

# OpGen Reports Second Quarter 2023 Financial Results and Provides Business Update

08.10.23

- Total revenue for the first half of 2023 was approximately \$1.65 million, an increase of approximately 15% compared to approximately \$1.44 million in the first half of 2022
- Signed FIND R&D collaboration contract extension
- Entered distribution agreement with Fisher Healthcare for the distribution of the Unyvero A50 platform in the U.S.
- Management conference call is scheduled for August 10, 2023, at 4:30 p.m. ET

ROCKVILLE, Md., Aug. 10, 2023 (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 second quarter and first half of 2023 financial and operating results. Management will host an investor call to discuss quarterly results and provide a business update.

## Second Quarter 2023 and First Half 2023 Financial Results of OpGen, Inc.

- Total revenue for the second quarter of 2023 was approximately \$0.7 million compared to the company's revenue of approximately \$1.0 million in the second quarter of 2022, which was primarily driven by the one-time sale of a pool of Unyvero instrument systems to Menarini in Q2-2022. Total revenue for the first half of 2023 was approximately \$1.65 million, an increase of approximately 15% compared to the company's revenue of approximately \$1.44 million in the first half of 2022.
- Total operating expenses decreased in the second quarter of 2023 to approximately \$5.9 million compared to approximately \$6.2 million for the second quarter of 2022. Total operating expenses decreased by approximately 6% in the first half of 2023 to approximately \$11.9 million compared to approximately \$12.6 million for the same period in 2022.
- Cash and cash equivalents were approximately \$3.2 million as of June 30, 2023, compared with approximately \$7.4 million as of December 31, 2022.

As previously reported, and in light of the Company's business performance and current cash position, the Company does not expect that its current cash will be sufficient to fund operations beyond September 2023. Since the end of the second quarter, the Company has pursued options to improve its cash position or mitigate a liquidity shortfall. Nevertheless, the Company has concluded that there is substantial doubt about the Company's ability to continue as a going concern. The Company continues to consider all alternatives, including restructuring or refinancing its debt, seeking additional debt or equity capital, reducing or delaying the Company's business activities, selling assets, and other strategic transactions or other measures, including obtaining relief under U.S. as well as applicable foreign bankruptcy laws. There is no guarantee that the Company will be able to identify and execute on any of these alternatives or that any of them will be successful.

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

- OpGen subsidiary, Curetis, and FIND signed an extension to their R&D collaboration agreement for the development of an AMR panel on the Unyvero A30 RQ platform for low- and middle-income countries. This next phase covers full development of AMR assay and cartridge, analytical testing and software development.
- Curetis successfully completed the first phase of its FIND collaboration, including the expanded scope of the FIND project in Q1 and Q2, respectively. The FIND collaboration contributed \$609 thousand to first half 2023 revenue.
- In June 2023, OpGen received ten Unyvero A30 C-Series instruments which will be used in the next phase of the FIND collaboration.
- Curetis announced the completion of two interim milestones of its collaboration project with InfectoGnostics under the PREPLEX grant.
- The Company submitted a *De Novo* classification request to the FDA for marketing authorization of the Unyvero Urinary Tract Infection (UTI) panel. Following the FDA's substantive review of the Company's submission, the Company received a formal communication from the FDA requesting certain additional information on June 30, 2023. The FDA has provided OpGen with 180 days to fully respond to their requests.
- OpGen entered into a distribution agreement with Fisher Healthcare, a division of Thermo Fisher Scientific, for the
  distribution of the Unyvero A50 platform and in vitro diagnostic tests for pneumonia and urinary tract infections in the U.S.
  During the second quarter and year-to-date, the Company successfully completed vendor set-up of OpGen under Fisher
  Healthcare's systems, trained the Fisher Healthcare sales teams across the U.S., created digital marketing campaigns, and

identified several hundred potential high priority leads with the Fisher Healthcare team. In several territories, the teams are already working towards commercial customer contract opportunities.

- With the assistance of a U.S.-Chinese strategic advisory firm, OpGen continues to have an active strategic corporate business development campaign to over 40 Chinese corporate IVD companies potentially interested in the Unyvero A30 RQ.
- Following a successful feasibility assessment, the Ares team recently signed an annual genomic surveillance contract with a major U.S. healthcare network to sequence and analyze pathogen isolates on a twice weekly basis. In addition, the team has signed multiple new ARESiss contracts for isolate sequencing and new AREScloud subscriptions for web-based sequence analysis.
- On the IP front, OpGen's subsidiary, Ares Genetics, successfully defended a key patent that was being contested in Europe. In the ruling, the European Patent Office ruled in favor of maintaining the patent, which broadly covers the prediction of AMR in pathogens based on any genetic determinants involving two or more nucleotides.
- Ares recently announced a new feature release for its AREScloud software designed to enhance genomic surveillance.
   These features include a Single Nucleotide Polymorphism (SNP) analysis module and interpretation of plasmids with reporting customized for the needs of hospital epidemiologists.

#### **Conference Call Information**

OpGen's management will host a conference call today, August 10, 2023 at 4:30 p.m. ET, to review the second quarter 2023 financial results and business activities, but will not be taking any questions.

## **Conference Call Details**

U.S. Dial-in Number: 1-877-704-4453 International Dial-in Number: 1-201-389-0920

Webcast: <a href="https://viavid.webcasts.com/starthere.jsp?ei=1618010&tp\_key=fc7c8907d6">https://viavid.webcasts.com/starthere.jsp?ei=1618010&tp\_key=fc7c8907d6</a>

Following the conclusion of the conference call, a replay will be available through August 24, 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 <a href="www.opgen.com">www.opgen.com</a>. 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*.

## **Replay Details**

 U.S. Dial-in Number:
 1-844-512-2921

 International Dial-in Number:
 1-412-317-6671

 Replay PIN:
 13739109

## 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 Al-powered bioinformatics solutions for antibiotic response prediction including ARESiss, ARESid, ARESasp, and AREScloud.

For more information, please visit www.opgen.com

## **Forward-Looking Statements**

This press release includes statements regarding the second quarter 2023 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, our ability to continue to finance our business and operations, the result of any alternatives to mitigate the Company's cash position, including restructuring or refinancing of our debt, seeking additional debt or equity capital, reducing or delaying our business activities, selling assets, other strategic transactions or other measures, including obtaining relief under U.S. bankruptcy laws, and the terms, value and timing of any transaction resulting from such alternatives, our ability to satisfy debt obligations under our loan with the European Investment Bank, and our liquidity and working capital requirements. 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:

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# OpGen, Inc. Consolidated Balance Sheets (unaudited)

	J	une 30, 2023	December 31, 2022		
Assets					
Current assets					
Cash and cash equivalents	\$	3,237,176	\$	7,440,030	
Accounts receivable, net		619,575		514,372	
Inventory, net		1,735,122		1,345,137	
Prepaid expenses and other current assets		1,637,593		1,355,949	
Total current assets		7,229,466		10,655,488	
Property and equipment, net		3,849,734		3,457,531	
Finance lease right-of-use assets, net		1,833		3,500	
Operating lease right-of-use assets		2,041,010		1,459,413	
Intangible assets, net		7,206,382		7,440,974	
Strategic inventory		1,609,643		2,300,614	
Other noncurrent assets		496,894		495,629	
Total assets	\$	22,434,962	\$	25,813,149	
Liabilities and Stockholders' Equity					
Current liabilities					
Current maturities of long-term debt	\$	9,191,151	\$	7,023,901	
Accounts payable		195,253		420,821	
Accrued compensation and benefits		1,439,181		1,097,654	
Accrued liabilities		1,043,123		1,526,204	
Deferred revenue		27,279		142,061	
Short-term finance lease liabilities		1,962		3,364	
Short-term operating lease liabilities		517,602		377,626	
Total current liabilities		12,415,551		10,591,631	
Long-term debt, net		· · · —		4,850,686	
Derivative liabilities		45,656		99,498	
Long-term finance lease liabilities		_		280	
Long-term operating lease liabilities		2,987,194		2,566,138	
Other long-term liabilities		126,671		129,368	
Total liabilities		15,575,072		18,237,601	
Stockholders' equity		•		· · · · · · · · · · · · · · · · · · ·	
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and					
outstanding at June 30, 2023 and December 31, 2022, respectively		_		_	
Common stock, \$0.01 par value; 100,000,000 shares authorized; 6,967,699 and					
2,899,911 shares issued and outstanding at June 30, 2023 and					
December 31, 2022, respectively		69,677		28,999	
Additional paid-in capital		291,935,388		281,167,161	
Accumulated deficit		(284,388,698)		(272,824,772)	
Accumulated other comprehensive loss		(756,477)		(795,840)	
Total stockholders' equity		6,859,890		7,575,548	
Total liabilities and stockholders' equity	\$	22,434,962	\$	25,813,149	

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

	2023	2022	2023	2022
Revenue				 _
Product sales	\$ 439,672	\$ 889,271	\$ 850,569	\$ 1,255,323
Laboratory services	44,003	20,570	65,676	63,499
Collaboration revenue	 252,462	57,364	 733,336	118,128
Total revenue	736,137	967,205	1,649,581	1,436,950
Operating expenses				
Cost of products sold	714,392	646,389	1,306,770	938,386
Cost of services	204,102	15,650	332,408	46,212
Research and development	1,388,792	2,273,756	3,201,624	4,590,197
General and administrative	2,425,007	2,134,266	4,848,960	4,759,319
Sales and marketing	 1,160,200	1,169,349	 2,186,287	2,220,781
Total operating expenses	 5,892,493	6,239,410	 11,876,049	12,554,895
Operating loss	(5,156,356)	(5,272,205)	(10,226,468)	(11,117,945)
Other (expense) income				
Interest and other income	31,215	13,851	61,323	16,972
Interest expense	(684,498)	(779,912)	(1,301,796)	(2,049,493)
Foreign currency transaction (losses) gains	(60,401)	271,967	(152,396)	470,707
Change in fair value of derivative financial instruments	 42,717	(74,116)	 55,411	35,628
Total other expense	 (670,967)	(568,210)	 (1,337,458)	(1,526,186)
Loss before income taxes	(5,827,323)	(5,840,415)	(11,563,926)	(12,644,131)
Provision for income taxes	 	_	 _	
Net loss	\$ (5,827,323)	\$ (5,840,415)	\$ (11,563,926)	\$ (12,644,131)
Net loss available to common stockholders	\$ (5,827,323)	\$ (5,840,415)	\$ (11,563,926)	\$ (12,644,131)
Net loss per common share - basic and diluted	\$ (0.93)	\$ (2.51)	\$ (2.13)	\$ (5.43)
Weighted average shares outstanding - basic and diluted	 6,246,326	 2,328,725	 5,424,542	 2,326,485
Net loss	\$ (5,827,323)	\$ (5,840,415)	\$ (11,563,926)	\$ (12,644,131)
Other comprehensive (loss) income - foreign currency				
translation	 (113,704)	(1,227,142)	 39,363	 (1,710,991)
Comprehensive loss	\$ (5,941,027)	\$ (7,067,557)	\$ (11,524,563)	\$ (14,355,122)



Source: OpGen, Inc.