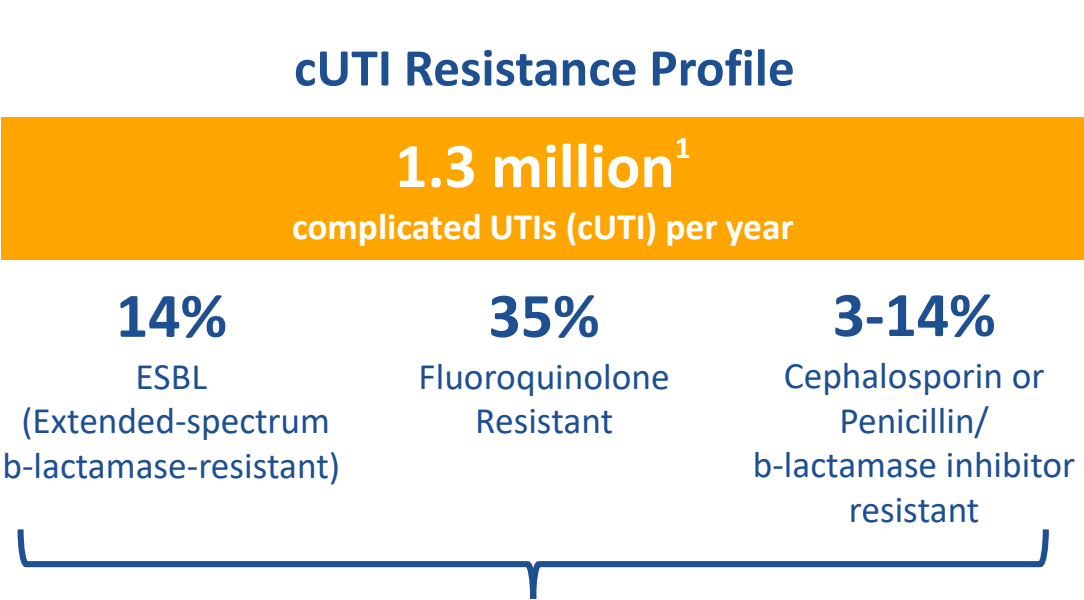
- **Resistant to 3rd generation cephalosporin antibiotics, require last-resort carbapenem or restricted antibiotics**
- **Patient treatments can range from $25,000-60,000[2]**

cUTI Management

	< 3 Hours	15 Hours	16 Hours	25 Hours+
Acuitas®	UTI +/- ID/ Resistance			
Culture + MALDI + AST		UTI +/-	ID	AST

OpGen's Acuitas® workflow provides Pathogen ID, level and antibiotic resistance profile in <3 hours

Vs.

Current patient work-up provides full lab results in 48-72 hours

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Acuitas Lighthouse® Antibiotic Resistance Prediction

*Data supporting prediction of antibiotic resistance using Acuitas AMR Gene Panel and Acuitas Lighthouse Software was published in peer-reviewed journal **Antimicrobial Agents and Chemotherapy***

- Evaluated more than **7,500 highly antibiotic-resistant clinical isolates** of *E.coli, K. pneumonia, P. mirabilis*, and *P. aeruginosa*
- Isolates selected from Merck's SMART surveillance network, including **two million data points** from patients globally
- **41 proprietary prediction algorithms** coded into the Acuitas Lighthouse Software

	Sensitivity	Specificity	Accuracy	Positive Predictive Value (PPV)	Negative Predictive Value (NPV)
E. coli	91%	90%	91%	91%	85%
K. pneumonia	90%	83%	88%	93%	68%

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Acuitas® AMR Gene Panel

Molecular test detects five pathogens and 47 resistance genes, predicting resistance for 12 antibiotics

Pathogen Targets

- *E. coli*
- *E. faecalis*
- *K. pneumoniae*
- *P. mirabilis*
- *P. aeruginosa*

Semi-quantitates detected organisms and resistance genes to one of the following levels (in copies per ml of urine): $<10^3$, 10^4, 10^5, 10^6, $>10^6$

No semi-quantitation for colony isolates

Predicting Antibiotic Resistance in Gram-Negative Bacilli by Rapid Detection of Resistance Genes. G.T. Walker, et al. ASM/ESCMID Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance. 2017

Species Identification

ID Assay	Isolates Correctly Identified	Expected Cross-Activity
E. coli	88 of 88 (100%)	some *Shigella* spp.
E. faecalis	65 of 65 (100%)	
K. pneumoniae/variicola	87 of 88 (99%)	
P. aeruginosa	91 of 91 (100%)	
P. mirabilis/vulgaris	84 of 85 (99%)	

Organisms Spiked per ml Urine (x-axis), **Organisms Detected per ml Urine** (y-axis)

1. For Research Use Only. Not for use in diagnostic procedures.

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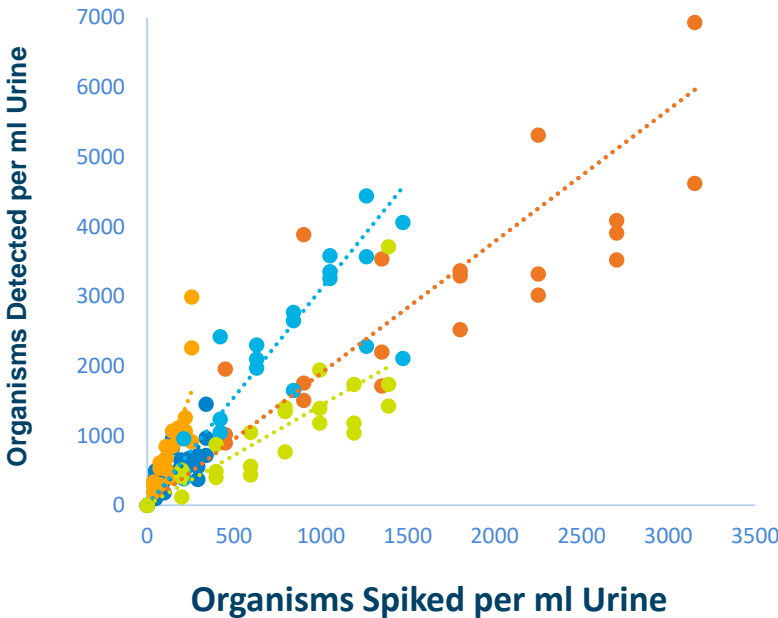
Acuitas® Product Portfolio Regulatory Pathways

	AMR Gene Panel (Isolates) 510(k), FDA Class II (FDA Submission May 2019)	AMR Gene Panel (Urine) *De Novo* 510(k), FDA Class II[2] (FDA Submission Q4 2019 – Q1 2020)	Acuitas Lighthouse Software *De Novo* 510(k), FDA Class II[2]
Indication[1]	Identification of bacterial nucleic acids and gene sequences associated with antimicrobial resistance in pure bacterial colonies[3] and detection of forty-seven gene sequences associated with antimicrobial resistance to nine antibiotic classes[3].	Aid in the diagnosis of specific agents of urinary tract infections (UTI) for patients at risk of complicated UTI (cUTI). Semi-quantitation of Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa and Enterococcus faecalis and forty-seven gene sequences associated with antimicrobial resistance to nine antibiotic classes[4]	Evaluation of data from the Acuitas AMR Gene Panel u5.47 assay using a series of predictive models and, based on species identified[5] to predict resistance for nine classes of antibiotics[4]
Sample Type	Isolates from any primary sample (blood, urine, lung, wounds, other)	Urine	
Clinical Trial	~900 stock isolates, 50 fresh isolates, 4 sites	1,500 fresh urine samples, ~300 contrived urine samples, 5-8 sites	2,000 globally and phenotypically representative stock isolates, 1,500 urine samples and resulting isolates, ~300 contrived urine samples

1. Final labeling subject to negation with FDA upon actual Instruction for Use labeling.
2. Final classification subject to FDA determination.
3. For use with the following bacterial isolate types: *Enterobacteriaceae, Pseudomonas aeruginosa and Enterococcus feacalis*
4. Aminoglycosides, Carbapenems, Cephalosporins, Fluoroquinolones, Polymyxins, Penicillins, Sulfonamides, Trimethoprim, and Vancomycin.
5. For use with the following organisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, and Enterococcus faecalis*.

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Commercialization Strategy

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Acuitas Test and Software Commercialization

Building Total Infectious Disease Solutions
for Hospitals & Health Systems

Expanded Distribution

Acuitas Lighthouse Predictions

2020

Co-marketing Relationships

Bacterial Isolates FDA Clearance[1]

Urine (UTI) FDA Clearance[1]

80+ Hospital Accounts

2019

New York State Initiative
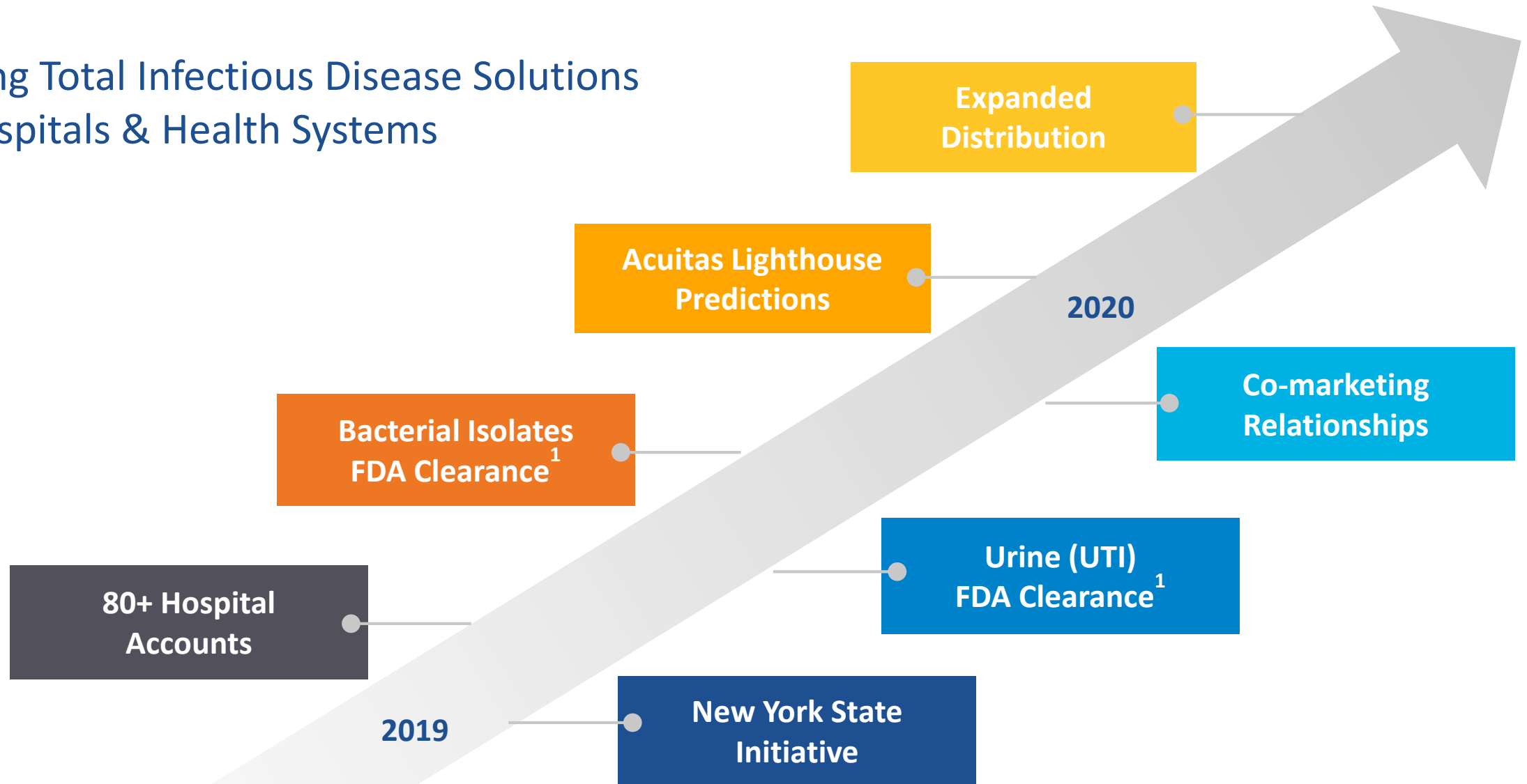
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Value-Generating Collaboration with NY Dept. of Health & ILÚM (Merck)

OpGen will work together with DoH's Wadsworth Center and ILÚM to develop an infectious disease digital health and precision medicine platform that connects healthcare institutions to DoH and uses genomic microbiology for statewide surveillance and control of antimicrobial resistance

- Implementation based on AMR Gene Panel and Acuitas Lighthouse Software
- $1.6 million Phase 1 revenue
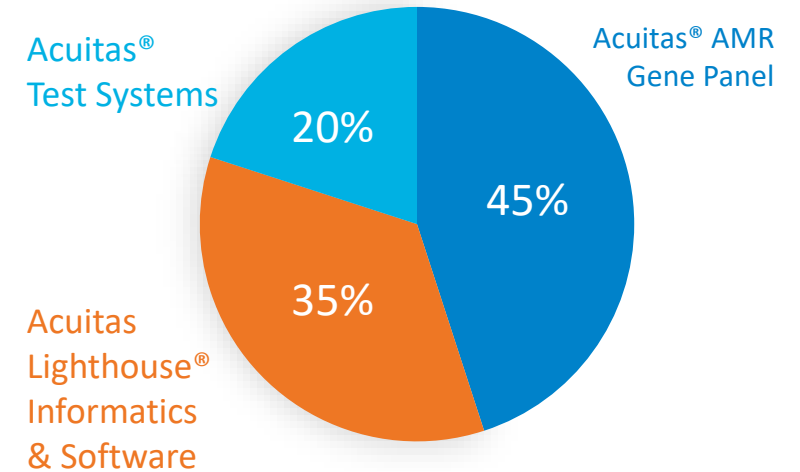- Five year revenue potential, including expansion to additional states approximately $20 million[1]

Acuitas® Test Systems — 20%

Acuitas® AMR Gene Panel — 45%

Acuitas Lighthouse® Informatics & Software — 35%

"Groundbreaking partnership between ILÚM Health Solutions, a wholly-owned subsidiary of Merck & Co, OpGen, and the New York State Department of Health to develop a state-of-the-art research program to detect, track and manage antimicrobial-resistant infections at healthcare institutions statewide."

– Gov. Andrew Cuomo, Sept. 2018

1. These numbers are solely for illustrative purposes and do not represent any actual transactions. There is no assurance we will capture any share of the estimated revenues illustrated in any of the markets.

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Infectious Disease Digital Health & Precision Medicine Platform

NYC Pilot creates critical mass of metro area accounts and revenue generation starting Q1 2019

- Hospital LDT validations and initial testing
- Customized Lighthouse Software and real time data monitoring

Q1 2019

Q2 2019

Q3 / Q4 2019

- Three Tier 1 health systems: 35 hospitals, 12,000 beds, Acuitas Lighthouse® Software and AMR Gene Panel Systems installations
- Wadsworth DoH LDT validation

- Prospective AMR Gene Panel Tests

Acuitas® Rapid Test Commercial Strategy

Economics: 300-500 bed hospital

5-10 tests per day

+

~3,000 tests per year

+

$150-$200 ASP

↓

Estimated $500 million annual U.S. revenue opportunity[1]

Key Commercialization Milestones

1H 2019

- NY State Precision Medicine Initiative
- Acuitas® AMR Gene Panel (Isolates) FDA submission

2H 2019

- Acuitas® AMR Gene Panel (Isolates) FDA clearance
- Acuitas® AMR Gene Panel (Urine) FDA submission
- Acuitas® AMR Gene Panel commercialization

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U.S. Commercial Opportunity and Expansion Plans

Expanding base of Acuitas® AMR Gene Panel Systems

- 12 system placements in Tier One Health Systems and service laboratories
- New York City Acuitas installations (3 Health Systems, 35 hospitals)

Acuitas Isolate/Urine indication initial launch

- Post FDA clearance promotional activities
- Expanded commercial organization

**South America / Colombia**

- INVIMA QuickFISH® regulatory clearance
- Clinical decision support software opportunity

U.S. Acuitas Rapid Testing Markets ($ millions)[1]	
State surveillance initiatives	$50
Direct urine testing and antibiotic resistance programs	$150
Isolate testing and expanded indications	$150
Acuitas® testing systems	$100
Total	**$450**

Developing Differentiated Precision Medicine Capabilities

OpGen is the only offering combining rapid molecular testing with fast antibiotic-resistance results[1]
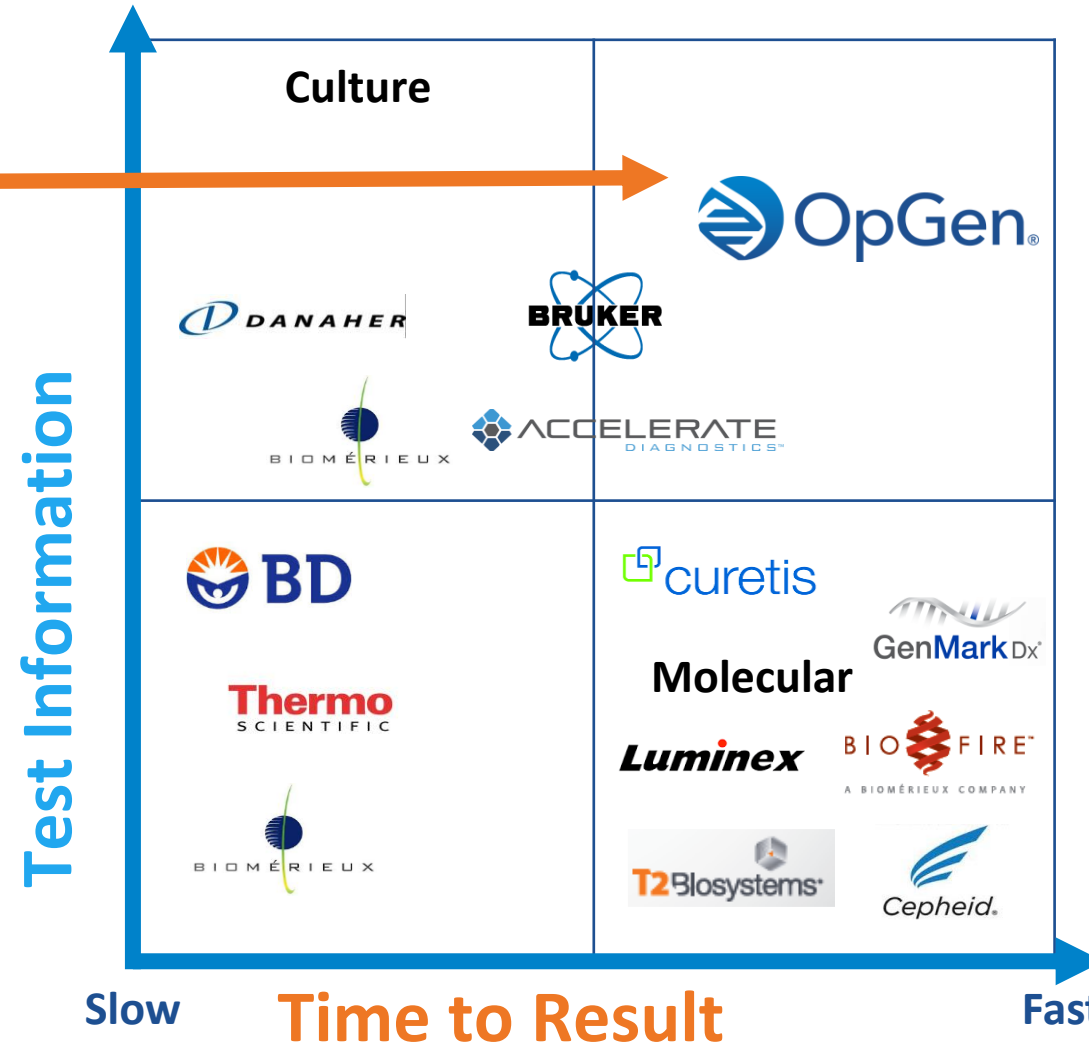
Established Molecular players are focused on pathogen detection with limited ability to do antibiotic decision making.

OpGen is paving the way by bringing a differentiated product to the diagnostics ecosystem.

Culture

OpGen

DANAHER

BRUKER

BIOMÉRIEUX

ACCELERATE DIAGNOSTICS

BD

curetis

GenMark Dx

Molecular

Thermo SCIENTIFIC

Luminex

BIO FIRE
A BIOMÉRIEUX COMPANY

BIOMÉRIEUX

T2 Biosystems

Cepheid.

Test Information

Slow ← **Time to Result** → **Fast**

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Financial and Operating Highlights

	Q1 2019 ($ Millions)	FY 2018 ($ Millions)
Revenue	$1.0	$3.0
Net Income (Loss)	($3.9)	($13.4)
Cash Balance	$6.0	$4.6

(Following March 2019 Public Offering)	Shares Outstanding	%
Common Stock	17,645,720	83%
Warrants[1]	3,525,797	16%
Equity Awards[2]	211,559	1%
Fully Diluted Shares Outstanding	21,383,076	100%

Q1 2019 Financial Highlights
- Completed isolate clinical trials
- Completed $5.4 million equity offering
- Completed first milestone on NY State contract

FY 2018 Financial Highlights
- Recurring revenue base of $2.4 million
- Completion of $860 thousand CDC Contract
- $11 million cash burn

Other Key Items
- 15,000 sq. ft. FDA registered facility (R&D & Mfg.)
- 48 Employees
- 15 Acuitas® AMR Gene Panel System placements

Guidance
- Expect growth in top line revenue from Acuitas AMR Gene Panel products (2H19)
- Anticipate recognizing the first $1 million from NY State demonstration project milestones (1H19)

1. Average exercise price - $14.84/share
2. Average option exercise price - $20.58/share

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Experienced Management Team

Evan Jones
Chairman & Chief Executive Officer

Timothy Dec
Chief Financial Officer

Vadim Sapiro
Chief Information Officer

Terry Walker, Ph.D.
SVP, R&D

Michael Farmer
VP, Marketing

Upcoming and Recent Milestones

Building momentum for commercialization throughout 2019

Q2 - Q4 19	Acuitas® Gene Panel IVD FDA submissions
1H 19	South America commercial expansion
2019	NY State demonstration project milestones
2H 19	Rapid IVD commercialization partnerships
2019	AMR Gene Panel publications/system placements
2020	Acuitas Lighthouse® IVD FDA submission
2019/2020	Acuitas® FDA clearances

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A New Light on Antibiotic Resistance

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