

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 12, 2022
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 2.02 — Results of Operations and Financial Condition

On May 12, 2022, OpGen, Inc. issued a press release announcing its first quarter financial results for the quarter ended March 31, 2022. The full text of such press release is furnished as Exhibit 99.1 to this report.

Item 9.01 — Financial Statements and Exhibits.

(d) Exhibits

99.1 [Press Release, dated May 12, 2022](#)

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

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: May 12, 2022

OpGen, Inc.

By: /s/ Oliver Schacht

Name: Oliver Schacht

Title: Chief Executive Officer



OpGen Reports First Quarter 2022 Financial Results and Provides Business Update

- *Total Q1 2022 revenues of \$0.5 million*
- *Cash position of approximately \$30.7 million to reach into Q1-2023*
- *Management conference call scheduled for May 12, 2022, at 4:30 p.m. EDT*

ROCKVILLE, Md., May 12th, 2022 (GLOBE NEWSWIRE) – OpGen, Inc. (Nasdaq: OPGN, “OpGen” or “the Company”), a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease, reported its first quarter 2022 financial and operating results. Management will host an investor call to discuss quarterly results and provide a business update.

“We are excited about our 2022 progress to date, as we continue to achieve our key milestones,” said Oliver Schacht, President & CEO of OpGen. “We started off the year with successful V&V testing of our Unyvero A30 RQ instrument, and we received positive interim data results of the Unyvero Urinary Tract Infection (UTI) Panel and we are moving forward towards completing the enrollment of the UTI clinical trial and anticipated subsequent FDA submission in the second half of 2022.”

Dr. Schacht continued, “we are executing on our key milestones and expanding and nurturing our network of partnerships and collaborations. Also, we have seen over 76% growth in direct sales in the U.S. compared to the first quarter of last year. We are excited about the year ahead and look forward to continuing the fight against antimicrobial resistance.”

First Quarter 2022 Financial Results of OpGen, Inc.

- Total revenue for the first quarter of 2022 was approximately \$0.47 million, compared with \$0.83 million in the first quarter of 2021.
- Operating expenses for the first quarter of 2022 were approximately \$6.3 million, compared with \$7.1 million in the first quarter of 2021.
- The net loss available to common stockholders for the first quarter of 2022 was approximately \$6.8 million, or \$0.15 per share, compared with \$14.9 million, or \$0.50 per share, in the first quarter of 2021. This was primarily due to a one-time non-cash accounting charge for the Company’s warrant inducement transaction consummated in Q1-2021.
- Cash and cash equivalents were approximately \$30.7 million as of March 31, 2022, compared with \$36.1 million as of December 31, 2021.

“Despite the continued COVID headwinds, there were bright spots in the growth in direct product sales in the U.S.” said Albert Weber, OpGen’s Chief Financial Officer. “Based on this progress and a healthy funnel of commercial opportunities, we remain optimistic about the future growth trajectory of the company in the coming quarters.”

Mr. Weber also commented on the restructuring of the repayment of the first tranche of the loan from the European Investment Bank (EIB) to OpGen's German subsidiary, Curetis GmbH (Curetis). In April, OpGen announced that Curetis and the EIB plan to restructure the repayment of the first debt tranche which became due in April 2022. Based on this plan, the Company repaid euro 5 million in April 2022 and expects to amortize the remainder of the debt tranche of approximately euro 8.35 million (balance as of the twelve-month period beginning in May 2022) in monthly instalments of about euro 0.7 million. Mr. Weber stated that, "we've approached our debt repayment in a strategic way that gives us greater flexibility to manage our cash and avoid reserving large amounts of shares from our authorized common at a time when share price has been under quite some pressure."

In the reporting quarter and year to date, the Company reached the following key milestones:

- OpGen completed the successful verification and validation (V&V) and lifetime testing of its Unyvero A30 RQ instruments. This testing clears the path for the Company to finalize the new platform instrument and prepare the build of its first set of series-ready instruments which is expected to occur later this year.
- In February 2022, OpGen data was published in the Journal of Clinical Microbiology for its Acuitas AMR Gene Panel Multicenter Clinical Trial.
- OpGen received positive interim data results on the Unyvero UTI Panel and is on track to complete enrollment of the UTI clinical trial in the second half of 2022 and subsequently submit to the FDA.
- Ares Genetics and Sandoz extended their existing master services agreement until January 31, 2025. This collaboration focuses on next-generation sequencing (NGS) and artificial intelligence (AI) assisted bioinformatics solutions for surveillance and drug repurposing efforts.
- Ares Genetics commercially launched new sequencing and analysis services globally, which includes ARESid and ARESiss Express, aimed at clinical microbiologists and specialists in public health and infection prevention and control. These services are performed at Ares Genetics' service laboratory in Vienna, Austria and are anticipated to be launched in the U.S. later this year.
- OpGen's subsidiary Curetis and the EIB plan to restructure the first tranche of debt that came due in April 2022. Subject to finalization of definitive legal agreements, Curetis repaid euro 5.0 million in cash in April 2022 and will pay the remainder of the debt tranche amounting to approximately euro 8.35 million or approximately \$9 million at current foreign exchange rates. Payments of such amount will be amortized over the course of the next 12 month-period and paid in equal monthly installments of approximately euro 0.7 million in cash, beginning at the end of May 2022. Interest rates on the remaining debt would remain unchanged at 10% per annum. The equity linked percent participation interest or PPI would increase from 0.3% to 0.75% of OpGen's market cap as of June 2024. The remaining two tranches of debt maturing in 2023 and 2024 are unchanged at this time.

In terms of fiscal 2022 guidance, OpGen expects:

- U.S. direct product sales of Unyvero and Acuitas are anticipated to grow by at least 50%;
 - Continued growth in its European and international distribution business for Unyvero products albeit at more moderate growth rates;
 - Improved traction of Ares Genetics related services and software solutions business;
 - Overall, 2022 revenue growth of approximately around 25% to 50% year over year from the products and services business; and
 - Potential upside from future strategic partnering or licensing deal(s) for the Unyvero A30 platform or the Ares database assets.
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Conference Call Information

OpGen's management will host a conference call today, May 12th at 4:30 p.m. EDT, to go over the first quarter financial results and business activities, as well as answer analyst questions.

Dial-in Information

U.S. Dial-in Number: +1-877-704-4453

International Dial-in Number: +1-201-389-0920

Webcast: <https://services.choruscall.com/mediaframe/webcast.html?webcastid=n37Dadqy>

Conference ID: 13729189

Following the conclusion of the conference call, a replay will be available through May 26th, 2022.

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: 13729189

About OpGen, Inc.

OpGen, Inc. (Rockville, MD, USA) is a precision medicine company harnessing the power of molecular diagnostics and bioinformatics to help combat infectious disease. Along with our 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 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 first quarter 2022 financials of OpGen 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, the success of our commercialization efforts, 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, the continued realization of expected benefits of our business combination transaction with Curetis GmbH, the continued impact of COVID-19 on the Company's operations, financial results, and commercialization efforts as well as on capital markets and general economic conditions, our ability to satisfy debt obligations under our loan with the European Investment Bank, the effect of the military action in Russia and Ukraine on our distributors, collaborators and service providers, our liquidity and working capital requirements, 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, 2022</u>	<u>December 31, 2021</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 30,653,410	\$ 36,080,392
Accounts receivable, net	265,885	1,172,396
Inventory, net	1,361,221	1,239,456
Prepaid expenses and other current assets	1,212,195	1,250,331
Total current assets	33,492,711	39,742,575
Property and equipment, net	3,721,720	4,011,748
Finance lease right-of-use assets, net	50,756	90,467
Operating lease right-of-use assets	1,706,346	1,814,396
Goodwill	7,316,883	7,453,007
Intangible assets, net	14,054,168	14,530,209
Strategic inventory	3,448,808	3,472,337
Other noncurrent assets	468,041	551,794
Total assets	\$ 64,259,433	\$ 71,666,533
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 865,440	\$ 1,307,081
Accrued compensation and benefits	1,695,557	1,621,788
Accrued liabilities	1,582,882	1,965,845
Current maturities of long-term debt	14,394,824	14,519,113
Short-term finance lease liabilities	26,462	43,150
Short-term operating lease liabilities	447,710	459,792
Total current liabilities	19,012,875	19,916,769
Long-term debt, net	7,955,483	7,176,251
Derivative liabilities	114,804	228,589
Long-term finance lease liabilities	2,803	3,644
Long-term operating lease liabilities	2,860,703	2,977,402
Other long-term liabilities	141,631	146,798
Total liabilities	30,088,299	30,449,453
Stockholders' equity		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at March 31, 2022 and December 31, 2021, respectively	—	—
Common stock, \$0.01 par value; 100,000,000 shares authorized; 46,557,750 and 46,450,250 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	465,578	464,503
Additional paid-in capital	275,949,034	275,708,490
Accumulated deficit	(242,345,255)	(235,541,539)
Accumulated other comprehensive income	101,777	585,626
Total stockholders' equity	34,171,134	41,217,080
Total liabilities and stockholders' equity	\$ 64,259,433	\$ 71,666,533

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

	Three Months Ended March 31,	
	2022	2021
Revenue		
Product sales	\$ 366,052	\$ 613,918
Laboratory services	42,929	97,726
Collaboration revenue	60,764	118,072
Total revenue	469,745	829,716
Operating expenses		
Cost of products sold	291,997	554,054
Cost of services	30,562	104,984
Research and development	2,316,441	2,813,491
General and administrative	2,625,053	2,663,657
Sales and marketing	1,051,432	899,252
Impairment of right-of-use asset	—	55,496
Total operating expenses	6,315,485	7,090,934
Operating loss	(5,845,740)	(6,261,218)
Other (expense) income		
Warrant inducement expense	—	(7,755,541)
Interest and other income	3,121	4,925
Interest expense	(1,269,581)	(1,164,982)
Foreign currency transaction gains	198,740	427,615
Change in fair value of derivative financial instruments	109,744	(101,390)
Total other expense	(957,976)	(8,589,373)
Loss before income taxes	(6,803,716)	(14,850,591)
Provision for income taxes	—	—
Net loss	\$ (6,803,716)	\$ (14,850,591)
Net loss available to common stockholders	\$ (6,803,716)	\$ (14,850,591)
Net loss per common share - basic and diluted	\$ (0.15)	\$ (0.50)
Weighted average shares outstanding - basic and diluted	46,483,694	29,485,067
Net loss	\$ (6,803,716)	\$ (14,850,591)
Other comprehensive loss - foreign currency translation	(483,849)	(1,078,479)
Comprehensive loss	\$ (7,287,565)	\$ (15,929,070)

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