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

FORM 10-Q

(Mark one)

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

For the fiscal year ended March 31, 2023

☐ **TRANSITION REPORT UNDER 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)**

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

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 registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

6,119,449 shares of the Company's common stock, par value $0.01 per share, were outstanding as of May 11, 2023.

OPGEN, INC.

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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 I Item 1A "Risk Factors" of our most recent annual report on Form 10-K and any risk factors included in Part II Item 1A "Risk Factors" of this quarterly report on Form 10-Q. 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:

- our liquidity and working capital requirements, including our cash requirements over the next 12 months;
- our ability to satisfy our debt obligations;
- 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 meet our obligations and extend our relationships under our collaboration and distribution agreements;
- our ability to obtain regulatory clearance for and commercialize our product and services offerings;
- our ability to establish and grow 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 (RUO) products;
- regulations and changes in laws or regulations applicable to our business, including regulation by the FDA, European Union, including new IVDR requirements, and China's NMPA;
- our ability to successfully transfer, and realize the expected benefits of the transfer of, the manufacturing of our Acuitas AMR Gene Panel from our Rockville, Maryland facility to our Bodelshausen, Germany manufacturing facility;
- 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 Russia's war against Ukraine;
- adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non-performance by financial institutions that could adversely affect our business, financial condition or results of operations;
- 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 I Item 1A "Risk Factors" of our most recent annual report on Form 10-K and any risk factors included 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)

	March 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 7,039,375	$ 7,440,030
Accounts receivable, net	666,765	514,372
Inventory, net	1,577,762	1,345,137
Prepaid expenses and other current assets	1,455,815	1,355,949
Total current assets	**10,739,717**	**10,655,488**
Property and equipment, net	3,666,823	3,457,531
Finance lease right-of-use assets, net	2,671	3,500
Operating lease right-of-use assets	2,139,974	1,459,413
Intangible assets, net	7,398,333	7,440,974
Strategic inventory, net	2,066,795	2,300,614
Other noncurrent assets	497,055	495,629
Total assets	**$ 26,511,368**	**$ 25,813,149**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 266,637	$ 420,821
Accrued compensation and benefits	1,424,602	1,097,654
Accrued liabilities	1,436,014	1,526,204
Deferred revenue	46,003	142,061
Current maturities of long-term debt	4,959,417	7,023,901
Short-term finance lease liabilities	2,803	3,364
Short-term operating lease liabilities	500,994	377,626
Total current liabilities	**8,636,470**	**10,591,631**
Long-term debt, net	5,358,433	4,850,686
Long-term finance lease liabilities	—	280
Long-term operating lease liabilities	3,121,433	2,566,138
Derivative liabilities	88,635	99,498
Other long-term liabilities	129,213	129,368
Total liabilities	**17,334,184**	**18,237,601**
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.01 par value; 100,000,000 shares authorized; 5,495,546 and 2,899,911 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	54,955	28,999
Additional paid-in capital	288,326,377	281,167,161
Accumulated deficit	(278,561,375)	(272,824,772)
Accumulated other comprehensive loss	(642,773)	(795,840)
Total stockholders' equity	**9,177,184**	**7,575,548**
Total liabilities and stockholders' equity	**$ 26,511,368**	**$ 25,813,149**

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 March 31, 2023	2022
Revenue		
Product sales	$ 410,897	$ 366,052
Laboratory services	21,673	42,929
Collaboration revenue	480,874	60,764
Total revenue	**913,444**	**469,745**
Operating expenses		
Cost of products sold	592,378	291,997
Cost of services	128,306	30,562
Research and development, net	1,812,831	2,316,441
General and administrative	2,423,953	2,625,053
Sales and marketing	1,026,087	1,051,432
Total operating expenses	**5,983,555**	**6,315,485**
Operating loss	**(5,070,111)**	**(5,845,740)**
Other (expense) income		
Interest and other income	30,106	3,121
Interest expense	(617,298)	(1,269,581)
Foreign currency transaction (losses) gains	(91,994)	198,740
Change in fair value of derivative financial instruments	12,694	109,744
Total other expense	**(666,492)**	**(957,976)**
Loss before income taxes	**(5,736,603)**	**(6,803,716)**
Provision for income taxes	—	—
Net loss	**$ (5,736,603)**	**$ (6,803,716)**
Net loss available to common stockholders	**$ (5,736,603)**	**$ (6,803,716)**
Basic and diluted net loss per share attributable to common stockholders	**$ (1.25)**	**$ (2.93)**
Weighted average shares outstanding - basic and diluted	4,577,269	2,324,184
Net loss	$ (5,736,603)	$ (6,803,716)
Other comprehensive income (loss) - foreign currency translation	153,067	(483,849)
Comprehensive loss	**$ (5,583,536)**	**$ (7,287,565)**

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, 2021	**2,322,511**	**$ 23,225**	**—**	**$ —**	**$ 276,149,768**	**$ 585,626**	**$ (235,541,539)**	**$ 41,217,080**
Issuance of RSUs	5,375	54	—	—	(54)	—	—	—
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	**2,327,886**	**$ 23,279**	**—**	**$ —**	**$ 276,391,333**	**$ 101,777**	**$ (242,345,255)**	**$ 34,171,134**
Balances at December 31, 2022	**2,899,911**	**$ 28,999**	**—**	**$ —**	**$ 281,167,161**	**$ (795,840)**	**$ (272,824,772)**	**$ 7,575,548**
Issuance of RSUs	11,627	116	—	—	(116)	—	—	—
Stock compensation expense	—	—	—	—	211,122	—	—	211,122
Offering of common stock and warrants, net of issuance costs	2,586,207	25,862	—	—	6,948,188	—	—	6,974,050
Share cancellation	(2,199)	(22)	—	—	22	—	—	—
Foreign currency translation	—	—	—	—	—	153,067	—	153,067
Net loss	—	—	—	—	—	—	(5,736,603)	(5,736,603)
Balances at March 31, 2023	**5,495,546**	**$ 54,955**	**—**	**$ —**	**$ 288,326,377**	**$ (642,773)**	**$ (278,561,375)**	**$ 9,177,184**

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three months ended March 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (5,736,603)	$ (6,803,716)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	350,452	514,269
Non-cash interest expense	456,679	1,091,843
Stock compensation expense	211,122	241,619
Change in inventory reserve	256,814	—
Change in fair value of derivative liabilities	(12,694)	(109,744)
Changes in operating assets and liabilities		
Accounts receivable	(142,177)	889,810
Inventory	(195,029)	(170,028)
Other assets	3,498	110,332
Accounts payable	(157,139)	(423,955)
Accrued compensation and other liabilities	100,388	(381,830)
Deferred revenue	(97,929)	—
Net cash used in operating activities	**(4,962,618)**	**(5,041,400)**
Cash flows from investing activities		
Purchases of property and equipment	(330,446)	(38,713)
Net cash used in investing activities	**(330,446)**	**(38,713)**
Cash flows from financing activities		
Proceeds from issuance of common stock and pre-funded warrants, net of issuance costs	6,974,050	—
Payments on debt	(2,229,560)	—
Payments on finance lease obligations	(841)	(17,529)
Net cash provided by (used in) financing activities	**4,743,649**	**(17,529)**
Effects of exchange rates on cash	150,186	(413,093)
Net decrease in cash and cash equivalents and restricted cash	(399,229)	(5,510,735)
Cash and cash equivalents and restricted cash at beginning of period	7,935,659	36,632,186
Cash and cash equivalents and restricted cash at end of period	**$ 7,536,430**	**$ 31,121,451**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 56,320	$ 1,120
Supplemental disclosures of noncash investing and financing activities		
Right-of-use assets acquired through operating leases	$ 801,321	$ —

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 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"). As of December 31, 2022, Crystal GmbH was dissolved and merged into Curetis GmbH. 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 AMR surveillance, outbreak analysis, and antibiotic response prediction including ARESiss, ARESid, ARESasp, and AREScloud, as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit.

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 offers 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 a research use only, or RUO, product to hospitals, public health departments, clinical laboratories, pharmaceutical companies, and contract research organizations, or CROs. In addition, following successful completion of a prospective multi-center clinical trial, the UTI product was submitted to the FDA in the second quarter of 2023. OpGen is also commercializing its CE-marked Unyvero Panels in Europe and other global markets via distributors, and, following the signing of a distribution deal with Fisher Healthcare in April 2023, the Company is using a mix of direct and distributor sales in the United States.

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 2023 and 2024. The Company has funded its operations primarily through external investor financing arrangements and significant actions taken by the Company, including the following:

- On January 11, 2023, the Company closed a best-efforts public offering pursuant to a Securities Purchase Agreement entered into with a certain institutional investor for the purchase of (i) 321,207 shares of the Company's common stock, par value $0.01 per share, (ii) pre-funded warrants to purchase up to an aggregate of 2,265,000 shares of common stock (the "Pre-funded Warrants"), (iii) Series A-1 common warrants to purchase an aggregate of 2,586,207 shares of common stock (the "Series A-1 Warrants"), and (iv) Series A-2 common warrants to purchase an aggregate of 2,586,207 shares of common stock (the "Series A-2 Warrants," and together with the Series A-1 Warrants, the "Common Warrants"). Each share of common stock and accompanying Common Warrants were sold at a price of $2.90 per share and accompanying Common Warrants, and each Pre-funded Warrant and accompanying Common Warrants were sold at an offering price of $2.89 per share underlying such Pre-funded Warrants and accompanying Common Warrants, for aggregate gross proceeds of approximately $7.5 million before deducting the placement agent's fees and the offering expenses, and net proceeds of approximately $6.9 million. The Common Warrants have an exercise price of $2.65 per share. The Series A-1 Warrants were immediately exercisable upon issuance, and will expire five years following the issuance date. The Series A-2 Warrants were immediately exercisable upon issuance, and will expire eighteen months following the issuance date. Subject to certain ownership limitations described in the Pre-funded Warrants, the Pre-funded Warrants were immediately exercisable and could be exercised at a nominal consideration of $0.01 per share of common stock any time until all the Pre-funded Warrants are exercised in full. All Pre-funded Warrants were exercised by February 15, 2023.

- On October 3, 2022, the Company closed a registered direct offering of shares of common stock and Series C Mirroring Preferred Stock pursuant to a Securities Purchase Agreement entered into with a certain institutional investor. In the offering, the Company agreed to issue and sell to the investor (i) 268,000 shares of the Company's common stock, par value $0.01 per share, (ii) 33,810 shares of the Company's Series C Mirroring Preferred Stock, par value $0.01 per share and stated value of $0.01 per share, and (iii) pre-funded warrants to purchase an aggregate of 215,000 shares of common stock. Each share of common stock was sold at a price of $7.00 per share, each share of preferred stock was sold at a price of $0.01 per share, and each pre-funded warrant was sold at an offering price of $6.80 per share underlying such pre-funded warrants, for aggregate gross proceeds of $3.34 million before deducting the placement agent's fees and the offering expenses, and net proceeds of $3.04 million. Under the purchase agreement, the Company also agreed to issue and sell to the investor in a concurrent private placement warrants to purchase an aggregate of 483,000 shares of common stock. In connection with the offering, the Company also entered into a warrant amendment agreement with the investor pursuant to which the Company agreed to amend certain existing warrants to purchase up to 741,489 shares of common stock that were previously issued in 2018 and 2021 to the investor, with exercise prices ranging from $41.00 to $1,300.00 per share as a condition to their purchase of the securities in the offering, as follows: (i) lower the exercise price of the investor's existing warrants to $7.54 per share, (ii) provide that the existing warrants, as amended, will not be exercisable until six months following the closing date of the offering, and (iii) extend the original expiration date of the existing warrants by five and one-half years following the close of the offering. The increase in fair value resulting from the warrant modifications is accounted for as an equity issuance cost, resulting in a debit and credit to additional paid in capital for approximately $1.8 million. As of December 31, 2022, all 215,000 pre-funded warrants were exercised.

- On June 24, 2022, the Company entered into an At-the-Market, or ATM, Offering Agreement (the "2022 ATM 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 Wainwright. As of December 31, 2022, the Company sold 85,732 shares under the 2022 ATM Agreement totaling $1.03 million in gross proceeds and $0.99 million in net proceeds. The Company has not sold any shares under the 2022 ATM Agreement in 2023.

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, restructuring of outstanding indebtedness, licensing and/or partnering arrangements, including non-dilutive funding via various government agencies as well as non-governmental organizations ("NGOs") in the United States and Europe. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or at all. 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 July 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 before or during the third quarter of 2023 or restructure its outstanding indebtedness, the Company will not have sufficient cash flows and liquidity to finance its business operations beyond the third quarter of 2023 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, and its subsidiaries, 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.

The accompanying unaudited condensed consolidated financial statements do not include any adjustments related to the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

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, 2022 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 and for the three months ended March 31, 2023; 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 of the subsidiaries 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 March 31, 2023 and December 31, 2022.

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 equivalents, 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. On March 10, 2023, the Company learned that Silicon Valley Bank ("SVB"), the Company's primary bank at the time, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. The Company did not experience any losses in such accounts, but since the Company was exposed to credit risk with the failure of SVB, management diversified the Company's holdings to minimize credit risk in the future.

At March 31, 2023 and December 31, 2022, the Company had funds totaling $497,055 and $495,629, 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:

	March 31, 2023	December 31, 2022	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 7,039,375	$ 7,440,030	$ 30,653,410	$ 36,080,392
Restricted cash	497,055	495,629	468,041	551,794
Total cash and cash equivalents and restricted cash in the condensed consolidated statements of cash flows	$ 7,536,430	$ 7,935,659	$ 31,121,451	$ 36,632,186

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 March 31, 2023 and December 31, 2022, respectively.

At March 31, 2023, the Company had accounts receivable from two customers which individually represented 42% and 13% of total accounts receivable, respectively. At December 31, 2022, the Company had accounts receivable from two customers which individually represented 41% and 21% of total accounts receivable, respectively. For the three months ended March 31, 2023, revenue earned from two customers represented 46% and 19% of total revenues, respectively. For the three months ended March 31, 2022, revenue earned from three customers represented 27%, 27% and 12% 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:

	March 31, 2023	December 31, 2022
Raw materials and supplies	$ 1,259,859	$ 1,011,476
Work-in-process	33,245	37,445
Finished goods	2,351,453	2,596,830
Total	$ 3,644,557	$ 3,645,751

Inventory includes Unyvero system instruments, Unyvero cartridges, reagents and components for Unyvero and Acuitas kits, and reagents and supplies used for the Company's laboratory services.

The Company periodically 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. Based on the Company's assumptions and estimates, inventory reserves for obsolescence, expirations, and slow-moving inventory were $1,974,030 and $1,694,843 at March 31, 2023 and December 31, 2022, respectively.

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 months ended March 31, 2023 and 2022, 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. The Company did not identify any impaired ROU assets for three months ended March 31, 2023 and 2022.

Intangible assets

As of March 31, 2023, the Company's intangible assets with net balances are all finite-lived.

Finite-lived and indefinite-lived intangible assets

Intangible assets include trademarks, developed technology and software, In-Process Research & Development ("IPR&D"), and customer relationships and consisted of the following as of March 31, 2023 and December 31, 2022:

			March 31, 2023			December 31, 2022		
	Subsidiary	Cost	Accumulated Amortization and Impairment	Effect of Foreign Exchange Rates	Net Balance	Accumulated Amortization and Impairment	Effect of Foreign Exchange Rates	Net Balance
Trademarks and tradenames	Curetis	$ 1,768,000	$ (521,674)	$ (29,101)	$ 1,217,225	$ (469,011)	$ (62,520)	$ 1,236,469
Distributor relationships	Curetis	2,362,000	(464,633)	(38,879)	1,858,488	(417,728)	(83,525)	1,860,747
A50 – Developed technology	Curetis	349,000	(147,126)	(5,744)	196,130	(132,273)	(12,342)	204,385
Ares – Developed technology	Ares Genetics	5,333,000	(1,123,957)	(82,553)	4,126,490	(1,010,495)	(183,132)	4,139,373
A30 – In-Process Research & Development	Curetis	5,706,000	(5,612,078)	(93,922)	—	(5,407,699)	(298,301)	—
		$ 15,518,000	$ (7,869,468)	$ (250,199)	$ 7,398,333	$ (7,437,206)	$ (639,820)	$ 7,440,974

Identifiable intangible assets are 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 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 the 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. During the Company's annual impairment test for its IPR&D intangible asset at December 31, 2022, it was determined that the infinite-lived intangible asset was impaired because although the Company has an ongoing collaboration utilizing the intangible asset, at the time, the contracted cash flow associated with this collaboration and projected future cash flows did not support the carrying amount. As a result, the Company recorded an impairment charge in the amount of $5,407,699 for the year ended December 31, 2022.

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 $186,377 and $192,025 for the three months ended March 31, 2023 and 2022, respectively. Expected future amortization of intangible assets is as follows:

Year Ending December 31,	
2023 (April to December)	$ 564,347
2024	752,463
2025	752,463
2026	752,463
2027	715,644
Thereafter	3,860,953
Total	$ 7,398,333

In accordance with ASC 360-10, *Property, Plant and Equipment*, intangible assets, other than IPR&D as discussed above, 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. During the three months ended March 31, 2023 and 2022, 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 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 year ended December 31, 2022, the Company performed qualitative and quantitative analyses, assessing trends in market capitalization, current and future cash flows, revenue growth rates, and the impact of global unrest and the COVID-19 pandemic on the Company and its performance. Based on the analysis performed, and primarily due to changes in the Company's stock price and market capitalization in the third quarter of 2022, it was determined that goodwill was impaired. As a result, the Company recorded a goodwill impairment charge in the full amount of $6,940,549 for the year ended December 31, 2022.

Revenue recognition

The Company derives revenues from (i) the sale of Unyvero Application cartridges, Unyvero instruments, SARS CoV-2 tests, Acuitas AMR Gene Panel test products, (ii) providing laboratory services, (iii) providing collaboration services (e.g., with the Foundation for Innovative New Diagnostics (FIND) on the Unyvero A30 platform) including funded software and license arrangements, and (iv) granting access to subsets 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.

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 March 31, 2023 and 2022, the Company recognized $133,938 and $108,465 as a reduction of research and development expense related to government grant arrangements, respectively. The Company had earned but not yet received $544,489 and $401,436 related to these agreements and incentives included in prepaid expenses and other current assets, as of March 31, 2023 and December 31, 2022, respectively.

Research and development costs, net

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.

Stock-based compensation

Stock-based compensation expense is recognized at grant date 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. For restricted stock awards with a time-based vesting condition, the fair value, which is fixed at the grant date for purposes of recognizing compensation costs, is determined by reference to the Company's stock price on the grant date. 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.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the instruments' specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity ("ASC 480"), and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the instruments are free standing financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the instruments meet all of the requirements for equity classification under ASC 815, including whether the instruments are indexed to the Company's own ordinary shares and whether the instrument holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent period end date while the instruments are outstanding.

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 $232,682,072 and $202,015,062 at December 31, 2022 and 2021, respectively. Despite the NOL carryforwards, which began expiring 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 $170,661,923 at December 31, 2022 from their foreign subsidiaries. $162,712,615 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) unvested 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 6.7 million shares and 1.0 million shares as of March 31, 2023 and 2022, respectively.

Adopted accounting pronouncements

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2021-04"). ASU 2021-04 clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options, including warrants, that remain equity-classified after modification or exchange. ASU 2021-04 requires an entity to treat a modification or an exchange of a freestanding equity-classified written call option that remains equity-classified after the modification or exchange as an exchange of the original instrument for a new instrument and provides guidance on measuring and recognizing the effect of a modification or an exchange. The Company adopted ASU 2021-04 on January 1, 2022. The adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

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 and laboratory services to hospitals, clinical laboratories and other healthcare providing customers, and enters into collaboration agreements with government agencies, non-governmental organizations, and healthcare providers. The revenues by type of service consist of the following:

	Three Months Ended March 31,	
	2023	2022
Product sales	$ 410,897	$ 366,052
Laboratory services	21,673	42,929
Collaboration revenue	480,874	60,764
Total revenue	$ 913,444	$ 469,745

Revenues by geography are as follows:

	Three Months Ended March 31,	
	2023	2022
Domestic	$ 114,949	$ 156,410
International	798,495	313,335
Total revenue	$ 913,444	$ 469,745

Deferred revenue

Changes in deferred revenue for the period were as follows:

Balance at December 31, 2022	$ 142,061
Contracts with customers	45,577
Recognized in the current period	(143,506)
Currency translation adjustment	1,871
Balance at March 31, 2023	$ 46,003

Contract assets

The Company had no contract assets as of March 31, 2023 and December 31, 2022, 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 March 31, 2023 and December 31, 2022.

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 months ended March 31, 2023, 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 2016, Curetis entered into a contract for an up to €25.0 million senior, unsecured loan financing facility from the European Investment Bank ("EIB") (see Note 6). 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% participation percentage interest ("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. 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 three months ended March 31, 2023 was as follows:

Description	Balance at December 31, 2022	Change in Fair Value	Effect of Foreign Exchange Rates	Balance at March 31, 2023
Participation percentage interest liability	$ 99,498	$ (12,694)	$ 1,831	$ 88,635
Total	$ 99,498	$ (12,694)	$ 1,831	$ 88,635

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 March 31, 2023, the Company did not record any such impairment expenses. During the year ended December 31, 2022, the Company recorded impairment expense of $6,940,549 related to its goodwill (see Note 3) and $5,407,699 related to its indefinite-lived intangible asset (see Note 3).

Note 6 – Debt

The following table summarizes the Company's long-term debt and short-term borrowings as of March 31, 2023 and December 31, 2022:

	March 31, 2023	December 31, 2022
EIB	$ 11,631,738	$ 13,489,178
Total debt obligations	11,631,738	13,489,178
Unamortized debt discount	(1,313,888)	(1,614,591)
Carrying value of debt	10,317,850	11,874,587
Less current portion	(4,959,417)	(7,023,901)
Non-current portion of long-term debt	$ 5,358,433	$ 4,850,686

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 funding could be drawn in up to five tranches within 36 months of entry into the contract, 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 had 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 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 the 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 EIB 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 will be 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 €13.4 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. Accordingly, the Company agreed to pay a monthly amount of approximately €0.7 million through April 2023. 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 and will become due and payable by the Company to the EIB in June 2023 and June 2024, respectively. 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 March 31, 2023, the outstanding borrowings under all tranches were €10.7 million (approximately USD $11.6 million), including deferred interest payable at maturity of €2.0 million (approximately USD $2.2 million).

Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $617,298 and $1,269,581 for the three months ended March 31, 2023 and 2022, respectively.

Note 7 – Stockholders' equity

As of March 31, 2023, the Company had 100,000,000 shares of authorized common stock and 5,495,546 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 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. Following receipt of approval from stockholders at a special meeting of stockholders held on November 30, 2022, 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, which reverse stock split was effective January 5, 2023. 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 an At-the-Market Offering (the "2022 ATM 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 Wainwright. As of December 31, 2022, the Company sold 85,732 shares under the 2022 ATM Offering totaling $1.03 million in gross proceeds and $0.99 million in net proceeds. The Company has not sold any shares under the 2022 ATM Agreement in 2023.

On October 3, 2022, the Company closed a registered direct offering of shares of common stock and Series C Mirroring Preferred Stock pursuant to a securities purchase agreement entered into with a certain institutional investor. In the offering, the Company agreed to issue and sell to the investor (i) 268,000 shares of the Company's common stock, par value $0.01 per share, (ii) 33,810 shares of the Company's Series C Mirroring Preferred Stock, par value $0.01 per share and stated value of $0.01 per share, and (iii) pre-funded warrants to purchase an aggregate of 215,000 shares of common stock. Each share of common stock was sold at a price of $7.00 per share, each share of preferred stock was sold at a price of $0.01 per share, and each pre-funded warrant was sold at an offering price of $6.80 per share underlying such pre-funded warrants, for aggregate gross proceeds of $3.34 million before deducting the placement agent's fees and the offering expenses, and net proceeds of $3.04 million. Under the purchase agreement, the Company also agreed to issue and sell to the investor in a concurrent private placement warrants to purchase an aggregate of 483,000 shares of common stock. In connection with the offering, the Company also entered into a warrant amendment agreement with the investor pursuant to which the Company agreed to amend certain existing warrants to purchase up to 741,489 shares of common stock that were previously issued in 2018 and 2021 to the investor, with exercise prices ranging from $41.00 to $1,300.00 per share as a condition to their purchase of the securities in the offering, as follows: (i) lower the exercise price of the investor's existing warrants to $7.54 per share, (ii) provide that the existing warrants, as amended, will not be exercisable until six months following the closing date of the offering, and (iii) extend the original expiration date of the existing warrants by five and one-half years following the closing of the offering. The increase in fair value resulting from the warrant modifications is accounted for as an equity issuance cost, resulting in a debit and credit to additional paid in capital for approximately $1.8 million. As of December 31, 2022, all 215,000 pre-funded warrants issued in the offering were exercised.

On January 11, 2023, the Company closed a best-efforts public offering pursuant to a securities purchase agreement entered into with a certain institutional investor for the purchase of (i) 321,207 shares of the Company's common stock, par value $0.01 per share, (ii) pre-funded warrants to purchase up to an aggregate of 2,265,000 shares of common stock, (iii) Series A-1 common warrants to purchase an aggregate of 2,586,207 shares of common stock, and (iv) Series A-2 common warrants to purchase an aggregate of 2,586,207 shares of common stock. Each share of common stock and accompanying Series A-1 Warrant and Series A-2 Warrant (collectively, the "Common Warrants") was sold at a price of $2.90 per share and accompanying Common Warrants, and each Pre-funded Warrant and accompanying Series A-1 Warrant and Series A-2 Warrant was sold at an offering price of $2.89 per share underlying such Pre-funded Warrants and accompanying Common Warrants, for aggregate gross proceeds of approximately $7.5 million before deducting the placement agent's fees and the offering expenses, and net proceeds of approximately $6.9 million. The Common Warrants have an exercise price of $2.65 per share. The Series A-1 Warrants were immediately exercisable upon issuance, and will expire five years following the issuance date. The Series A-2 Warrants were immediately exercisable upon issuance, and will expire eighteen months following the issuance date. Subject to certain ownership limitations described in the Pre-funded Warrants, the Pre-funded Warrants were immediately exercisable and could be exercised at a nominal consideration of $0.01 per share of common stock any time until all the Pre-funded Warrants are exercised in full. All Pre-funded Warrants were exercised by February 15, 2023.

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, 115,996 shares were automatically added to the 2015 Plan in 2023. 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 March 31, 2023, 89,146 shares remain available for issuance under the 2015 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.

For the three months ended March 31, 2023 and 2022, the Company recognized share-based compensation expense as follows:

	Three months ended March 31,	
	2023	2022
Cost of services	$ —	$ 2,835
Research and development	70,364	66,998
General and administrative	105,832	140,882
Sales and marketing	34,926	30,904
	$ 211,122	$ 241,619

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 did not grant any options during the three months ended March 31, 2023. During the three months ended March 31, 2023, there were no option forfeitures or expirations.

The Company had total stock options to acquire 107,597 shares of common stock outstanding at March 31, 2023 under all of its equity compensation plans.

Restricted stock units

The Company granted 93,000 restricted stock units during the three months ended March 31, 2023, 11,627 restricted stock units vested and none were forfeited. The Company had 124,280 total restricted stock units outstanding at March 31, 2023.

Stock purchase warrants

At March 31, 2023 and December 31, 2022, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at March, 31, 2023 (1)	Outstanding at December 31, 2022 (1)
February 2015	$ 66,000.00	February 2025	23	23
February 2018	$ 1,625.00	February 2023	—	462
February 2018	$ 1,300.00	February 2023	—	3,848
October 2019	$ 40.00	October 2024	17,700	17,700
October 2019	$ 52.00	October 2024	11,750	11,750
November 2020	$ 50.44	May 2026	12,107	12,107
February 2021	$ 78.00	August 2026	20,834	20,834
October 2022	$ 7.54	April 2028	1,224,489	1,224,489
January 2023	$ 2.65	July 2024	2,586,207	—
January 2023	$ 2.65	January 2028	2,586,207	—
			6,459,317	1,291,213

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 splits on August 22, 2019 and January 5, 2023 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 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 5 systems that it commits to purchase in the following quarter. As of March 31, 2023, the Company had acquired twenty-four QuantStudio 5 systems, including none during the three months ended March 31, 2023. As of March 31, 2023, the Company has not committed to acquiring additional QuantStudio 5 systems.

Curetis places frame-work orders for Unyvero instruments 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 instruments 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 $0.1 million.

Note 9 – Leases

The following table presents the Company's ROU assets and lease liabilities as of March 31, 2023 and December 31, 2022:

Lease Classification	March 31, 2023	December 31, 2022
ROU Assets:		
Operating	$ 2,139,974	$ 1,459,413
Financing	2,671	3,500
Total ROU assets	$ 2,142,645	$ 1,462,913
Liabilities		
Current:		
Operating	$ 500,994	$ 377,626
Finance	2,803	3,364
Noncurrent:		
Operating	3,121,433	2,566,138
Finance	—	280
Total lease liabilities	$ 3,625,230	$ 2,947,408

Maturities of lease liabilities as of March 31, 2023 by fiscal year are as follows:

Maturity of Lease Liabilities	Operating	Finance	Total
2023 (April to December)	$ 611,511	$ 2,523	$ 614,034
2024	827,783	280	828,063
2025	735,009	—	735,009
2026	582,753	—	582,753
2027	593,156	—	593,156
Thereafter	1,737,689	—	1,737,689
Total lease payments	5,087,901	2,803	5,090,704
Less: Interest	(1,465,474)	—	(1,465,474)
Present value of lease liabilities	$ 3,622,427	$ 2,803	$ 3,625,230

Condensed consolidated statements of operations classification of lease costs as of the three months ended March 31, 2023 and 2022 are as follows:

Lease Cost	Classification	Three months ended March 31, 2023	2022
Operating	Operating expenses	$ 137,797	$ 174,914
Finance:			
Amortization	Operating expenses	829	39,711
Interest expense	Other expenses	—	905
Total lease costs		$ 138,626	$ 215,530

Other lease information as of March 31, 2023 is as follows:

Other Information	Total
Weighted average remaining lease term (in years)	
Operating leases	6.7
Finance leases	0.8
Weighted average discount rate:	
Operating leases	9.6%
Finance leases	1.0%

Supplemental cash flow information as of the three months ended March 31, 2023 and 2022 is as follows:

Supplemental Cash Flow Information	2023	2022
Cash paid for amounts included in the measurement of lease liabilities		
Cash used in operating activities		
Operating leases	$ 137,797	$ 174,914
Finance leases	$ —	$ 905
Cash used in financing activities		
Finance leases	$ 841	$ 17,529
ROU assets obtained in exchange for lease obligations:		
Operating leases	$ 801,321	$ —

Note 10 – License agreements, research collaborations and development agreements

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’s anti-infective portfolio.

Under the terms of the framework agreement, which had an initial term of 36 months and 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 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 AREStools 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, AREStools. 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.

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 $1,943 and $2,779 the three months ended March 31, 2023 and 2022, respectively.

Foundation for Innovative New Diagnostics (FIND)

On September 20, 2022, Curetis GmbH and FIND entered into a research and development collaboration agreement for a total amount due to Curetis of €0.7 million to develop a simple to use molecular diagnostic test for identification of pathogens and antibiotic resistances in positive blood cultures for deployment in low- and middle-income countries ("LMICs"). If successful, after demonstrating feasibility and completing the initial research and development project phase, both parties have agreed to discuss the option of a potential future collaboration and commercialization agreement. During the three months ended March 31, 2023, the Company recognized €0.4 million related to the collaboration, bringing the total amount recognized through March 31, 2023 to €0.7 million.

Note 11 - Subsequent Events

The Company evaluates subsequent events and transactions that occur after the balance sheet date up to the date that the unaudited condensed consolidated financial statements are issued.

Other than as disclosed in this Note 11 and as may be disclosed elsewhere in the notes to the accompanying unaudited condensed consolidated financial statements, there have been no subsequent events that require adjustment or disclosure in the accompanying unaudited condensed consolidated financial statements.

On April 5, 2023, the Company reported that it signed an amendment to its research and development collaboration agreement with FIND, to expand the collaboration which was originally started in fall of 2022. The amendment is for an additional €130 thousand, increasing the total project volume to €830 thousand in revenue potential.

On May 1, 2023, the Company entered into, and on May 4, 2023, the Company closed the transactions contemplated by a securities purchase agreement with a certain institutional investor, pursuant to which the Company agreed to issue and sell to the Investor in a best-efforts public offering (i) 605,000 shares of the Company's common stock, par value $0.01 per share, (ii) pre-funded warrants to purchase up to an aggregate of 3,890,825 shares of common stock, and (iii) common warrants to purchase up to an aggregate of 4,495,825 shares of common stock. Each share of common stock and accompanying common warrant was sold at a price of $0.7785 per share and accompanying common warrant, and each pre-funded warrant and accompanying common warrant was sold at an offering price of $0.7685 per share underlying such pre-funded warrant and accompanying common warrant, for aggregate gross proceeds of approximately $3.5 million and net proceeds of approximately $3.0 million. The common warrants have an exercise price of $0.7785 per share and will be exercisable beginning on the date of stockholder approval of the exercisability of the warrants under Nasdaq rules. The common warrants will expire on the five-year anniversary of the date of such stockholder approval. Each pre-funded warrant has an exercise price per share of common stock equal to $0.01 per share and may be exercised at any time until the pre-funded warrants are exercised in full. In connection with the offering, the Company also entered into a warrant amendment agreement with the investor pursuant to which the Company agreed to amend certain existing warrants to purchase up to 6,396,903 shares of common stock that were previously issued in 2018, 2021, 2022 and 2023 to the investor, with exercise prices ranging from $2.65 to $7.54 per share, in consideration for their purchase of the securities in the offering, as follows: (i) lower the exercise price of the existing warrants to $0.7785 per share, (ii) provide that the existing warrants, as amended, will not be exercisable until the receipt of stockholder approval for the exercisability of the common warrants in the offering, and (iii) extend the original expiration date of the existing warrants by five years following the receipt of such stockholder approval. The increase in fair value resulting from the warrant modifications is accounted for as an equity issuance cost, resulting in a debit and credit to additional paid in capital of approximately $0.3 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, 2022.

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 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. The Company'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 AMR surveillance, outbreak analysis, and antibiotic response prediction including ARESiss, ARESid, ARESasp, and AREScloud, as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit.

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. The Company has 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. The Company believes 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 U.S. Centers for Disease Control and Prevention, or CDC.

- Following registration of the Unyvero instrument system as an in vitro diagnostics (IVD) platform for " Following registration of the Unyvero instrument system as an in vitro diagnostics (IVD) platform for the Chinese market in early 2021, the Company is supporting its strategic partner Beijing Clear Biotech (BCB) in pursuing execution of a supplemental clinical trial with the Unyvero Hospitalized Pneumonia (HPN) test. As requested by the Chinese regulatory authority National Medical Products Administration (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 the continued impact of strict COVID-19 restrictions in China during 2022, the initiation of this supplementary study has been delayed, and the timing for its initiation remains uncertain. In the third quarter of 2022, regulatory advisors to BCB informed OpGen that the NMPA implemented a mandatory new electronic filing regime that requires the Company to re-submit its clinical trial plan under the new regime. The regulatory advisors estimated a total duration for the review and approval process to be between 24 to 30 months from submission, and during that time, the clinical study is believed to take approximately 10 to 12 months.

- 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. The Company had initiated a prospective multi-center clinical trial for the Unyvero UTI in the United States in the third quarter of 2021 and completed enrollment of more than 1,800 patient samples by the end of the third quarter of 2022. Following the announcement of preliminary top line data in December 2022, the Company concluded reference testing in early 2023 and submitted a De Novo classification request to the U.S. Food and Drug Administration (FDA) seeking marketing authorization for its Unyvero UTI panel in April 2023. The FDA confirmed that the submission is complete, and they have initiated their substantive review. If cleared, the Unyvero UTI would become the first rapid sample-to-answer test for urinary tract infections available as an FDA-cleared IVD test in the United States.

- The Unyvero Invasive Joint Infection, or IJI, test, which is a variant of the ITI cartridge being developed for the U.S. market, has also been selected for analytical and clinical performance evaluation on the Unyvero A30 platform including clinical trials towards a future submission to the FDA. Such clinical trial is not expected to start before the second half of 2023 and will be subject to availability of funding. 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. The Company believes that Unyvero IJI could be useful in identifying pathogens as well as their antimicrobial resistance, or AMR, markers to help guide optimal antibiotic treatment for these patients.

- In September 2021, the Company received clearance from the FDA for its Acuitas AMR Gene Panel for bacterial isolates. The Acuitas AMR Gene Panel detects 28 genetic AMR markers in isolated bacterial colonies from 26 different pathogens in under 3 hours. The Company believes the panel provides clinicians with a valuable diagnostic tool that informs about potential AMR patterns early and supports appropriate antibiotic treatment decisions in this indication. During 2022, the Company signed two commercial customer contracts and installed the first two systems for the Acuitas AMR Gene Panel for isolates. The Company expects to enter into additional commercial contracts that are currently in its funnel of contract proposals during 2023.

- In September 2022, the Company entered into a research and development, or R&D, collaboration agreement with the Foundation for Innovative New Diagnostics (FIND), the global alliance for diagnostics, to assist in funding the development of the Unyvero A30 *RQ* platform for use in low- and middle-income countries (LMICs). The initial project focused on a feasibility study for the rapid detection of AMR markers from blood culture. The feasibility phase of this initial R&D project concluded in the first quarter of 2023 and was funded by FIND for €0.7 million (approximately $0.7 million). On April 5, 2023, the Company reported that it signed an amendment to its research and development collaboration agreement with FIND, to expand the collaboration for an additional €130 thousand, increasing the total project volume to €830 thousand in revenue potential.

- In October 2022, the Company announced that its subsidiary Curetis and BioVersys AG, a Swiss biotech company developing novel antibiotics against drug resistant infections, entered into a collaboration agreement. Under that collaboration agreement, BioVersys will be using the Unyvero systems and HPN tests at all its sites for its upcoming BV100 phase II clinical trial which is targeted to treat Carbapenem-resistant *Acinetobacter baumannii*.

- The Company is also developing novel bioinformatics tools and solutions to accompany or augment its 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 its portfolio of IVD products or even as a standalone bioinformatics product.

- The Company commenced offering validated high-quality sequencing and analysis services with rapid turnaround times for key applications in microbiology from our Ares Genetics laboratories in Vienna, Austria and Rockville, MD. The unique and differentiated offering for rapid and comprehensive genetic characterization of bacterial isolates and interpretive services include whole genome sequencing, taxonomic identification and typing, detection of plasmids, and other mobile elements, AMR, and virulence markers. Furthermore, the RUO services provide detection of local outbreak clusters via isolate relatedness analysis and the prediction of genomic antibiotic susceptibility based on the Company's ARESdb database. Customers with in-house sequencing capabilities can access the aforementioned data interpretative capabilities via the Company's commercial AREScloud web application. These technologies are particularly applicable to programs of Infection Prevention and Control (IPC), antibiotic stewardship and surveillance, all of which are part of the U.S. national strategy to protect against rising antimicrobial resistance.

OpGen has extensive offerings of additional IVD tests including CE-IVD-marked Unyvero tests for intra-abdominal and blood stream infections. The Company's portfolio included a CE-IVD-marked polymerase chain reaction, or PCR, based rapid test kit for SARS-CoV-2 detection in combination with its PCR compatible universal lysis buffer (PULB) in 2022, but the Company has ceased all commercial operations on the SARS-CoV-2 test kit in 2023.

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 130,000 bacterial isolates that have been sequenced using Next Generation Sequencing, or NGS, technology and tested for susceptibility with applicable antibiotics from a range of over 100 antimicrobial drugs. In late 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. Clinical Laboratory Improvement Amendments, or CLIA, certified laboratory, a contract research organization, or CRO, a major University Medical Center, the Belgian national reference laboratory at the University Hospital Leuven as well as several U.S. state public health labs have been initiated and are ongoing and the collaboration master service agreement with Sandoz has 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 Artificial Intelligence, or 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 academic, public health, healthcare and biotechnology institutions from the United States and various European countries.

Our Unyvero A50 system 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 to 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 verification and validation testing of the A30 *RQ* instruments and, in addition to the new collaboration with FIND, is actively engaged in ongoing partnering discussions and due diligence.

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 of the Unyvero A50 product line to currently 12 countries and Beijing Clear Biotech Co. Ltd. for Unyvero A50 product distribution in China. The Company has a network of other distributors covering countries in Europe, the Middle East and Africa, Asia Pacific, Latin America, and the United States.

OpGen will continue to develop and seek FDA and other regulatory clearances or approvals, as applicable, for its Unyvero UTI and IJI products as well as for its Unyvero A30 *RQ* platform. 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 RUO products to hospitals, public health departments, clinical laboratories, pharmaceutical companies and CROs in the United States. Curetis continues its efforts in ensuring compliance with the new In-Vitro-Diagnostic Device Regulation (IVDR) in the European Union (EU), which officially went into effect in May 2022. Given the limited number of designated EU Notified Bodies at this time, and with the EU commission IVDR amendment in early 2022 providing for multi-year grace periods for certain IVD products with former In-Vitro-Diagnostic Device Directive (IVDD) CE marking, it is now possible for Curetis to continue commercializing 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.

The Company's headquarters are in Rockville, Maryland, and its principal operations are in Rockville, Maryland, and Holzgerlingen and Bodelshausen, both in Germany. The Company also has operations in Vienna, Austria. The Company operates in one business segment.

Financial Overview

Revenue

We recognize three types of revenues: product sales, laboratory services and collaboration revenue. We generate product revenues from sales of our products, including through our distribution partners, such as our Unyvero systems and our Acuitas AMR Gene Panel test. We also generate revenue from sales by OpGen's subsidiary Ares Genetics of its AI-powered prediction models and solutions. Revenues generated from our laboratory services relate to services that we and our subsidiaries provide to customers. Lastly, our collaboration revenues consist of revenue received from research and development collaborations that we have entered into with third parties, such as our collaboration agreement with FIND.

Cost of Products, Cost of Services, and Operating Expenses

Our cost of products consist of product and inventory costs, including materials costs and overhead, and other costs related to the recognition of revenue. Cost of services relate to the material and labor costs associated with providing our services. Research and development expenses currently consist primarily of expenses incurred in connection with our clinical and pre-clinical research activities, such as our prior clinical trials for our initiated clinical trial for the Unyvero UTI in the United States. Selling, general and administrative expenses consist of public company costs and salaries and related costs for administrative and sales and business development personnel.

Results of operations for the three months ended March 31, 2023 and 2022

Revenues

	Three months ended March 31,	
	2023	2022
Product sales	$ 410,897	$ 366,052
Laboratory services	21,673	42,929
Collaboration revenue	480,874	60,764
Total revenue	$ 913,444	$ 469,745

Total revenue for the three months ended March 31, 2023 increased approximately 94% when compared to the same period in 2022. This increase is primarily attributable to:

- Product Sales: the increase in revenue of approximately 12% in the 2023 period compared to the 2022 period is primarily attributable to additional cartridge and master mix sales in 2023;
- Laboratory Services: the decrease in revenue of approximately 50% in the 2023 period compared to the 2022 period is primarily attributable to a decrease in COVID testing services performed by Curetis GmbH; and
- Collaboration Revenue: the increase in revenue of approximately 691% in the 2023 period compared to the 2022 period is primarily the result of the Company's collaboration agreement with FIND.

Operating expenses

	Three months ended March 31,	
	2023	2022
Cost of products sold	$ 592,378	$ 291,997
Cost of services	128,306	30,562
Research and development	1,812,831	2,316,441
General and administrative	2,423,953	2,625,053
Sales and marketing	1,026,087	1,051,432
Total operating expenses	$ 5,983,555	$ 6,315,485

Our total operating expenses for the three months ended March 31, 2023 decreased approximately 5% when compared to the same period in 2022. Operating expenses changed as follows:

- Cost of products sold: cost of products sold for the three months ended March 31, 2023 increased approximately 103% when compared to the same period in 2022. The increase in cost of products sold aligns with the increase in product revenue generated in the first quarter of 2023 when compared to the same period in 2022, and it also increased due to increases in inventory reserves for obsolescence, expirations, and slow-moving inventory;
- Cost of services: cost of services for the three months ended March 31, 2023 increased approximately 320% when compared to the same period in 2022. The increase in cost of services aligns with the significant increase in collaboration revenue generated in the first quarter of 2023 primarily from the Company's collaboration with FIND;
- Research and development: research and development expenses for the three months ended March 31, 2023 decreased approximately 22% when compared to the same period in 2022. The decrease in research and development is primarily attributable to a reduction in payroll related costs as well as the conclusion of the prospective multi-center clinical trial for the Unyvero UTI in the third quarter of 2022;

- General and administrative: general and administrative expenses for the three months ended March 31, 2023 decreased approximately 8% when compared to the same period in 2022, primarily attributable to a reduction in payroll related costs; and
- Sales and marketing: sales and marketing expenses for the three months ended March 31, 2023 decreased approximately 2% when compared to the same period in 2022, primarily attributable to a reduction in payroll related costs.

Other (expense) income

	Three months ended March 31,	
	2023	2022
Interest expense	$ (617,298)	$ (1,269,581)
Foreign currency transaction (losses) gains	(91,994)	198,740
Interest and other income, net	30,106	3,121
Change in fair value of derivative financial instruments	12,694	109,744
Total other expense	$ (666,492)	$ (957,976)

Our total other expense for the three months ended March 31, 2023 decreased when compared to the same period in 2022 primarily due to reduced interest expense on the EIB debt as the outstanding balance decreases over time due to ongoing payments.

Liquidity and capital resources

As of March 31, 2023, we had cash and cash equivalents of $7.0 million compared to $7.4 million at December 31, 2022. We have funded our operations primarily through external investor financing arrangements and have raised funds in 2023 and 2022, including:

- On June 24, 2022, we entered into the 2022 ATM Agreement with H.C. 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 December 31, 2022, the Company sold 85,732 shares under the 2022 ATM Offering totaling $1.03 million in gross proceeds and $0.99 million in net proceeds. The Company has not sold any shares under the 2022 ATM Agreement in 2023.

- On October 3, 2022, we closed a registered direct offering for the purchase of 268,000 shares of the Company’s common stock, 33,810 shares of the Company’s Series C Mirroring Preferred Stock, and pre-funded warrants to purchase an aggregate of 215,000 shares of common stock. The offering raised aggregate gross proceeds of $3.34 million before deducting the placement agent’s fees and the offering expenses, and net proceeds of $3.04 million.

- On January 11, 2023, we closed a best-efforts public offering for the purchase of (i) 321,207 shares of common stock, (ii) pre-funded warrants to purchase up to an aggregate of 2,265,000 shares of Common Stock, (iii) Series A-1 common warrants to purchase an aggregate of 2,586,207 shares of Common Stock, and (iv) Series A-2 common warrants to purchase an aggregate of 2,586,207 shares of common stock. The offering raised aggregate gross proceeds of approximately $7.5 million before deducting the placement agent’s fees and the offering expenses, and net proceeds of approximately $6.9 million.

- In addition, subsequent to March 31, 2023, on May 1, 2023, the Company entered into, and on May 4, 2023, the Company closed the transactions contemplated by a securities purchase agreement with a certain institutional investor, pursuant to which the Company agreed to issue and sell to the investor in a best-efforts public offering (i) 605,000 shares of the Company’s common stock, par value $0.01 per share, (ii) pre-funded warrants to purchase up to an aggregate of 3,890,825 shares of common stock, and (iii) common warrants to purchase up to an aggregate of 4,495,825 shares of common stock. The offering raised aggregate gross proceeds of approximately $3.5 million and net proceeds of approximately $3.0 million.

To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions, restructuring of outstanding indebtedness, 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 third 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 before or during the end of the third quarter of 2023 or restructure our outstanding indebtedness, 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.

On March 10, 2023, the Company learned that Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver, due to the sudden and massive financial collapse of the bank. On March 12, 2023, the Secretary of the Treasury, the chair of the Federal Reserve Board and the chairman of the FDIC released a joint statement related to the FDIC's resolution of the SVB receivership (the "Statement"). The Statement provided that "[d]epositors will have access to all of their money starting Monday, March 13." At the time, the Company had most of its cash and cash equivalents held in deposit accounts at SVB, which the Statement said the Company would have access to starting on March 13, 2023. While we regained access to our accounts at Silicon Valley Bank and created additional banking relationships to diversify our holdings, future disruptions of financial institutions where we bank or have credit arrangements, or disruptions of the financial services industry in general, could adversely affect our ability to access our cash and cash equivalents. If we are unable to access our cash and cash equivalents as needed, our financial position and ability to operate our business will be adversely affected.

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:

	Three months ended March 31,	
	2023	2022
Net cash used in operating activities	$ (4,962,618)	$ (5,041,400)
Net cash used in investing activities	(330,446)	(38,713)
Net cash provided by (used in) financing activities	4,743,649	(17,529)

Net cash used in operating activities
Net cash used in operating activities for the three months ended March 31, 2023 consists primarily of our net loss of $5.7 million, reduced by certain noncash items, including depreciation and amortization expense of $0.4 million, noncash interest expense of $0.5 million, change in inventory reserve of $0.3 million, and share-based compensation expense of $0.2 million. Net cash used in operating activities for the three months ended March 31, 2022 consists primarily of our net loss of $6.8 million, reduced by certain noncash items, including depreciation and amortization expense of $0.5 million, noncash interest expense of $1.1 million, and share-based compensation expense of $0.2 million.

Net cash used in investing activities
Net cash used in investing activities for the three months ended March 31, 2023 and 2022 consisted of the purchases of property and equipment.

Net cash provided by (used in) financing activities
Net cash provided by financing activities for the three months ended March 31, 2023 consisted of proceeds from the issuance of common stock and warrants, net of issuance costs, in connection with the best-efforts public offering closed in January 2023, net of payments on the Company's debt with the EIB. Net cash used in financing activities for the three months ended March 31, 2022 consisted of payments on finance leases.

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"). Following the consummation of our business combination with Curetis in April 2020, the Company guaranteed Curetis' obligations under the loan financing facility. 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 tranche had and second tranche has a floating interest rate of EURIBOR plus 4% payable after each 12-month-period from the draw-down-date and an 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 March 31, 2023, the outstanding borrowings under all tranches were €10.7 million (approximately USD $11.6 million), including deferred interest payable at maturity of €2.0 million (approximately USD $2.2 million). 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 €13.4 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 a twelve-month period beginning in May 2022. As a result, the Company paid eleven monthly installments totaling approximately €7.7 million through March 2023, and the Company paid the last monthly installment of €0.7 million in April 2023. 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. Accordingly, unless the indebtedness is further restructured, approximately €4.0 million and €6.7 million for the second and third tranches will become due and payable by the Company in June 2023 and June 2024, respectively.

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, 2022.

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 March 31, 2023 and December 31, 2022, we did not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, the Company is 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 March 31, 2023. 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 March 31, 2023, 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

Reference is made to the Risk Factors included in our Annual Report on Form 10-K for the year ended December 31, 2022.

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
3.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of OpGen, Inc., filed with the Secretary of the State of Delaware on January 4, 2023.
4.1	Form of Pre-funded Warrant (incorporated by reference to Exhibit 4.20 to the Company's Registration Statement on Form S-1/A (File No. 333-268648) filed on January 5, 2023).
4.2	Form of Series A-1 and Series A-2 Warrants (incorporated by reference to Exhibit 4.21 to the Company's Registration Statement on Form S-1/A (File No. 333-268648) filed on January 5, 2023).
10.1	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.55 to the Company's Registration Statement on Form S-1/A (File No. 333-268648) filed on January 5, 2023).
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: May 15, 2023

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: May 15, 2023

/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: May 15, 2023

/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 March 31, 2023 (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: May 15, 2023

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

Date: May 15, 2023

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.