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

August 20, 2020 Date of Report (date of earliest event reported)

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 Number)

708 Quince Orchard Road, Suite 205 Gaithersburg, MD 20878 (Address of principal executive offices)

(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	OPGN	The Nasdaq Capital Market
THE CONTRACT STREET		

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 [X]

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 August 20, 2020, OpGen, Inc. updated its corporate presentation, which it made available on its website. A copy of the presentation is furnished as Exhibit 99.1 to this report.

Item 8.01 Other Events.

On August 20, 2020, OpGen, Inc. issued a press release announcing its subsidiary, Curetis GmbH, has obtained the CE mark certification in the European Union for its SARS-CoV-2 test kit that tests for the detection of SARS-CoV-2, the virus that causes COVID-19. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Document
99.1	Corporate Presentation dated August 2020
99.2	Press Release issued by OpGen, Inc. dated August 20, 2020

The information included in Item 7.01 of this report and Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

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.

Date: August 20, 2020

OpGen, Inc.

By: /s/ Timothy C. Dec

Name:Timothy C. DecTitle:Chief Financial Officer





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 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.



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Recent newsflow

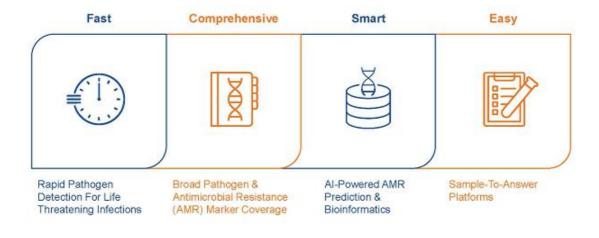
OpGen has recently announced several key updates and milestones

- Curetis has successfully obtained CE IVD marking of its proprietary, rapid SARS CoV-2 PCR test kit expect to launch in Europe in Q3 and cease distribution of BGIO kit immediately
- OpGen announced a strategic co-promotion partnership with Menarini Silicon Biosystems to market and sell Menarini's portfolio of COVID-19 related products including the Healgen 10-minute antibody test kit that detects both IgG and IgM
- OpGen Releases Preliminary Data from Collaboration with Karolinska Institute, Stockholm, Sweden, Investigator-initiated clinical study demonstrates that Unyvero HPN Panel for Pneumonia Identifies Life-Threatening Bacterial Co-Infections in COVID-19 Patients in Just Five Hours
- · OpGen expands partnership with New York State Department of Health and IDC to detect antimicrobial resistant infections
- · OpGen publishes first half year 2020 financial results and provides business update
- OpGen expects that its submission to the U.S. Food and Drug Administration ("FDA") for clearance of the Acuitas® AMR Gene Panel (Isolates) for the detection of antimicrobial resistance genes in bacterial isolates is nearing completion.
- Ares Genetics completed all three phases of the R&D program on ARESdb in its R&D collaboration. Won new undisclosed global IVD
 company for feasibility and technology evaluation. Won Siemens Technology Accelerator and Austrian AGES agency as new customers.
 Published strong results from its collaborations with Sandoz, Johns Hopkins and Mayo Clinic



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OpGen and its group companies: Striving to innovate molecular microbiology





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Combined company's portfolio: Synergistic products & capabilities

Unyvero Platform & Syndromic Tests	Acuitas Tests & Acuitas Lighthouse	Global Commercial Presence	Ares Genetics NGS & Bioinformatics
	Acuitas		ares genetics
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 tests in clinical trials (Urine) and pending FDA clearance (isolates) to improve antibiotic decision making; Lighthouse knowledge base deployed for public health use	Direct sales in U.S., European and China distribution with partners; 18 distributors covering 43 countries; CoV-2 test kit distribution in EMEA	Ares Technology for Al-powered AMR prediction combining ARESdb with NGS; Strategic partnerships with globally leading IVD & pharma companies



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Strategic rationale and benefits

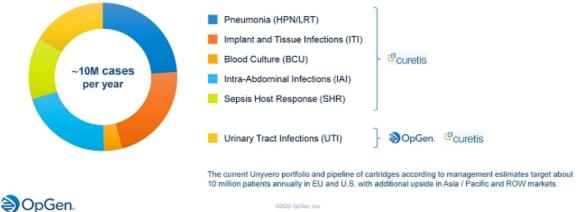


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Combined company to address unmet clinical needs and large available market opportunities

U.S. and European markets with ~10 million hospitalized patients annually addressed through hospital-focused sales channels



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Strategic rationale and benefits

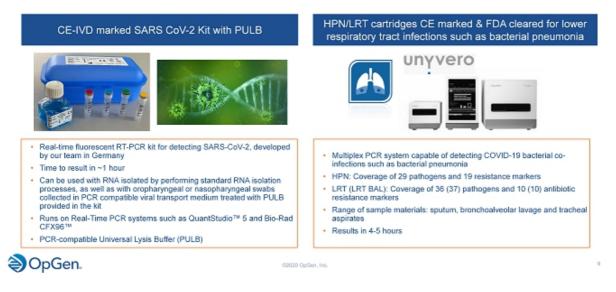


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We help fight the COVID-19 global pandemic

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



Sample-to-answer high-throughput testing capabilities

Innovating molecular microbiology through proprietary platforms and content

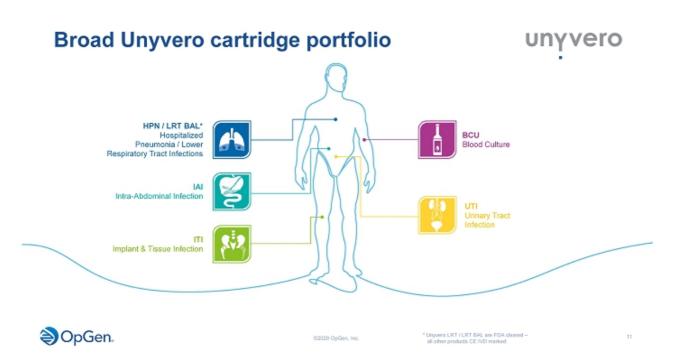
Striving for molecular microbiology innovation



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

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Unique and differentiated syndromic panels Unyvero



Cartridge		Indication area	Number of targets covered	Sample types	Clearance status
HPN**	A	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	84	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***	d.	Bloodstream infections	103 targets, pathogens (86) and antibiotic resistance markers (17)	Positively flagged blood cultures	CE-IVD marked Singapore (HAS) Thailand
IAI	g	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 (I/AI fluids such as ascitus)	CE-IVD marked
UTI	8	Severe cases of Urinary Tract Infections	103 targets, pathogens (88) and antibiotic resistance markers (15)	Midstream urine, suprapubic aspiration, tissue	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.

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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 (for isolates FDA clearance decision pending) – and in clinical trials for cUTI



Detects most deadly superbugs

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



Identifies

Up to 47 Resistance Genes, spanning 9 Antibiotic Classes

Tests

Directly from Urine (in Clinical Trials) or Isolated Colonies (FDA Clearance Decision Pending), Sample-to-Answer Multiplex PCR from Bacterial Isolates (or Native Urine Specimen) in under 3 hours



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



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



Platform available for partnering to rapidly create menu of tests and commercial channel(s)

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Key Design Features

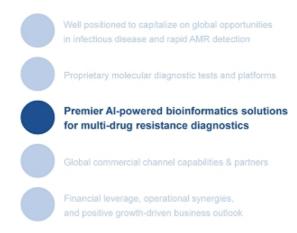
- · Fully integrated, closed, sample-to-answer MDx platform
- · Universal real-time PCR technology for low- to mid-plex testing
- · Flexible cartridge fluidics for numerous chemistries and assay formats
- · Fast turn-around time of 45-90 minutes
- · Light-weight, stackable benchtop design with small 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

- Currently working towards clinical proof of concept from sample to answer with various assays including SARS CoV-2
- Multiplex PCR successfully demonstrated on functional prototypes
- Manufacturing aspects fully specified and in development or implementation phase
- Curetis aims at having Unyvero A30 RQ platform ready for partnering in 2020

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Strategic rationale and benefits



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Ares Genetics & ARESdb*



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

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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

Acuitas Lighthouse[®]: Diagnostics data management platform for antibiotic resistant pathogens*



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Strategic rationale and benefits



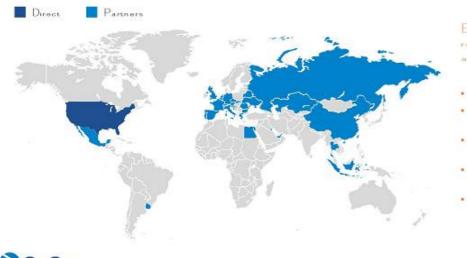
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Dual commercial model

Leveraging synergies from our now combined commercial team structures

Multiple products to same hospital call points via same sales channel to drive synergies and cost efficiencies



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

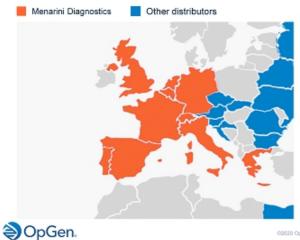
- Direct sales in the U.S.
- European distribution through Menarini Diagnostics
- China distribution through Beijing Clear Biotech
- 26 distributors covering 45 countries in EU, ME, LATAM, and Asia
- EMEA distribution and sales or BGI's SARS CoV-2 test kits

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Pan-European distribution via Menarini

Currently 11 EU countries – option to expand relationship to further EMEA markets and additional product lines



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Menarini Diagnostics & Curetis Collaboration (since Q1-2019)

- 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 EMEA countries



OpGen and MSB Co-Market COVID-19 Antibody Test Kit

OpGen is marketing and promoting CELLSEARCH system, CELLSEARCH CEC kit, and certain COVID-19 related products sold and distributed by Menarini Silicon Biosystems

Co-Promotion Agreement

- OpGen is authorized to market and promote such products in the United States, Canada, and Mexico
 under a strategic co-promotion agreement entered into by OpGen and MSB
- COVID-19 related products include an IgG/IgM Rapid Test Cassette that is manufactured by Healgen
 and sold by MSB, which is an antibody test that provides results in as fast as 10 minutes
- IgG/IgM Rapid Test Cassette has been authorized by the FDA under an emergency use authorization for use by authorized laboratories
- The test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens
- Under the terms of the co-promotion agreement, OpGen is entitled to certain payments based on MSB's net sales from customers referred by OpGen for such products, including the IgG/IgM Rapid Test Cassette
- The parties expect to continue to expand the portfolio of COVID-19 products available as part of the non-exclusive co-promotion relationship



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Strategic rationale and benefits



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Financial considerations as of June 30, 2020

Proforma Combined Revenue:

- FY 2018 revenues of \$4.5
 FY 2019 revenues of \$6.0 million
 H1 2020 revenues of \$2.8 million

Reported Revenue:

- · 2Q 2020 revenues of \$1.2 million
- H1 FY revenues of \$1.8 million (excluding \$1.0 million of Curret's revenue during Q1 2020)
 No revenue guidance for 2020 at this time due to COVID-19 situation

Cash position:

- June 30, 2020- \$12.9 million
- Cash raised via ATM and warrant exercises through June 2020 \$20.1 million
- Cash raised via ATM and warrant exercises through June 2000 \$20.1 million
 ATM gross capacity \$3.7 million
 ATM gross capacity \$3.7 million
 ATM gross capacity reset for another \$ 6.4 million
 EUR 6 million tranche in non-dictive debt financing for COVID-19 related R&D from the European Investment Bank (EIB)
 Warrants outstanding 1.03% (ISK4 at warrage price of \$2.16)
 Cash Burn estimated to be approximately \$5.0-\$6.0 million per quarter
- Capital Structure Shares Outstanding
- Common Stock 17,693,932
- Common Stock 17, 953, 932
 Warrants 1, 033, 938 (854,000 warrants avg. exercise price \$2.16)
 Convertible 311, 003
 Equity Awards 152, 189
 Fully Diluted Shares Outstanding 19, 190, 510



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Operations

Other Key Items

- · 20,000 sq. ft. Corporate HQ and FDA registered R&D/ manufacturing facility in Gaithersburg, Maryland, USA
- 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
- 15 Acuitas AMR Gene Panel system placements in the U.S.
- · Legacy FISH products from AdvanDx sold via combined U.S. commercial team and via Curetis GmbH in Europe
- ~170 Unyvero Analyzer placements globally

Employee count:

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



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OpGen Inc. executive leadership team and board

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

Chief Executive Officer:	Oliver Schacht, Ph.D.	
Chief Financial Officer:	Timothy (Tim) C. Dec	
Chief Operating Officer:	Johannes (Jan) Bacher	
Board Members:	William (Bill) Rhodes (Chairman)	
	Evan Jones	
	Mario Crovetto	
	Don Elsey	
	Prabhavathi Fernandes, Ph.D.	
	Oliver Schacht, Ph.D. (CEO)	



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Upcoming milestones, newsflow & catalysts

Unyvero & Acuitas® rapid molecular tests

- · Final study data from Karolinska Institutet, Stockholm, Sweden in COVID-19 bacterial pneumonia co-infection clinical study
- FDA clearance decision Acuitas[®] AMR Gene Panel (isolates)
- USA commercial updates on Unyvero LRT / LRT BAL
- Unyvero A30 RQ partnering deal(s)
- · Clinical trial updates (FDA trial enrollment, data read-out, China clinical trial etc.)
- Regulatory submissions (e.g. next FDA submission upon trial completion)
- China NMPA approval and launch for Unyvero HPN test

Ares Genetics

- · Potential future expansion of the partnership with global IVD corporation (e.g. option for 90 day exclusive negotiation about licensing)
- Further partnering / licensing deal(s)



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Contact info

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OpGen Announces CE-IVD Marking and Commercial Launch in Europe of its Own Developed Molecular Diagnostic SARS-CoV-2 Kit with PULB for Detection of the Virus Causing COVID-19

- Own developed SARS-CoV-2 Kit with PULB for COVID-19 uses real-time PCR (RT-PCR) technology on open PCR platforms, designed to provide results in approximately one hour

100% Sensitivity and 97.3% Specificity demonstrated in isolated RNA

- Inclusion of PCR-Compatible Universal Lysis Buffer (PULB) in the kit as a workflow option allows labs to circumvent the need for extraction equipment and reagents.

GAITHERSBURG, Md., and Holzgerlingen, Germany, August 20, 2020 -- OpGen, Inc. (Nasdaq: OPGN, "OpGen"), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, announced today that its subsidiary Curetis GmbH has obtained the CE mark certification in the European Union for its own SARS-CoV-2 Kit with PULB for the detection of SARS-CoV-2, the virus that causes COVID-19.

Developed and manufactured by Curetis' team in Germany, the SARS-CoV-2 Kit with PULB uses real-time reverse transcription polymerase chain reaction (RT-PCR) technology for qualitative detection of the SARS-CoV-2 virus isolated from oropharyngeal and nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider or for screening of asymptomatic individuals. This kit 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 PCR-Compatible Universal Lysis Buffer (PULB) provided in the kit. Including PULB in the kit as a workflow option allows labs to circumvent the need for extraction equipment and extraction kits/reagents, thereby providing operational and workflow efficiencies, time and cost savings. The kit is designed to provide time to results in approximately one hour, and it runs on open real-time PCR instruments such as the QuantStudio™ 5 Real-Time PCR System and the Bio-Rad CFX96TM Real-Time PCR Detection System.

"The CE-IVD Marking is an important step in advancing our efforts to support critical COVID-19 testing; the Curetis SARS-CoV-2 Kit with PULB provides additional testing capacity in countries that recognize the CE Mark to test patients," said Johannes Bacher, COO of OpGen.

"By launching this new product in Europe, we are committed to helping our distributors and customers to expand the availability of SARS-CoV-2 diagnostic testing, and our own-developed CE-IVD marked SARS-CoV-2 Kit with PULB is expected to help increase availability of these much-needed tests," said Oliver Schacht, PhD, CEO of OpGen. "Our customers will benefit from an optimized workflow and a test that delivers great performance and significantly shorter time-to-result at favorable economics compared to many of the commercially available open PCR platform COVID-19 tests including the BGI SARS-CoV-2 kit. Having access to our own SARS-CoV-2 kit allows us to have that product distributed rather than the BGI test kit which we will cease distributing effective immediately."

About OpGen, Inc.

OpGen, Inc. (Gaithersburg, MD, USA) is a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease. Along with subsidiaries, Curetis GmbH and Ares Genetics GmbH, we are developing and commercializing molecular microbiology solutions helping to guide clinicians with more rapid and actionable information about life threatening infections to improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. OpGen's product portfolio includes Unyvero, Acuitas AMR Gene Panel and Acuitas® Lighthouse, and the ARES Technology Platform including ARESdb, using NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction.

For more information, please visit www.opgen.com.

Forward-Looking Statements by OpGen

This press release includes statements regarding the commercial launch of a SARS-CoV-2 Kit by OpGen's subsidiary, Curetis GmbH. These statements and other statements regarding OpGen's SARS-CoV-2 test kits, their commercialization and launch, 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 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 success of our commercialization efforts, the 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 realization of expected benefits of our business combination transaction with Curetis GmbH, 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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Source: OpGen, Inc.