

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

May 11, 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

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 8.01 Other Events.

On May 11, 2020, OpGen, Inc. (the “Company”) issued a press release consisting of letters to its stockholders describing recent Company developments. A copy of the press release is included as Exhibit 20.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

20.1 [Press Release, dated May 11, 2020.](#)

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: May 11, 2020

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec
Title: Chief Financial Officer



OpGen CEO and Chairman of the Board Issue Letters to Stockholders

GAITHERSBURG, Md., May 11, 2020 – OpGen, Inc. (Nasdaq: OPGN, “OpGen”), a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease, to issued two letters to stockholders from new OpGen CEO Oliver Schacht and Chairman of the Board William Rhodes. Both letters can be found in full below:

Dear Stockholders,

As the newly appointed president and CEO of OpGen I want to take a moment to formally introduce myself and share the vision our new management team has for the company with regards to our business outlook, product pipeline and growth strategy for this year and beyond. This is an exciting time for OpGen, and I very much look forward to working with the entire team through the next phase of its growth.

For the past nine years I served as CEO of Curetis and have a strong background in corporate finance and molecular diagnostics, as demonstrated by my 13 years as CFO of Epigenomics AG (Berlin, Germany) and the six years also as CEO of Epigenomics Inc. (Seattle, USA). Our newly blended management team here at OpGen has extensive experience in developing and implementing commercial strategies and financing measures – critical assets as the company moves forward. I expect seamless operational continuity with Tim Dec, OpGen’s CFO who will continue in his role, and Curetis’ Johannes Bacher, OpGen’s new COO, in captaining the ship that is our newly combined company.

This business combination is centered on achieving high growth while leveraging operational efficiencies and maintaining financial discipline as we press forward toward our primary vision – to help solve the looming AMR crisis while preserving antibiotics as effective weapons through more advanced, rapid diagnostic testing. Our state-of-the-art robotic manufacturing facility in Germany, as well as our strong U.S. sales and marketing team and dedicated European commercial partner support team, will be key assets in our post-combination success. OpGen, with Ares Genetics, has access to even more advanced bioinformatics capabilities that can be leveraged to integrate the company’s AMR databases, data analytics and reporting platforms to innovate next-generation sequencing-based solutions for infectious disease diagnostics in the future. These synergies are undoubtedly drivers of the core business and are expected to increase stockholder value.

Our mission at OpGen is to develop, manufacture and commercialize novel solutions for rapid, molecular diagnostics of severe life-threatening infectious diseases in hospitalized patients. Our company offers integrated solutions that cover unique and differentiated diagnostics test panels, powerful AI-driven bioinformatics and software tools that help find and track multidrug-resistant microorganisms (MDROs). Our ability to do so will depend on us achieving certain milestones in the short, medium, and long term, as I’ll outline below.

We must first complete the post-combination integration between the OpGen and Curetis and Ares Genetics businesses across all international teams within the U.S., Germany and Austria offices, which we are working on with full speed to complete as soon as possible. From a product standpoint, our near-term business rollout includes the anticipation of combining Ares Genetics and Acuitas Lighthouse databases and bioinformatics capabilities to bring a combined offering to customers, partners and labs globally. A key milestone for the company will be the expected near-term FDA clearance decision for our Acuitas AMR Gene Panel (Isolates) diagnostic test. We are working actively with the FDA to address any last remaining open items from the interactive review process. While we anticipate the review process is nearing completion, we still expect COVID-19 related delays to the second interactive response review and final timing is hard to predict at this point. As we work through that FDA process, we will also evaluate and prioritize across the entire OpGen group portfolio of R&D programs, platforms, and product development opportunities to select those that we believe have biggest impact and stockholder value creation potential in the near term as well as longer term growth potential.



As we look beyond this year, we will seek to consolidate the existing OpGen and Curetis diagnostic test menu on fewer platforms and anticipate bringing the Unyvero A30 RQ platform to market with strategic partners. The rollout and launch of the Unyvero platform and pneumonia test pending China NMPA approval will be a key milestone for the company. Additionally, we hope to bring the combined OpGen portfolio of products to global markets in Europe, Asia Pacific and other global markets through our strong distribution network that we expect to continue to expand further over time. We will also seek to raise additional capital for OpGen. We will consider all instruments at our disposal in terms of equity, debt, non-dilutive grant funding as well as partnering and licensing models as a source of further non-dilutive funding with the consistent goal of optimizing stockholder value.

In closing, I am confident that we will be able to establish OpGen as an industry leader in the fight against AMR. We anticipate this business combination will maximize value for our stockholders through a broad and exciting product portfolio with proprietary assets for developing and commercializing innovative, data-driven solutions in infectious disease diagnostics. We anticipate for these reasons our top-line revenue will continue to grow in the years ahead as we use operational efficiencies and synergies to reduce cash burn. Together, with your continued support, we aim to create sustainable stockholder value and expand our proprietary product portfolio capabilities through seeking opportunities that present significant growth potential for the company.

Yours sincerely,
Oliver Schacht, PhD
CEO, OpGen, Inc.



Dear Stockholders,

In this exciting time for OpGen, I am honored to have been elected as the Chairman of the Board of the Directors of OpGen following the completion of its business combination transaction with Curetis. After five years as Chairman of the Supervisory Board for Curetis and a 14-year career at Becton Dickinson and Company (BD, 1998-2012), where I held several senior leadership positions, I am delighted to be chairing this distinguished Board of Directors and anticipate significant, value-creating opportunities for the company. OpGen has been developing industry leading, AI-powered diagnostics and data-driven solutions serving hospitals and patients successfully for many years. This is a particularly dynamic time for our enterprise as we integrate the two businesses and push to further diversify our product portfolio.

Our newly constituted Board consists of six members representing expertise from both companies; there are currently four members named by Curetis and two from the pre-combination Board of OpGen. Changes to the Board include Evan Jones, formally OpGen chairman and CEO to join as a non executive director who will help with the transition. Don Elsey will continue as chair of the audit committee joined by Mario Crovetto and Prabha Fernandes, former Supervisory Board directors of Curetis. Thus, the reconstituted Board of Directors consists of myself, Mr. Schacht, Mr. Jones, Mr. Crovetto, Dr. Fernandes, and Don Elsey. These individuals bring a strong understanding of the diagnostic and AMR space as well as significant finance, healthcare, marketing and business development expertise. I look forward to working with such a diverse and talented group of individuals as we lead the company towards value-creating opportunities.

Since the beginning, the cornerstone of success of our pre-combination businesses has been the shared vision and mission to develop, manufacture and commercialize proprietary solutions for rapid, molecular diagnostics of severe life-threatening infectious diseases. Following completion of our combination, our fundamental business now offers a much broader, diversified portfolio of products, platforms and bioinformatic solutions. Not only do our business outlooks and industry goals mirror one another, but our combined management and executive teams complement each other as one new combined team.

As we embark on integrating our businesses, teams and products over the coming months, the pace and success of our pipeline rollout will largely be determined by the successful execution of our integration strategies. Additionally, a key driver of the Curetis' core business will be OpGen's existing Nasdaq listing and thereby access to U.S. capital markets. This opportunity provides access to a much broader and deeper pool of capital within the U.S. market, ultimately giving the company a larger platform to drive business and pipeline growth.

We are excited about the prospects for the company, as we expect to be able to achieve more sustainable growth combined than as separate entities. We anticipate multiple FDA clearance opportunities and we strive to integrate our premier bioinformatics solutions and databases. We will deploy our PCR platforms such as Unyvero and Acuitas as well as our ARESdb and Lighthouse knowledgebase and offer services and strategic partnering opportunities for our next generation sequencing and AI-powered prediction algorithms. Ultimately, the prospect of having the ability to control our own destiny and steer our proprietary platforms is exciting. This offers partnering, commercial and financing opportunities that will likely provide stockholders with attractive entry and exit opportunities.

In conclusion, on behalf of the Board, I thank you for your unwavering support of the new OpGen. We remain committed to our mission and to the hospitals and communities that we serve. 2020 will be an exciting year as we continue to build the business and deliver on our commitment to premier AI-powered solutions to the AMR crisis.

Yours sincerely,
William E. Rhodes
Chairman of the Board, OpGen, Inc. Board of Directors



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 the integration of OpGen with its acquired subsidiaries, Curetis GmbH and Ares Genetics GmbH, the current business and strategic initiatives of OpGen and general market conditions. 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 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.

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