UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2022

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 001-37367

OPGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware	**06-1614015**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. employer identification no.)**
9717 Key West Avenue, Suite 100, Rockville, MD	**20850**
(Address of principal executive offices)	**(Zip code)**

Registrant's telephone number, including area code: (240) 813-1260

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbols	Name of each exchange on which registered
Common Stock	OPGN	Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

48,326,942 shares of the Company's common stock, par value $0.01 per share, were outstanding as of August 12, 2022.

OPGEN, INC.

TABLE OF CONTENTS FOR FORM 10-Q

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q of OpGen, Inc. contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In this quarterly report, we refer to OpGen, Inc. as the "Company," "we," "our" or "us." All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect" or the negative version of these words and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II Item 1A "Risk Factors." In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances included herein may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the continued impact of COVID-19 on our business and operations;
- our liquidity and working capital requirements, including our cash requirements over the next 12 months;
- our use of proceeds from capital financing transactions;
- our ability to maintain compliance with the ongoing listing requirements for the Nasdaq Capital Market;
- the completion of our development efforts for our Unyvero UTI and IJI panels, Unyvero A30 *RQ* platform and ARESdb and the timing of regulatory submissions;
- our ability to obtain regulatory clearance for and commercialize our product and services offerings;
- our ability to establish a market for and sell our Acuitas AMR Gene Panel test for use with bacterial isolates;
- our ability to sustain or grow our customer base for our Unyvero IVD and Acuitas AMR Gene Panel products as well as our current research use only products;
- regulations and changes in laws or regulations applicable to our business, including regulation by the FDA, European Union, including pending IVDR requirements, and China's NMPA;
- our ability to further integrate the OpGen, Curetis, and Ares Genetics businesses;
- our ability to satisfy our debt obligations;
- adverse effects on our business condition and results of operations from general economic and market conditions and overall fluctuations in the United States and international markets, including deteriorating market conditions due to investor concerns regarding inflation and hostilities between Russia and Ukraine;
- anticipated trends and challenges in our business and the competition that we face;
- the execution of our business plan and our growth strategy;
- our expectations regarding the size of and growth in potential markets;
- our opportunity to successfully enter into new collaborative or strategic agreements;
- compliance with the U.S. and international regulations applicable to our business; and
- our expectations regarding future revenue and expenses.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. These risks should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to the risk factors described in Part II, Item 1A of this quarterly report. Other risks may be described from time to time in our filings made under the securities laws. New risks emerge from time to time. It is not possible for our management to predict all risks. All forward-looking statements in this quarterly report speak only as of the date made and are based on our current beliefs and expectations. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

NOTE REGARDING TRADEMARKS

We own various U.S. federal trademark registrations and applications and unregistered trademarks and servicemarks, including but not limited to OpGen®, Curetis®, Unyvero®, ARES® and ARES GENETICS®, and Acuitas®. All other trademarks, servicemarks or trade names referred to in this quarterly report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this quarterly report are sometimes referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies, products or services.

Part I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

OpGen, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets
(unaudited)

	June 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 16,586,577	$ 36,080,392
Accounts receivable, net	738,148	1,172,396
Inventory, net	1,196,956	1,239,456
Prepaid expenses and other current assets	1,687,564	1,250,331
Total current assets	**20,209,245**	**39,742,575**
Property and equipment, net	3,209,311	4,011,748
Finance lease right-of-use assets, net	19,660	90,467
Operating lease right-of-use assets	1,582,325	1,814,396
Goodwill	6,884,915	7,453,007
Intangible assets, net	12,969,215	14,530,209
Strategic inventory	3,492,602	3,472,337
Other noncurrent assets	441,320	551,794
Total assets	**$ 48,808,593**	**$ 71,666,533**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 731,845	$ 1,307,081
Accrued compensation and benefits	1,575,299	1,621,788
Accrued liabilities	788,153	1,965,845
Current maturities of long-term debt	10,887,469	14,519,113
Short-term finance lease liabilities	16,731	43,150
Short-term operating lease liabilities	394,027	459,792
Total current liabilities	**14,393,524**	**19,916,769**
Long-term debt, net	4,024,413	7,176,251
Long-term finance lease liabilities	1,962	3,644
Long-term operating lease liabilities	2,721,233	2,977,402
Derivative liabilities	175,498	228,589
Other long-term liabilities	130,983	146,798
Total liabilities	**21,447,613**	**30,449,453**
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, $0.01 par value; 100,000,000 shares authorized; 46,623,618 and 46,450,250 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	466,237	464,503
Additional paid-in capital	276,205,778	275,708,490
Accumulated deficit	(248,185,670)	(235,541,539)
Accumulated other comprehensive (loss) income	(1,125,365)	585,626
Total stockholders' equity	**27,360,980**	**41,217,080**
Total liabilities and stockholders' equity	**$ 48,808,593**	**$ 71,666,533**

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Revenue				
Product sales	$ 889,271	$ 307,804	$ 1,255,323	$ 835,383
Laboratory services	20,570	266,784	63,499	450,849
Collaboration revenue	57,364	237,027	118,128	355,099
Total revenue	**967,205**	**811,615**	**1,436,950**	**1,641,331**
Operating expenses				
Cost of products sold	646,389	342,580	938,386	896,634
Cost of services	15,650	137,934	46,212	242,918
Research and development	2,273,756	2,859,590	4,590,197	5,673,081
General and administrative	2,134,266	2,692,255	4,759,319	5,355,912
Sales and marketing	1,169,349	802,549	2,220,781	1,701,801
Impairment of right-of-use asset	—	115,218	—	170,714
Total operating expenses	**6,239,410**	**6,950,126**	**12,554,895**	**14,041,060**
Operating loss	**(5,272,205)**	**(6,138,511)**	**(11,117,945)**	**(12,399,729)**
Other (expense) income				
Gain on extinguishment of debt	—	259,353	—	259,353
Warrant inducement expense	—	—	—	(7,755,541)
Interest and other income	13,851	4,702	16,972	9,627
Interest expense	(779,912)	(1,198,169)	(2,049,493)	(2,363,151)
Foreign currency transaction gains (losses)	271,967	(915)	470,707	426,700
Change in fair value of derivative financial instruments	(74,116)	(13,021)	35,628	(114,411)
Total other expense	**(568,210)**	**(948,050)**	**(1,526,186)**	**(9,537,423)**
Loss before income taxes	**(5,840,415)**	**(7,086,561)**	**(12,644,131)**	**(21,937,152)**
Provision for income taxes	—	—	—	—
Net loss	**$ (5,840,415)**	**$ (7,086,561)**	**$ (12,644,131)**	**$ (21,937,152)**
Net loss available to common stockholders	**$ (5,840,415)**	**$ (7,086,561)**	**$ (12,644,131)**	**$ (21,937,152)**
Net loss per common share - basic and diluted	**$ (0.13)**	**$ (0.19)**	**$ (0.27)**	**$ (0.65)**
Weighted average shares outstanding - basic and diluted	46,574,512	38,268,293	46,529,718	33,900,964
Net loss	$ (5,840,415)	$ (7,086,561)	$ (12,644,131)	$ (21,937,152)
Other comprehensive income (loss) - foreign currency translation	(1,227,142)	529,651	(1,710,991)	(548,828)
Comprehensive loss	**$ (7,067,557)**	**$ (6,556,910)**	**$ (14,355,122)**	**$ (22,485,980)**

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Equity
(unaudited)

	Common Stock		Preferred Stock					
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balances at December 31, 2020	**25,085,534**	**$ 250,855**	**—**	**$ —**	**$ 219,129,045**	**$ 2,547,182**	**$ (200,735,827)**	**$ 21,191,255**
Offering of common stock and warrants, net of issuance costs	8,333,333	83,334	—	—	23,390,628	—	—	23,473,962
Inducement expense related to warrant reprice	—	—	—	—	7,755,541	—	—	7,755,541
Common stock warrant exercises, net of issuance costs	4,847,615	48,476	—	—	9,045,696	—	—	9,094,172
Proceeds from issuance of common stock warrants	—	—	—	—	255,751	—	—	255,751
Stock compensation expense	—	—	—	—	189,670	—	—	189,670
Foreign currency translation	—	—	—	—	—	(1,078,479)	—	(1,078,479)
Net loss	—	—	—	—	—	—	(14,850,591)	(14,850,591)
Balances at March 31, 2021	**38,266,482**	**382,665**	**—**	**—**	**259,766,331**	**1,468,703**	**(215,586,418)**	**46,031,281**
Issuance of RSUs	3,768	38	—	—	(38)	—	—	—
Stock compensation expense	—	—	—	—	261,548	—	—	261,548
Foreign currency translation	—	—	—	—	—	529,651	—	529,651
Net loss	—	—	—	—	—	—	(7,086,561)	(7,086,561)
Balances at June 30, 2021	**38,270,250**	**$ 382,703**	**—**	**$ —**	**$ 260,027,841**	**$ 1,998,354**	**$ (222,672,979)**	**$ 39,735,919**
Balances at December 31, 2021	**46,450,250**	**$ 464,503**	**—**	**$ —**	**$ 275,708,490**	**$ 585,626**	**$ (235,541,539)**	**$ 41,217,080**
Issuance of RSUs	107,500	1,075	—	—	(1,075)	—	—	—
Stock compensation expense	—	—	—	—	241,619	—	—	241,619
Foreign currency translation	—	—	—	—	—	(483,849)	—	(483,849)
Net loss	—	—	—	—	—	—	(6,803,716)	(6,803,716)
Balances at March 31, 2022	**46,557,750**	**465,578**	**—**	**—**	**275,949,034**	**101,777**	**(242,345,255)**	**34,171,134**
Issuance of RSUs	65,868	659	—	—	(659)	—	—	—
Stock compensation expense	—	—	—	—	257,403	—	—	257,403
Foreign currency translation	—	—	—	—	—	(1,227,142)	—	(1,227,142)
Net loss	—	—	—	—	—	—	(5,840,415)	(5,840,415)
Balances at June 30, 2022	**46,623,618**	**$ 466,237**	**—**	**$ —**	**$ 276,205,778**	**$ (1,125,365)**	**$ (248,185,670)**	**$ 27,360,980**

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Six months ended June 30,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (12,644,131)	$ (21,937,152)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	978,287	1,290,139
Noncash interest expense	1,613,662	1,934,356
Loss on disposal of equipment	15,979	—
Stock compensation expense	499,022	451,218
Gain on extinguishment of debt	—	(259,353)
Inducement expense related to warrant reprice	—	7,755,541
Change in fair value of derivative liabilities	(35,628)	114,411
Impairment of right-of-use asset	—	170,714
Changes in operating assets and liabilities		
Accounts receivable	361,943	172,048
Inventory	(288,447)	(1,253,260)
Other assets	(350,237)	(303,073)
Accounts payable	(508,949)	(627,285)
Accrued compensation and other liabilities	(1,342,405)	(57,706)
Deferred revenue	—	(9,808)
Net cash used in operating activities	**(11,700,904)**	**(12,559,210)**
Cash flows from investing activities		
Purchases of property and equipment	(83,563)	(1,723,064)
Net cash used in investing activities	**(83,563)**	**(1,723,064)**
Cash flows from financing activities		
Proceeds from issuance of common stock warrants	—	255,751
Proceeds from issuance of common stock and pre-funded warrants in registered offering, net of selling costs	—	23,473,962
Proceeds from the exercise of common stock warrants, net of issuance costs	—	9,094,172
Payments on debt	(6,819,405)	(441,076)
Payments on finance lease obligations	(28,101)	(177,742)
Net cash (used in) provided by financing activities	**(6,847,506)**	**32,205,067**
Effects of exchange rates on cash	(972,316)	(296,403)
Net (decrease) increase in cash and cash equivalents and restricted cash	(19,604,289)	17,626,390
Cash and cash equivalents and restricted cash at beginning of period	36,632,186	14,107,255
Cash and cash equivalents and restricted cash at end of period	**$ 17,027,897**	**$ 31,733,645**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 838,452	$ 888,374
Supplemental disclosures of noncash investing and financing activities		
Right-of-use assets acquired through operating leases	$ —	$ 748,294
Property and equipment transferred to inventory	$ 152,243	$ —

See accompanying notes to unaudited condensed consolidated financial statements.

Note 1 – Organization

OpGen, Inc. ("OpGen" or the "Company") was incorporated in Delaware in 2001. On April 1, 2020, OpGen completed its business combination transaction (the "Transaction") with Curetis N.V., a public company with limited liability under the laws of the Netherlands (the "Seller" or "Curetis N.V."), as contemplated by the Implementation Agreement, dated as of September 4, 2019 (the "Implementation Agreement"), by and among the Company, the Seller, and Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and wholly-owned subsidiary of the Company (the "Purchaser"). Pursuant to the Implementation Agreement, the Purchaser acquired all of the shares of Curetis GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany ("Curetis GmbH"), and certain other assets and liabilities of the Seller (together, "Curetis"). References to the "Company" include OpGen and its wholly-owned subsidiaries. The Company's headquarters are in Rockville, Maryland, and the Company's principal operations are in Rockville, Maryland; Holzgerlingen and Bodelshausen, Germany; and Vienna, Austria. The Company operates in one business segment.

OpGen Overview

OpGen is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. Along with its subsidiaries, Curetis GmbH and Ares Genetics GmbH, the Company is 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, and AREScloud, as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit.

Following its initial announcement in October 2020, the Company discontinued its QuickFISH and PNA FISH product portfolio in its entirety during the first quarter of 2021 (see Note 10). The Company's FISH customers and distribution partners had been informed accordingly and last orders were received and processed in the first quarter of 2021. The discontinuance of these product lines did not qualify for discontinued operations reporting.

The focus of OpGen is on its combined broad portfolio of products, which include high impact rapid diagnostics and bioinformatics to interpret antimicrobial resistance (AMR) genetic data. OpGen will continue to develop and seek FDA and other regulatory clearances or approvals, as applicable, for the Unyvero UTI and IJI products. OpGen will continue to offer the FDA-cleared Unyvero LRT and LRT BAL Panels, the FDA-cleared Acuitas AMR Gene Panel diagnostic test, as well as the Unyvero UTI Panel as an RUO product to hospitals, public health departments, clinical laboratories, pharmaceutical companies, and contract research organizations, or CROs. OpGen will also continue to commercialize its CE Marked Unyvero Panels in Europe and other global markets via distributors.

Note 2 – Going Concern and Management's Plans

The accompanying unaudited condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Since inception, the Company has incurred, and continues to incur, significant losses from operations and negative operating cash flows and has a significant amount of debt coming due in 2022. The Company has funded its operations primarily through external investor financing arrangements and significant actions taken by the Company, including the following:

- On June 24, 2022, the Company entered into an At the Market Common Offering (the "2022 Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), as a sales agent, pursuant to which the Company may offer and sell from time to time in an "at the market offering", at its option, up to an aggregate of $10.65 million of shares of the Company's common stock through the sales agent (the "2022 ATM Offering"). As of June 30, 2022, the Company had not sold any shares under the 2022 ATM Offering (see Note 11).

- On May 23, 2022, the Company, as guarantor, the Company's German operating subsidiary Curetis GmbH, as borrower, the Company's operating subsidiary Ares Genetics GmbH, as an additional guarantor, and the European Investment Bank (the "EIB") entered into a Waiver and Amendment Letter (the "Amendment") relating to the amendment of that certain Finance Contract, dated December 12, 2016 (the "Finance Contract"), as amended, between the EIB and Curetis pursuant to which Curetis borrowed an aggregate amount of €18.0 million in three tranches. The Amendment restructured the first tranche of approximately €13.35 million (including accumulated and deferred interest) of the Company's indebtedness with the EIB. Pursuant to the Amendment, the Company repaid €5.0 million to the EIB in April 2022. The Company also agreed, among other things, to amortize the remainder of the debt tranche over the twelve-month period beginning in May 2022. The Amendment also provides for the increase of the percent participation interest ("PPI") under the Finance Contract from 0.3% to 0.75% beginning in June 2024. The terms of the second and third tranches of the Company's indebtedness of €3.0 million and €5.0 million in principal, respectively, plus accumulated deferred interest remain unchanged pursuant to the Amendment.

- On October 18, 2021, the Company closed a registered direct offering (the “October 2021 Offering”) with a single healthcare-focused institutional investor of 150,000 shares of convertible preferred stock and warrants to purchase up to an aggregate of 7,500,000 shares of common stock. The shares of preferred stock had a stated value of $100 per share and were converted into an aggregate of 7,500,000 shares of common stock at a conversion price of $2.00 per share after the Company received stockholder approval for an increase to its number of authorized shares of common stock, which approval occurred at the Company’s special meeting of stockholders held in December 2021. Thereafter, all shares of preferred stock sold in the October 2021 Offering were converted into 7,500,000 shares of common stock in December 2021 so that there were no shares of preferred stock outstanding as of June 30, 2022. The warrants have an exercise price of $2.05 per share, became exercisable six months following the date of issuance, and will expire five years following the initial exercise date. The October 2021 Offering raised aggregate net proceeds of $13.9 million, and gross proceeds of $15.0 million.

- On March 9, 2021, the Company entered into a Warrant Exercise Agreement (the “Exercise Agreement”) with the institutional investor (the “Holder”) from our 2020 PIPE financing. Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of the remaining 4,842,615 outstanding warrants acquired in the 2020 PIPE (the “Existing Warrants”) for cash, pursuant to the terms of and subject to beneficial ownership limitations contained in the Existing Warrants, the Company agreed to issue to the Holder new warrants (the “New Warrants”) to purchase 0.65 shares of common stock for each share of common stock issued upon such exercise of the Existing Warrants pursuant to the Exercise Agreement for an aggregate of 3,147,700 New Warrants. The terms of the New Warrants are substantially similar to those of the Existing Warrants, except that the New Warrants have an exercise price of $3.56. The New Warrants are immediately exercisable and will expire five years from the date of the Exercise Agreement. The Holder paid an aggregate of $255,751 to the Company for the purchase of the New Warrants. The Company received aggregate gross proceeds before expenses of approximately $9.65 million from the exercise of the remaining Existing Warrants held by the Holder and the payment of the purchase price for the New Warrants (together, the “2021 Warrant Exercise”). As additional compensation, A.G.P./Alliance Global Partners, the Company’s placement agent for such warrant exchange, will receive a cash fee equal to $200,000 upon the cash exercise in full of the New Warrants.
- On February 11, 2021, the Company closed a registered direct offering (the "February 2021 Offering”) with a single U.S.-based, healthcare-focused institutional investor for the purchase of (i) 2,784,184 shares of common stock and (ii) 5,549,149 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock. The Company also issued to the investor, in a concurrent private placement, unregistered common share purchase warrants to purchase 4,166,666 shares of the Company’s common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of $3.00, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of $2.99. The pre-funded warrants were immediately exercisable, at an exercise price of $0.01, and could be exercised at any time until all of the pre-funded warrants are exercised in full. The common warrants have an exercise price of $3.55 per share, are exercisable commencing on the six-month anniversary of the date of issuance, and will expire five and one-half (5.5) years from the date of issuance. The February 2021 Offering raised aggregate net proceeds of $23.5 million, and gross proceeds of $25.0 million. As of December 31, 2021, all 5,549,149 pre-funded warrants issued in the February 2021 Offering were exercised.
- On February 11, 2020, the Company entered into an At the Market Common Offering (the “ATM Agreement”) with Wainwright which was amended and restated on November 13, 2020 to add BTIG, LLC (“BTIG”) as a sales agent, pursuant to which the Company may offer and sell from time to time in an “at the market offering”, at its option, up to an aggregate of $22.1 million of shares of the Company's common stock through the sales agents (the “2020 ATM Offering”). During the year ended December 31, 2021, the Company sold 680,000 shares of its common stock under the 2020 ATM Offering, resulting in aggregate net proceeds to the Company of approximately $1.48 million, and gross proceeds of approximately $1.55 million. The Company terminated the ATM Agreement in conjunction with the execution of the 2022 ATM Agreement.

On February 28, 2022, the Listing Qualifications Staff of The Nasdaq Stock Market LLC notified the Company that the closing bid price of the Company's common stock had, for 30 consecutive business days preceding the date of such notice, been below the $1.00 per share minimum required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Marketplace Rule 5550(a)(2). In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), the Company was provided 180 calendar days, or until August 29, 2022, to regain compliance. If at any time before August 29, 2022, the closing bid price of the Common Stock is at least $1 for a minimum of ten (10) consecutive trading days, the Company can regain compliance. If the Company is not compliance with the minimum bid price requirement by August 29, 2022, the Company may be entitled to an additional 180-day grace period if the Company meets the continued listing requirements for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market at such time.

To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, strategic financings or other transactions, additional equity financings, debt financings and other funding transactions, licensing and/or partnering arrangements. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. The Company believes that current cash will be sufficient to repay or refinance the current portion of the Company's debt and fund operations into the first quarter of 2023. This has led management to conclude that there is substantial doubt about the Company's ability to continue as a going concern. In the event the Company is unable to successfully raise additional capital during or before the end of the first quarter of 2023, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances, the Company would be compelled to immediately reduce general and administrative expenses and delay research and development projects, pause or abort clinical trials including the purchase of scientific equipment and supplies, until it is able to obtain sufficient financing. If such sufficient financing is not received on a timely basis, the Company would then need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

Note 3 – Summary of Significant Accounting Policies

Basis of presentation and consolidation

The Company has prepared the accompanying unaudited condensed consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") and the standards of accounting measurement set forth in the Interim Reporting Topic of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"). Certain information and note disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted, although the Company believes that the disclosures made are adequate to make the information not misleading. The Company recommends that the unaudited condensed consolidated financial statements be read in conjunction with the audited consolidated financial statements and the notes thereto included in the Company's latest Annual Report on Form 10-K. In the opinion of management, all adjustments that are necessary for a fair presentation of the Company's financial position for the periods presented have been reflected. All adjustments are of a normal, recurring nature, unless otherwise stated. The interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2021 consolidated balance sheet included herein was derived from the audited consolidated financial statements, but does not include all disclosures including notes required by GAAP for complete financial statements.

The accompanying unaudited condensed consolidated financial statements include the accounts of OpGen and its wholly-owned subsidiaries as of June 30, 2022 including Curetis GmbH and subsidiaries acquired on April 1, 2020; all intercompany transactions and balances have been eliminated.

Foreign currency

The Company has subsidiaries located in Holzgerlingen, Germany; and Vienna, Austria, each of which use currencies other than the U.S. dollar as their functional currency. As a result, all assets and liabilities are translated into U.S. dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at the average exchange rates prevailing during the reporting period. Translation adjustments are reported in accumulated other comprehensive income (loss), a component of stockholders' equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive income (loss) at June 30, 2022 and December 31, 2021.

Foreign currency transaction gains and losses, excluding gains and losses on intercompany balances where there is no current intent to settle such amounts in the foreseeable future, are included in the determination of net loss. Unless otherwise noted, all references to "$" or "dollar" refer to the United States dollar.

Use of estimates

In preparing financial statements in conformity with GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In the accompanying unaudited condensed consolidated financial statements, estimates are used for, but not limited to, liquidity assumptions, revenue recognition, inducement expense related to warrant repricing, stock-based compensation, allowances for doubtful accounts and inventory obsolescence, discount rates used to discount unpaid lease payments to present values, valuation of derivative financial instruments measured at fair value on a recurring basis, deferred tax assets and liabilities and related valuation allowance, determining the fair value of assets acquired and liabilities assumed in business combinations, the estimated useful lives of long-lived assets, and the recoverability of long-lived assets. Actual results could differ from those estimates.

Fair value of financial instruments

Financial instruments classified as current assets and liabilities (including cash and cash equivalent, receivables, accounts payable, deferred revenue and short-term notes) are carried at cost, which approximates fair value, because of the short-term maturities of those instruments.

Cash and cash equivalents and restricted cash

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. The Company has cash and cash equivalents deposited in financial institutions in which the balances occasionally exceed the Federal Deposit Insurance Corporation (“FDIC”) insured limit of $250,000. The Company has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk.

At June 30, 2022 and December 31, 2021, the Company had funds totaling $441,320 and $551,794, respectively, which are required as collateral for letters of credit benefiting its landlords and for credit card processors. These funds are reflected in other noncurrent assets on the accompanying unaudited condensed consolidated balance sheets.

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows:

	June 30, 2022	December 31, 2021	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 16,586,577	$ 36,080,392	$ 31,182,385	$ 13,360,463
Restricted cash	441,320	551,794	551,260	746,792
Total cash and cash equivalents and restricted cash in the condensed consolidated statements of cash flows	$ 17,027,897	$ 36,632,186	$ 31,733,645	$ 14,107,255

Accounts receivable

The Company’s accounts receivable result from revenues earned but not yet collected from customers. Credit is extended based on an evaluation of a customer’s financial condition and, generally, collateral is not required. Accounts receivable are due within 30 to 90 days and are stated at amounts due from customers. The Company evaluates if an allowance is necessary by considering a number of factors, including the length of time accounts receivable are past due, the Company’s previous loss history and the customer’s current ability to pay its obligation. If amounts become uncollectible, they are charged to operations when that determination is made. The allowance for doubtful accounts was $0 as of June 30, 2022 and December 31, 2021, respectively.

At June 30, 2022, the Company had accounts receivable from one customer which individually represented 75% of total accounts receivable. At December 31, 2021, the Company had accounts receivable from two customers which individually represented 52% and 14% of total accounts receivable, respectively. For the three months ended June 30, 2022, revenue earned from two customers represented 57% and 12% of total revenues, respectively. For the three months ended June 30, 2021, revenue earned from two customers represented 29% and 13% of total revenues, respectively. For the six months ended June 30, 2022, revenue earned from two customers represented 47% and 15% of total revenues, respectively. For the six months ended June 30, 2021, revenue earned from three customers represented 21%, 13%, and 11% of total revenues, respectively.

Inventory

Inventories are valued using the first-in, first-out cost method and stated at the lower of cost or net realizable value and consist of the following:

	June 30, 2022	December 31, 2021
Raw materials and supplies	$ 884,474	$ 866,963
Work-in-process	48,680	100,801
Finished goods	3,756,404	3,744,029
Total	$ 4,689,558	$ 4,711,793

Inventory includes Unyvero instrument systems, Unyvero cartridges, reagents and components for Unyvero, Acuitas, Curetis SARS CoV-2 test kits, and reagents and supplies used for the Company's laboratory services. Inventory reserves for obsolescence and expirations were $105,722 and $98,064 at June 30, 2022 and December 31, 2021, respectively.

The Company reviews inventory quantities on hand and analyzes the provision for excess and obsolete inventory based primarily on product expiration dating and its estimated sales forecast, which is based on sales history and anticipated future demand. The Company's estimates of future product demand may not be accurate, and it may understate or overstate the provision required for excess and obsolete inventory. Accordingly, any significant unanticipated changes in demand could have a significant impact on the value of the Company's inventory and results of operations.

The Company classifies finished good inventory it does not expect to sell or use in clinical studies within 12 months of the unaudited condensed consolidated balance sheets date as strategic inventory, a non-current asset.

Long-lived assets

Property and equipment

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the three and six months ended June 30, 2022 and 2021, the Company determined that its property and equipment were not impaired.

Leases

The Company determines if an arrangement is a lease at inception. For leases where the Company is the lessee, right-of-use ("ROU") assets represent the Company's right to use the underlying asset for the term of the lease and the lease liabilities represent an obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of the future lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at the commencement date of the underlying lease arrangement to determine the present value of lease payments. The ROU asset also includes any prepaid lease payments and any lease incentives received. The lease term to calculate the ROU asset and related lease liability includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise the option. The Company's lease agreements generally do not contain any material variable lease payments, residual value guarantees or restrictive covenants.

Lease expense for operating leases is recognized on a straight-line basis over the lease term as an operating expense while expense for financing leases is recognized as depreciation expense and interest expense using the effective interest method of recognition. The Company has made certain accounting policy elections whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12 months or less) and (ii) combines lease and non-lease elements of our operating leases.

ROU assets

ROU assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which the Company can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the six months ended June 30, 2021, the Company had determined that the ROU asset associated with its San Diego, California office lease may not be recoverable. As a result, the Company had recorded an impairment charge of $115,218 and $170,714 during the three and six months ended June 30, 2021, respectively.

Intangible assets and goodwill

Intangible assets and goodwill as of June 30, 2022 consist of finite-lived and indefinite-lived intangible assets and goodwill.

Finite-lived and indefinite-lived intangible assets

Intangible assets include trademarks, developed technology, In-Process Research & Development, software and customer relationships and consisted of the following as of June 30, 2022 and December 31, 2021:

		June 30, 2022			December 31, 2021		
	Subsidiary	Cost	Accumulated Amortization	Effect of Foreign Exchange Rates	Net Balance	Accumulated Amortization	Effect of Foreign Exchange Rates	Net Balance
Trademarks and tradenames	Curetis	$ 1,768,000	$ (373,698)	$ (107,132)	$ 1,287,170	$ (316,930)	$ 43,015	$ 1,494,085
Distributor relationships	Curetis	2,362,000	(332,838)	(143,124)	1,886,038	(282,277)	57,465	2,137,188
A50 - Developed technology	Curetis	349,000	(105,393)	(21,147)	222,460	(89,384)	8,492	268,108
Ares - Developed technology	Curetis	5,333,000	(805,142)	(323,155)	4,204,703	(682,833)	129,745	4,779,912
A30 - In-Process Research & Development	Curetis	5,706,000	—	(337,156)	5,368,844	—	144,916	5,850,916
		$ 15,518,000	$ (1,617,071)	$ (931,714)	$ 12,969,215	$ (1,371,424)	$ 383,633	$ 14,530,209

Identifiable intangible assets will be amortized on a straight-line basis over their estimated useful lives. The estimated useful lives of the intangibles are:

	Estimated Useful Life
Trademarks and tradenames	10 years
Customer/distributor relationships	15 years
A50 – Developed technology	7 years
Ares – Developed technology	14 years
A30 – Acquired in-process research & development	Indefinite

Acquired in-process research and development (“IPR&D”) represents the fair value assigned to those research and development projects that were acquired in a business combination for which the related products have not received regulatory approval and have no alternative future use. IPR&D is capitalized at its fair value as an indefinite-lived intangible asset, and any development costs incurred after the acquisition are expensed as incurred. Upon achieving regulatory approval or commercial viability for the related product, the indefinite-lived intangible asset is accounted for as a finite-lived asset and is amortized on a straight-line basis over its estimated useful life. If the project is not completed or is terminated or abandoned, the Company may have an impairment related to the IPR&D which is charged to expense. Indefinite-lived intangible assets are tested for impairment annually and whenever events or changes in circumstances indicate that the carrying amount may be impaired. Impairment is calculated as the excess of the asset’s carrying value over its fair value.

The Company reviews the useful lives of intangible assets when events or changes in circumstances occur which may potentially impact the estimated useful life of the intangible assets.

Total amortization expense of intangible assets was $182,993 and $204,800 for the three months ended June 30, 2022 and 2021, respectively. Total amortization expense of intangible assets was $375,018 and $402,642 for the six months ended June 30, 2022 and 2021, respectively. Expected future amortization of intangible assets is as follows:

Year Ending December 31,		
2022 (Six months)	$	359,349
2023		718,697
2024		718,697
2025		718,697
2026		718,697
2027		683,530
Thereafter		3,682,704
Total	$	7,600,371

Intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If any indicators were present, the Company would test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i.e., the asset is not recoverable), the Company would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any.

In accordance with ASC 360-10, *Property, Plant and Equipment*, the Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that long-lived assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. During the three and six months ended June 30, 2022 and 2021, the Company determined that its finite-lived intangible assets were not impaired.

Goodwill

Goodwill represents the excess of the purchase price paid when the Company acquired AdvanDx, Inc. in July 2015 and Curetis in April 2020, over the fair values of the acquired tangible or intangible assets and assumed liabilities. Goodwill is not tax deductible in any relevant jurisdictions. The Company's goodwill balance as of June 30, 2022 and December 31, 2021 was $6,884,915 and $7,453,007, respectively.

The changes in the carrying amount of goodwill as of June 30, 2022, and since December 31, 2021, were as follows:

Balance as of December 31, 2021	$	7,453,007
Changes in currency translation		(568,092)
Balance as of June 30, 2022	$	6,884,915

The Company conducts an impairment test of goodwill on an annual basis, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company's fair value below its net equity value. During the three and six months ended June 30, 2022 and 2021, the Company determined that its goodwill was not impaired.

Revenue recognition

The Company derives revenues from (i) the sale of Unyvero Application cartridges, Unyvero Systems, SARS CoV-2 tests, and Acuitas AMR Gene Panel test products, (ii) providing laboratory services, (iii) providing collaboration services including funded software arrangements, and license arrangements, and (iv) granting access to a subset of the proprietary ARESdb data asset.

The Company analyzes contracts to determine the appropriate revenue recognition using the following steps: (i) identification of contracts with customers, (ii) identification of distinct performance obligations in the contract, (iii) determination of contract transaction price, (iv) allocation of contract transaction price to the performance obligations and (v) determination of revenue recognition based on timing of satisfaction of the performance obligation.

The Company recognizes revenues upon the satisfaction of its performance obligation (upon transfer of control of promised goods or services to our customers) in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services.

The Company defers incremental costs of obtaining a customer contract and amortizes the deferred costs over the period that the goods and services are transferred to the customer. The Company had no material incremental costs to obtain customer contracts in any period presented.

Deferred revenue results from amounts billed in advance to customers or cash received from customers in advance of services being provided.

Research and development costs

Research and development costs are expensed as incurred. Research and development costs primarily consist of salaries and related expenses for personnel, other resources, laboratory supplies, and fees paid to consultants and outside service partners.

Government grant agreements and research incentives

From time to time, the Company may enter into arrangements with governmental entities for the purposes of obtaining funding for research and development activities. The Company recognizes funding from grants and research incentives received from Austrian government agencies in the condensed consolidated statements of operations and comprehensive loss in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants or incentives were provided have been met. For grants under funding agreements and for proceeds under research incentive programs, the Company recognizes grant and incentive income in an amount equal to the estimated qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage. The Company classifies government grants received under these arrangements as a reduction to the related research and development expense incurred. The Company analyzes each arrangement on a case-by-case basis. For the three months ended June 30, 2022 and 2021, the Company recognized $111,414 and $154,850 as a reduction of research and development expense related to government grant arrangements, respectively. For the six months ended June 30, 2022 and 2021, the Company recognized $219,879 and $374,072 as a reduction of research and development expense related to government grant arrangements, respectively. The Company had earned but not yet received $572,133 and $396,365 related to these agreements and incentives included in prepaid expenses and other current assets, as of June 30, 2022 and December 31, 2021, respectively.

Stock-based compensation

Stock-based compensation expense is recognized at fair value. The fair value of stock-based compensation to employees and directors is estimated, on the date of grant, using the Black-Scholes model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option. For all time-vesting awards granted, expense is amortized using the straight-line attribution method. The Company accounts for forfeitures as they occur.

Option valuation models, including the Black-Scholes model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the expected future tax consequences attributable to temporary differences between financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred income tax assets to the amount expected to be realized.

Tax benefits are initially recognized in the financial statements when it is more likely than not the position will be sustained upon examination by the tax authorities. Such tax positions are initially, and subsequently, measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and all relevant facts.

The Company had federal net operating loss ("NOL") carryforwards of $202,015,062 and $196,511,928 at December 31, 2021 and 2020, respectively. Despite the NOL carryforwards, which begin to expire in 2022, the Company may have state tax requirements. Also, use of the NOL carryforwards may be subject to an annual limitation as provided by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"). To date, the Company has not performed a formal study to determine if any of its remaining NOL and credit attributes might be further limited due to the ownership change rules of Section 382 or Section 383 of the Code. The Company will continue to monitor this matter going forward. There can be no assurance that the NOL carryforwards will ever be fully utilized.

The Company also has foreign NOL carryforwards of $170,607,782 at December 31, 2021 from their foreign subsidiaries. $147,313,786 of those foreign NOL carryforwards are from the Company's operations in Germany. Despite the NOL carryforwards, the Company may have a current and future tax liability due to the nuances of German tax law around the use of NOLs within a consolidated group. There is no assurance that the NOL carryforwards will ever be fully utilized.

Loss per share

Basic loss per share is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period.

For periods of net income, and when the effects are not anti-dilutive, diluted earnings per share is computed by dividing net income available to common stockholders by the weighted average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options and stock purchase warrants using the treasury stock method, and convertible preferred stock and convertible debt using the if-converted method.

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. The number of anti-dilutive shares, consisting of (i) common stock options, (ii) stock purchase warrants, and (iii) restricted stock units representing the right to acquire shares of common stock which have been excluded from the computation of diluted loss per share, was 19.3 million shares and 11.0 million shares as of June 30, 2022 and 2021, respectively.

Recently issued accounting standards

The Company has evaluated all other issued and unadopted ASUs and believes the adoption of these standards will not have a material impact on its results of operations, financial position or cash flows.

Note 4 – Revenue from contracts with customers

Disaggregated revenue

The Company provides diagnostic test products, laboratory services to hospitals, clinical laboratories and other healthcare provider customers, and enters into collaboration agreements with government agencies and healthcare providers. The revenues by type of service consist of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Product sales	$ 889,271	$ 307,804	$ 1,255,323	$ 835,383
Laboratory services	20,570	266,784	63,499	450,849
Collaboration revenue	57,364	237,027	118,128	355,099
Total revenue	$ 967,205	$ 811,615	$ 1,436,950	$ 1,641,331

Revenues by geography are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Domestic	$ 123,659	$ 305,617	$ 280,069	$ 649,624
International	843,546	505,998	1,156,881	991,707
Total revenue	$ 967,205	$ 811,615	$ 1,436,950	$ 1,641,331

Deferred revenue

The Company had no deferred revenue at June 30, 2022 and December 31, 2021.

Contract assets

The Company had $51,935 and $0 of contract assets as of June 30, 2022 and December 31, 2021, respectively, which are generated when contractual billing schedules differ from revenue recognition timing. Contract assets represent a conditional right to consideration for satisfied performance obligations that becomes a billed receivable when the conditions are satisfied.

Unsatisfied performance obligations

The Company had no unsatisfied performance obligations related to its contracts with customers at June 30, 2022 and December 31, 2021.

Note 5 – Fair value measurements

The Company classifies its financial instruments using a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 - defined as observable inputs such as quoted prices in active markets;
- Level 2 - defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and
- Level 3 - defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions such as expected revenue growth and discount factors applied to cash flow projections.

For the three and six months ended June 30, 2022, the Company has not transferred any assets between fair value measurement levels.

Financial assets and liabilities measured at fair value on a recurring basis

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the hierarchy.

In June 2019, Curetis drew down a third tranche of €5.0 million from the EIB. In return for the EIB waiving the condition precedent of a minimum cumulative equity capital raised of €15.0 million to disburse this €5.0 million tranche, the parties agreed on a 2.1% PPI. Upon maturity of the tranche, the EIB would be entitled to an additional payment that is equity-linked and equivalent to 2.1% of the then total valuation of Curetis N.V. On July 9, 2020, the Company negotiated an amendment to the EIB debt financing facility. As part of the amendment, the parties adjusted the PPI percentage applicable to the previous EIB tranche of €5.0 million, which was funded in June 2019 from its original 2.1% PPI in Curetis N.V.'s equity value upon maturity to a new 0.3% PPI in OpGen's equity value. On May 23, 2022, the Company entered into a Waiver and Amendment Letter which increased the PPI to 0.75% upon maturity between mid-2024 and mid-2025. This right constitutes an embedded derivative, which is separated and measured at fair value with changes being accounted for through profit or loss. The Company determines the fair value of the derivative using a Monte Carlo simulation model. Using this model, Level 3 unobservable inputs include estimated discount rates and estimated risk-free interest rates.

The fair value of Level 3 liabilities measured at fair value on a recurring basis for the six months ended June 30, 2022 was as follows:

Description	Balance at December 31, 2021	Change in Fair Value	Effect of Foreign Exchange Rates	Balance at June 30, 2022
Participation percentage interest liability	$ 228,589	$ (35,628)	$ (17,463)	$ 175,498
Total	$ 228,589	$ (35,628)	$ (17,463)	$ 175,498

Financial assets and liabilities carried at fair value on a non-recurring basis

The Company does not have any financial assets and liabilities measured at fair value on a non-recurring basis.

Non-financial assets and liabilities carried at fair value on a recurring basis

The Company does not have any non-financial assets and liabilities measured at fair value on a recurring basis.

Non-financial assets and liabilities carried at fair value on a non-recurring basis

The Company measures its long-lived assets, including property and equipment and intangible assets (including goodwill), at fair value on a non-recurring basis when a triggering event requires such evaluation. During the three months ended June 30, 2021, the Company recorded impairment expense of $115,218 related to its ROU assets. During the six months ended June 30, 2021, the Company recorded impairment expense of $170,714 related to its ROU assets.

Note 6 – Debt

The following table summarizes the Company's long-term debt and short-term borrowings as of June 30, 2022 and December 31, 2021:

	June 30, 2022	December 31, 2021
EIB	$ 17,026,715	$ 25,161,855
Total debt obligations	17,026,715	25,161,855
Unamortized debt discount	(2,114,833)	(3,466,491)
Carrying value of debt	14,911,882	21,695,364
Less current portion	(10,887,469)	(14,519,113)
Long-term debt	$ 4,024,413	$ 7,176,251

EIB Loan Facility

In 2016, Curetis entered into a contract for an up to €25.0 million senior, unsecured loan financing facility from the EIB. The financing is in the first growth capital loan under the European Growth Finance Facility ("EGFF"), launched in November 2016. It is backed by a guarantee from the European Fund for Strategic Investment ("EFSI"). EFSI is an essential pillar of the Investment Plan for Europe ("IPE"), under which the EIB and the European Commission are working as strategic partners to support investments and bring back jobs and growth to Europe.

The funding can be drawn in up to five tranches within 36 months, under the EIB amendment, and each tranche is to be repaid upon maturity five years after draw-down.

In April 2017, Curetis drew down a first tranche of €10.0 million from this facility. This tranche has a floating interest rate of EURIBOR plus 4% payable after each 12-month-period from the draw-down-date and another additional 6% interest per annum that is deferred and payable at maturity together with the principal. In June 2018, a second tranche of €3.0 million was drawn down. The terms and conditions are analogous to the first one.

In June 2019, Curetis drew down a third tranche of €5.0 million from the EIB. In line with all prior tranches, the majority of interest is also deferred until repayment upon maturity. In return for the EIB waiving the condition precedent of a minimum cumulative equity capital raised of €15.0 million to disburse this €5.0 million tranche, the parties agreed on a 2.1% PPI. Upon maturity of the tranche, not before approximately mid-2024 (and no later than mid-2025), the EIB would be entitled to an additional payment that is equity-linked and equivalent to 2.1% of the then total valuation of Curetis N.V. As part of an amendment between the Company and the EIB on July 9, 2020, the parties adjusted the PPI percentage applicable to the third EIB tranche of €5.0 million, which was funded in June 2019, from its original 2.1% PPI in Curetis N.V.'s equity value upon maturity to a new 0.3% PPI in OpGen's equity value upon maturity. This right constitutes an embedded derivative, which is separated and measured at fair value with changes being accounted for through income or loss.

The debt was measured and recognized at fair value as of the acquisition date. The fair value of the EIB debt was approximately $15.8 million as of the acquisition date. The resulting debt discount is being amortized over the life of the EIB debt as an increase to interest expense.

On May 23, 2022, the Company and the EIB entered into a Waiver and Amendment Letter (the "2022 EIB Amendment") relating to the amendment of the EIB loan facility, between the EIB and Curetis pursuant to which Curetis borrowed an aggregate amount of €18.0 million in three tranches. The 2022 EIB Amendment restructured the first tranche of approximately €13.35 million (including accumulated and deferred interest) of the Company's outstanding indebtedness with the EIB. Pursuant to the 2022 EIB Amendment, the Company repaid €5.0 million to the EIB in April 2022. The Company also agreed, among other things, to amortize the remainder of the debt tranche over the twelve-month period beginning in May 2022. The Amendment also provides for an increase of the PPI applicable to the third tranche under the loan facility from 0.3% to 0.75% beginning in June 2024. The terms of the second and third tranches of the Company's indebtedness of €3.0 million and €5.0 million, respectively, plus accumulated deferred interest remain unchanged pursuant to the 2022 EIB Amendment. As the effective borrowing rate under the amended agreement is less than the effective borrowing rate under the previous agreement, a concession is deemed to have been granted under ASC 470-60. As a concession has been granted, the agreement was accounted for as a troubled debt restructuring under ASC 470-60. The amendment did not result in a gain on restructuring as the future undiscounted cash outflows required under the amended agreement exceed the carrying value of the debt immediately prior to the amendment.

As of June 30, 2022, the outstanding borrowings under all tranches were €16,392,331 ($17,026,715), including deferred interest payable at maturity of €1,634,551 ($1,697,808).

PPP

On April 22, 2020, the Company entered into a Term Note (the "Company Note") with Silicon Valley Bank (the "Bank") pursuant to the Paycheck Protection Program (the "PPP") of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") administered by the U.S. Small Business Administration. The Company's wholly-owned subsidiary, Curetis USA Inc. ("Curetis USA" and collectively with the Company, the "Borrowers"), also entered into a Term Note with the Bank (the "Subsidiary Note," and collectively with the Company Note, the "Notes"). The Notes were dated April 22, 2020. The principal amount of the Company Note was $879,630, and the principal amount of the Subsidiary Note was $259,353.

In accordance with the requirements of the CARES Act, the Borrowers used the proceeds from the Notes in accordance with the requirements of the PPP to cover certain qualified expenses, including payroll costs, rent and utility costs. Interest accrued on the Notes at the rate of 1.00% per annum. The Borrowers applied for forgiveness of amounts due under the Notes, in an amount equal to the sum of qualified expenses under the PPP, which include payroll costs, rent obligations, and covered utility payments incurred during the twenty-four weeks following disbursement under the Notes. The entire proceeds were used under the Notes for such qualifying expenses. The Company Note was forgiven in November 2020. In May 2021, the Subsidiary Note was forgiven.

Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $779,912 and $1,198,169 for the three months ended June 30, 2022 and 2021, respectively. Total interest expense (including accretion of fair value to book value and amortization of debt discounts and financing fees) on all debt instruments was $2,049,493 and $2,363,151 for the six months ended June 30, 2022 and 2021, respectively.

Note 7 – Stockholders' equity

As of June 30, 2022, the Company had 100,000,000 shares of authorized common stock and 46,623,618 shares issued and outstanding, and 10,000,000 shares of authorized preferred stock, of which none were issued or outstanding

Following receipt of approval from stockholders at a special meeting of stockholders held on December 8, 2021, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to increase the authorized shares of common stock from 50,000,000 to 100,000,000 shares.

Following receipt of approval from stockholders at a special meeting of stockholders held on January 17, 2018, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to effect a reverse stock split of the issued and outstanding shares of common stock, at a ratio of one share for twenty-five shares. Additionally, following receipt of approval from stockholders at a special meeting of stockholders held on August 22, 2019, the Company filed an additional amendment to its Amended and Restated Certificate of Incorporation to effect a reverse stock split of the issued and outstanding shares of common stock, at a ratio of one share for twenty shares. All share amounts and per share prices in this Quarterly Report have been adjusted to reflect the reverse stock splits.

On June 24, 2022, the Company entered into the 2022 ATM Agreement with Wainwright, as a sales agent, pursuant to which the Company may offer and sell from time to time in an "at the market offering", at its option, up to an aggregate of $10.65 million of shares of the Company's common stock through the sales agent. As of June 30, 2022, the Company had not sold any shares under the 2022 ATM Offering (see Note 11).

On December 8, 2021, the Company received stockholder approval to increase the number of authorized shares of common stock of the Company. As of December 31, 2021, all 150,000 shares of convertible preferred stock were converted into an aggregate of 7,500,000 shares of common stock. The October 2021 Offering raised aggregate net proceeds of $13.9 million, and gross proceeds of $15.0 million.

On October 18, 2021, the Company closed the October 2021 Offering with a single healthcare-focused institutional investor of 150,000 shares of convertible preferred stock and warrants to purchase up to an aggregate of 7,500,000 shares of common stock. The shares of preferred stock had a stated value of $100 per share and were converted into an aggregate of 7,500,000 shares of common stock at a conversion price of $2.00 per share after the Company received stockholder approval for an increase to its number of authorized shares of common stock, which approval occurred at the Company's special meeting of stockholders held in December 2021. The warrants have an exercise price of $2.05 per share, will become exercisable six months following the date of issuance, and will expire five years following the initial exercise date. The warrants are classified as permanent equity at June 30, 2022. In connection with the issuance of convertible preferred stock, the Company recognized a beneficial conversion feature of $7,166,752 as a deemed dividend to the preferred stockholders in the fourth quarter of 2021.

On March 9, 2021, the Company entered into an Exercise Agreement with the Holder from our 2020 PIPE financing. Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of the remaining 4,842,615 Existing Warrants for cash, pursuant to the terms of and subject to beneficial ownership limitations contained in the Existing Warrants, the Company agreed to issue to the Holder, New Warrants to purchase 0.65 shares of common stock for each share of common stock issued upon such exercise of the remaining Existing Warrants pursuant to the Exercise Agreement for an aggregate of 3,147,700 New Warrants. The terms of the New Warrants are substantially similar to those of the Existing Warrants, except that the New Warrants have an exercise price of $3.56. The New Warrants are immediately exercisable and will expire five years from the date of the Exercise Agreement. The Holder paid an aggregate of $255,751 to the Company for the purchase of the New Warrants. The Company received aggregate gross proceeds before expenses of approximately $9.65 million from the exercise of the remaining Existing Warrants held by the Holder and the payment of the purchase price for the New Warrants. The Company recognized approximately $7.8 million of non-cash warrant inducement expense during year ended December 31, 2021 related to this transaction representing the fair value of the New Warrants issued to induce the exercise. The fair values were calculated using the Black-Scholes option pricing model.

On February 11, 2021, the Company closed the February 2021 Offering with a single U.S.-based, healthcare-focused institutional investor for the purchase of (i) 2,784,184 shares of common stock and (ii) 5,549,149 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock. The Company also issued to the investor, in a concurrent private placement, unregistered common warrants to purchase 4,166,666 shares of the Company's common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of $3.00, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of $2.99. The pre-funded warrants are immediately exercisable, at an exercise price of $0.01, and may be exercised at any time until all of the pre-funded warrants are exercised in full. The common warrants will have an exercise price of $3.55 per share, will be exercisable commencing on the six-month anniversary of the date of issuance, and will expire five and one-half (5.5) years from the date of issuance. The February 2021 Offering raised aggregate net proceeds of $23.5 million, and gross proceeds of $25.0 million. As of December 31, 2021, all pre-funded warrants issued in the February 2021 Offering have been exercised.

On April 1, 2020, the Company acquired all of the shares of Curetis GmbH, and certain other assets and liabilities of Curetis N.V., as further described in Note 1, and paid, as the sole consideration, 2,028,208 shares of the Company's common stock to the Seller.

On February 11, 2020, the Company entered into an ATM Agreement with Wainwright, which was amended and restated on November 13, 2020 to add BTIG, LLC as a sales agent, pursuant to which the Company could offer and sell from time to time in an "at the market offering," at its option, up to an aggregate of $22.1 million of shares of the Company's common stock through the sales agents. During the year ended December 31, 2021, the Company sold 680,000 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately $1.48 million, and gross proceeds of $1.55 million. The Company terminated the ATM Agreement in June 2022 in conjunction with the execution of the 2022 ATM Agreement.

Stock options

In 2008, the Company adopted the 2008 Stock Option and Restricted Stock Plan (the "2008 Plan"), pursuant to which the Company's Board of Directors could grant either incentive or non-qualified stock options or shares of restricted stock to directors, key employees, consultants and advisors.

In April 2015, the Company adopted, and the Company's stockholders approved, the 2015 Equity Incentive Plan (the "2015 Plan"); the 2015 Plan became effective upon the execution and delivery of the underwriting agreement for the Company's initial public offering in May 2015. Following the effectiveness of the 2015 Plan, no further grants will be made under the 2008 Plan. The 2015 Plan provides for the granting of incentive stock options within the meaning of Section 422 of the Code to employees and the granting of non-qualified stock options to employees, non-employee directors and consultants. The 2015 Plan also provides for the grants of restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants.

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 2,710 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date, that are subsequently forfeited or terminated for any reason before being exercised or settled, plus (3) the number of shares subject to vesting restrictions under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited. In addition, the number of shares that have been authorized for issuance under the 2015 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to the lesser of (1) 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (2) another lesser amount determined by the Company's Board of Directors. Following Board of Director approval, 1,858,010 shares were automatically added to the 2015 Plan in 2022. Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled, or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited. As of June 30, 2022, 1,284,296 shares remain available for issuance under the 2015 Plan.

On September 30, 2020, the Company held its 2020 Annual Meeting of Stockholders (the "Annual Meeting"). At the Annual Meeting, stockholders of the Company voted to approve, among other things, a plan under which stock options to purchase an aggregate of 1,300,000 shares of the Company's common stock would be made by the Board of Directors of the Company outside of the stockholder-approved equity incentive plan to its executive officers and non-employee directors (the "2020 Stock Options Plan"). The 2020 Stock Options Plan and the grant made thereunder were approved by the Board of Directors on August 6, 2020, subject to receipt of stockholder approval at the Annual Meeting. The aggregate number of shares of the Company's common stock authorized for issuance is 1,300,000 shares of common stock and all 1,300,000 stock options were issued on September 30, 2020. Shares subject to awards granted under the 2020 Stock Options Plan that are forfeited or terminated before being exercised will not be available for re-issuance under the 2020 Stock Options Plan. As of June 30, 2022, no shares remain available for issuance under the 2020 Stock Options Plan.

In connection with the appointment of Albert Weber as Chief Financial Officer, OpGen granted Mr. Weber an inducement grant of stock options to purchase an aggregate of 210,000 shares of OpGen's common stock with a grant date of January 3, 2022. The equity award was granted as a component of Mr. Weber's employment compensation and was granted as an inducement material to his acceptance of employment with OpGen. The options have an exercise price of $1.08, a ten-year term and a vesting schedule of 25% vesting of the award on the first annual anniversary of the date of grant and then 6.25% vesting each quarter thereafter over three additional years. The award is subject to Mr. Weber's continued service with OpGen through the applicable vesting dates.

Replacement awards

In connection with the acquisition of Curetis, the Company issued equity awards to Curetis employees consisting of stock options ("replacement awards") in exchange for their Curetis equity awards. The replacement awards consisted of 134,371 stock options with a weighted average grant date fair value of $1.68. The terms of these replacement awards are substantially similar to the original Curetis equity awards. The fair value of the replacement awards for services rendered through April 1, 2020, the acquisition date, was recognized as a component of the purchase consideration, with the remaining fair value of the replacement awards related to the post-combination services recorded as stock-based compensation over the remaining vesting period.

For the three and six months ended June 30, 2022 and 2021, the Company recognized share-based compensation expense as follows:

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Cost of services	$ 8,266	$ 2,944	$ 11,101	$ 4,346
Research and development	73,981	67,783	140,979	102,756
General and administrative	138,438	172,790	279,320	314,781
Sales and marketing	36,718	18,031	67,622	29,335
	$ 257,403	$ 261,548	$ 499,022	$ 451,218

No income tax benefit for share-based compensation arrangements was recognized in the condensed consolidated statements of operations and comprehensive loss due to the Company's net loss position.

The Company granted no options during the three months ended June 30, 2022. During the three months ended June 30, 2022, 7,691 options were forfeited, and 28,367 options expired. The Company granted 542,500 options during the six months ended June 30, 2022. During the six months ended June 30, 2022, 10,191 options were forfeited, and 29,903 options expired.

The Company had total stock options to acquire 2,215,755 shares of common stock outstanding at June 30, 2022 under all of its equity compensation plans.

Restricted stock units

The Company granted 60,000 restricted stock units during the three months ended June 30, 2022, and 65,868 restricted stock units vested and 7,826 were forfeited. The Company granted 730,572 restricted stock units during the six months ended June 30, 2022, and 173,368 restricted stock units vested and 10,402 were forfeited. The Company had 833,066 total restricted stock units outstanding at June 30, 2022.

Stock purchase warrants

At June 30, 2022 and December 31, 2021, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at June 30, 2022 (1)	Outstanding at December 31, 2021 (1)
February 2015	$ 3,300.00	February 2025	451	451
June 2017	$ 390.00	June 2022	—	938
July 2017	$ 345.00	July 2022	318	318
July 2017	$ 250.00	July 2022	2,501	2,501
July 2017	$ 212.60	July 2022	50,006	50,006
February 2018	$ 81.25	February 2023	9,232	9,232
February 2018	$ 65.00	February 2023	92,338	92,338
October 2019	$ 2.00	October 2024	354,000	354,000
October 2019	$ 2.60	October 2024	235,000	235,000
November 2020	$ 2.52	May 2026	242,130	242,130
February 2021	$ 3.55	August 2026	4,166,666	4,166,666
February 2021	$ 3.90	August 2026	416,666	416,666
March 2021	$ 3.56	March 2026	3,147,700	3,147,700
October 2021	$ 2.05	April 2027	7,500,000	7,500,000
			16,217,008	16,217,946

The warrants listed above were issued in connection with various debt, equity or development contract agreements.

(1) Warrants to purchase fractional shares of common stock resulting from the reverse stock split on August 22, 2019 were rounded up to the next whole share of common stock on a holder by holder basis.

Note 8 – Commitments and Contingencies

Registration and other stockholder rights

In connection with the various investment transactions, the Company entered into certain registration rights agreements with stockholders, pursuant to which the investors were granted certain demand registration rights and/or piggyback and/or resale registration rights in connection with subsequent registered offerings of the Company's common stock.

Supply agreements

In June 2017, the Company entered into an agreement with Life Technologies Corporation, a subsidiary of Thermo Fisher Scientific ("LTC"), to supply the Company with Thermo Fisher Scientific's QuantStudio 5 Real-Time PCR Systems ("QuantStudio 5") to be used to run OpGen's Acuitas AMR Gene Panel tests. Under the terms of the agreement, the Company must notify LTC of the number of QuantStudio 5s that it commits to purchase in the following quarter. As of June 30, 2022, the Company had acquired twenty-four QuantStudio 5s including none during the three and six months ended June 30, 2022. As of June 30, 2022, the Company has not committed to acquiring additional QuantStudio 5s in the next three months.

Curetis places frame-work orders for Unyvero Systems and for raw materials for its cartridge manufacturing to ensure availability during commercial ramp-up-phase and also to gain volume-scale-effects with regards to purchase prices. Some of the electronic parts used for the production of Unyvero Systems have lead times of several months, hence it is necessary to order such systems with long-term framework-orders to ensure the demands from the market are covered. The aggregate purchase commitments over the next twelve months are approximately $0.5 million.

COVID-19 Impact

In December 2019 and early 2020, the coronavirus known as COVID-19 was reported to have surfaced in China. The spread of this virus including its variants and mutations globally in 2020, 2021 as well as into 2022 has caused significant business disruption domestically in the United States and in Europe, as well as China, the areas in which the Company primarily operates or has significant business interest. While the disruption is currently expected to be temporary, such disruption is still ongoing and there remains considerable uncertainty around the duration of this disruption. Therefore, while the Company expects that this matter will continue to impact the Company's financial condition, results of operations, or cash flows, the extent of the financial impact and duration cannot be reasonably estimated at this time.

Note 9 – Leases

The following table presents the Company's ROU assets and lease liabilities as of June 30, 2022 and December 31, 2021:

Lease Classification	June 30, 2022	December 31, 2021
ROU Assets:		
Operating	$ 1,582,325	$ 1,814,396
Financing	19,660	90,467
Total ROU assets	$ 1,601,985	$ 1,904,863
Liabilities		
Current:		
Operating	$ 394,027	$ 459,792
Finance	16,731	43,150
Noncurrent:		
Operating	2,721,233	2,977,402
Finance	1,962	3,644
Total lease liabilities	$ 3,133,953	$ 3,483,988

Maturities of lease liabilities as of June 30, 2022 by fiscal year are as follows:

Maturity of Lease Liabilities	Operating	Finance	Total
2022 (Six months)	$ 329,771	$ 15,336	$ 345,107
2023	615,068	3,364	618,432
2024	624,663	280	624,943
2025	529,481	—	529,481
2026	378,279	—	378,279
Thereafter	2,126,368	—	2,126,368
Total lease payments	4,603,630	18,980	4,622,610
Less: Interest	(1,488,370)	(287)	(1,488,657)
Present value of lease liabilities	$ 3,115,260	$ 18,693	$ 3,133,953

Condensed consolidated statements of operations classification of lease costs as of the three and six months ended June 30, 2022 and 2021 are as follows:

Lease Cost	Classification	Three months ended June 30, 2022	Three months ended June 30, 2021	Six months ended June 30, 2022	Six months ended June 30, 2021
Operating	Operating expenses	$ 152,784	$ 298,331	$ 327,699	$ 646,369
Finance:					
Amortization	Operating expenses	31,096	111,464	70,807	222,420
Interest expense	Other expenses	509	4,491	1,414	11,350
Total lease costs		$ 184,389	$ 414,286	$ 399,920	$ 880,139

Other lease information as of June 30, 2022 is as follows:

Other Information	Total
Weighted average remaining lease term (in years)	
Operating leases	7.7
Finance leases	0.6
Weighted average discount rate:	
Operating leases	9.2%
Finance leases	7.3%

Supplemental cash flow information as of the six months ended June 30, 2022 and 2021 is as follows:

Supplemental Cash Flow Information	2022	2021
Cash paid for amounts included in the measurement of lease liabilities		
Cash used in operating activities		
Operating leases	$ 327,699	$ 646,369
Finance leases	$ 1,414	$ 11,350
Cash used in financing activities		
Finance leases	$ 28,101	$ 177,742
ROU assets obtained in exchange for lease obligations:		
Operating leases	$ —	$ 748,294

Note 10 – License agreements, research collaborations and development agreements

NYSDOH

In 2018, the Company announced a collaboration with the New York State Department of Health (“DOH”) and ILÚM Health Solutions, LLC (“ILÚM”), a wholly-owned subsidiary of Merck’s Healthcare Services and Solutions division, to develop a state-of-the-art research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions statewide. ILÚM has since been acquired by Infectious Disease Connect, Inc. (“IDC”), a University of Pittsburgh Medical Center (“UPMC”) Enterprise company. The Company was working together with DOH’s Wadsworth Center and IDC to continue development of an infectious disease digital health and precision medicine platform that connects healthcare institutions to DOH and uses genomic microbiology for statewide surveillance and control of antimicrobial resistance. As part of the collaboration, the Company received approximately $1.6 million over the 15-month demonstration portion of the project. The demonstration project began in early 2019 and was completed in the first quarter of 2020. In April 2020, the Company began a second-year expansion phase to build on the successes and experience of the first-year pilot phase while focusing on accomplishing the goal of the effort to improve patient outcomes and save healthcare dollars by integrating real-time epidemiologic surveillance with rapid delivery of antibiotic resistance results to care-givers via web-based and mobile platforms. The second-year contract included a quarterly retainer-based project fee as well as volume-dependent per test fees for a total contract value of up to $450,000 to OpGen. In April 2021, the Company extended its second-year expansion phase by another six months through September 30, 2021 at which point the project was completed and has ended. The six-month extension and expansion contract included a quarterly retainer-based project fee as well as volume-dependent per test fees for a total contract value of up to an additional $540,000. During the three months ended June 30, 2022 and 2021, the Company recognized $0 and $237,000 of revenue related to the contract, respectively. During the six months ended June 30, 2022 and 2021, the Company recognized $0 and $345,000 of revenue related to the contract, respectively.

Sandoz

In December 2018, Ares Genetics entered into a service frame agreement with Sandoz International GmbH ("Sandoz"), to leverage Ares Genetics' database on the genetics of antibiotic resistance, ARESdb, and the ARES Technology Platform for Sandoz' anti-infective portfolio.

Under the terms of the framework agreement, which had an initial term of 36 months that was subsequently extended to January 31, 2025, Ares Genetics and Sandoz intend to develop a digital anti-infectives platform, combining established microbiology laboratory methods with advanced bioinformatics and artificial intelligence methods to support drug development and life-cycle management. The collaboration, in the short- to mid-term, aims to both rapidly and cost-effectively re-purpose existing antibiotics and design value-added medicines with the objective of expanding indication areas and to overcome antibiotic resistance, in particular with regards to infections with bacteria that have already developed resistance against multiple treatment options. In the longer-term, the platform is expected to enable surveillance for antimicrobial resistant pathogens to inform antimicrobial stewardship and the development of novel anti-infectives that are less prone to encounter resistance and thereby preserve antibiotics as an effective treatment option.

Qiagen

On February 18, 2019, Ares Genetics and Qiagen GmbH, or Qiagen, entered into a strategic licensing agreement for ARESdb and ARESstools, in the area of antimicrobial resistance ("AMR") research. The agreement has a term of 20 years and may be terminated by Qiagen for convenience with 180 days written notice.

Ares Genetics has retained the rights to use ARESdb and ARESstools for AMR research, customized bioinformatics services, and for the development of specific AMR assays and applications for the Curetis Group (including Ares Genetics), as well as third parties (e.g., other diagnostics companies or partners in the pharmaceutical industry). As the Qiagen research offering is expected to also enable advanced molecular diagnostic services and products, Qiagen's customers may obtain a diagnostic use license from Ares Genetics.

Under the terms of the original agreement, Qiagen, in exchange for a moderate six figure up-front licensing payment, has received an exclusive RUO license to develop and commercialize general bioinformatics offerings and services for AMR research use only, based on Ares Genetics' database on the genetics of antimicrobial resistance, ARESdb, as well as on the ARES bioinformatics AMR toolbox, ARESstools. Under the agreement, the parties had agreed to a mid-single digit percentage royalty rate on Qiagen net sales, which is subject to a minimum royalty rate that steps up upon certain achieved milestones, which is payable to Ares Genetics. The parties also agreed to further modest six figure milestone payments upon certain product launches. The contract was subsequently amended in May 2021 to a non-exclusive license and a flat annual license fee as well as a royalty percentage on potential future panel-based products that are developed by Qiagen.

FISH License

The Company was party to one license agreement with Life Technologies to acquire certain patent rights and technologies related to its FISH product line. Royalties were incurred upon the sale of a product or service which utilizes the licensed technology. The Company terminated this license agreement in October 2020 effective as of June 30, 2021 in conjunction with its announced exit of the FISH business in June 2021. The Company paid a one-time settlement fee of $350,000 and paid a 10% royalty on the sale of eligible products through June 2021 but is no longer subject to any minimum royalty obligations. The Company recognized net royalty expense of $0 for the three months ended June 30, 2022 and 2021, respectively. The Company recognized net royalty expense of $0 and $8,996 for the six months ended June 30, 2022 and 2021, respectively.

Siemens

In 2016, Ares Genetics acquired the GEAR assets from Siemens Technology Accelerator GmbH ("STA"), providing the original foundation to ARESdb. Under the agreement with STA, Ares Genetics incurs royalties on revenues from licensed product sales or sublicensing proceeds. Royalty rates under the Siemens agreement range from 1.3% to 40% depending on the specifics of the licenses and rights provided by Ares Genetics to third parties and whether such third parties may have been originally introduced by Siemens to Ares Genetics. The total net royalty expense related to this agreement was $703 and $178 for the three months ended June 30, 2022 and 2021, respectively. The total net royalty expense related to this agreement was $3,482 and $794 for the six months ended June 30, 2022 and 2021, respectively.

Note 11 - Subsequent Events

Subsequent to June 30, 2022, the Company sold 1,703,324 shares of its common stock under the 2022 ATM Offering resulting in aggregate gross proceeds to the Company of approximately $1.0 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited condensed consolidated financial statements and the accompanying notes thereto included in Part I, Item 1 of this quarterly report on Form 10-Q. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under Part II. Item 1A. "Risk Factors" of this quarterly report on Form 10-Q and Part 1. Item 1A of our annual report on Form 10-K for the year ended December 31, 2021.

Overview

OpGen, Inc. (the "Company") is a precision medicine company harnessing the power of molecular diagnostics and informatics 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. Our 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, and AREScloud, as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit. The Company exited its FISH business in early 2021, and the Company's license agreement with Life Technologies, a subsidiary of Thermo Fisher, was terminated as of June 30, 2021.

On April 1, 2020, the Company completed a business combination transaction whereby the Company acquired Curetis GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany ("Curetis GmbH"). Curetis is an early commercial-stage molecular diagnostics (MDx) company focused on rapid infectious disease testing for hospitalized patients with the aim to improve the treatment of hospitalized, critically ill patients with suspected microbial infection and has developed the innovative Unyvero molecular diagnostic solution for comprehensive infectious disease testing. The business combination transaction was designed principally to leverage each company's existing research and development and relationships with hospitals and clinical laboratories to accelerate the sales of both companies' products and services.

The focus of OpGen is on its combined broad portfolio of products, which includes high impact rapid diagnostics and bioinformatics to interpret AMR genetic data. The Company currently expects to focus on the following products for lower respiratory infection, urinary tract infection and invasive joint infection:

- The Unyvero Lower Respiratory Tract, or LRT, test (e.g., for bacterial pneumonias) is the first U.S. Food and Drug Administration, or FDA, cleared test that can be used for the detection of more than 90% of common causative agents of pneumonia in hospitalized patients. According to the National Center for Health Statistics (2018), pneumonia is a leading cause of admissions to the hospital and is associated with substantial morbidity and mortality. It also increases in elderly patients, transplant, cancer or other immunocompromised patients. The Unyvero LRT automated test detects 19 pathogens within less than five hours, with approximately two minutes of hands-on time and provides clinicians with a comprehensive overview of 10 genetic antibiotic resistance markers. We have commercialized the Unyvero LRT BAL test for testing bronchoalveolar lavage, or BAL, specimens from patients with lower respiratory tract infections following FDA clearance received by Curetis in December 2019. The Unyvero LRT BAL automated test simultaneously detects 20 pathogens and 10 antibiotic resistance markers, and it is the first and only FDA-cleared panel that also includes Pneumocystis jirovecii, a key fungal pathogen often found in immunocompromised patients (such as AIDS and transplant patients) that can be difficult to diagnose, as the 20th pathogen on the panel. We believe the Unyvero LRT and LRT BAL tests have the ability to help address a significant, previously unmet medical need that causes over $10 billion in annual costs for the U.S. healthcare system, according to the Centers for Disease Control, or CDC.

- Following registration of the Unyvero instrument system as an IVD for the Chinese market in early 2021, we are supporting our strategic partner Beijing Clear Biotech (BCB) in pursuing execution of a supplemental clinical trial with the Unyvero HPN test. As requested by the Chinese regulatory authority NMPA, this study is geared towards generating additional data in China that will complement a larger data set with data from abroad compiled from other clinical and analytical studies performed in the past. Due to continued impact of COVID restrictions in China, this supplementary study has not yet been initiated and OpGen currently does not have visibility on the timelines for such a clinical study to start, given China's "zero COVID" policies.

- The Unyvero Urinary Tract Infection, or UTI, test, which is CE-IVD marked in Europe, is currently being made available to laboratories in the United States as a research use only or RUO kit. The test detects a broad range of pathogens as well as antimicrobial resistance markers directly from native urine specimens. We initiated a prospective multi-center clinical trial for the Unyvero UTI in the United States in the third quarter of 2021 and have recently announced enrollment of more than 1,000 patient samples. We currently expect enrollment to be completed in the coming months and expect final data read-out from the UTI clinical trial in H2-2022 for a subsequent FDA submission.

- The Unyvero Invasive Joint Infection, or IJI, test, which is a variant being developed for the U.S. market, has also been selected for analytical and clinical performance evaluation including clinical trials towards a future U.S. FDA submission. Microbial diagnosis of IJI is difficult because of challenges in sample collection, usually at surgery, and patients being on prior antibiotic therapy which minimizes the chances of recovering viable bacteria. We believe that Unyvero IJI could be useful in identifying pathogens as well as their AMR markers to help guide optimal antibiotic treatment for these patients.

- On September 30, 2021, we received clearance from the FDA for our Acuitas AMR Gene Panel for bacterial isolates. The Acuitas AMR Gene Panel detects 28 genetic antimicrobial resistance, or AMR, markers in isolated bacterial colonies from 26 different pathogens. We believe the panel provides clinicians with a valuable diagnostic tool that informs about potential antimicrobial resistance patterns early and supports appropriate antibiotic treatment decisions in this indication. We have signed the first two commercial customer contracts for the Acuitas AMR Gene Panel for isolates and have a funnel of several additional commercial contract proposals that we expect to enter into during the coming months.

- We are also developing novel bioinformatics tools and solutions to accompany or augment our current and potential future IVD products and may seek regulatory clearance for such bioinformatics tools and solutions to the extent they would be required either as part of our portfolio of IVD products or even as a standalone bioinformatics product.

OpGen has extensive offerings of additional IVD tests including CE-IVD-marked Unyvero tests for hospitalized pneumonia patients who are hospitalized, implant and tissue infections, intra-abdominal infections, complicated urinary tract infections, and blood stream infections. Our portfolio furthermore includes a CE-IVD-marked PCR based rapid test kit for SARS-CoV-2 detection in combination with our PCR compatible universal lysis buffer (PULB).

OpGen's combined AMR bioinformatics offerings, when and if such products are cleared for marketing, will offer important new tools to clinicians treating patients with AMR infections. OpGen's subsidiary Ares Genetics' ARESdb is a comprehensive database of genetic and phenotypic information. ARESdb was originally designed based on the Siemens microbiology strain collection covering resistant pathogens and its development has significantly expanded, as a result of transferring data from the discontinued Acuitas Lighthouse into ARESdb to now cover more than 78,000 bacterial isolates that have been sequenced using NGS technology and tested for susceptibility with applicable antibiotics from a range of over 100 antimicrobial drugs. In the fourth quarter of 2021, Ares Genetics entered into a strategic database access deal with one of the world's leading microbiology and IVD corporations for their non-exclusive access to approximately 1.1% of Ares Genetics' total database asset at the time of signing. Ares Genetics continues to explore various discussions with several interested parties in potential future collaboration or licensing opportunities. Additional partnerships with a U.S. CLIA lab, a contract research organization ("CRO") and a major University Medical Center as well as the Belgian national reference laboratory at UZ Leuven have been initiated and are ongoing and the collaboration master service agreement with Sandoz has recently been extended until January 2025.

In addition to potential future licensing and partnering, Ares Genetics intends to independently utilize the proprietary biomarker content in this database, as well as to build an independent business in NGS and AI based offerings for AMR research and diagnostics in collaboration with its current and potential future partners in the life science, pharmaceutical and diagnostics industries. Ares Genetics' customers for such offerings include Siemens Technology Accelerator and AGES (Austrian Agency for Health and Food Safety), as well as several other national institutions from various European countries as new customers.

OpGen's subsidiary Curetis' Unyvero A50 tests for up to 130 diagnostic targets (pathogens and resistance genes) in under five hours with approximately two minutes of hands-on time. The system was first CE-IVD-marked in 2012 and was FDA cleared in 2018 along with the LRT test through a *De Novo* request. The Unyvero A30 *RQ* is a new device designed to address the low-to mid-plex testing market for 5-30 DNA targets and to provide results in approximately 30 to 90 minutes with 2-5 minutes of hands-on time. The Unyvero A30 *RQ* has a small benchtop footprint and has an attractive cost of goods profile. Curetis has been following a partnering strategy for the Unyvero A30 *RQ* and, following the successful completion of a key development milestone, Curetis has completed final verification and validation testing of the A30 instruments and is actively engaged in several ongoing partnering discussions and due diligence under respective material transfer agreements.

The Company has extensive partner and distribution relationships to help accelerate the establishment of a global infectious disease diagnostic testing and informatics business. The Company's partners include A. Menarini Diagnostics S.r.l. for Pan-European distribution to currently 12 countries and Beijing Clear Biotech Co. Ltd. for Unyvero A50 product distribution in China. We have a network of distributors covering countries in Europe, the Middle East and Africa, Asia Pacific and Latin America. With the discontinuation of our FISH products business in Europe, we have reduced our network of distributors to only those distributors actively commercializing our Unyvero line of products or CE-IVD-marked SARS-CoV-2 test kits.

OpGen will continue to develop and seek FDA and other regulatory clearances or approvals, as applicable, for our Unyvero UTI and IJI products. OpGen will continue to offer the FDA-cleared Unyvero LRT and LRT BAL Panels, and FDA-cleared Acuitas AMR Gene Panel tests, as well as the Unyvero UTI Panel as a RUO product to hospitals, public health departments, clinical laboratories, pharmaceutical companies and CROs. OpGen's subsidiary, Curetis, continues its efforts in ensuring compliance with the new European Union's In-Vitro-Diagnostic Device Regulation (IVDR), which officially went into effect in May 2022. Given the lack of designated Notified Bodies at this time, and with the recently approved EU commission proposal to provide for generous multi-year grace periods for IVD products with current In-Vitro-Diagnostic Device Directive (IVDD) CE marking, it is now possible for Curetis to continue its portfolio of existing CE-IVD marked products until at least May 2025 and May 2026, respectively, as long as no material changes are being made to any of its products. Following May 2022, however, any new or changed CE marked products will be required to be IVDR compliant from the outset.

Our headquarters are in Rockville, Maryland, and our principal operations are in Rockville, Maryland and Holzgerlingen and Bodelshausen, both in Germany. We also have operations in Vienna, Austria. We operate in one business segment.

Recent developments

COVID-19

On March 11, 2020, the World Health Organization declared the novel coronavirus ("COVID-19") a pandemic, and on March 13, 2020, the United States declared a national emergency with respect to COVID-19. COVID-19 has negatively impacted the global economy, disrupted global supply chains and created significant volatility and disruption in the financial markets.

As a result of the outbreak, we have experienced a material impact on our business, financial condition and results of operations for the three and six months ended June 30, 2022 as well as significant business disruptions. For example, some of our employees are currently still working remotely from home and we are still not always able to physically meet with future and current customers to sell and market our products.

We continue to monitor the impacts of COVID-19 on the global economy and on our business operations. However, at this time, it is difficult to predict how long the potential operational impacts of COVID-19 will remain in effect or to what degree they will impact our operations and financial results. An extended period of global supply chain and economic disruption could materially affect our business, results of operations, access to sources of liquidity and financial condition, as well as our ability to execute our business strategies and initiatives in their respective expected time frames.

Financings

Since inception, we have incurred, and continue to incur, significant losses from operations. We have funded our operations primarily through external investor financing arrangements. During 2021, we raised net proceeds of approximately $48 million.

Results of operations for the three months ended June 30, 2022 and 2021

Revenues

	Three months ended June 30,	
	2022	2021
Product sales	$ 889,271	$ 307,804
Laboratory services	20,570	266,784
Collaboration revenue	57,364	237,027
Total revenue	$ 967,205	$ 811,615

Total revenue for the three months ended June 30, 2022 increased approximately 19% when compared to the same period in 2021, with a change in the mix of revenue, as follows:

- Product Sales: an increase in revenue of approximately 189% in the 2022 period compared to the 2021 period is primarily attributable to the one-time sale of a pool of Unyvero A50 instrument systems to our Pan-European distribution partner Menarini and an increase in domestic Unyvero sales;

- Laboratory Services: a decrease in revenue of approximately 92% in the 2022 period compared to the 2021 period is primarily attributable to a decrease in COVID testing services performed by Curetis GmbH; and
- Collaboration Revenue: a decrease in revenue of approximately 76% in the 2022 period compared to the 2021 period is primarily the result of revenue from our contract with the New York State DOH, which ended in the third quarter of 2021.

Operating expenses

	Three months ended June 30,	
	2022	2021
Cost of products sold	$ 646,389	$ 342,580
Cost of services	15,650	137,934
Research and development	2,273,756	2,859,590
General and administrative	2,134,266	2,692,255
Sales and marketing	1,169,349	802,549
Impairment of right-of-use asset	—	115,218
Total operating expenses	$ 6,239,410	$ 6,950,126

Our total operating expenses for the three months ended June 30, 2022 decreased approximately 10% when compared to the same period in 2021. Operating expenses changed as follows:

- Cost of products sold: cost of products sold for the three months ended June 30, 2022 increased approximately 89% when compared to the same period in 2021. The increase is primarily attributable to the one-time sale of a pool of Unyvero A50 instrument systems to our Pan-European distribution partner Menarini, which also contributed to the Company's improved gross margin. Additionally, the Company saw a significant increase in domestic Unyvero sales over the same period;
- Cost of services: cost of services for the three months ended June 30, 2022 decreased approximately 89% when compared to the same period in 2021. The decrease in cost of services is primarily attributable to lower cost of services related to the conclusion of our contract with the New York State DOH in the third quarter of 2021 and a decrease in COVID testing services by Curetis;
- Research and development: research and development expenses for the three months ended June 30, 2022 decreased approximately 20% when compared to the same period in 2021. The decrease in research and development is primarily attributable to a reduction in payroll related costs resulting primarily from streamlining operations and reducing headcount in R&D and operations at our Rockville headquarters;
- General and administrative: general and administrative expenses for the three months ended June 30, 2022 decreased approximately 21% when compared to the same period in 2021, primarily due to a reduction in payroll related costs;
- Sales and marketing: sales and marketing expenses for the three months ended June 30, 2022 increased approximately 46% when compared to the same period in 2021, primarily due to the expansion of the Company's sales force as well as the return of various international and domestic trade shows and exhibitions post COVID; and
- Impairment of right-of-use asset: impairment of right-of-use asset for the three months ended June 30, 2021 represents the impairment of our San Diego, California ROU asset.

Other (expense) income

	Three months ended June 30,	
	2022	2021
Gain on extinguishment of debt	$ —	$ 259,353
Interest expense	(779,912)	(1,198,169)
Foreign currency transaction gains (losses)	271,967	(915)
Other income	13,851	4,702
Change in fair value of derivative financial instruments	(74,116)	(13,021)
Total other expense	$ (568,210)	$ (948,050)

Our total other expense for the three months ended June 30, 2022 decreased when compared to the same period in 2021 primarily due to lower interest expense and foreign currency transaction gains.

Results of operations for the six months ended June 30, 2022 and 2021

Revenues

	Six months ended June 30,	
	2022	2021
Product sales	$ 1,255,323	$ 835,383
Laboratory services	63,499	450,849
Collaboration revenue	118,128	355,099
Total revenue	$ 1,436,950	$ 1,641,331

Total revenue for the six months ended June 30, 2022 decreased approximately 12% when compared to the same period in 2021, with a change in the mix of revenue, as follows:

- Product Sales: an increase in revenue of approximately 50% in the 2022 period compared to the 2021 period is primarily attributable to the one-time sale of a pool of Unyvero A50 instrument systems to our Pan-European distribution partner Menarini and an increase in domestic Unyvero sales;

- Laboratory Services: a decrease in revenue of approximately 86% in the 2022 period compared to the 2021 period is primarily attributable to a decrease in COVID testing services performed by Curetis GmbH; and

- Collaboration Revenue: a decrease in revenue of approximately 67% in the 2022 period compared to the 2021 period is primarily attributable to revenue from our contract with the New York State DOH, which ended in the third quarter of 2021.

Operating expenses

	Six months ended June 30,	
	2022	2021
Cost of products sold	$ 938,386	$ 896,634
Cost of services	46,212	242,918
Research and development	4,590,197	5,673,081
General and administrative	4,759,319	5,355,912
Sales and marketing	2,220,781	1,701,801
Impairment of right-of-use asset	—	170,714
Total operating expenses	$ 12,554,895	$ 14,041,060

Our total operating expenses for the six months ended June 30, 2022 decreased approximately 11% when compared to the same period in 2021. Operating expenses changed as follows:

- Costs of products sold: cost of products sold for the six months ended June 30, 2022 increased approximately 5% when compared to the same period in 2021. The increase is primarily attributable to the one-time sale of a pool of Unyvero A50 instrument systems to our Pan-European distribution partner Menarini, which also contributed to the Company's improved gross margin. Additionally, the Company saw a significant increase in domestic Unyvero sales over the same period;

- Costs of services: cost of services for the six months ended June 30, 2022 decreased approximately 81% when compared to the same period in 2021. The decrease in cost of services is primarily attributable to lower cost of services related to the conclusion of our contract with the New York State DOH in the third quarter of 2021 and a decrease in COVID testing services by Curetis;

- Research and development: research and development expenses for the six months ended June 30, 2022 decreased approximately 19% when compared to the same period in 2021. The decrease in research and development is primarily attributable to a reduction in payroll related costs resulting primarily from streamlining operations and reducing headcount in R&D and operations at our Rockville headquarters;

- General and administrative: general and administrative expenses for the six months ended June 30, 2022 decreased approximately 11% when compared to the same period in 2021, which is primarily due to a reduction in payroll related costs;

- Sales and marketing: sales and marketing expenses for the six months ended June 30, 2022 increased approximately 30% when compared to the same period in 2021, which is primarily due to the expansion of the Company's sales force as well as the return of various international and domestic trade shows and exhibitions post COVID; and

- Impairment of right-of-use asset: impairment of right-of-use asset for the six months ended June 30, 2021 represents the impairment of our San Diego, California ROU asset.

Other expense

	Six months ended June 30,	
	2022	2021
Warrant inducement expense	$ —	$ (7,755,541)
Gain on extinguishment of debt	—	259,353
Interest expense	(2,049,493)	(2,363,151)
Foreign currency transaction gains (losses)	470,707	426,700
Other income	16,972	9,627
Change in fair value of derivative financial instruments	35,628	(114,411)
Total other expense	$ (1,526,186)	$ (9,537,423)

Our total other expense for the six months ended June 30, 2022 decreased when compared to the same period in 2021 primarily due to warrant inducement expense related to our 2021 Warrant Exercise.

Liquidity and capital resources

As of June 30, 2022, we had cash and cash equivalents of $16.6 million compared to $36.1 million at December 31, 2021. We have funded our operations primarily through external investor financing arrangements and have raised funds in 2022 and 2021, including:

During the year ended December 31, 2021, we sold 680,000 shares of common stock under the ATM Agreement resulting in aggregate net proceeds to us of approximately $1.48 million, and gross proceeds of $1.55 million.

On February 11, 2021, we closed the February 2021 Offering for the purchase of (i) 2,784,184 shares of common stock, (ii) 5,549,149 pre-funded warrants, and (iii) unregistered common share purchase warrants to purchase 4,166,666 shares. The February 2021 Offering raised aggregate net proceeds of $23.5 million, and gross proceeds of $25.0 million.

On March 9, 2021, we closed the 2021 Warrant Exercise resulting in the issuance of 4,842,615 shares of common stock and raising gross proceeds of approximately $9.65 million and net proceeds of $9.3 million.

On October 18, 2021, we closed the October 2021 Offering of 150,000 shares of convertible preferred stock and warrants to purchase up to an aggregate of 7,500,000 shares of common stock. The October 2021 Offering raised aggregate net proceeds of $13.9 million, and gross proceeds of $15.0 million.

On June 24, 2022, the Company entered into the 2022 ATM Agreement with Wainwright, as a sales agent, pursuant to which the Company may offer and sell from time to time in an at the market offering, at its option, up to an aggregate of $10.65 million of shares of the Company's common stock through the sales agent. As of June 30, 2022, the Company had not sold any shares under the 2022 ATM Offering (see Note 11).

To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions, and licensing and/or partnering arrangements. There can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise. We believe that current cash on hand will be sufficient to fund operations into the first quarter of 2023. This has led management to conclude that there is substantial doubt about our ability to continue as a going concern. In the event we are unable to successfully raise additional capital during or before the end of the first quarter of 2023, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to immediately reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until we are able to obtain sufficient financing. If such sufficient financing is not received on a timely basis, we would then need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

Sources and uses of cash

Our principal source of liquidity is from financing activities, including issuances of equity and debt securities. The following table summarizes the net cash and cash equivalents provided by (used in) operating activities, investing activities and financing activities for the periods indicated:

	Six months ended June 30,	
	2022	2021
Net cash used in operating activities	$ (11,700,904)	$ (12,559,210)
Net cash used in investing activities	(83,563)	(1,723,064)
Net cash (used in) provided by financing activities	(6,847,506)	32,205,067

Net cash used in operating activities
Net cash used in operating activities for the six months ended June 30, 2022 consisted primarily of our net loss of $12.6 million, reduced by certain noncash items, including depreciation and amortization expense of $1.0 million, noncash interest expense of $1.6 million, and share-based compensation expense of $0.5 million. Net cash used in operating activities for the six months ended June 30, 2021 consisted primarily of our net loss of $21.9 million, reduced by certain noncash items, including inducement expense related to warrant repricing of $7.8 million, depreciation and amortization expense of $1.3 million, noncash interest expense of $1.9 million, and share-based compensation expense of $0.5 million.

Net cash used in investing activities
Net cash used in investing activities for the six months ended June 30, 2022 and 2021 consisted of purchases of property and equipment. The majority of the purchases of property and equipment in 2021 were related to the Company's new corporate headquarters in Rockville, Maryland.

Net cash (used in) provided by financing activities
Net cash used in financing activities for the six months ended June 30, 2022 consisted of payments on the Company's EIB debt and finance leases. Net cash provided by financing activities for the six months ended June 30, 2021 consisted primarily of the net proceeds from the February 2021 Offering, 2021 Warrant Exercise, October 2021 Offering, and exercises of common stock warrants, net of payments on debt and insurance financings.

Contractual Commitments

OpGen's subsidiary, Curetis, has contractual commitments under its 2016 senior, unsecured loan financing facility of up to €25.0 million with the European Investment Bank ("EIB"). Curetis drew down three tranches under the facility: €10.0 million in April 2017, €3.0 million in June 2018, and €5.0 million in June 2019. The first and second tranches have a floating interest rate of EURIBOR plus 4% payable after each 12-month-period from the draw-down-date and another additional 6% interest per annum that is deferred and payable at maturity together with the principal. The third tranche originally had a 2.1% PPI. Upon maturity of the third tranche, which is not before approximately mid-2024 (and no later than mid-2025), the EIB would have been entitled to an additional payment that is equity-linked and equivalent to 2.1% of the then total valuation of Curetis N.V. As part of an amendment between the Company and the EIB on July 9, 2020, the parties adjusted the PPI percentage applicable to the third EIB tranche of €5.0 million, which was funded in June 2019 from its original 2.1% PPI in Curetis N.V.'s equity value upon maturity to a new 0.3% PPI in OpGen's equity value upon maturity. This right constitutes an embedded derivative, which is separated and measured at fair value with changes being accounted for through income or loss.

As of June 30, 2022, the outstanding borrowings under all tranches were €16,392,331 ($17,026,715), including deferred interest payable at maturity of €1,634,551 ($1,697,808). On May 23, 2022, the Company and the EIB entered into a Waiver and Amendment Letter (the "2022 EIB Amendment"), which amended the EIB loan facility. The 2022 EIB Amendment restructured the first tranche of approximately €13.35 million (including accumulated and deferred interest) of the Company's indebtedness with the EIB. Pursuant to the 2022 EIB Amendment, the Company repaid €5.0 million to the EIB in April 2022. The Company also agreed, among other things, to amortize the remainder of the debt tranche over the twelve-month period beginning in May 2022. The 2022 EIB Amendment also provides for the increase of the PPI of the third tranche under the loan facility from 0.3% to 0.75% beginning in June 2024. The terms of the second and third tranches of the Company's indebtedness of €3.0 million and €5.0 million, respectively, plus accumulated deferred interest remain unchanged.

Critical accounting policies and use of estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our audited consolidated financial statements, estimates are used for, but not limited to, liquidity assumptions, revenue recognition, share-based compensation, allowances for doubtful accounts and inventory obsolescence, valuation of derivative financial instruments measured at fair value on a recurring basis, deferred tax assets and liabilities and related valuation allowance, estimated useful lives of long-lived assets, and the recoverability of long-lived assets. Actual results could differ from those estimates.

A summary of our significant accounting policies is included in Note 3 "Summary of significant accounting policies" to the accompanying unaudited condensed consolidated financial statements. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain. Our critical policies are summarized in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2021.

Recently issued accounting pronouncements

See Note 3 "Summary of significant accounting policies" in this Form 10-Q for a full description of recent accounting pronouncements, including the respective expected dates of adoption and effects on our unaudited condensed consolidated financial statements.

Off-balance sheet arrangements

As of June 30, 2022, and December 31, 2021, we did not have any off-balance sheet arrangements.

JOBS Act

Prior to December 31, 2020, the Company was an "emerging growth company" ("EGC") as defined in the Jumpstart Our Business Startups Act, (JOBS Act), and elected to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies until the Company is no longer an EGC, including using the extended transition period for complying with new or revised accounting standards. As of December 31, 2020, the Company has become a non-accelerated filer under the rules of the SEC and is no longer classified as an EGC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of June 30, 2022. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

For the quarter ended June 30, 2022, there have been no changes in the Company's internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal controls over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Our business and financial results are subject to numerous risks and uncertainties. As a result, the risks and uncertainties discussed in Part I, Item 1A. Risk Factors in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 should be carefully considered. There have been no material changes in the assessment of the risk factors set forth in such Form 10-K, except for the additional risk factors noted below, which update the risk factors included in Part II, Item 1A of our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2022:

If our goodwill, acquired in-process research and development costs or finite-lived tangible and intangible assets become impaired in the future, we may be required to record non-cash charges to earnings, which could be material and could reduce stockholders' equity or otherwise adversely affect the Company's financial condition.

We review long-lived assets, including property and equipment and identifiable amortizing intangible assets, for impairment whenever changes in circumstances or events may indicate that the carrying amounts are not recoverable. If the fair value is less than the carrying amount of the asset, an impairment is recognized for the difference. Factors which may cause an impairment of long-lived assets include significant changes in the manner of use of these assets, negative industry or market trends, a significant underperformance relative to historical or projected future operating results, extended period of idleness or a likely sale or disposal of the asset before the end of its estimated useful life. In 2021, the Company had determined that the right-of-use asset associated with the Company's San Diego, California office lease may not be recoverable, and, as a result, the Company recorded an impairment charge of $170,714 during the six months ended June 30, 2021. There can be no assurance that our other long-lived assets and intangible assets will not be further impaired. If our property and equipment and identifiable amortizing intangible assets are determined to be impaired in the future, we may be required to record non-cash charges to earnings during the period in which the impairment is determined, which could be material and have an adverse effect on our financial position and results of operations.

In addition, we review and test goodwill for impairment at least annually and whenever changes in circumstances indicate that the carrying value of the goodwill may not be recoverable. The impairment test for goodwill consists of comparing the fair value of the reporting unit and acquired IPR&D, which is estimated using both the income and market approach, to its carrying value. The process of impairment testing for our goodwill involves a number of judgments and estimates made by management including future cash flows, revenue growth rates, profitability assumptions, terminal growth rates and discount rates with regards to our reporting unit. Our internally generated long-range plan includes assumptions regarding pricing and operating forecasts for our products and technologies. If the judgments and estimates used in our analysis are not realized or are affected by external factors, then actual results may not be consistent with these judgments and estimates, and we may be required to record a goodwill impairment charge in the future, which could be material, could reduce stockholders' equity and have an adverse effect on our financial position and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description
10.1	Waiver and Amendment Letter, dated May 23, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 24, 2022).
10.2	At the Market Offering Agreement, dated June 24, 2022, by and between OpGen, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed on June 24, 2022).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) the Unaudited Condensed Consolidated Balance Sheets, (ii) the Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Unaudited Condensed Consolidated Statements of Cash Flows and (iv) the Notes to Unaudited Condensed Consolidated Financial Statements.

* Filed or furnished herewith

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.

OPGEN, INC.

By: /s/ Albert Weber
Albert Weber
Chief Financial Officer (principal financial officer and principal accounting officer)

Date: August 12, 2022

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO RULE 13A-14(A)/15D-14(A)

I, Oliver Schacht, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OpGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2022

/s/ Oliver Schacht

Oliver Schacht, Ph.D.
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO RULE 13A-14(A)/15D-14(A)

I, Albert Weber, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OpGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2022

/s/ Albert Weber

Albert Weber
Chief Financial Officer
(principal financial officer and principal accounting officer)

Exhibit 32.1

CERTIFICATION

PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of OpGen, Inc. (the "Company") for the quarterly period ended June 30, 2022 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is provided solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Date: August 12, 2022

By: /s/ Oliver Schacht
Oliver Schacht, Ph.D.
Chief Executive Officer
(principal executive officer)

Date: August 12, 2022

By: /s/ Albert Weber
Albert Weber
Chief Financial Officer
(principal financial officer and principal accounting officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.