



CORRECTION – OpGen Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

March 30, 2023

ROCKVILLE, Md., March 30, 2023 (GLOBE NEWSWIRE) -- In a release published March 29, 2023 under the same headline by OpGen, Inc. (Nasdaq: OPGN), the financial tables were incorrect. The corrected release follows:

- *Total revenue for 2022 was approximately \$2.6 million*
- *Balance sheet strengthened by recently closed public offering with gross proceeds of \$7.5 million*
- *Conference call to be held March 29, 2023 at 4:30 p.m. ET*

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 today its fourth quarter 2022 and full-year 2022 financial and operating results and provided a business update.

OpGen's revenue for the fourth quarter of 2022 was approximately \$722 thousand. Its total revenue for 2022 was approximately \$2.6 million which was in line with the Company's most recent guidance.

"Overall, in 2022 there were several business advancements for OpGen with the completion of a successful UTI clinical trial and initial commercial contracts for our Acuitas AMR Gene Panel in the U.S.," said Oliver Schacht, President & CEO of OpGen. "We believe recent milestones, as well as upcoming near-term catalysts and continued commercialization of approved products put OpGen in a good position to increase revenues."

Mr. Schacht continued, "As we proceed through 2023, we expect several announcements including commercialization of our AI-powered NGS-based ARESiss services in the U.S., ARESdb expansion, finalizing our Unyvero A50 UTI FDA submission, exploring multiple collaboration and non-dilutive financing opportunities, and updates regarding a recently initiated strategic corporate business development campaign in China for our Unyvero A30 platform."

Fourth Quarter and Full Year 2022 Financial Results of OpGen, Inc.

- Fourth quarter revenue for 2022 was approximately \$722 thousand, compared with approximately \$1.4 million in the fourth quarter of 2021. Our fourth quarter revenues, however, represent a 61% increase over our third quarter 2022 revenues of \$449 thousand. For the twelve months ended December 31, 2022, total revenue was approximately \$2.6 million compared to the twelve months ended December 31, 2021 of approximately \$4.3 million, which was in line with OpGen's most recent guidance.
- Total operating expenses in the fourth quarter of 2022 were \$10.7 million compared to \$7.2 million for the same quarter in 2021. This includes a one-time non-cash accounting charge for the impairment of the Company's in-process R&D (IPR&D) indefinite-lived intangible asset of \$5.4 million. For the twelve months ended December 31, 2022, operating expenses amounted to \$37.2 million, compared to \$27.6 million in 2021. The full year numbers include the impairment of both goodwill as well as IPR&D totaling \$12.3 million.
- Cash and cash equivalents as of December 31, 2022 were approximately \$7.4 million, a decrease compared to the balance at December 31, 2021 of \$36.1 million.

In reporting OpGen's fourth quarter and full year financials for 2022, Albert Weber, OpGen's Chief Financial Officer (CFO), said, "In 2022, our operating expenses remained in line with our initial expectations and tracked well against our guidance for yearly net cash consumption. We reduced our R&D expenses significantly and also reduced our general administrative expenses. We started growing our sales and marketing expenses in line with the planned shift to more commercial operations, with a clear focus on the U.S. market."

"Compared to the third quarter of 2022, we achieved a 61% increase in revenue during the final quarter of 2022," said Mr. Weber. "This increase was primarily due to the revenue generated from the FIND collaboration project, Unyvero product sales and revenue we received from our Acuitas AMR Gene Panel commercial contracts." He continued, "while we experienced an overall revenue decline from 2021 to 2022, due to the termination of the FISH product line and the one-off non-exclusive sale of a portion of the ARES database, both in 2021, we are working towards increasing product sales across all platforms (i.e. Unyvero, Acuitas and ARES) in 2023."

OpGen's management believes that, given the abrupt change by the Chinese government in the first quarter of 2023 on their zero COVID policy, there is now a realistic opportunity for OpGen's local partner, Beijing Clear Biotech, to initiate the outstanding clinical study in China for the Unyvero pneumonia product, thereby adding to the upcoming catalysts for OpGen in 2023.

The Company announced reaching the following key milestones, as well as recent developments in the fourth quarter of 2022 and into 2023 to date:

- On the commercial front, subsidiary Ares Genetics (Ares), announced a successful move to a new Vienna location and received a key patent grant in China. Ares also received the first commercial customer orders in the U.S., with revenue generation expecting to commence in the first quarter of 2023.

- With significant 28% growth in the number of datasets in the ARESdb database in the first quarter of 2023, Ares is well positioned to continue executing on plans to expand and improve the menu of its accurate AI models to predict antibiotic susceptibility from genomic data.
- Based on the final data read-out from the Unyvero UTI Panel's clinical trial in the U.S., OpGen is now in the process of finalizing the FDA submission package, aiming for an imminent submission of the *De Novo* classification request early in the second quarter of 2023.
- At the beginning of 2023, we announced that we achieved several key milestones under our Unyvero A30 platform collaboration with the Foundation for Innovative New Diagnostics (FIND) in December 2022, which triggered a EUR 200 thousand milestone payment received in the first quarter of 2023. Data on the final milestone deliverables under the initial contract is expected in the near term. Conditional on such successful milestone achievements, we believe there is great potential for future collaboration opportunities with FIND. Discussions have already commenced for a follow-on deal that would cover product development steps, including clinical trials and regulatory filings, as well as manufacturing scale up and preparation for launch of the Unyvero A30 in certain low- and middle-income countries.
- On the Unyvero A30 platform front, the focus is on non-dilutive partnership opportunities with other non-governmental organizations similar to FIND as well as U.S. government entities that offer funding opportunities. We have also teamed up with a strategic advisory firm to support a Unyvero A30 specific corporate business development campaign in China where there is an attractive opportunity for us to partner with and possibly license or monetize the A30 platform.

As part of OpGen's 2023 initiatives, Mr. Schacht commented, "We expect future growth in the commercial roll out of Unyvero products and the Acuitas AMR Gene Panel. We have focused on expanding and progressing our commercial pipeline for the AMR Gene Panel as well as Unyvero LRT and UTI and we are engaging in several ongoing discussions with hospitals. In the post-COVID fourth quarter of 2022 and into the first quarter of 2023, we have seen that hospitals have a significant backlog of investment needs and are taking longer than pre-COVID to complete contracts. Nonetheless, OpGen has multiple contracts for Unyvero and Acuitas that we believe are in final review with purchasing departments at several hospitals."

In terms of guidance for 2023, OpGen expects to:

- have a net cash consumption of around \$4.5 to \$5 million per quarter from its current operations;
- maintain an active dialog with the European Investment Bank (EIB) regarding the potential to restructure the second tranche of its loan with a principal amount of EUR 3 million, plus accumulated and deferred interest, which becomes due at the end of June 2023;
- pursue significant revenue growth opportunities, especially with Unyvero product sales and with ARESiss services, both in the U.S. and internationally;
- see global revenues from our products, services and collaborations for 2023 to be in a range of approximately \$4 to \$5 million;
- actively pursue the commercial opportunities in our funnel, which includes proposals that we believe are currently in the final review and negotiation stages, clearly indicating significant revenue growth potential for OpGen; and
- following the upcoming regulatory submission of the Unyvero UTI product to the FDA based on the final UTI clinical trial data read-out, expect to enter interactive review with the FDA towards a clearance decision on the *De Novo* classification request.

Conference Call Information

OpGen's management will host a conference call today, March 29th at 4:30 p.m. EDT, to discuss the fourth quarter and full-year 2022 financial results and other business activities, as well as answer questions. Dial-in information is below:

Conference Call Details

- U.S. Dial-in Number: 1-877-704-4453
- International Dial-in Number: 1-201-389-0920
- Webcast: https://viaavid.webcasts.com/starthere.jsp?ei=1595064&tp_key=d21054e901
- Conference ID: 13735798

Replay Details

- U.S. Dial-in Number: 1-844-512-2921
- International Dial-in Number: 1-412-317-6671
- Replay PIN: 13735798

Following the conclusion of the conference call, a replay will be available through April 12, 2023. 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 under Financials & Filings.

About OpGen, Inc.

OpGen, Inc. (Rockville, Md., U.S.A.) 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 current product portfolio includes Unyvero, Acuitas AMR Gene Panel, and the ARES Technology Platform including ARESdb, NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction including ARESiss, ARESid, ARESasp, and AREScloud, as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit.

For more information, please visit www.opgen.com.

Forward-Looking Statements

This press release includes statements regarding the fourth quarter 2022 and full year 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 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, our ability to realize any anticipated benefits from the reverse stock split, including maintaining its listing on the Nasdaq Capital Market and attracting new investors, 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. Consolidated Balance Sheets (unaudited)

	<u>December 31, 2022</u>	<u>December 31, 2021</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 7,440,030	\$ 36,080,392
Accounts receivable, net	514,372	1,172,396
Inventory, net	1,345,137	1,239,456
Prepaid expenses and other current assets	1,355,949	1,250,331
Total current assets	10,655,488	39,742,575
Property and equipment, net	3,457,531	4,011,748
Finance lease right-of-use assets, net	3,500	90,467
Operating lease right-of-use assets	1,459,413	1,814,396
Goodwill	—	7,453,007
Intangible assets, net	7,440,974	14,530,209
Strategic inventory	2,300,614	3,472,337
Other noncurrent assets	495,629	551,794
Total assets	\$ 25,813,149	\$ 71,666,533
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 420,821	\$ 1,307,081
Accrued compensation and benefits	1,097,654	1,621,788
Accrued liabilities	1,526,204	1,965,845
Deferred revenue	142,061	—
Short-term notes payable	7,023,901	14,519,113
Short-term finance lease liabilities	3,364	43,150
Short-term operating lease liabilities	377,626	459,792
Total current liabilities	10,591,631	19,916,769

Note payable	4,850,686	7,176,251
Derivative liabilities	99,498	228,589
Long-term finance lease liabilities	280	3,644
Long-term operating lease liabilities	2,566,138	2,977,402
Other long term liabilities	129,368	146,798
Total liabilities	18,237,601	30,449,453
Stockholders' equity		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2022 and December 31, 2021, respectively	—	—
Common stock, \$0.01 par value; 100,000,000 shares authorized; 2,899,911 and 2,322,511 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	28,999	23,225
Additional paid-in capital	281,167,161	276,149,768
Accumulated deficit	(272,824,772)	(235,541,539)
Accumulated other comprehensive (loss) income	(795,840)	585,626
Total stockholders' equity	7,575,548	41,217,080
Total liabilities and stockholders' equity	\$ 25,813,149	\$ 71,666,533

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Revenue				
Product sales	\$ 279,427	\$ 1,177,399	\$ 1,893,862	\$ 2,656,669
Laboratory services	78,118	169,608	172,633	813,210
Collaboration revenue	364,085	78,561	540,798	836,152
Total revenue	721,630	1,425,568	2,607,293	4,306,031
Operating expenses				
Cost of products sold	495,009	750,896	3,319,586	2,295,828
Cost of services	40,955	106,388	104,405	552,620
Research and development, net	1,552,125	2,855,295	8,173,435	10,910,679
General and administrative	2,104,311	2,491,825	8,884,084	9,935,963
Sales and marketing	1,092,379	1,007,885	4,344,656	3,713,263
Impairment of right-of-use asset	—	—	—	170,714
Impairment of intangible assets	5,407,699	—	5,407,699	—
Goodwill impairment charge	(34,971)	—	6,940,549	—
Total operating expenses	10,657,507	7,212,289	37,174,414	27,579,067
Operating loss	(9,935,877)	(5,786,721)	(34,567,121)	(23,273,036)
Other expense				
Gain on extinguishment of debt	—	—	—	259,353
Warrant inducement expense	—	—	—	(7,755,541)
Interest and other income, net	18,788	3,708	46,935	45,179
Interest expense	(637,611)	(1,213,313)	(3,256,410)	(4,799,331)
Foreign currency transaction (losses) gains	(39,538)	235,449	379,622	891,223
Change in fair value of derivative financial instruments	59,118	(7,159)	113,741	(129,731)
Total other expense	(599,243)	(981,315)	(2,716,112)	(11,488,848)
Loss before income taxes	(10,535,120)	(6,768,036)	(37,283,233)	(34,761,884)
Provision for income taxes	—	43,828	—	43,828
Net loss	(10,535,120)	(6,811,864)	(37,283,233)	(34,805,712)
Deemed dividend on beneficial conversion feature	—	(7,166,752)	—	(7,166,752)
Net loss available to common stockholders	\$ (10,535,120)	\$ (13,978,616)	\$ (37,283,233)	\$ (41,972,464)
Basic and diluted net loss per share attributable to common stockholders	\$ (3.87)	\$ (6.91)	\$ (15.27)	\$ (22.89)
Weighted average shares outstanding - basic and diluted	2,720,574	2,022,240	2,441,580	1,833,704
Net loss	\$ (10,535,120)	\$ (6,811,864)	\$ (37,283,233)	\$ (34,805,712)
Other comprehensive loss - foreign currency translation	866,283	(815,201)	(1,381,466)	(1,961,556)
Comprehensive loss	\$ (9,668,837)	\$ (7,627,065)	\$ (38,664,699)	\$ (36,767,268)



Source: OpGen, Inc.