

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 16, 2016

OpGen, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

001-37367

(Commission
File Number)

06-1614015

(I.R.S. Employer
Identification No.)

708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878

(Address of principal executive offices, including zip code)

(240) 813-1260

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01 Regulation FD Disclosure.

On November 16, 2016, OpGen, Inc. (the "Company") is first making a corporate presentation that provides a current overview about the Company. The information provided during such corporate presentation is attached as an exhibit to this Form 8-K.

The information in this Form 8-K and the Exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit **Description**

99.1 Corporation Presentation of OpGen, Inc., November 2016

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec
Title: Chief Financial Officer

Date: November 16, 2016



CORPORATE PRESENTATION

November 2016

Forward-Looking Statement

This presentation includes statements relating to the company's Acuitas® MDRO, Acuitas Lighthouse® and QuickFISH® products and services, 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, 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.



The OpGen Opportunity

- **Uniquely positioned to address rising antibiotic resistance crisis**
 - Leader in leveraging genomics and informatics for infectious disease
- **Significant global challenge and market opportunity**
 - Equating to a >\$2 billion market in need of a solution to the infectious disease crisis and associated health care costs
- **Disruptive technologies that shift the paradigm for diagnosing and managing infectious diseases**
 - Harnessing the power of rapid diagnostics and genetic profiles for pathogens and decision-making analytics database to help deliver the right antibiotics to patients
- **Compelling data from distinguished U.S. health systems and collaborations**
 - External studies validating efficiency and cost-savings; Merck Global Health Innovation Fund investment
- **Experienced management team with a proven track record of value creation in diagnostics**
 - Supported by an operational team with strong expertise across all diagnostic disciplines



Antibiotic Resistance – A Building Crisis

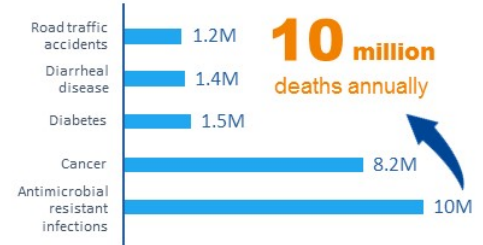
National Action Plan for Combating Antibiotic-Resistant Bacteria supports \$1B+ federal investments to combat drug resistant infections with rapid diagnostics, surveillance and accelerated discovery and development of new antibiotics

2 million
ILLNESSES IN THE
U.S. EACH YEAR¹
&
23,000
OF THESE PATIENTS DIE¹

\$20 billion

excess direct health care
costs¹

2050: A BIGGER KILLER THAN CANCER²



¹"Antibiotic Resistance Threats in the United States." Prepared by the CDC (2013)

²O'Neill, Jim. "Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations." Review on Antimicrobial Resistance (December 2014)

Significant Financial Toll on Hospitals and Healthcare System

Direct Costs

- Increased length of stay
- Drug costs
- CMS financial penalties

Indirect Costs

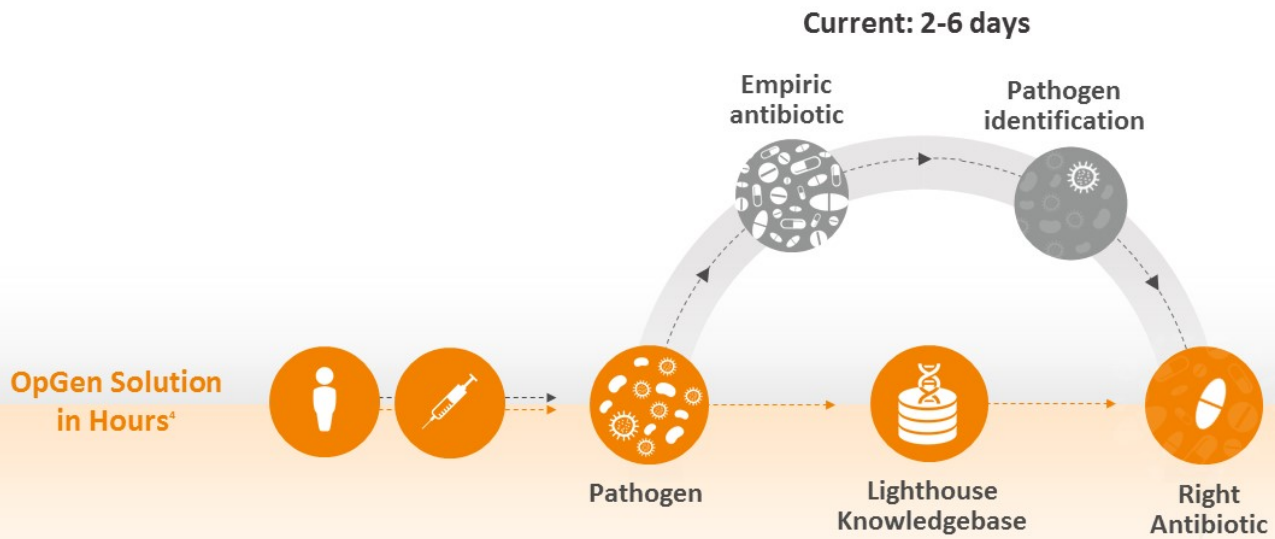
- Mortality risk
- Resistance and C. diff rise
- Risk of infection spreading

Significant hospital costs

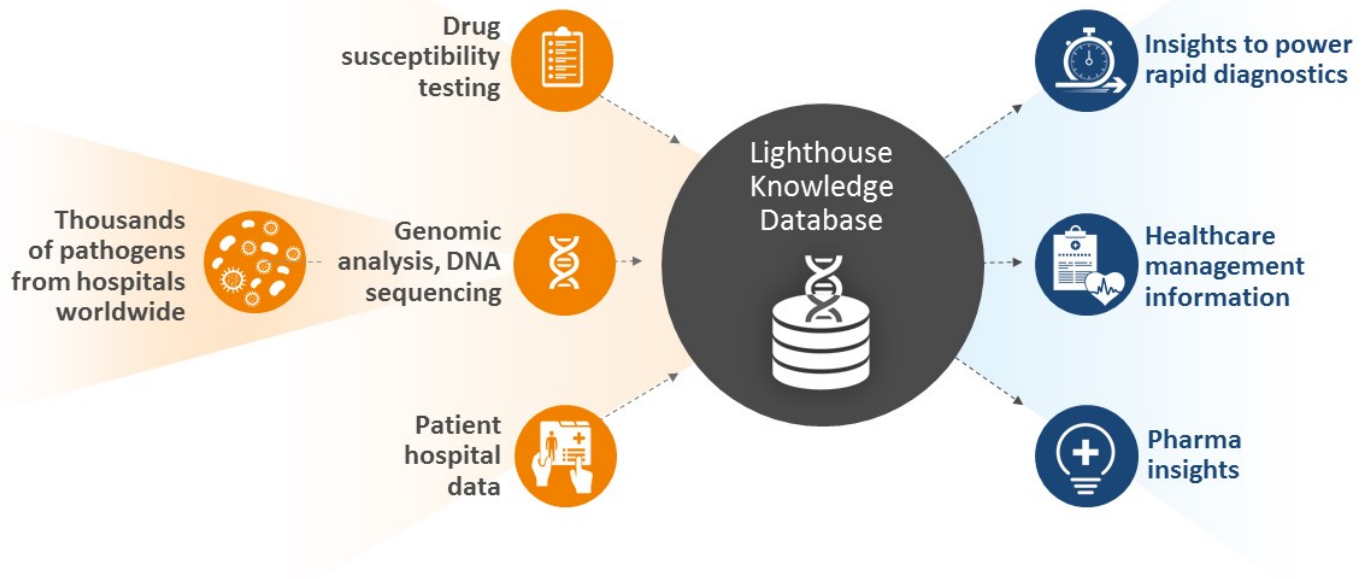
\$25,000 - \$80,000 average
cost per MDRO patient³

Costs projected to double
over next 7 years³

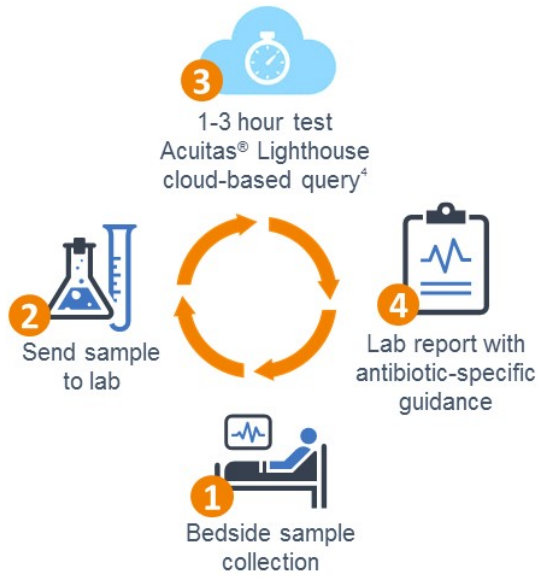
Revolutionary Approach to Antibiotic Decision Making



OpGen Solution: Genomic Knowledgebase of Drug-Resistant Pathogens



Sample Workflow and Report

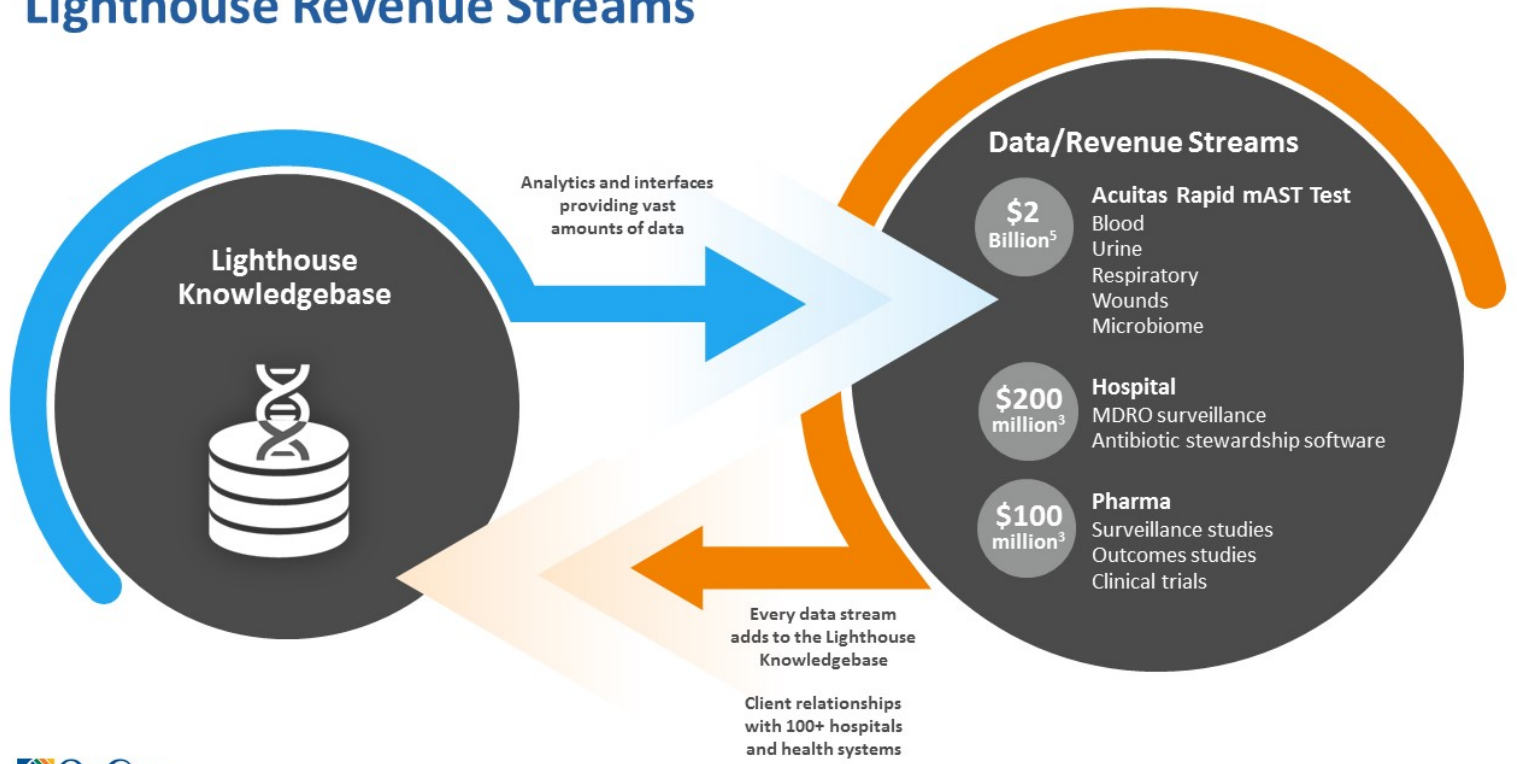


Acuitas mAST™

Lighthouse Profile	Organism	Antibiotic Resistance Genes
K1:KPC1_SHV4_TEM7	K. pneumoniae	KPC, SHV ESBL, TEM7

Predicted Antibiotic Resistance			
Cefepime	Imipenem	Gentamicin	Tigecycline
83	95	48	0

Lighthouse Revenue Streams



External Validation Drivers



Intermountain Healthcare MDRO Cost & Outcomes Study

Significant opportunities to improve outcomes and reduce costs

- Leading integrated HMO retrospective study
- Costs projected to double
- Potential savings from rapid antibiotic decision-making
- Results support multiple data/revenue streams



Rapid Complicated Urinary Tract Infection Management

OpGen – <3 Hours[†]
 Current – 2+ Days

	30 [†] min	<3 [†] hrs	15 hrs	16 hrs	25 hrs
Acuitas	UTI +/- ID	mAST			
Culture + MALDI + AST			UTI +/-	ID	AST

1.5 million U.S. patients at risk
300 thousand cUTI cases annually

Blood Stream Infection Patient Management

OpGen – 1-4 Hours Post Blood Culture; Future: 4 Hours Direct from Blood
Current – 2-3 Days

	12-24 hrs	1 hr	1-3 hrs ⁴	36-48 hrs
Acuitas	Blood culture	QuickFISH® ID	mAST	
Culture + MALDI + AST	Blood culture	MALDI ID		AST

More than a million U.S. patients with severe sepsis annually⁶

An estimated 28-50% of these people die – far more than the number of U.S. deaths from prostate cancer, breast cancer and AIDS combined⁷



⁴ In development
⁶ National Center for Health Statistics Data Brief No. 62 June 2011. Inpatient care for septicemia or sepsis: a challenge for patients and hospitals
⁷ Wood KA, Angus DC. Pharmacoeconomic implications of new therapies in sepsis. *Pharmacoeconomics*. 2004;22(14):895-906.

Hospital ICU MDRO Management

Transplant, Oncology, High-Acuity ICUs, Pre-surgical Admissions

OpGen CLIA Complete MDRO Solution
Current VRE, MRSA Screening

Successful Pilots:
 HARP-DC, 16 Hospitals
 Intermountain Healthcare, Utah

	24 hrs	48 hrs	72 hrs
Acuitas	+/- MDRO	Molecular Profile mAST Data	AST
Culture + MALDI + AST	Initial +/-	VRE +/-	AST



Acuitas MDRO Surveillance

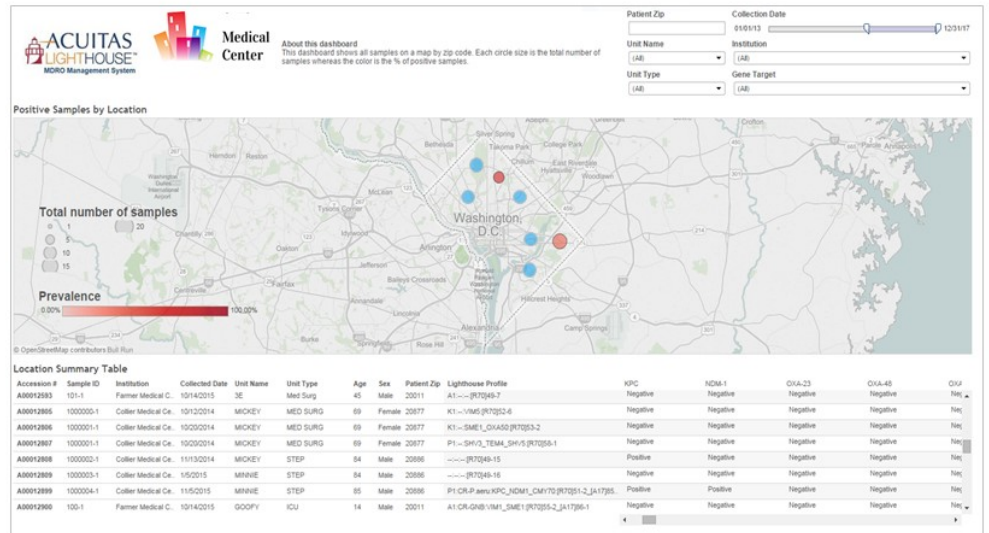
- HARP-DC MDRO Surveillance Study
- Nation's capital leads in proactively addressing MDROs in communities and health facilities
- Acuitas solution deployed in 16 D.C. health care facilities during the course of the study



Acuitas Lighthouse Used in HARP-DC MDRO Surveillance Initiative in Collaboration with CDC and Public Health Lab

Individual hospital and patient reporting with geospatial analysis

- ✓ Advanced analytics engine
- ✓ Direct connection to LIMS database
- ✓ Cloud-based
- ✓ HIPAA compliant
- ✓ Security
 - End-to-end encryption (database, connectors, browser SSL)
 - Federated access permissions



Merck GHI Investment

- Merck Global Health Investment Fund invests where Merck's expertise can help accelerate revenue growth and enhance value creation
 - \$10.5 million investment
- November 2016: Research collaboration with Merck to develop novel rapid diagnostics and informatics tools to combat antibiotic resistance
 - Access to Merck's 200,000 pathogen bacterial archive



Product Development Momentum

Today

Automation of current DNA tests



Lighthouse



Acuitas mAST Development Path

	Status
Genomic Discovery Engine	
CLIA Lab for microbial sequence/antibiotic phenotype analysis	Complete/Commercial
Custom genotyping & DNA sequencing tests	Complete/Commercial
Verification of test performance	Complete
Test thousands of pathogens	Underway
Informatics Infrastructure	
Lighthouse Data Warehouse & Portal	Complete/Commercial
Genotype/phenotype predictive algorithms	Underway
mAST antibiotic analytics engine	Underway – 4Q 2016
Database of ~10K + MDRO pathogens	Underway – 2Q 2017
IVD Test Development	
Initial mAST performance confirmation on top six pathogens	Complete
Verification of mAST test	Underway – Q2 2017
mAST ASR/LDT	Underway – 2017
Initial mAST IVD	Underway – 2018
Automated rapid pathogen ID	Underway – 2017

Large Rapid Antibiotic Decision-Making Markets

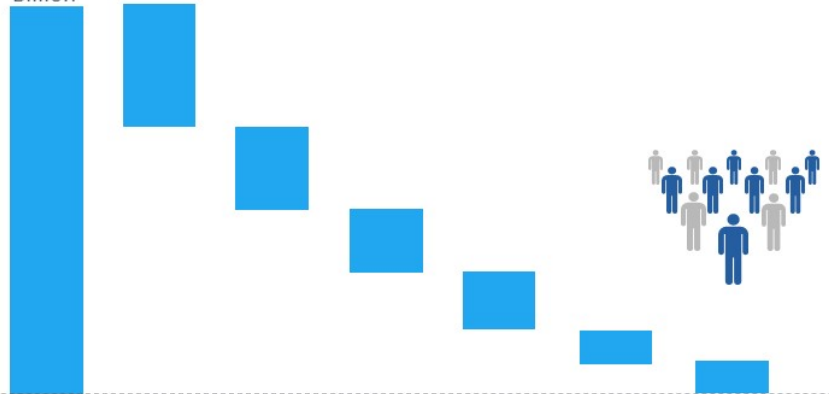
\$2B Global Market

19% CAGR: One of the fastest growing U.S. molecular diagnostic segments

Multiple high-acuity patient types

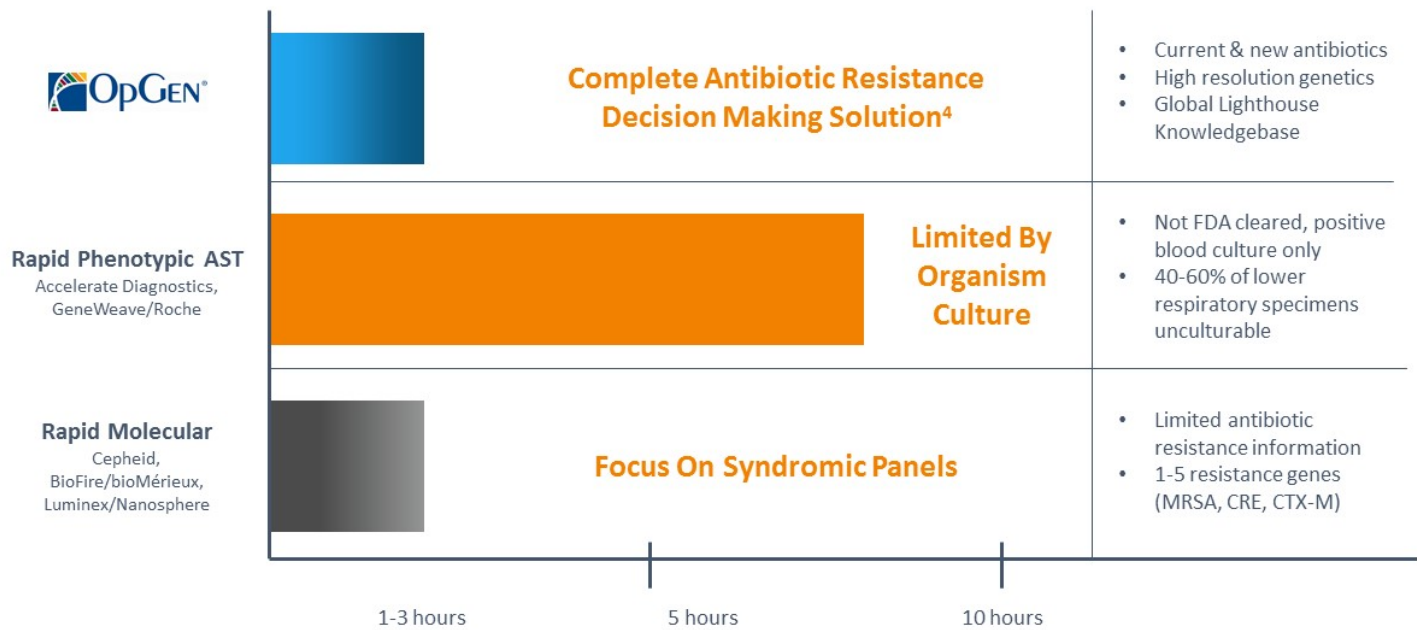
Global Hospital Acquired Infection Testing Revenue 2012

\$2.2 Billion



⁵ Hospital Acquired Infection Testing Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2013 - 2019

Competitive Landscape



Acuitas mAST Commercial Strategy

mAST economics: >500 bed hospital



5-10 tests per day



~3,000 tests per year



\$150-\$200 ASP



Estimated \$500 million
annual U.S. revenue
opportunity¹¹

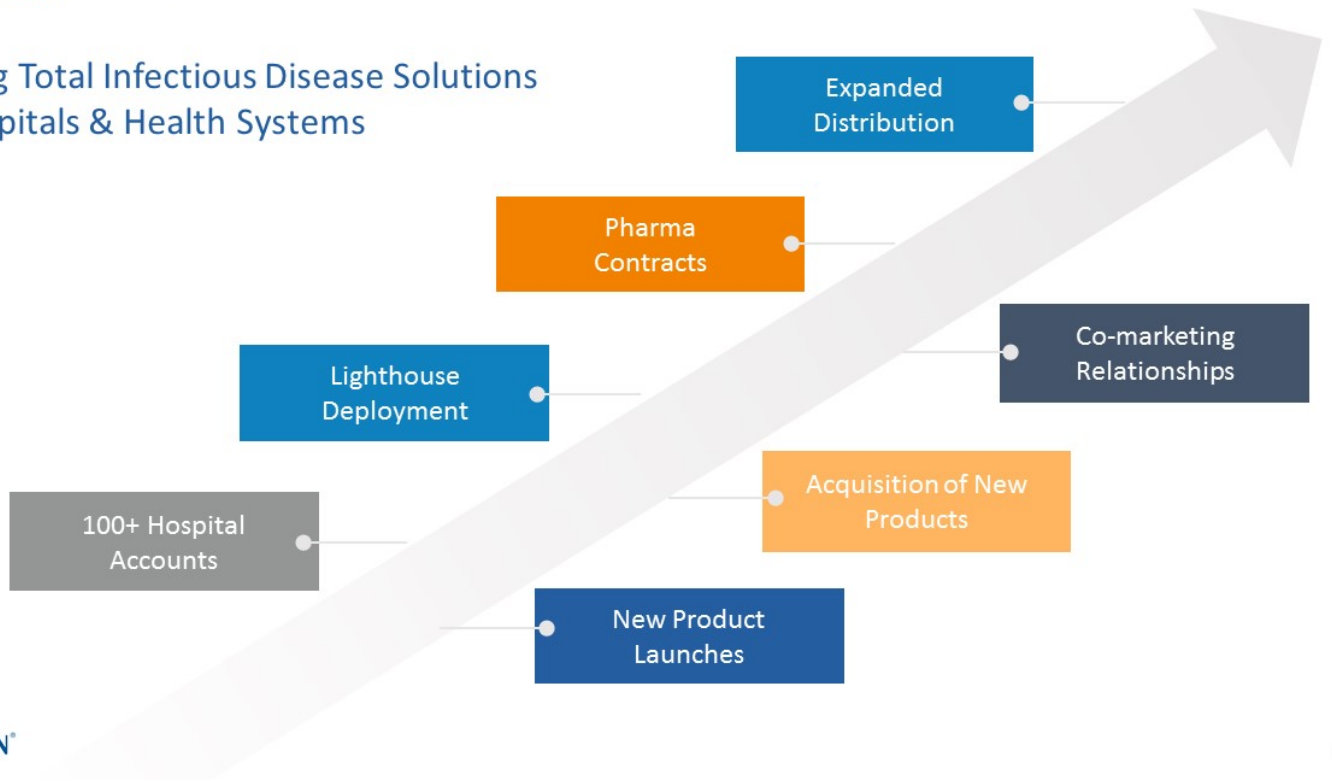
Key commercialization milestones



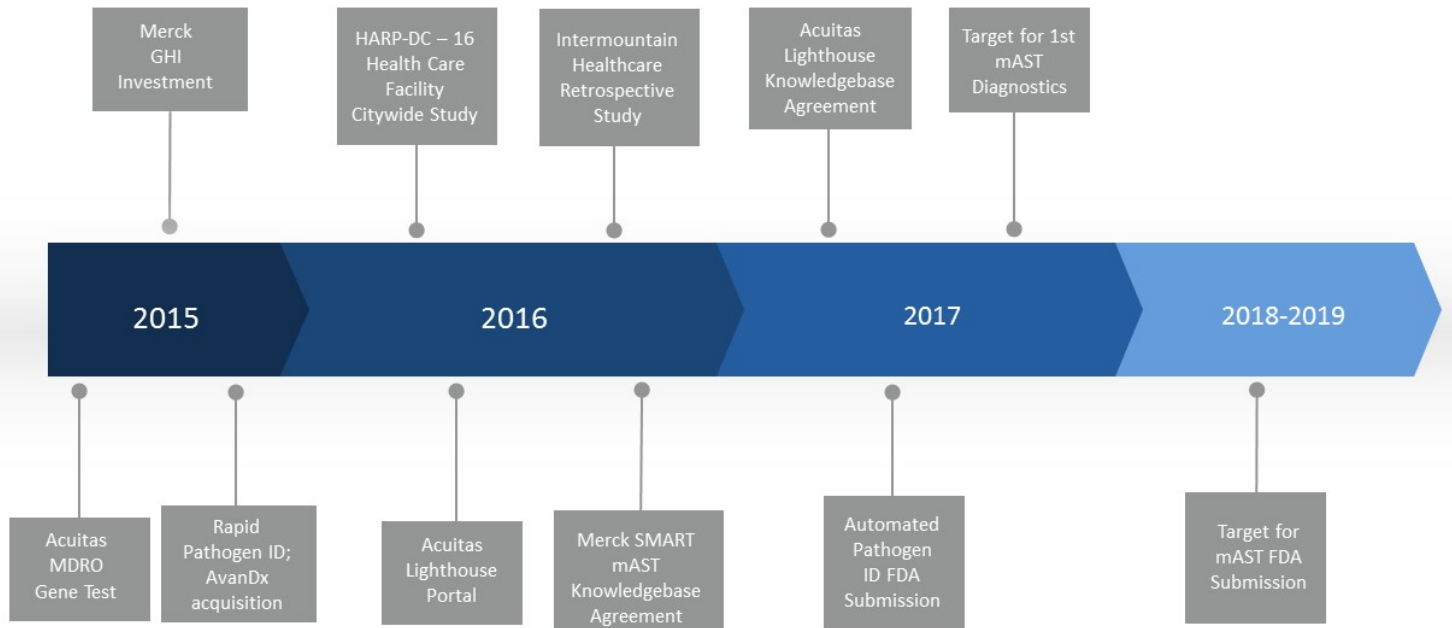
- 2017: Commercialize ASR/LDT in U.S. and QuickFISH digital imager
- 2018: mAST ASR/LDT revenue
- 2018: RUO/CE mark
- 2019: mAST IVD revenue
- IVD development and licensing agreements
- Targeted pharma clinical trial agreements

Strategy for Growth

Building Total Infectious Disease Solutions
for Hospitals & Health Systems



Building on First Mover Advantage



Financial Highlights

- **Nine months ended September 30, 2016**

- \$3.0 million total revenue - up 65% from 2015 (\$1.8 million)
- \$2.7 million product revenue – up 90% from 2015 (\$1.5 million)
- 53% gross margin on product sales

- **Q3 ended September 30, 2016**

- \$760 thousand total revenue – down 23% from 2015 (1.0 million)
- \$730 thousand product revenue – down 21% from 2015 (\$929 thousand)
- \$4.8 million net loss

- **Balance sheet (as of September 30, 2016)**

- \$4.3 million cash
- \$11.5 million ATM program

Major Stockholders (September 30, 2016)	
Merck GHI	25.0%
jVen Capital and affiliates	18.1%
Versant Ventures	11.8%
<u>Sabby, LLC</u>	<u>9.9%</u>
Total (21.7 million shares)	64.8%

Excludes:

6.8M warrants with \$1.31/share exercise price

3.7M warrants with \$6.60/share exercise price

3.0M stock options outstanding with \$1.68 average strike price



Experienced Management Team

Evan Jones
Chairman & Chief Executive Officer



Timothy Dec
Chief Financial Officer



Robert McG. Lilley
Chief Commercial Officer



Vadim Sapiro
Chief Information Officer



Geoff McKinley, Ph.D.
SVP, R&D, Business Development



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



Near-Term Milestones

Q4 16	IHC Health Outcomes Study
Q1 17	Pharma information agreement
Q1 17	mAST performance verification
Q1 17	Health system information services
Q2 17	Automated rapid pathogen ID FDA submission
2H 17	Automated pathogen ID launch
2H 17	mAST clinical trials and ASR/LDT
2H 17	Third party development funding

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CORPORATE PRESENTATION

Thank You