

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): January 9, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On January 9, 2018, OpGen, Inc. (the "Company") is first making a corporate presentation to investors 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., January 2018](#)

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: January 9, 2018



CORPORATE PRESENTATION

January 2018



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Forward-Looking Statement

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



OpGen and the Investment Opportunity

- **OpGen is a precision medicine informatics company focused on the rapidly growing Multi-Drug Resistant Organism (MDRO) market**
 - Collaboration and investment from Merck provides differentiated competitive advantage
- **Addressing a significant global challenge and market opportunity**
 - >\$2 billion market in need of novel solutions to help combat the rise of multi-drug resistant infections
- **Uniquely positioned with disruptive technologies for helping guide precision antibiotic therapy**
 - Acuitas® Lighthouse is a proprietary and continually evolving MDRO knowledge database with analytic tools enabling actionable clinical decision support
- **Validation of OpGen value proposition from early adopter U.S. health systems**
- **Experienced management team with a proven track record of value creation**



Advancing Molecular Diagnostics and Informatics for Precision Antibiotic Therapy

Completed Preliminary Development of Lead Product Offering

- **AMR Gene Panel u5.47 for Complicated Urinary Tract Infection (cUTI)**
 - ✓ Produced first RUO test kits
 - ✓ Completed Analytical Verification studies for RUO product
 - ✓ Initiated Clinical Verification studies with flagship IDN hospitals for RUO product
 - ✓ Implemented Thermo Fisher QuantStudio™ 5 (QS5) Global Supply Agreement
- **Acuitas Lighthouse & Informatics Platform**
 - ✓ Curated Knowledgebase of 10,000 isolates tested from Merck SMART surveillance network
 - ✓ Developed and presented groundbreaking antibiotic resistance prediction capabilities
 - ✓ Awarded CDC contract to develop smartphone-based clinical decision support solutions for antimicrobial stewardship in developing economies

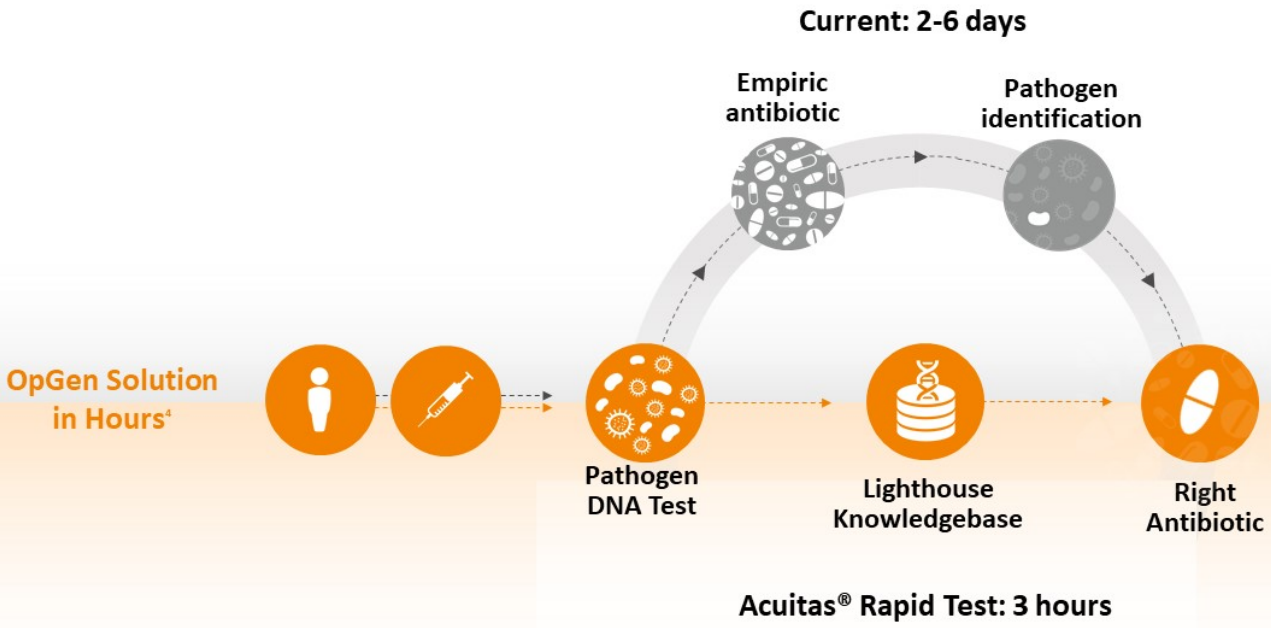
2018: Transitioning to Commercial Phase for Molecular Informatics Business

AMR Gene Panel u5.47 and Lighthouse Knowledgebase FDA Submissions and commercial release. We are planning

- Q1 RUO release for AMR Gene Panel u5.47 for clinical isolate testing and cUTI research studies
- Completing 3rd party RUO Clinical Verification studies and FDA clinical trials for IVD u5.47
- Making FDA 510(k) submission of u5.47 Gene Panel to support full commercial launch
- Adding QS5 and Qiagen EZ1 revenue generating system placements
- Finalizing Lighthouse Knowledgebase Portal and prediction technology
- Conducting CDC smartphone demonstration pilot in Colombia with potential expansion opportunities



Revolutionary Approach to Antibiotic Decision Making



First AMR Gene Panel RUO Release Planned Q1 2018

Acuitas Lighthouse: 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



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Acuitas AMR Gene Panel u5.47 & Acuitas Lighthouse Knowledgebase²



RESULTS:
<3 hours



DETECTS:
5 pathogens
47 resistance genes and mutations





PREDICTS RESISTANCE FOR:
12 antibiotics



SPECIMEN TYPES:
Urine
Isolates



Report Date: 07/25/2017 Sample ID: 646547 Test: Acuitas[®] AMR Gene Panel u5.47
 Test Date: 07/25/2017 Sample Type: Urine Plate ID: P23894

MDRO STATUS: **Risk for CRE detected**

Organisms Detected	Antibiotic Support																
<table border="1"> <thead> <tr> <th>Organism</th> <th>Copies/mL</th> </tr> </thead> <tbody> <tr> <td>E. coli</td> <td>≥10⁴ to < 10⁶</td> </tr> <tr> <td>E. faecalis</td> <td>Not Detected</td> </tr> <tr> <td>P. mirabilis</td> <td>Not Detected</td> </tr> <tr> <td>K. pneumoniae</td> <td>Not Detected</td> </tr> <tr> <td>P. aeruginosa</td> <td>Not Detected</td> </tr> </tbody> </table>	Organism	Copies/mL	E. coli	≥10 ⁴ to < 10 ⁶	E. faecalis	Not Detected	P. mirabilis	Not Detected	K. pneumoniae	Not Detected	P. aeruginosa	Not Detected	<table border="1"> <thead> <tr> <th>Antibiotic Support</th> </tr> </thead> <tbody> <tr> <td>NO EVIDENCE OF RESISTANCE Predicted for: Aminomycin, Colistin, Coligene, Colistinase, Ertapenem, Levofloxacin, Meropenem, Piperacillin, Tobramycin, Trimethoprim/Sulfamethoxazole</td> </tr> <tr> <td>POSSIBLE RESISTANCE Predicted for: Colistinase, Colistinase, Cephalosporin, Ertapenem, Vancomycin</td> </tr> <tr> <td>RESISTANCE Predicted for: Ingram</td> </tr> </tbody> </table>	Antibiotic Support	NO EVIDENCE OF RESISTANCE Predicted for: Aminomycin, Colistin, Coligene, Colistinase, Ertapenem, Levofloxacin, Meropenem, Piperacillin, Tobramycin, Trimethoprim/Sulfamethoxazole	POSSIBLE RESISTANCE Predicted for: Colistinase, Colistinase, Cephalosporin, Ertapenem, Vancomycin	RESISTANCE Predicted for: Ingram
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Antibiotic Resistance Genes Detected

Gene	Antibiotic class	copies/mL of urine
KPC	Carbapenems	≥10 ⁴ to < 10 ⁶
APH	Aminoglycosides	≥10 ⁴ to < 10 ⁶

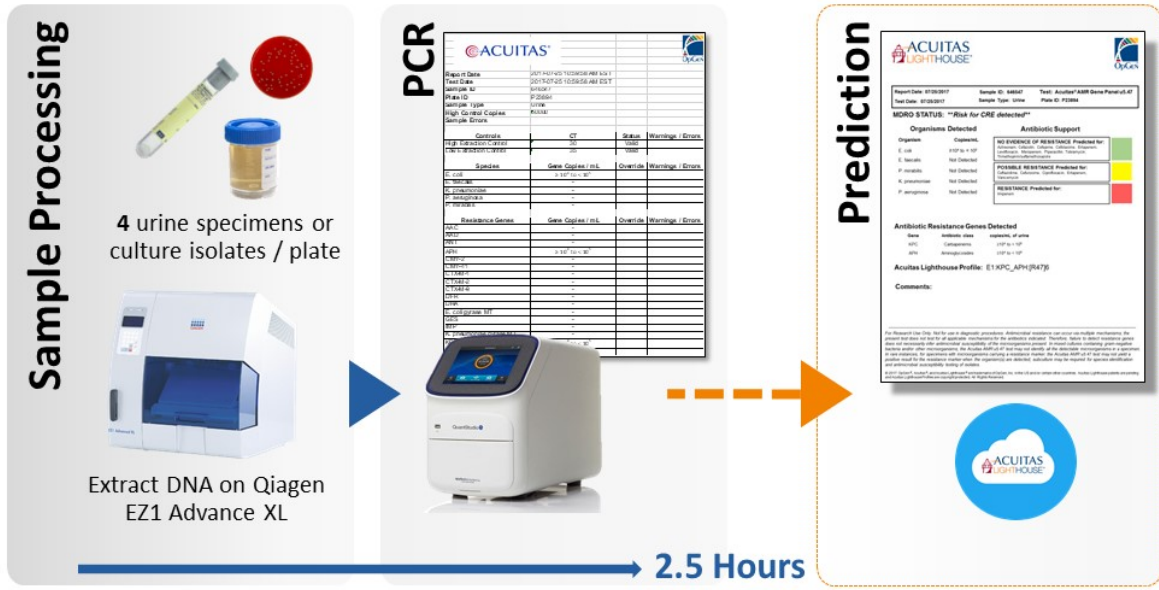
Acuitas Lighthouse Profile: E1.KPC_APH[R47]6

Comments:

For Research Use Only. Not for use in diagnostic procedures. Antimicrobial resistance can occur via multiple mechanisms, the present test does not test for all applicable mechanisms for the antibiotics indicated. Therefore, failure to detect resistance genes does not necessarily infer antimicrobial susceptibility of the microorganisms present. In mixed cultures containing gram-negative bacteria and/or other microorganisms, the Acuitas AMR u5.47 test may not identify all the detectable microorganisms in a specimen. In rare instances, for specimens with microorganisms carrying a resistance marker, the Acuitas AMR u5.47 test may not yield a positive result for the resistance marker when the organism(s) are detected; subculture may be required for species identification and antimicrobial susceptibility testing of isolates.

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Acuitas AMR Gene Panel u5.47 Workflow²



Acuitas AMR Gene Panel u5.47 Pathogen Targets²

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

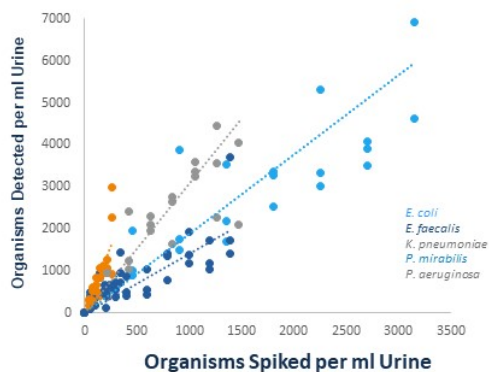
Semi-quantitates detected organisms and resistance genes to one of the following levels (in copies per ml of urine):
 $<10^3$, 10^4 , 10^5 , 10^6 , $>10^6$

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
<i>E. coli</i>	88 of 88 (100%)	some <i>Shigella</i> spp.
<i>E. faecalis</i>	65 of 65 (100%)	
<i>K. pneumoniae/variicola</i>	87 of 88 (99%)	
<i>P. aeruginosa</i>	91 of 91 (100%)	
<i>P. mirabilis/vulgaris</i>	84 of 85 (99%)	



Acuitas Lighthouse Antibiotic Resistance Prediction

Final training set data and program update

- 2 million Lighthouse data points evaluated from Merck SMART surveillance network
- 41 unique prediction algorithms coded into Lighthouse reporting engine
- Final training set data supporting prediction algorithms³

	Sensitivity	Specificity	Accuracy	PPV	NPV
Enterobacteriaceae 1 Average for 12 FDA approved cUTI antibiotics	91%	90%	91%	94%	86%
Enterobacteriaceae 2 Average for 12 FDA approved cUTI antibiotics	89%	83%	88%	94%	66%

- Anticipate Blinded Isolate Panel testing in conjunction with FDA 510(k) process



³ Source: company data, in development, for Research Use Only

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Rapid Complicated Urinary Tract Infection Management

- **OpGen** – <3 Hours⁴

Current – 2+ Days

	1-3⁴ hrs	15 hrs	16 hrs	25 hrs
Acuitas	mAST			
Culture + MALDI + AST		UTI +/-	ID	AST

1.5 million U.S. patients at risk

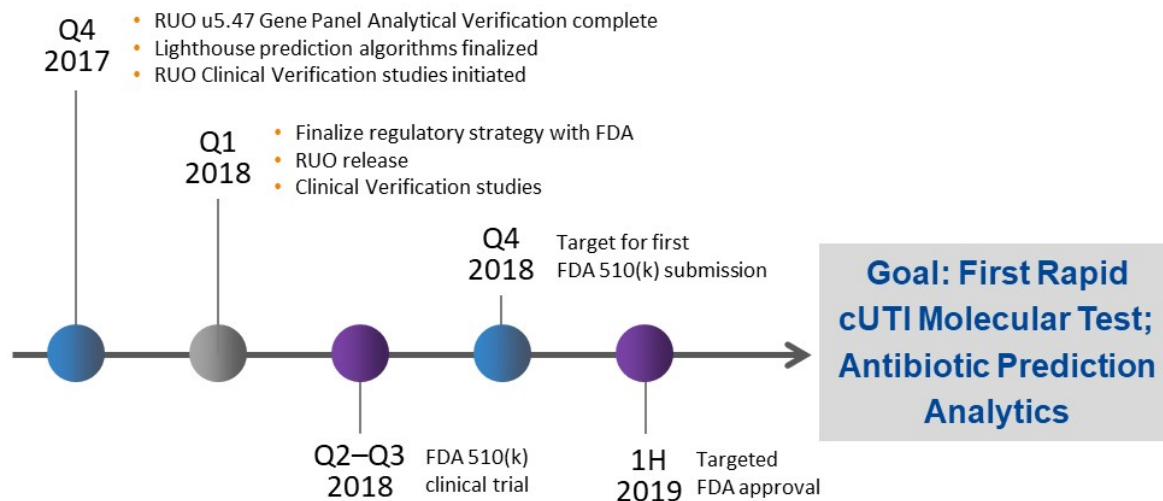
300 thousand cUTI cases annually

⁴ In development



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Acuitas Gene Panel / Lighthouse Regulatory and Commercialization Milestones



Acuitas Rapid Test Commercial Strategy



Economics: >500 Bed Hospital

5-10 tests per day



~3,000 tests per year



\$150-\$200 ASP



Estimated \$500 million
annual U.S. revenue
opportunity⁴



Key Commercialization Milestones

2018

RUO initial revenue
FDA, CE mark filings
IVD development/licensing agreements
Pharma partnering

2019

Target for FDA clearance

Rapid Diagnostics – Growth Drivers



OpGen Brand:

- Global supply agreement with Thermo Fisher Scientific for QuantStudio™ 5 Rapid PCR Technology
- Additional tests & new drug indications
- Health system development collaborations
- Geographic expansion

Strategic Partners:

- Expanded channel access on established Rapid IVD platforms
- Access to OpGen test content & Acuitas Lighthouse Knowledgebase

QuantStudio™ is a registered trademark of Thermo Fisher Scientific

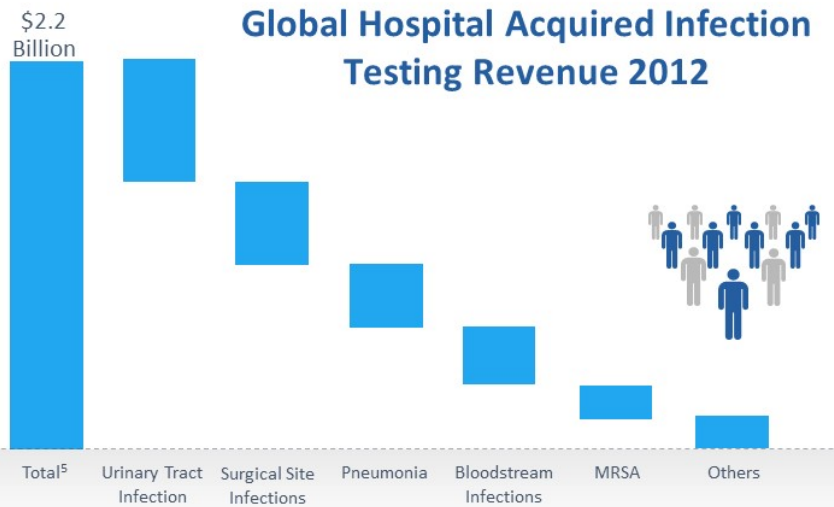


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Large Market for Precision Medicine MDRO Solutions

Lead Product: cUTI, Clinical Isolates. Second Product Target: Lower Respiratory Infection

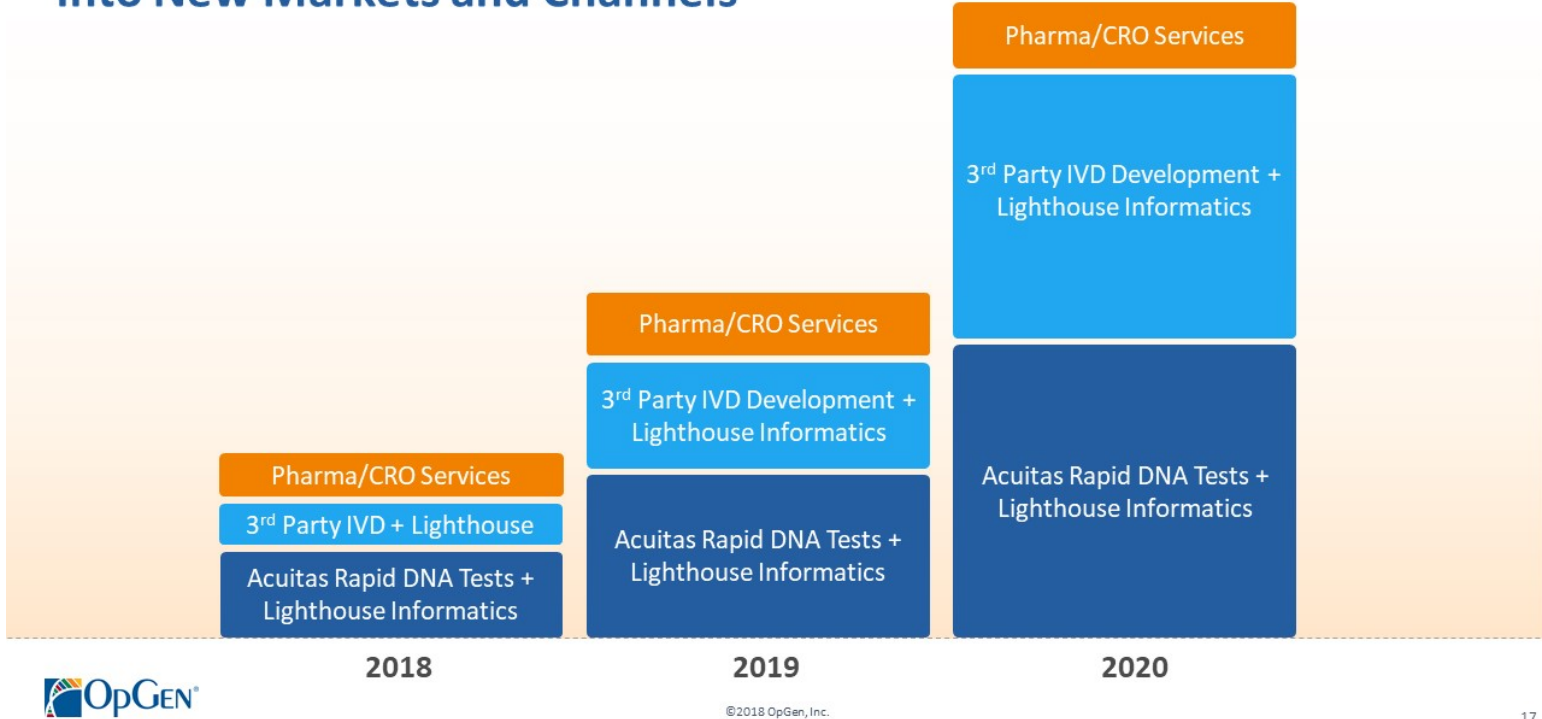
- \$2B Global Market
- 19% CAGR: One of the fastest growing U.S. molecular diagnostic segments
- Multiple high-acuity patient types



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



Leveraging Acuitas Lighthouse into New Markets and Channels



2018

2019

2020

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Acuitas Lighthouse Information Services – Commercial Opportunities



CDC Smartphone Clinical Decision Support Award

Develop clinical decision support solutions for antimicrobial stewardship (AMS) and infection control in low- and middle-income countries.

- \$860,000 one year award
- Teaming Partners: Ilúm (Merck HSS); Universidad El Bosque, Colombia
- Plan to connect to World Health Organization 4,000 hospital WHONET



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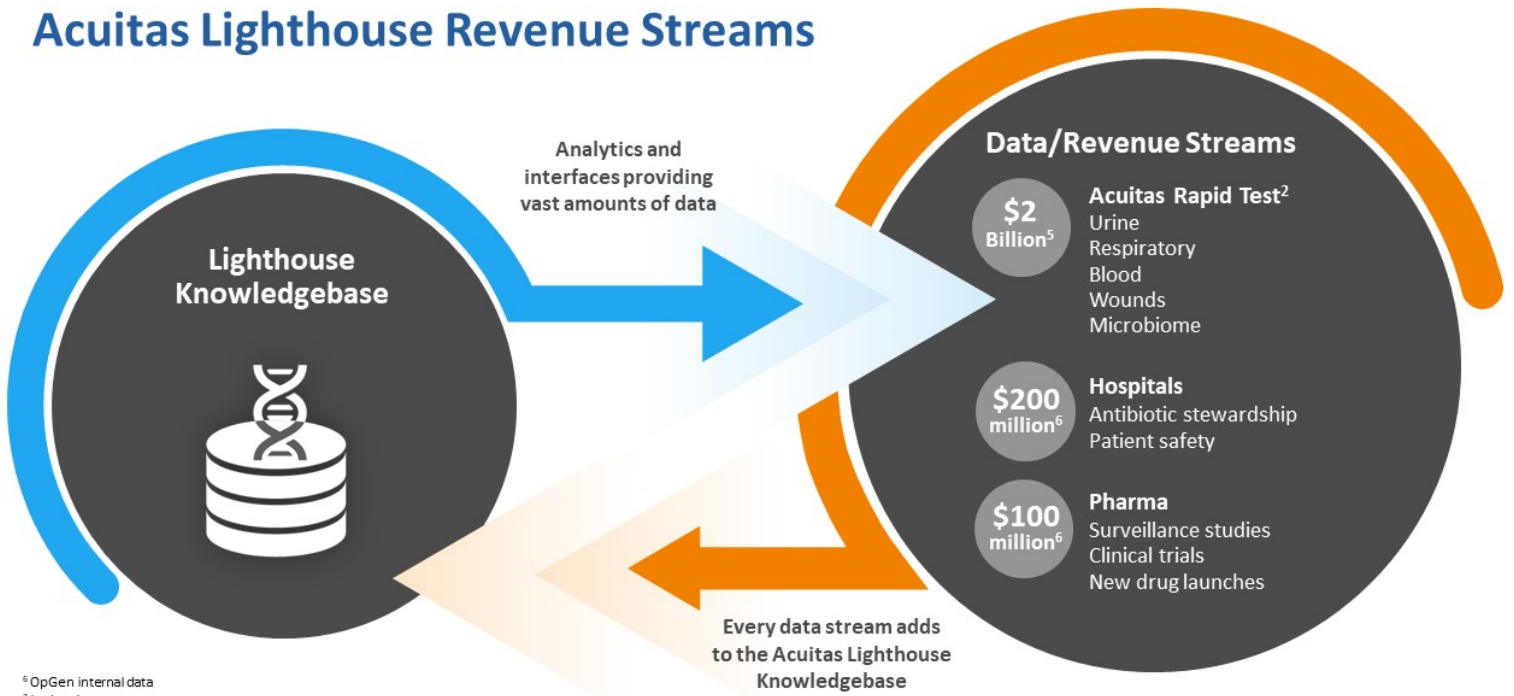
Merck Collaborations

- Merck Global Health Investment Fund invests where Merck's expertise can help accelerate revenue growth and enhance value creation
 - \$10.5 million investment (May 2016, July 2015)
- November 2016: Research collaboration with Merck to develop novel rapid diagnostics and informatics tools to combat antibiotic resistance
 - Access to Merck's 250,000 SMART pathogen bacterial archive
- December 2017: Ilúm /OpGen CDC smartphone antibiotic stewardship collaboration agreement



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Acuitas Lighthouse Revenue Streams



Client relationships with 100+ hospitals and health systems

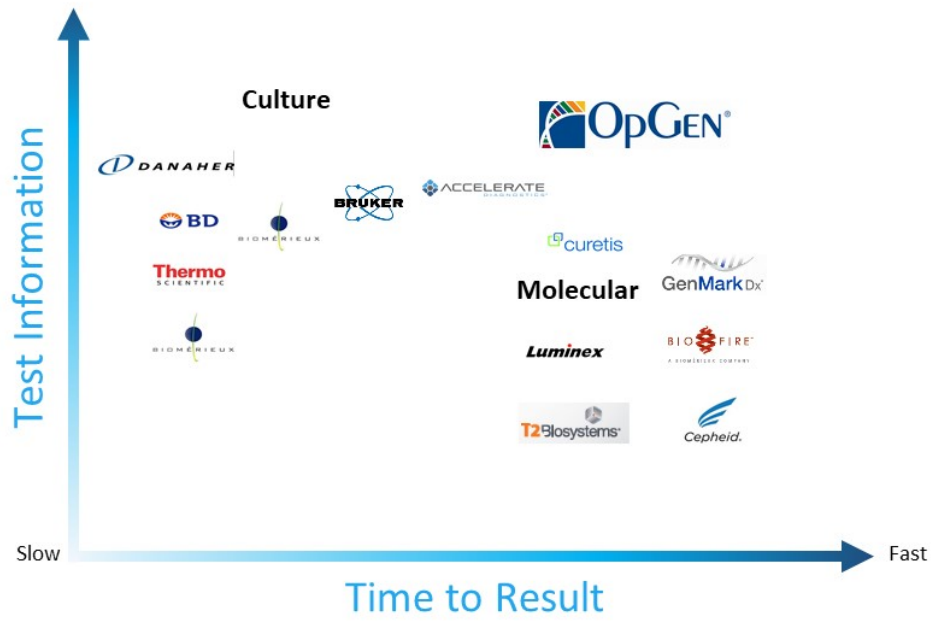
⁶ OpGen internal data

² In development

⁵ Hospital Acquired Infection Testing Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2013 – 2019; Acuitas Rapid Test under development



OpGen – Developing Breakthrough Microbiology Capabilities



Experienced Leadership Team

Evan Jones
Chairman & Chief Executive Officer



Timothy Dec
Chief Financial Officer



Vadim Sapiro
Chief Information Officer



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



Thomas Guiel
VP, Operations



Financial Highlights (as of September 30, 2017)

Revenue

- \$2.2 million total revenue through September 30, 2017
- \$4.0 million total revenue in 2016
 - \$3.1 million from ongoing FISH business
 - \$0.9 million from legacy and other

Balance Sheet

- Raised \$8.8 million in net proceeds in July 2017
- Cash balance \$4.9 million
- \$11.5 million ATM program (raised \$8.8M to date - \$2.7M remaining capacity)

December 2017 Update

- Filed S1 Registration Statement to raise up to \$7 million of equity capital
- Special meeting for reverse stock split January 2018



Near-Term Milestones

Q1 18	Initial Acuitas Gene Panel RUO commercialization
Q1/Q3 18	Acuitas RUO Clinical Verification, IVD FDA clinical trial
Q2/Q3 18	CDC Smartphone Pilot evaluation
Q4 2018	Acuitas Gene Panel IVD FDA submission
2018	Rapid IVD commercialization partnerships
2018	Third-party development funding
2019	Acuitas AMR Gene Panel FDA Approval

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CORPORATE PRESENTATION

Thank You