

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

November 4, 2021
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)

9717 Key West Ave, Suite 100
Rockville, MD 20850
(Address of principal executive offices)(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))

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 7.01 — Regulation FD Disclosure.

On November 4, 2021, Oliver Schacht, Ph.D., Chief Executive Officer of OpGen, Inc. (the “Company”), participated in a video interview relating to, among other things, the Company’s Special Meeting of Stockholders scheduled for December 8, 2021 (the “Special Meeting”). A transcript of the interview is filed as Exhibit 99.1 of this Current Report on Form 8-K.

The information in this Current Report on 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.

Forward-Looking Statements

This Current Report on Form 8-K and its exhibit includes statements regarding the Company’s Special Meeting of Stockholders as well as the Company’s current operations and business plans. These statements and other statements regarding the Company’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 Company’s ability to successfully, timely and cost-effectively develop, seek and obtain regulatory clearance for and commercialize its product and services offerings, the Company’s ability to obtain stockholder approval for an increase in its authorized shares of common stock or otherwise pursue alternative means of continued financing for its operations, the rate of adoption of the Company’s products and services by hospitals and other healthcare providers, the fact that the Company may not effectively use proceeds from our financings, the realization of expected benefits of the Company’s business combination transaction with Curetis GmbH, the success of the Company’s 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 the Company’s 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 the Company’s business, investors should carefully review the Company’s filings with the Securities and Exchange Commission (the “SEC”). Readers are cautioned not to place undue reliance on these forward-looking statements, which are based on the Company’s expectations as of the date of this Current Report on Form 8-K and speak only as such date. The Company undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by laws.

Additional Information

In connection with the Special Meeting, the Company filed with the SEC on October 29, 2021 a proxy statement for the Special Meeting and may also file other relevant documents with the SEC regarding the proposals to be considered at the Special Meeting. This report is not a substitute for the proxy statement or any other document that the Company may file with the SEC. The proxy statement has been made available to stockholders. Investors and security holders are urged to read the proxy statement and any other relevant documents that may be filed with the SEC, as well as any amendments or supplements to those documents, carefully and in their entirety if and when they become available because they contain or will contain important information about the Company and the proposals to be considered at the Special Meeting. Investors and security holders will be able to obtain free copies of the proxy statement and other documents containing important information about the Company and the Special Meeting through the website maintained by the SEC at <http://www.sec.gov>. Copies of the documents filed with the SEC by the Company may be obtained free of charge on the Company’s website at www.opgen.com.

Item 9.01 — Financial Statements and Exhibits.

(d) Exhibits

99.1	Interview transcript
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 4, 2021

OpGen, Inc.

By: /s/ Oliver Schacht PhD

Name: Oliver Schacht PhD

Title: Chief Executive Officer

Executive Video Interview with Oliver Schacht, Ph.D., OpGen CEO

Publication Date: November 4, 2021

Transcript as follows:

Caroline Woods (Edison Group):

Hello and welcome. I'm Caroline Woods and we're here today to discuss the whys and wherefores of the fifteen million dollar capital raise by listed diagnostics business OpGen.

OpGen describes itself as 'a precision medicine company, harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease'.

Perhaps the most exciting part of its mission is to lengthen the life of current antibiotics in the face of growing antimicrobial resistance, also known as AMR. A significant threat to humanity, AMR has already cost the US healthcare system an estimated twenty billion dollars and is now set to spiral into a global pandemic, with projections of up to 10 million deaths by 2050.

On October 4, OpGen's fight against AMR reached a significant milestone. Its Acuitas AMR Gene Panel - which is able to detect 28 different genetic markers associated with AMR, from sample to answer in hours not days - was cleared by the FDA.

With the panel's commercial launch already under way, OpGen has also opened - and closed - a fifteen-million-dollar capital raise.

To the outside world it seems like a swift change in pace for the business. After an elongated period of waiting for the FDA, everything is now moving very quickly. And while shareholders prepare to vote on the increase of common stock from 50 million to 100 million shares of common stock - management has faced many questions from investors. Not least regarding voting rights and dilution.

Which is why today we'll be putting CEO Oliver Schacht on the spot and asking for clarity.

Welcome Oliver.

Oliver Schacht:

Hi. Thanks. I appreciate the opportunity.

Caroline:

Right! Let's get straight to it. Can you help us understand OpGen's busy start to the fourth quarter of 2021?

Oliver:

Absolutely – this has been a really exciting start into Q4 of 2021. After more than two years of waiting for the FDA clearance, we finally got our first OpGen molecular diagnostics product cleared by the FDA - allowing us commercialize the Acuitas AMR Gene Panel right away. It's the final piece of moving OpGen from an R&D-driven company into a commercial-stage enterprise, poised for growth in the coming years.

Caroline:

What, in your view, is the significance of the FDA clearance for Acuitas?

Oliver:

Getting FDA clearance is always a tough hurdle. This is now the third FDA cleared product that OpGen and its subsidiary Curetis have successfully pushed over the regulatory finish line in the U.S. - and the third product we are now offering commercially in the U.S. as an IVD.

We think this helps to reduce the risk profile of the company from the perspective of investors and over time the capital market will come to appreciate our new commercial profile. It may also reduce the risk that the market attaches to our future FDA submissions. We clearly have a team that knows how to successfully conclude trials and FDA submissions.

Caroline:

I think it's fair to say there's a been some concern over the structure and impact of the capital raise, especially how it will affect existing shareholders. Could you describe the mechanic in more detail?

Oliver:

Certainly.

Back in June, July and August we proposed at our shareholder meeting, which we had to adjourn twice due to insufficient turnout, that we should increase the authorized common stock. We had already stated that if that pathway were not made available, we might have to use the authorized preferred stock for future financings. Since we did not receive approval due to a lack of sufficient stockholders voting at the meeting, we have issued the 150,000 preferred stock from our 10 million authorized in order to complete this financing.

The board, upon detailed discussion and extensive discussions with Nasdaq, has attached 30,000 votes to each of these preferred shares, which was an important consideration for the investor. But to be clear – these voting rights are exclusively for the two voting items proposed in the special meeting to be held on December 8, 2021 - namely the reduction of the required majority in our charter from 66 and 2/3% to 50% and secondly the authorization of the increase in common shares.

And to be absolutely clear - the holders of the preferred stock cannot vote on any other item thereafter. Not now and not ever.

To enshrine this OpGen, in accordance with Nasdaq rules, to use a mirroring mechanism for voting. For all subsequent votes, the common stockholders will vote as usual. The holders of the preferred stock will not.

However, the votes of the preferred stock vote will be allocated. And allocated in the exact same percentage split as the result for the common vote.

At which point you might ask: Why bother? Well, there is a big benefit to all shareholders.

The preferred stockholder votes are allocated automatically. And this means they'll almost certainly be enough votes to reach a decision. It also guarantees the decision will also be one which reflects the opinion of the common stockholders who vote - and not necessarily the option the board is asking for nor the opinion of those who do not bother to vote at all. This is good for everyone because it means we can get decisions and move forward.

We are very fortunate to enjoy a lot of popularity with retail investors. However, one less positive consequence has been the money we've had to spend on proxy solicitation to gain a quorum. Which is why two thirds of the common stockholders who voted this summer, voted to support the proposal to increase the common stock. This new mechanic ensures it is their voices and votes that will continue to be heard. There is no automatic dilution from an increase in authorized but not issued common stock. But we will have the flexibility, as every biotech company that is pre profitability needs, to access the capital markets from time-to-time.

Caroline:

What is OpGen going to do with the fifteen million dollars raised?

Oliver:

As we have outlined in the SEC filings, the \$15 million additional financing will allow OpGen to continue executing our business strategy.

As of October 2021, we have close to 40 million dollars of cash on our balance sheet. If we can use all of that for operations rather than having to use the extra cash to repay debt, then we have quite some runway given our guidance of \$5 to \$6 million in quarterly cash burn.

What this means is that we can focus on the commercial launch and roll out of Acuitas AMR in the USA. We can focus on driving the commercial ramp of our Unyvero business in the U.S. and abroad in areas such as pneumonia, urinary tract infections and other indications. We'll be able to fund clinical trials such as the UTI FDA trial and the planned IJI trial in the US as well.

Furthermore, Ares Genetics, which has recently launched its first commercial software offering with AREScLOUD, will continue the commercial roll out of its offerings and services in Europe. We also intend to bring Ares' offerings to the U.S. which will require dedicated commercial and operational resources in 2022 and beyond.

What the \$15 million will do then, is provide us with the option to re-pay the first tranche of EIB debt. This is 10 million EUR, plus accrued interest of about 3 million EUR and becomes due in April 2022.

However, our preferred route would be to restructure the outstanding debt. We have begun discussions with EIB regarding potential restructuring options including the possibility of potentially converting the debt into equity over time.

Caroline:

OK, so talk to us about some of the other details now. Why wasn't the raise open to the public? And how did you select the buyer?

Oliver:

Given what we need from this transaction there was a rather narrow list of potential buyers. Our stipulation was that the preferred shares would not be tradeable. And there is no guarantee that the shareholder vote will authorize the common stock needed for the preferred shares to convert automatically to common in December.

We also had a very defined time window. Meanwhile, the feedback from our bankers talking to a significant number of other institutional investors was we would need to tailor special asks for each and every investor we brought in.

Under these circumstances, doing a deal with a single investor who knows the company well and who has supported OpGen in previous financings made most sense. And to the warrants that are attached at a strike of \$2.05 - which have the potential to bring in another \$15 million of capital.

That said, it remains our objective to bring more long-term, growth-oriented institutional investors into the OpGen stock. But that does not happen overnight and requires patience, execution on the fundamentals and the ability to issue common stock.

Caroline:

From what I understand shareholders are also asking questions about insider buying and whether the ultimate stock dilution is worth the price being paid. How are you answering those questions?

Oliver:

Look – myself, my family and our COO Johannes Bacher recently bought shares at the \$2.25 and \$3.08 price points. We fundamentally believe in the long term value creation and growth potential. A huge proportion of my own personal long term compensation is tied to the OpGen stock – be it as stock options that vest over several years or be it as RSUs. At the current price levels there is basically zero value in these equity components to us. Our interest is 100% aligned with all common shareholders.

Caroline:

So what's the expectation of further capital raises?

Oliver:

As said before – as of October 2021 we now have close to \$ 40 million cash on hand. With the 7.5 million warrants at \$2.05 and another 7.7 million warrants at either \$3.55 and \$3.56, we have the potential for more than \$42.6 million cash coming into OpGen in the coming years. There are currently no specific plans for any specific future financing.

However, we need to retain flexibility. If one looks at the successful companies in our sector that have been built, financed for growth and seen successful exits recently (such as GenMark, Mesa Biotech, Mobidiag and Luminex) they all were properly financed. That allowed them to drive deals on the M&A side that were highly attractive to their shareholders.

Caroline:

What would the consequences be if shareholders refused to approve the increase in authorized common shares?

Oliver:

Prior to the recent financing, our cash reach, including the EIB debt tranche, would have been April 2022. This has now been extended by two to three quarters. Thus shareholders would be much worse off if OpGen had to repay the EIB's 13 million Euros or \$15+ million in cash in April 2022 - rather than having the option to carefully and smartly restructure the debt over time.

This proposal delivers a significant reduction in cash burn. The only other way to achieve that would have been by scrapping commercial activities, stopping clinical trials and reducing operations and staffing - which would have been a huge loss for shareholder value.

Caroline:

There are also operational questions being asked. Could we turn to some of those now?

Oliver:

Yes, of course.

Caroline:

Thank you. A month on from approval, where is OpGen with the launch of Acuitas? Is there a sales pipeline for the panel?

Oliver:

Yes absolutely!

We prepared the launch plan and marketing collateral - and we trained the sales team - prior to FDA clearance. We also manufactured several batches of Acuitas AMR kits.

Immediately upon receiving FDA clearance, we've begun a major marketing and sales campaign, addressing several hundred institutions across the United States, with well over a thousand key individual stakeholders within these institutions.

But to manage people's expectations here. This is a first-in-class molecular diagnostic product. Sales cycles in our industry tend to be in the 6 to 12 month range. While we have certainly generated some leads and have also worked closely with several hospitals and labs across the state of New York, the marketing and sales effort can only now begin. This will be a story to commercially unfold in 2022.

Caroline:

Could you also provide any update on the progress internationally, as well as the performance of OpGen's other products?

Oliver:

At this point, there are no plans to commercialize the Acuitas AMR product outside of the USA – we do not have any regulatory clearance in any other region nor are we currently planning on seeking it short term.

With European IVDR on the horizon for 2022 and the lengthy and complex processes in Asia, our focus for the Acuitas product remains on the U.S.

Meanwhile, our Unyvero portfolio is making good progress. We have defined the details of a clinical study to supplement the submission in China. We are working out final details on the control concept and logistics – our partner has already obtained IRB approval from the ethics committee of the first of three hospitals to participate in this small scale study.

Our partner Annar in Colombia has been successful to gain preliminary registration for Unyvero and just days ago we have sold the first Unyvero system there. Vietnam is still very much in lockdown due to Covid, and we currently do not have a reliable sense of regulatory timelines there.

A clear area of business focus and revenue growth for OpGen globally is our Ares Genetics NGS and AI-powered bioinformatics suite of products. We have integrated the data from Lighthouse into Aresdb and the latter will be our core bioinformatics platform moving forward. Lighthouse is not a platform that we plan to continue taking forward as the Arescloud and Aresdb are superior both technically and commercially and have seen significant initial customer interest.

We anticipate growing the Ares business along its software and services arms and, longer term, with kits and other products as well. To that end Ares Genetics has recently strengthened its commercial footprint by hiring an experienced European business development manager and we are looking to add an Ares executive team member for commercial operations in the U.S. for 2022 as well.

Caroline:

And finally, is there any news on the appointment of a new CFO?

Oliver:

There most certainly is – as we stated in our recent public announcement – the search has been completed! We have identified our CFO and have all pieces in place such that our board can formally appoint the new CFO. As soon as that happens, we'll be able to make the public announcement. We are excited for the individual who will join the executive leadership team with extensive corporate finance expertise in global diagnostics business operations. Watch this space for news in due course.

Caroline:

Thank you Oliver.

And that's all we have time for today. For analysis of OpGen's long-term prospects do visit Edison Research. Just click on the link at the end.

Thank you for watching.