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 11, 2020
Date of Report (date of earliest event reported)

OpGen, Inc.
(Exact name of Registrant as specified in its charter)

Delaware	**001-37367**	**06-1614015**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

708 Quince Orchard Road, Suite 205
Gaithersburg, MD 20878
(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 [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 2.02 Results of Operations and Financial Condition.

On November 11, 2020, the Company issued a press release announcing its third quarter financial results for the quarter ended September 30, 2020. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, dated November 11, 2020.

The information included in Item 2.02 herein and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 ("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 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: November 12, 2020

OpGen, Inc.

By: /s/ Timothy C. Dec

Name: Timothy C. Dec
Title: Chief Financial Officer

OpGen Reports Third Quarter 2020 Financial Results and Provides Business Update

- *OpGen takes strategic steps to expand the Unyvero platform and product pipeline, to focus on the pending Acuitas AMR Gene Panel (isolates) FDA clearance and expects to invest significantly in bioinformatics*
- *OpGen subsidiary Ares Genetics received notification of exercise of option to negotiate for a potential future license by its IVD Partner*
- *OpGen has discontinued Acuitas AMR Gene Panel (urine) clinical trial and will discontinue FISH product line globally by mid-2021*
- *Total Revenue for Q3 2020 was approximately $1.1 million dollars*
- *Maintained strong balance sheet with $10.5 million cash as of September 30, 2020*

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

GAITHERSBURG, Md., November 11, 2020 (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 and nine months ended September 30, 2020 and provided a business update. Total OpGen revenue for the third quarter of 2020 was approximately $1.1 million, up from $0.6 million in the third quarter of 2019. The financial results for the three months ended September 30, 2020 reflect the consummation of our business combination with Curetis GmbH on April 1, 2020. OpGen's cash as of September 30, 2020 was approximately $10.5 million. The company has access to an additional $6.4 million under its expanded ATM program and has 594,000 warrants outstanding at an average exercise price of $2.16. In addition, the Company continues to have access to an additional €5.0 million tranche of non-dilutive debt financing for COVID-19 related R&D programs from the European Investment Bank.

As previously reported, OpGen announced details regarding a strategic reprioritization of its product portfolio, platform pipeline and priorities going forward. This reprioritization was based on feedback from extensive market research, a customer survey of 150 stakeholders in the decision making on new diagnostic platforms, and key-opinion-leader interviews conducted by an independent market research firm over the past two quarters. Following a review of this research, OpGen and its board decided to consolidate the company's product portfolio on its proprietary Unyvero platform and unique bioinformatics capabilities. As a result of this change in priority, the company anticipates the following key impacts:

- Product portfolio going forward is centered around rapid, molecular diagnostic platform offerings and increased focus on value added bioinformatics solutions, including Ares Genetics' next generation sequencing-based and artificial intelligence powered AMR and AST prediction capabilities.
- Following the successful completion of the three phases of the partnered R&D program as announced in the during our second quarter 2020 earnings call, Ares Genetics has recently received formal notification from its undisclosed global leading IVD corporation partner that they have exercised their option to exclusively negotiate with Ares Genetics the scope and terms of a potential exclusive license or other arrangement with Ares to Ares Genetics' technology in the field of human clinical diagnostics in the coming months.

- Platform consolidation to realize significant operational synergies and cost savings over time as fewer products and platforms would need to be maintained from a regulatory, quality management and logistics and service standpoint.
- Unyvero platform and product portfolio to be expanded beyond lower respiratory tract infections such as pneumonia (LRT / LRT BAL) to include complicated urinary tract infections (cUTI) and invasive joint infections (IJI) in the U.S. with clinical trials for future FDA submission and clearance anticipated to start in 2021. Similar products in both clinical indication areas using the same sample types have already been successfully developed and CE-IVD marked and are commercially available in Europe and other markets.
- Recent notification from the FDA has indicated that the agency plans to continue prioritizing emergency use authorization (EUA) requests for diagnostic products intended to address the COVID-19 pandemic for at least the remainder of the year, which will impact the statutory review periods for ongoing submissions. During this time, the FDA plans to provide monthly updates regarding the ongoing impact of such prioritization of EUAs on our Acuitas AMR Gene Panel for Isolates submission. Despite such impact, OpGen has remained in open and ongoing dialogue with the FDA regarding the status of the Acuitas AMR Gene Panel for Isolates submission since our October 2020 formal response to the FDA's Additional Information (AI) requests. If the Acuitas AMR Gene Panel for Isolates is cleared by the FDA, OpGen anticipates swift commercial launch in the U.S. in the following months.
- Legacy FISH products business including Quick FISH® and PNA FISH® to be discontinued by mid-2021 in Europe, the U.S. and rest of world with last production lots to be manufactured in early 2021. All customers in the U.S. and distributors in Europe have been informed of the discontinuation and OpGen expects last stocking orders to come in by year-end with several orders already received.
- Acuitas AMR Gene Panel (urine) clinical trial has been discontinued and all clinical trial sites have been notified as focus shifts to Unyvero platform for complicated UTI indication as well as additional future applications.

Oliver Schacht, President and CEO of OpGen commented, "Reprioritization efforts including the consolidation of our product portfolio highlights our focus on rapid, molecular diagnostic offerings and bioinformatics as we look to 2021 and beyond. Additionally, the discontinuation of the Acuitas AMR Gene Panel (urine) clinical trial and the Legacy FISH products business will result in significant operational synergies and cost savings for OpGen. We believe this shift will create meaningful, long term shareholder value for our investors, partners and healthcare provides alike as we continue to establish ourselves as industry leaders in molecular diagnostics and bioinformatics space."

Third Quarter and Nine Month 2020 Financial Results

- Total revenue for the third quarter of 2020 was approximately $1.1 million, up from $0.6 million in the third quarter of 2019. Total revenue for the nine months ended September 30, 2020 was $2.9 million, compared with $2.7 million for the nine months ended September 30, 2019;
- Operating expenses for the third quarter of 2020 were $7.2 million, compared with $4.1 million in the third quarter of 2019. Operating expenses for the nine months ended September 30, 2020 were $19.6 million, compared with $12.4 million for the nine months ended September 30, 2019;
- The net loss for the third quarter of 2020 was $7.7 million or $0.40 per share, compared with $3.5 million or $3.95 per share in the third quarter of 2019. The net loss for the nine months ended September 30, 2020 was $19.1 million or $1.36 per share, compared with a net loss of $9.9 million or $13.32 per share for the nine months ended September 30, 2019; and
- Cash and cash equivalents were $10.5 million as of September 30, 2020.

The company also announced accomplishment of the following key milestones in the third quarter of 2020 and year to date:

- OpGen's subsidiary Curetis GmbH obtained 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.
- OpGen announced that subsidiary Ares Genetics GmbH won the Austrian national digitization award and was also nominated for the 40th Austrian Innovation Award for its artificial intelligence powered, next-generation sequencing based molecular antibiotic susceptibility test marketed under the brand name ARESupa – Universal Pathogenome Assay.
- OpGen's subsidiary Curetis GmbH was awarded EUR 350 thousand in non-dilutive grant funding in a collaboration project with InfectoGnostics campus at Jena University Hospital.
- OpGen announced the award of a German Federal Government grant to its subsidiary, Curetis GmbH, and collaborators Carpegen GmbH and the Clinic for Small Animal Internal Medicine of the LMU Ludwig-Maximilians University to collaborate on a project focused on travel related and enteric diseases in small animals.
- OpGen's subsidiary Ares Genetics GmbH in collaboration with researchers from the Johns Hopkins University School of Medicine, announced the publishing of a peer-reviewed study on modifiable risk factors for the emergence of ceftolozane-tazobactam resistance in *P. aeruginosa* in the journal Clinical Infectious Diseases.
- OpGen announced the release of a new peer-reviewed publication that demonstrates the clinical utility of the Unyvero LRT panel and its potential impact on antibiotic use in hospitalized patients with suspected pneumonia compared to treatment directed based on microbiological culture results.
- OpGen successfully completed its study collaboration with Karolinska Institutet on bacterial co-infections in COVID-19 pneumonia patients and data on the Unyvero HPN Panel was presented by the Karolinska investigators at ECCVID 2020.
- OpGen significantly improved its working capital position in the third quarter of 2020 through the sale of approximately 1.8 million shares of common stock under the company's ATM program and the exercise of warrants from the October 2019 financing for gross proceeds of $4.3 million during the third quarter. During the nine months ended September 30, 2020, the Company sold approximately 11.4 million shares of common stock under the company's ATM program and upon exercise of warrants from the October 2019 offering for gross proceeds of $24.4 million.
- The German Federal Ministry for Economic Affairs and Energy (BMWi) concluded its investigation of the OpGen business combination with Curetis with regards to its impact on the public order and security of the Federal Republic of Germany as well as national healthcare interests in the light of the current COVID-19 pandemic. No further action is expected from the Federal government on this matter.

Mr. Schacht commented, “I am pleased with our third quarter financial results and am encouraged by the exciting business updates that were issued this quarter including the CE mark certification for our SARS-CoV-2 Kit, notable awards and grants, peer-reviewed publications and the submission of our formal response letter to the FDA, which upon continued positive interactions with the FDA, makes us believe there should be a near-term clearance decision once the COVID-19 related FDA delays allow the agency to respond. In addition to the business and pipeline progress achieved this quarter, we are excited to provide further details about our reprioritization strategy aimed at creating both near-term and long-term growth potential for the company. As we wrap up 2020 OpGen is in a strong position to achieve pipeline and growth targets in the years ahead and I look forward to the company’s continued successes.”

Conference Call Information

OpGen’s management will host a conference call today, November 11 at 4:30 p.m. ET to discuss the third 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.viavid.com/index.php?id=142176
Conference ID: 13712431

Following the conclusion of the conference call, a replay will be available through November 25, 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. 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: 13712431

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 third quarter 2020 results, the company's strategic portfolio and product pipeline priorities, the ongoing integration of OpGen with its acquired subsidiaries, Curetis GmbH and Ares Genetics GmbH, and the impact of COVID-19 on the company 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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OpGen, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 10,488,072	$ 2,708,223
Accounts receivable, net	423,432	567,811
Inventory, net	2,975,060	473,030
Note receivable	—	2,521,479
Prepaid expenses and other current assets	1,072,364	396,760
Total current assets	**14,958,928**	**6,667,303**
Property and equipment, net	3,370,847	130,759
Finance lease right-of-use assets, net	571,329	958,590
Operating lease right-of-use assets	1,373,418	1,043,537
Goodwill	8,057,894	600,814
Intangible assets, net	16,071,680	817,550
Other noncurrent assets	300,744	203,271
Total assets	**$ 44,704,840**	**$ 10,421,824**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,240,351	$ 1,056,035
Accrued compensation and benefits	2,003,002	855,994
Accrued liabilities	2,664,581	1,046,661
Deferred revenue	51,622	9,808
Current maturities of long-term debt	1,156,517	373,599
Short-term finance lease liabilities	348,000	579,030
Short-term operating lease liabilities	1,142,435	1,017,414
Total current liabilities	**8,606,508**	**4,938,541**
Long-term debt, net	18,159,433	329,456
Long-term finance lease liabilities	76,701	313,263
Long-term operating lease liabilities	554,295	547,225
Derivative liabilities	74,239	—
Other long-term liabilities	154,716	—
Total liabilities	**27,625,892**	**6,128,485**
Commitments (Note 9)		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.01 par value; 50,000,000 shares authorized; 19,799,348 and 5,582,280 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	197,993	55,823
Additional paid-in capital	208,892,463	178,779,814
Accumulated deficit	(193,625,510)	(174,524,983)
Accumulated other comprehensive income (loss)	1,614,002	(17,315)
Total stockholders' equity	**17,078,948**	**4,293,339**
Total liabilities and stockholders' equity	**$ 44,704,840**	**$ 10,421,824**

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

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Revenue				
Product sales	$ 601,562	$ 573,035	$ 1,569,799	$ 1,597,505
Laboratory services	112,892	185	138,884	5,435
Collaboration revenue	342,311	75,000	1,153,400	1,075,000
Total revenue	**1,056,765**	**648,220**	**2,862,083**	**2,677,940**
Operating expenses				
Cost of products sold	1,350,296	262,373	2,340,766	681,568
Cost of services	159,794	196,184	550,115	592,647
Research and development	2,433,553	1,139,369	6,630,134	4,069,335
General and administrative	2,356,413	1,560,706	6,549,432	4,901,136
Sales and marketing	932,671	376,955	2,258,980	1,142,755
Transaction costs	—	538,061	470,322	538,061
Impairment of right-of-use asset	—	—	—	520,759
Impairment of intangibles assets	—	—	750,596	—
Total operating expenses	**7,232,727**	**4,073,648**	**19,550,345**	**12,446,261**
Operating loss	**(6,175,962)**	**(3,425,428)**	**(16,688,262)**	**(9,768,321)**
Other income (expense)				
Interest and other (expense) income	19,965	1,043	101,644	(8,213)
Interest expense	(1,183,927)	(49,099)	(2,267,085)	(142,672)
Foreign currency transaction gains (losses)	(501,168)	(8,954)	(794,832)	(9,426)
Change in fair value of derivative financial instruments	165,497	—	548,008	67
Total other income (expense)	**(1,499,633)**	**(57,010)**	**(2,412,265)**	**(160,244)**
Loss before income taxes	**(7,675,595)**	**(3,482,438)**	**(19,100,527)**	**(9,928,565)**
Provision for income taxes	—	—	—	—
Net loss	**$ (7,675,595)**	**$ (3,482,438)**	**$ (19,100,527)**	**$ (9,928,565)**
Net loss available to common stockholders	**$ (7,675,595)**	**$ (3,482,438)**	**$ (19,100,527)**	**$ (9,928,565)**
Net loss per common share - basic and diluted	**$ (0.40)**	**$ (3.95)**	**$ (1.36)**	**$ (13.32)**
Weighted average shares outstanding - basic and diluted	19,116,864	882,280	14,016,896	745,471
Net loss	$ (7,675,595)	$ (3,482,438)	$ (19,100,527)	$ (9,928,565)
Other comprehensive income - foreign currency translation	1,266,901	7,298	1,631,319	5,174
Comprehensive loss	**$ (6,408,694)**	**$ (3,475,140)**	**$ (17,469,208)**	**$ (9,923,391)**