



OpGen Reports First Quarter 2021 Financial Results and Provides Business Update

May 13, 2021

- Total Revenue for Q1 2021 was approximately \$0.8 million
- Balance sheet strengthened significantly with an additional \$34.7 million cash raised in Q1 2021

Conference call to be held at 8:30 a.m. Eastern Time today

GAITHERSBURG, Md., May 13, 2021 (GLOBE NEWSWIRE) -- OpGen, Inc. (Nasdaq: OPGN, "OpGen"), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, reported today its financial and operating results for the three months ended March 31, 2021 and provided a business update. Total OpGen revenue for the first quarter of 2021 was approximately \$830,000, up 34.5% from \$617,000 in the first quarter of 2020. Cash as of March 31, 2021 was approximately \$39.4 million, up significantly from the \$13.4 million at year-end 2020.

Oliver Schacht, President & CEO of OpGen, commented, "We are pleased with our first quarter results and are encouraged by the growth of our products and partnerships over the last several months. This excitement encompasses the recently announced extension and expansion of our strategic collaboration with the New York State and includes winning Chinese NMPA approval for the Curetis Unyvero instrument system as we await a clearance decision for the pneumonia cartridge in China, which is currently under review and pending approval. As the pandemic's effect on the global economy subsides, we believe our balanced product portfolio and long-term pipeline growth initiatives give us the ability to maintain momentum throughout 2021 and support our vision to be amongst the global leaders in infectious disease diagnostics."

First Quarter 2021 Financial Results of OpGen, Inc.

- Total revenue for the first quarter of 2021 was approximately \$830,000 up 34.5% from \$617,000 in the first quarter of 2020. This can be attributed to the business combination with Curetis which closed at the beginning of the second quarter of 2020.
- Operating expenses for the first quarter of 2021 were \$7.1 compared with \$4.6 million in the first quarter of 2020.
- The net loss for the first quarter of 2021 was \$14.9 or \$0.50 per share, compared with \$3.9 million or \$0.53 per share in the first quarter of 2020.
- Cash and cash equivalents were \$39.4 million as of March 31, 2021 compared to \$13.4 million as of December 31, 2020.

The company announced accomplishment of the following key milestones and recent developments in the first quarter as well as 2021 to date:

- Following the previously announced resumption of the FDA's review of the Acuitas AMR Gene Panel 510(k) submission, which had been delayed due to the FDA's prioritization of COVID-19 related emergency use authorizations, OpGen has worked closely with the FDA's review team to address any remaining edits and comments by the FDA to key documents such as the intended use statement, instructions for use, electronic user guide and others. The FDA recently informed OpGen that completion of its review would require additional time due to the current public health crisis. The FDA further informed OpGen that it intends to provide its written feedback to specific documents by the end of May 2021 and to complete its review by the end of August 2021. As of today, OpGen has already received feedback from the FDA on most of the aforementioned key documents under review. The FDA also clarified that these timelines can be affected by various factors including the FDA's other workload and public health priorities. Although the FDA has not committed to a clearance decision timeline, OpGen will continue to proactively engage with the FDA in order to facilitate a final clearance decision.
- OpGen announced signing an extension and expansion agreement for its strategic collaboration with the New York State Department of Health ("DOH") by another six months through September 30, 2021 with the focus of expanding the reach of the platform, increasing the volume of testing, and enhancing data collection.
- OpGen received Chinese NMPA approval for the IVD use of the Curetis Unyvero instrument system for the Chinese market with the application of the Unyvero cartridge for pneumonia currently under review and pending approval.
- OpGen subsidiary Curetis prepared and submitted a pre-submission request to the FDA to discuss and align on regulatory pathway and clinical trial design for the Unyvero UTI application. Due to the COVID pandemic, FDA has provided written feedback only in lieu of a meeting.
- OpGen subsidiary Curetis has continued to provide SARS-CoV-2 testing services, serving the community as a confirmatory PCR test lab for several local SARS-CoV-2 screening test centers.
- OpGen subsidiary Curetis entered into exclusive distribution partnership in Colombia with Annar Health Technologies for Curetis' Unyvero A50 platform.
- OpGen announced the results from its highly attended webinar titled "[Pneumonia Diagnosis: Bacterial Superinfection in](#)

[COVID-19 Patients](#),” where two infectious disease professionals presented their independent study results from the Unyvero Hospitalized Pneumonia (HPN) and Unyvero Lower Respiratory (LRT BAL) panels, demonstrating the importance of distinguishing COVID-19 patients with bacterial superinfection early and accurately, and highlighted that Unyvero detected bacterial pathogens up to 7 days earlier and would have enabled prompt and appropriate targeted antibiotics in 41.3% of cases and reduced time to appropriate therapy by 25.7 hours.

- OpGen announced publication of final study results of the Unyvero HPN Panel for Diagnosis of Bacterial Co-Infections in ICU Patients with COVID-19 pneumonia showcasing that high negative predictive value of 99.8% may allow for reduction in unnecessary antibiotic use and support antibiotic stewardship efforts.
- Several scientific contributions illustrating the benefits of the Unyvero Lower Respiratory panels and the utility of the Acuitas AMR Gene Panel will be presented at the [World Microbe Forum](#), June 20-24, 2021.
- OpGen subsidiary Ares Genetics announced publication of a study introducing best practice techniques for AI-powered prediction of antibiotic susceptibility testing which aimed at advancing good machine learning practices (GMLP) for WGS-based AST by describing best practice techniques for training and evaluation of predictive models, as well as introducing an optimized model architecture to reduce bias and promote robustness.
- OpGen subsidiary Ares Genetics signed several agreements with early access customers for the new Ares universal pathogen assay (ARESupa). The initial version of this target enrichment NGS panel is aimed at enabling testing for pathogens and AMR in native specimens and covers over 6,000 genetic markers for AMR selected from ARESdb.
- OpGen subsidiary Ares Genetics will be presenting at the upcoming Amazon Web Services (AWS) Healthcare & life Sciences Virtual Symposium on May 27, 2021 on “Bridging limitations in NGS-based infectious disease testing using machine learning.”
- OpGen completed a \$25 million registered direct offering priced at the market with one healthcare-focused U.S. institutional investor, as well as a warrant exercise and exchange deal for proceeds of \$ 9.7 million.

Mr. Schacht commented, “We had a busy quarter that resulted in great progress towards the fight against AMR with multiple publications issued supporting OpGen’s products and mission, new and existing partnership growth that will help drive topline revenue and OpGen also announced regulatory progress particularly with the Chinese NMPA. We also significantly strengthened our balance sheet during the first quarter. As we push through the second quarter, we believe we can achieve an FDA clearance decision for our Acuitas AMR Gene Panel as soon as the FDA’s timelines will permit and work towards pipeline and growth objectives in the year ahead and I look forward to the company’s continued successes.”

Conference Call Information

OpGen’s management will host a conference call today, May 13 at 8:30 a.m. EDT to discuss the first quarter financial results and other business activities, as well as answer questions. Dial-in information is below:

Dial-in Information

U.S. Dial-in Number: +1-877-705-6003

International Dial-in Number: +1-201-493-6725

Webcast: <http://public.viaavid.com/index.php?id=144749>

Conference ID: 13719409

Following the conclusion of the conference call, a replay will be available through May 27, 2021. 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. 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: +1-844-512-2921

International Dial-in Number: +1-412-317-6671

Replay PIN: 13719409

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

This press release includes statements regarding OpGen’s first quarter 2021 results and the current business of OpGen. 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, 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 fact that we may not effectively use proceeds from recent financings, including our November 2020 private placement, February 2021 Registered Direct and March 2021 warrant exercise and exchange, the realization of expected benefits of our business combination transaction with Curetis GmbH, 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 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.

OpGen, Inc.
Consolidated Balance Sheets
(unaudited)

| | <u>March 31,</u> <u>2021</u> | <u>December 31,</u> <u>2020</u> |
|---|---------------------------------|------------------------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 39,397,437 | \$ 13,360,463 |
| Accounts receivable, net | 485,983 | 653,104 |
| Inventory, net | 1,417,440 | 1,485,986 |
| Prepaid expenses and other current assets | 1,472,666 | 1,388,090 |
| Total current assets | 42,773,526 | 16,887,643 |
| Property and equipment, net | 3,649,747 | 3,259,487 |
| Finance lease right-of-use assets, net | 338,673 | 449,628 |
| Operating lease right-of-use assets | 2,383,364 | 2,082,300 |
| Goodwill | 7,694,401 | 8,024,729 |
| Intangible assets, net | 15,656,651 | 16,580,963 |
| Strategic inventory | 2,057,016 | 1,686,342 |
| Other noncurrent assets | 602,220 | 779,953 |
| Total assets | \$ 75,155,598 | \$ 49,751,045 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities | | |
| Accounts payable | \$ 1,249,461 | \$ 1,868,666 |
| Accrued compensation and benefits | 2,286,441 | 2,126,511 |
| Accrued liabilities | 1,712,008 | 1,437,141 |
| Deferred revenue | 9,808 | 9,808 |
| Current maturities of long-term debt | 282,055 | 699,000 |
| Short-term finance lease liabilities | 183,533 | 266,470 |
| Short-term operating lease liabilities | 849,895 | 964,434 |
| Total current liabilities | 6,573,201 | 7,372,030 |
| Long-term debt, net | 19,430,641 | 19,378,935 |
| Derivative liabilities | 206,973 | 112,852 |
| Long-term finance lease liabilities | 29,265 | 46,794 |
| Long-term operating lease liabilities | 2,737,211 | 1,492,544 |
| Other long term liabilities | 147,026 | 156,635 |
| Total liabilities | 29,124,317 | 28,559,790 |
| Stockholders' equity | | |
| Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2020 and 2019, respectively | — | — |
| Common stock, \$0.01 par value; 50,000,000 shares authorized; 38,266,482 and 25,085,534 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively | 382,665 | 250,855 |
| Additional paid-in capital | 259,766,331 | 219,129,045 |
| Accumulated deficit | (215,586,418) | (200,735,827) |
| Accumulated other comprehensive income | 1,468,703 | 2,547,182 |
| Total stockholders' equity | 46,031,281 | 21,191,255 |
| Total liabilities and stockholders' equity | \$ 75,155,598 | \$ 49,751,045 |

OpGen, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

| | Three Months Ended March 31, | |
|--|-------------------------------------|-----------------------|
| | 2021 | 2020 |
| Revenue | | |
| Product sales | \$ 613,918 | \$ 366,933 |
| Laboratory services | 97,726 | — |
| Collaboration revenue | 118,072 | 250,000 |
| Total revenue | 829,716 | 616,933 |
| Operating expenses | | |
| Cost of products sold | 554,054 | 276,554 |
| Cost of services | 104,984 | 137,666 |
| Research and development | 2,813,491 | 1,217,556 |
| General and administrative | 2,663,657 | 1,701,448 |
| Sales and marketing | 899,252 | 282,277 |
| Transaction costs | — | 245,322 |
| Impairment of intangibles assets | — | 750,596 |
| Impairment of right-of-use asset | 55,496 | — |
| Total operating expenses | 7,090,934 | 4,611,419 |
| Operating loss | (6,261,218) | (3,994,486) |
| Warrant inducement expense | (7,755,541) | — |
| Interest and other income | 4,925 | 87,335 |
| Interest expense | (1,164,982) | (38,267) |
| Foreign currency transaction gains (losses) | 427,615 | (3,876) |
| Change in fair value of derivative financial instruments | (101,390) | — |
| Total other expense | (8,589,373) | 45,192 |
| Loss before income taxes | (14,850,591) | (3,949,294) |
| Provision for income taxes | — | — |
| Net loss | \$ (14,850,591) | \$ (3,949,294) |
| Net loss available to common stockholders | \$ (14,850,591) | \$ (3,949,294) |
| Net loss per common share - basic and diluted | \$ (0.50) | \$ (0.53) |
| Weighted average shares outstanding - basic and diluted | 29,485,067 | 7,393,232 |
| Net loss | \$ (14,850,591) | \$ (3,949,294) |
| Other comprehensive loss - foreign currency translation | (1,078,479) | 39,477 |
| Comprehensive loss | \$ (15,929,070) | \$ (3,909,817) |

OpGen:

Oliver Schacht
President and CEO
InvestorRelations@opgen.com

OpGen Press Contact:

Matthew Bretzius
FischTank Marketing and PR
matt@fischtankpr.com

OpGen Investor Contact:

Megan Paul
Edison Group
mpaul@edisongroup.com



Source: OpGen, Inc.