



## OpGen Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update for OpGen and Curetis Group

March 24, 2020

- *Quorum achieved for OpGen stockholder vote on Curetis business combination with 99% of votes supporting transaction*
- *Transaction close anticipated by early April 2020*
- *Combined OpGen and Curetis business generated \$6 million in unaudited pro forma combined 2019 revenue (up from \$4.5 million in 2018)*
- *First shipments of BGI SARS-CoV-2 rapid PCR kits completed by Curetis in Europe. Additional actions planned to address the global COVID-19 pandemic*

*Conference call to be held at 4:30 p.m. Eastern Time today*

GAITHERSBURG, Md., March 24, 2020 (GLOBE NEWSWIRE) -- OpGen, Inc. (NASDAQ: OPGN), a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease, reported today its audited stand-alone financial and operating results for the three and 12 months ended December 31, 2019 and provided a business update. Total OpGen revenue for the fourth quarter of 2019 was \$821 thousand, compared with \$759 thousand for the fourth quarter of 2018, an 8.1% increase. Total revenue for 2019 was \$3.5 million compared with \$2.9 million reported for 2018, an 18.7% increase. Combined unaudited pro forma revenue for the OpGen and Curetis business was approximately \$6 million in 2019 revenue up from approximately \$4.5 million in 2018, a 33% increase.

A quorum has been achieved for OpGen's upcoming Special Meeting of Stockholders, scheduled for March 30, 2020, at which stockholders will vote on the business combination transaction with Curetis. As of March 23, 2020, more than 99% of votes cast support approval of the business combination transaction. OpGen anticipates receiving formal approval of the transaction at the upcoming Special Meeting on March 30. As previously announced, on March 10, 2020, Curetis N.V. shareholders voted to approve the transaction, making the approval of OpGen's shareholders the last major hurdle to closing the planned business combination. The Company anticipates closing the business combination transaction by early April 2020 following its approval at the Special Meeting. The expected near-term completion of this combination follows the successful addition of \$22.6 million in working capital over the last six months which has supported the continued execution of both companies' business plans and provides significant funding for the combined company going forward.

Evan Jones, Chairman and CEO of OpGen, stated, "We are pleased with OpGen's fourth quarter and fiscal year 2019 results and are truly excited to see the imminent completion of our business combination with Curetis. We have successfully executed on all steps needed to satisfy the conditions to closing the transaction and expect our stockholders to approve the transaction in the near term. Thus, we look forward to our combined 2020 growth and corporate development."

Mr. Jones continued, "These are unprecedented times with the COVID-19 pandemic impacting society and businesses globally. Curetis took early action to supply the BGI SARS-CoV-2 rapid PCR test kit in Europe, and first shipments of product were completed this week. Together at OpGen and Curetis we are mobilizing our companies to help make a difference in the fight against this new virus. Operations and programs have been impacted by the government, societal, and internal corporate actions to help combat the pandemic; however, both companies are currently supplying all of their products as needed to our healthcare customers.

"Together, we anticipate progressing development across our combined proprietary product portfolio. We will strive to integrate our commercial forces and R&D teams to further strengthen our position as one of the leaders in the antimicrobial resistance detection space and to contribute in the fight against the COVID-19 pandemic."

### **Fourth Quarter and Full Year 2019 audited Financial Results of OpGen, Inc. Stand-alone**

- Total revenue for the fourth quarter of 2019 was \$821 thousand, compared with \$759 thousand in the fourth quarter of 2018. Total revenue for the 12 months ended December 31, 2019 was \$3.5 million, compared to \$2.9 million for the 12 months ended December 31, 2018. Such revenue growth was driven by Acuitas® AMR Gene Panel and Acuitas Lighthouse® revenue, which increased 147% to approximately \$1.4 million, while revenues from OpGen's rapid FISH products decreased approximately 12% to \$2.1 million.
- Operating expenses for the fourth quarter of 2019 were \$3.3 million, compared with \$4.4 million in the fourth quarter of 2018. Total operating expenses for the 12 months ended December 31, 2019 were \$15.8 million, compared to \$16.1 million for the 12 months ended December 31, 2018.
- The net loss for the fourth quarter of 2019 was \$2.5 million or \$0.61 per share, compared with \$3.7 million or \$9.37 per share in the fourth quarter of 2018. The net loss for the 12 months ended December 31, 2019 was \$12.4 million or \$7.70 per share, compared to \$13.4 million or \$44.49 per share for the 12 months ended December 31, 2018.

The Company also provides the following business updates and advisories.

- 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. OpGen has responded, and is

continuing to respond, to the FDA's additional information requests such that OpGen now anticipates it is approaching a clearance decision for the Acuitas® AMR Gene Panel for isolates. Exact timing is unknown as a result of the COVID-19 pandemic.

- Clinical trials were initiated and have been ongoing at nine participating sites for the Acuitas AMR Gene Panel (Urine) test. Testing and the trial have been suspended due to hospital actions to focus resources on the COVID-19 pandemic.
- OpGen completed planned milestones in the groundbreaking collaboration with the New York State Department of Health and ILÚM Health Solutions, LLC, a wholly owned subsidiary of Merck's Healthcare Services and Solutions, to develop a state-of-the-art research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions statewide. In response to the COVID-19 emergency in New York State, testing under the program has been put on hold by the Wadsworth Center and participating hospitals.
- OpGen has significantly improved its working capital position in the first quarter of 2020 through \$5.1 million of sales under the Company's ATM program and \$8.1 million in proceeds from the exercise of warrants from the Company's public offering in October 2019.
- The U.S. Patent and Trademark Office (USPTO) issued a key OpGen patent covering the Acuitas Lighthouse® Profiling technology used in the Company's software for tracking AMR pathogens.

The following key business updates and milestones were achieved in 2019 and year to date by Curetis and Ares Genetics, which, going forward, will be operating as wholly owned subsidiaries of OpGen, Inc.

- Curetis launched the Unyvero LRT Panel for BAL specimens in the U.S. following receipt of 510(k) clearance by the U.S. FDA in December 2019. This is the first and only FDA cleared panel for lower respiratory tract infections such as pneumonia that includes *Pneumocystis jirovecii*, a difficult to diagnose pathogen that is a leading cause of pneumonia in immunocompromised individuals. The highly differentiated Unyvero LRT BAL panel has been commercially available to Curetis' U.S. customers since the end of January 2020 and it is expected to substantially increase the total addressable market for the Unyvero System in the U.S.
- Curetis has started offering a CE-IVD real-time PCR test kit for SARS-CoV-2, the causal pathogen of Coronavirus Disease 2019 (COVID-19), that was developed and recently CE-IVD-marked by Curetis' strategic partner BGI.
- Ares Genetics signed R&D, licensing, and option agreements and has executed on several key strategic partnerships and collaborations with Sandoz, QIAGEN, and an undisclosed global leading IVD corporation. Execution on all of these partnered programs continues within the framework of restrictions by COVID-19 measures imposed by the Austrian government.
- Ares Genetics opened an NGS service lab in Vienna, Austria to leverage ARESdb for services to pharma and diagnostics companies as well as CROs.
- Curetis GmbH and Quaphaco entered into an exclusive distribution partnership for Vietnam for an initial term of three years with Quaphaco committing to a minimum purchase totaling approximately EUR 1.9 million during such initial term. The regulatory filing process of all Unyvero tests in Vietnam is progressing on schedule.

Mr. Jones continued, "The launch of the Curetis Unyvero LRT BAL application as an FDA-cleared molecular diagnostic pneumonia panel opens the market opportunity for this important new test. With the expected surge of hospitalized patients in ICUs globally (many ventilated) with COVID-19 viral infections, the anticipated rise in bacterial pneumonia as a likely complication, and expected to lead to significant co-morbidity in many cases, the Unyvero lower respiratory tract infection test could become an important tool for hospitals combating the anticipated surge of severe COVID-19 cases. The anticipated FDA clearance and launch of our Acuitas AMR Gene Panel product for isolates during 2020, and the exciting combination of the Acuitas Lighthouse® database with the ARESdb attest to our ability to deliver premier AI-powered bioinformatics solutions and diagnostic products."

Mr. Jones continued, "Heading into 2020, we will continue to provide leading data-driven solutions to physicians and patients as shown through Curetis' offering BGI's CE-IVD real-time PCR test kit for SARS-CoV-2. We anticipate this test in combination with the Unyvero HPN panel for bacterial and fungal lower respiratory infections will bring diagnostic efficiency and improve care for patients suffering from COVID-19 at this time."

#### **Business and Operations Outlook Following the Expected Near-Term Successful Closing of the Business Combination with Curetis**

Operations for OpGen and Curetis are currently impacted by global stay-at-home restrictions, travel restrictions, and associated supply chain disruptions. The Company is currently reevaluating all program activities and prioritizing activities and actions in response to the global COVID-19 pandemic. The Company has sufficient cash and access to capital to continue operations in the near and medium term. Additional guidance will be provided following the completion of the planned business combination of OpGen and Curetis.

#### **Conference Call Information**

OpGen's management will host a conference call today, March 24 at 4:30 p.m. ET to discuss fourth quarter and full year 2019 financial results and other business activities, as well as answer questions. Dial-in information is below:

#### **Dial-in Information**

U.S. Dial-in Number: (844) 420-8185

International Dial-in Number: +1 (216) 562-0481

Webcast: <https://edge.media-server.com/mmc/p/n7dop5wx>

Conference ID: 3497986

Following the conclusion of the conference call, a replay will be available through March 31, 2020. The live, listen-only webcast of the conference call

may also be accessed by visiting the Investors section of the Company's website at [www.opgen.com](http://www.opgen.com). A replay of the webcast will be available following the conclusion of the call and will be archived on the Company's website for 90 days. Replay access information is below:

#### **Replay Information**

U.S. Dial-in Number: (855) 859-2056

International Dial-in Number: +1 (404) 537-3406

Conference ID: 3497986

#### **About OpGen**

OpGen, Inc. is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. We are developing molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs.

Our molecular diagnostics and informatics products, product candidates and services combine our Acuitas molecular diagnostics and Acuitas Lighthouse informatics platform for use with our proprietary, curated MDRO knowledgebase. We are working to deliver our products and services, some in development, to a global network of customers and partners. The Acuitas AMR Gene Panel (RUO) is intended for Research Use Only and is not for use in diagnostic procedures. The Acuitas Lighthouse Software is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures. For more information, please visit [www.opgen.com](http://www.opgen.com).

OpGen, Acuitas, and Acuitas Lighthouse are registered trademarks of OpGen, Inc.

#### **About Curetis**

Curetis N.V.'s (Euronext: CURE) goal is to become a leading provider of innovative solutions for molecular microbiology diagnostics designed to address the global challenge of detecting severe infectious diseases and identifying antibiotic resistances in hospitalized patients.

Curetis' Unyvero System is a versatile, fast and highly automated molecular diagnostic platform for easy-to-use, cartridge-based solutions for the comprehensive and rapid detection of pathogens and antimicrobial resistance markers in a range of severe infectious disease indications. Results are available within hours, a process that can take days or even weeks if performed with standard diagnostic procedures, thereby facilitating improved patient outcomes, stringent antibiotic stewardship and health-economic benefits. Unyvero in vitro diagnostic (IVD) products are marketed in Europe, the Middle East, Asia and the U.S.

Curetis' wholly-owned subsidiary Ares Genetics GmbH offers next-generation solutions for infectious disease diagnostics and therapeutics. The ARES Technology Platform combines what the Company believes to be the most comprehensive database worldwide on the genetics of antimicrobial resistances, ARESdb, with advanced bioinformatics and artificial intelligence.

For further information, please visit [www.curetis.com](http://www.curetis.com) and [www.ares-genetics.com](http://www.ares-genetics.com).

#### **Forward-Looking Statements**

This press release includes statements relating to OpGen's fourth quarter and full year 2019 results, the planned business combination with Curetis, and the current business of OpGen and Curetis. These statements and other statements regarding OpGen's 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 fact that we have broad discretion as to the use of proceeds from OpGen's at-the-market offering that commenced in February 2020 and recent warrant exercises and that we may not use such proceeds effectively, OpGen's ability to successfully combine the businesses of OpGen and Curetis, comply with the complexities of a global business, achieve the expected synergies, and implement the combined company's strategic and business goals, the impact of the COVID-19 pandemic on our business and operations, risks and uncertainties associated with market conditions, OpGen's ability to successfully, timely and cost-effectively seek and obtain regulatory clearance for and commercialize our product and services offerings, our ability to successfully complete the demonstration project portion of the New York State Infectious Disease Digital Health Initiative, 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. 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.

#### **No Offer or Solicitation**

This press release is neither an offer to purchase, nor a solicitation of an offer to sell, any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed transactions or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

#### **Additional Information and Where to Find It**

In connection with the transactions contemplated by the Implementation Agreement (the definitive agreement related to the proposed business combination between the Company and Curetis GmbH), a Registration Statement on Form S-4 (File No. 333-234657) has been filed with and declared effective by the Securities and Exchange Commission (the "SEC"). Investors and security holders are encouraged to read the registration statement and any other relevant documents filed with the SEC, including the proxy statement that forms a part of the registration statement. Such documents contain important information about the proposed transaction. The definitive proxy statement was first mailed to stockholders of the Company on or about January 27, 2020. This communication is not a substitute for the registration statement, the proxy statement or any other document that OpGen may send to its stockholders in connection with the proposed transaction. Investors and security holders will be able to obtain

the documents free of charge at the SEC's website, [www.sec.gov](http://www.sec.gov), or from the Company at its website, [www.opgen.com](http://www.opgen.com).

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**OpGen, Inc.**

**Consolidated Balance Sheets**

	2019	2018
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 2,708,223	\$ 4,572,487
Accounts receivable, net	567,811	373,858
Inventory, net	473,030	543,747
Note receivable	2,521,479	—
Prepaid expenses and other current assets	396,760	292,918
<b>Total current assets</b>	<b>6,667,303</b>	<b>5,783,010</b>
Property and equipment, net	130,759	1,221,827
Finance lease right-of-use assets, net	958,590	—
Operating lease right-of-use assets	1,043,537	—
Goodwill	600,814	600,814
Intangible assets, net	817,550	1,085,366
Other noncurrent assets	203,271	259,346
<b>Total assets</b>	<b>\$ 10,421,824</b>	<b>\$ 8,950,363</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 1,056,035	\$ 1,623,751
Accrued compensation and benefits	855,994	1,041,573
Accrued liabilities	1,046,661	902,019
Deferred revenue	9,808	15,824
Short-term notes payable	373,599	398,595
Short-term finance lease liabilities	579,030	399,345
Short-term operating lease liabilities	1,017,414	—
<b>Total current liabilities</b>	<b>4,938,541</b>	<b>4,381,107</b>
Deferred rent	—	162,919
Note payable	329,456	660,340
Warrant liability	—	67
Long-term finance lease liabilities	313,263	437,189
Long-term operating lease liabilities	547,225	—
<b>Total liabilities</b>	<b>6,128,485</b>	<b>5,641,622</b>
<b>Commitments</b>		
<b>Stockholders' equity</b>		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Common stock, \$0.01 par value; 50,000,000 shares authorized; 5,582,280 and 432,286 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	55,823	4,323
Additional paid-in capital	178,779,814	165,396,036
Accumulated deficit	(174,524,983 )	(162,078,525 )
Accumulated other comprehensive loss	(17,315 )	(13,093 )
<b>Total stockholders' equity</b>	<b>4,293,339</b>	<b>3,308,741</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 10,421,824</b>	<b>\$ 8,950,363</b>

OpGen, Inc.

Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
<b>Revenue</b>				
Product sales	\$ 570,674	\$ 589,749	\$ 2,168,179	\$ 2,395,626
Laboratory services	—	12,510	5,435	34,665
Collaboration revenue	250,000	156,700	1,325,000	516,016
<b>Total revenue</b>	<b>820,674</b>	<b>758,959</b>	<b>3,498,614</b>	<b>2,946,307</b>
<b>Operating expenses</b>				
Cost of products sold	229,997	283,440	911,565	1,222,919
Cost of services	127,509	179,372	720,156	625,516
Research and development	1,051,833	1,856,126	5,121,168	5,677,243
General and administrative	1,351,306	1,704,094	6,252,442	7,069,315
Sales and marketing	321,966	414,176	1,464,721	1,531,556
Transaction costs	240,987	—	779,048	—
Impairment of right-of-use asset	—	—	520,759	—
<b>Total operating expenses</b>	<b>3,323,598</b>	<b>4,437,208</b>	<b>15,769,859</b>	<b>16,126,549</b>
<b>Operating loss</b>	<b>(2,502,924 )</b>	<b>(3,678,249 )</b>	<b>(12,271,245 )</b>	<b>(13,180,242 )</b>
<b>Other (expense) income</b>				
Interest and other income, net	18,071	174	9,859	5,384
Interest expense	(44,877 )	(50,742 )	(187,549 )	(191,195 )
Foreign currency transaction gains/(losses)	11,836	(3,875 )	2,410	(10,431 )
Change in fair value of derivative financial instruments	—	316	67	8,386
<b>Total other expense</b>	<b>(14,970 )</b>	<b>(54,127 )</b>	<b>(175,213 )</b>	<b>(187,856 )</b>
<b>Loss before income taxes</b>	<b>(2,517,894 )</b>	<b>(3,732,376 )</b>	<b>(12,446,458 )</b>	<b>(13,368,098 )</b>
<b>Provision for income taxes</b>	—	—	—	—
<b>Net loss</b>	<b>\$ (2,517,894 )</b>	<b>\$ (3,732,376 )</b>	<b>\$ (12,446,458 )</b>	<b>\$ (13,368,098 )</b>
Net loss per common share - basic and diluted	<b>\$ (0.61 )</b>	<b>\$ (9.37 )</b>	<b>\$ (7.70 )</b>	<b>\$ (44.49 )</b>
Weighted average shares outstanding - basic and diluted	4,151,840	398,525	1,616,939	300,453
Net loss	\$ (2,517,894 )	\$ (3,732,376 )	\$ (12,446,458 )	\$ (13,368,098 )
Other comprehensive (loss)/income - foreign currency translation	(9,396 )	5,745	(4,222 )	12,807
<b>Comprehensive loss</b>	<b>\$ (2,527,290 )</b>	<b>\$ (3,726,631 )</b>	<b>\$ (12,450,680 )</b>	<b>\$ (13,355,291 )</b>



Source: OpGen, Inc.