

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

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2024

or

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

For the transition period from _____ to _____

Commission File Number 001-37367

OPGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

06-1614015

(I.R.S. employer
identification no.)

23219 Stringtown Road, Suite 300, Clarksburg, MD

(Address of principal executive offices)

20871

(Zip code)

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

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

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

10,068,111 shares of the Company's common stock, par value \$0.01 per share, were outstanding as of November 14, 2024.

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 regain and maintain compliance with the ongoing listing requirements for the Nasdaq Capital Market;
- our ability to execute upon and achieve the benefits of the strategic direction under the Company’s new leadership and Board;
- our ability to identify and realize the benefits of potential strategic transactions;
- 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;
- our use of proceeds from capital financing transactions;
- compliance with the U.S. 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[®]. 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)

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	\$ 1,633,166	\$ 1,151,823
Accounts receivable, net	24,401	103,316
Prepaid expenses and other current assets	1,559,786	324,735
Total current assets	3,217,353	1,579,874
Property and equipment, net	1,117,245	-
Finance lease right-of-use assets, net	-	138
Operating lease right-of-use assets	832,966	-
Other noncurrent assets	302,262	302,262
Total assets	\$ 5,469,826	\$ 1,882,274
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 103,868	\$ 111,149
Accrued compensation and benefits	49,146	127,601
Accrued liabilities	89,173	135,476
Deferred revenue	-	25,926
EIB loan guaranty	-	10,873,867
Short-term insurance financing	180,555	-
Short-term finance lease liabilities	-	280
Short-term operating lease liabilities	167,021	147,943
Total current liabilities	589,763	11,422,242
Long-term operating lease liabilities, net of short-term amount	1,893,794	2,021,616
Total liabilities	2,483,557	13,443,858
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit)		
Series D convertible preferred stock, \$0.01 par value; 1,000 shares authorized; 250 shares issued and outstanding at September 30, 2024 and December 31, 2023	2	2,500
Common stock, \$0.01 par value; 100,000,000 shares authorized; 10,068,111 and 1,282,686 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	100,681	12,827
Additional paid-in capital	300,736,192	293,991,529
Accumulated deficit	(297,850,606)	(305,493,302)
Accumulated other comprehensive loss	-	(75,138)
Total stockholders' equity (deficit)	2,986,269	(11,561,584)
Total liabilities and stockholders' equity	\$ 5,469,826	\$ 1,882,274

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Revenue				
Product sales	\$ -	\$ 558,965	\$ 169,373	\$ 1,409,534
Laboratory services	-	47,135	26,776	112,810
Collaboration revenue	-	92,922	-	826,257
Total revenue	-	699,022	196,149	2,348,601
Operating expenses				
Cost of products sold	-	618,796	31,636	1,925,566
Cost of services	-	73,174	1,575	405,582
Research and development, net	488	1,201,865	49,308	4,403,488
General and administrative	768,551	2,034,628	4,021,321	6,883,588
Sales and marketing	14,846	336,184	168,819	2,522,471
Total operating expenses	783,885	4,264,647	4,272,659	16,140,695
Operating loss	(783,885)	(3,565,625)	(4,076,510)	(13,792,094)
Other income (expense)				
Interest and other income	92,131	24,977	242,799	86,301
Interest expense	(3,238)	(396,768)	(4,317)	(1,698,564)
Gain on impairment adjustment	-	-	2,079,575	-
Gain on extinguishment of debt	9,738,487	-	9,738,487	-
Gain on settlement of compensation expenses	570,785	-	570,785	-
Foreign currency transaction (losses) gains	(2)	(135,930)	463	(288,326)
Change in fair value of derivative financial instruments	-	10,389	-	65,800
Change in fair value of EIB loan guaranty	(683,200)	-	(908,586)	-
Total other income (expense)	9,714,963	(497,332)	11,719,206	(1,834,789)
Income (loss) before income taxes	8,931,078	(4,062,957)	7,642,696	(15,626,883)
Provision for income taxes	-	-	-	-
Net income (loss)	\$ 8,931,078	\$ (4,062,957)	\$ 7,642,696	\$ (15,626,883)
Net income (loss) allocated to preferred stockholders – basic	(690,467)	-	(519,161)	-
Net income (loss) available to common stockholders – basic	\$ 8,240,611	\$ (4,062,957)	\$ 7,123,535	\$ (15,626,883)
Net income (loss)	\$ 8,931,078	\$ (4,062,957)	\$ 7,642,696	\$ (15,626,883)
Net income (loss) allocated to preferred stockholders – diluted	-	-	-	-
Net income (loss) available to common stockholders – diluted	\$ 8,931,078	\$ (4,062,957)	\$ 7,642,696	\$ (15,626,883)
Earnings (loss) per share attributable to common stockholders				
Basic	\$ 1.43	\$ (4.63)	\$ 2.51	\$ (23.80)
Diluted	\$ 1.35	\$ (4.63)	\$ 2.14	\$ (23.80)
Weighted average shares outstanding				
Basic	5,760,214	877,815	2,837,744	656,585
Diluted	6,603,804	877,815	3,571,505	656,585
Net income (loss)	\$ 8,931,078	\$ (4,062,957)	\$ 7,642,696	\$ (15,626,883)
Other comprehensive income – foreign currency translation	-	78,815	-	118,178
Comprehensive income (loss)	\$ 8,931,078	\$ (3,984,142)	\$ 7,642,696	\$ (15,508,705)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Common Stock		Preferred Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount				
Balances at December 31, 2022	289,992	\$ 2,900	-	\$ -	\$ 281,193,260	\$ (795,840)	\$ (272,824,772)	\$ 7,575,548
Issuance of RSUs	1,163	12	-	-	(12)	-	-	-
Stock compensation expense	-	-	-	-	211,122	-	-	211,122
Offering of common stock and warrants, net of issuance costs	258,621	2,586	-	-	6,971,464	-	-	6,974,050
Share cancellation	(220)	(2)	-	-	2	-	-	-
Foreign currency translation	-	-	-	-	-	153,067	-	153,067
Net loss	-	-	-	-	-	-	(5,736,603)	(5,736,603)
Balances at March 31, 2023	549,556	5,496	-	-	288,375,836	(642,773)	(278,561,375)	9,177,184
Issuance of RSUs	2,216	22	-	-	(22)	-	-	-
Stock compensation expense	-	-	-	-	156,529	-	-	156,529
Cash bonus taken in the form of stock compensation	-	-	-	-	283,554	-	-	283,554
Offering of common stock and warrants, net of issuance costs	145,000	1,450	-	-	3,182,200	-	-	3,183,650
Foreign currency translation	-	-	-	-	-	(113,704)	-	(113,704)
Net loss	-	-	-	-	-	-	(5,827,323)	(5,827,323)
Balances at June 30, 2023	696,772	6,968	-	-	291,998,097	(756,477)	(284,388,698)	6,859,890
Stock compensation expense	-	-	-	-	(229,483)	-	-	(229,483)
Offering of common stock and warrants, net of issuance costs	304,583	3,046	-	-	27,412	-	-	30,458
Foreign currency translation	-	-	-	-	-	78,815	-	78,815
Net loss	-	-	-	-	-	-	(4,062,957)	(4,062,957)
Balances at September 30, 2023	1,001,355	\$ 10,014	-	\$ -	\$ 291,796,026	\$ (677,662)	\$ (288,451,655)	\$ 2,676,723
Balances at December 31, 2023	1,282,686	\$ 12,827	250	\$ 2,500	\$ 293,991,529	\$ (75,138)	\$ (305,493,302)	\$ (11,561,584)
Issuance of RSUs	21,053	210	-	-	(210)	-	-	-
Stock compensation expense	-	-	-	-	188,237	-	-	188,237
Offering of preferred stock	-	-	200,000	2,000	198,000	-	-	200,000
Reclassification of preferred stock par value to additional paid-in capital (out of period adjustment; see Note 3)	-	-	-	(2,498)	2,498	-	-	-
Elimination of translation adjustments of previously dissolved subsidiaries (out of period adjustment; see Note 3)	-	-	-	-	-	75,138	-	75,138
Net income (As Restated)	-	-	-	-	-	-	287,967	287,967
Balances at March 31, 2024 (As Restated)	1,303,739	13,037	200,250	2,002	294,380,054	-	(305,205,335)	(10,810,242)
Issuance of RSUs	40,000	400	-	-	(400)	-	-	-
Stock compensation expense	-	-	-	-	368,391	-	-	368,391
Share issuance related to May 2024 Reverse Stock Split	5,238	53	-	-	(53)	-	-	-
Share cancellation related to May 2024 Reverse Stock Split	(3)	-	-	-	-	-	-	-
Offering of preferred stock	-	-	350,000	3,500	346,500	-	-	350,000
Net loss	-	-	-	-	-	-	(1,576,349)	(1,576,349)
Balances at June 30, 2024	1,348,974	13,490	550,250	5,502	295,094,492	-	(306,781,684)	(11,668,200)
Stock compensation expense	-	-	-	-	1,530	-	-	1,530
Cash compensation taken in the form of stock compensation	440,028	4,400	-	-	1,328,885	-	-	1,333,285
Offering of preferred stock	-	-	2,450,000	24,500	2,375,717	-	-	2,400,217
Conversion of preferred stock into common stock	7,200,000	72,000	(3,000,000)	(30,000)	(42,000)	-	-	-
Issuance of common stock pursuant to equity line of credit	1,079,109	10,791	-	-	1,977,568	-	-	1,988,359
Net income	-	-	-	-	-	-	8,931,078	8,931,078
Balances at September 30, 2024	10,068,111	\$ 100,681	250	\$ 2	\$ 300,736,192	\$ -	\$ (297,850,606)	\$ 2,986,269

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine months ended September 30,	
	2024	2023
Cash flows from operating activities		
Net income (loss)	\$ 7,642,696	\$ (15,626,883)
Adjustments to reconcile net income (loss) to net cash used in operating activities		
Depreciation and amortization	129,502	1,070,581
Noncash interest expense	-	1,261,495
Stock compensation expense	558,158	138,168
Change in inventory reserve	(54,830)	535,755
Cash bonus taken in the form of stock compensation	-	283,554
Gain on impairment adjustment	(2,079,575)	-
Gain on settlement of compensation expenses	(570,785)	-
Loss on deconsolidation of subsidiaries	75,138	-
Change in fair value of derivative liabilities	-	(65,800)
Change in fair value of EIB loan guaranty	(10,873,867)	-
Changes in operating assets and liabilities		
Accounts receivable	78,915	91,522
Inventory	54,830	290,366
Other assets	98,233	86,516
Accounts payable	(7,281)	399,197
Accrued compensation and other liabilities	337,284	(1,161,958)
Deferred revenue	(25,926)	54,388
Net cash used in operating activities	(4,637,508)	(12,643,099)
Cash flows from investing activities		
Purchases of property and equipment	-	(799,498)
Net cash used in investing activities	-	(799,498)
Cash flows from financing activities		
Proceeds from issuance of common stock and pre-funded warrants, net of issuance costs	-	10,188,158
Proceeds from issuance of preferred stock, net of issuance costs	2,950,217	-
Proceeds from issuance of common stock, net of issuance costs	1,988,359	-
Proceeds from short-term insurance financing	300,926	-
Payments on short-term insurance financing	(120,371)	-
Payments on debt	-	(3,910,010)
Payments on finance lease obligations	(280)	(2,523)
Net cash provided by financing activities	5,118,851	6,275,625
Effects of exchange rates on cash	-	15,977
Net increase (decrease) in cash and cash equivalents and restricted cash	481,343	(7,150,995)
Cash and cash equivalents and restricted cash at beginning of period	1,454,085	7,935,659
Cash and cash equivalents and restricted cash at end of period	\$ 1,935,428	\$ 784,664
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 4,317	\$ 1,422,343
Supplemental disclosures of noncash investing and financing activities		
Right-of-use assets acquired through operating leases	\$ -	\$ 801,321
Purchased equipment not yet paid for	\$ -	\$ 94,784
Settlement of deferred compensation and severance	\$ 1,333,285	\$ -
Issuance of common stock upon conversion of preferred stock	\$ 2,950,217	\$ -

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc. and Subsidiaries
Notes to Unaudited Condensed Consolidated Financial Statements
September 30, 2024

Note 1 – Organization

OpGen, Inc. (“OpGen” or the “Company”) was incorporated in Delaware in 2001. In April 2020, OpGen completed a business combination transaction with Curetis N.V., a public company with limited liability under the laws of the Netherlands, pursuant to which the Company 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 Curetis N.V., including Ares Genetics GmbH (“Ares Genetics”), a wholly owned subsidiary of Curetis GmbH (together, “Curetis”).

From inception until November 2023, OpGen operated as a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. The Company, along with its subsidiaries, Curetis and Ares Genetics, developed and commercialized 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. In November 2023, Curetis filed a petition for insolvency with the district court of Stuttgart, Germany, and Ares Genetics filed a petition for insolvency with the commercial court in Vienna, Austria. The insolvency proceedings of Curetis and Ares Genetics were adjudicated under the insolvency laws of Germany and Austria, respectively.

The insolvency administrators assumed control over the assets and liabilities of Curetis and Ares Genetics, respectively, which eliminated the authority and power of the Company and its officers to act on behalf of the subsidiaries. The loss of control required that the Company no longer include Curetis and Ares Genetics in its consolidated financial statements. Prior to the insolvency filings, Curetis and Ares Genetics had been included in the Company’s consolidated financial statements. As part of the insolvency proceedings, in April 2024, the insolvency administrator for Curetis notified the Company that all of Curetis’ assets were sold to Camtech Pte Ltd., a Singaporean family office (“Camtech”). In April 2024, the insolvency administrator for Ares Genetics notified the Company that all of Ares Genetics’ assets were sold to bioMerieux S.A.

In March 2024, the Company entered into a securities purchase agreement (the “March 2024 Purchase Agreement”) with David E. Lazar, pursuant to which the Company agreed to sell 3,000,000 shares of Series E Convertible Preferred Stock (“Series E Preferred Stock”) to Mr. Lazar at a price of \$1.00 per share for aggregate gross proceeds of \$3.0 million. In connection with the transactions contemplated by the March 2024 Purchase Agreement, the members of the Board of Directors, prior to the closing of such transactions, resigned and a new Board of Directors was appointed, of which Mr. Lazar was appointed Chairman. Furthermore, in April 2024, the Company entered into an employment agreement with David E. Lazar, pursuant to which the Company engaged Mr. Lazar to act as its Chief Executive Officer (“CEO”).

In April 2024, the Company entered into a lease assignment agreement where the Company assigned the lease of its Rockville, Maryland headquarters to a third party. The Company’s security deposit remains with the landlord and will be repaid over time as agreed upon with the third party assignee. The Company has a continuing liability under the lease; however, within the lease assignment agreement, the new tenant indemnifies the Company from and against any liabilities resulting from obligations arising on or after the lease assignment date.

In May 2024, the Company announced that it intended to effect a reverse stock split (the “Reverse Stock Split”) of its issued and outstanding shares of common stock, par value \$0.01 per share (the “Common Stock”), at a ratio of 1 post-reverse-split share for every 10 pre-reverse-split shares (the “Reverse Split Ratio”). The Common Stock continued to be traded on The Nasdaq Capital Market under the symbol “OPGN” and began trading on a split-adjusted basis when the markets opened on Monday, May 20, 2024, under a new CUSIP number, 68373L505. The Reverse Stock Split impacted all holders of OpGen’s common stock proportionally and did not impact any stockholders’ percentage ownership of common stock (except to the extent the Reverse Stock Split resulted in any stockholder owning a fractional share). No fractional shares were issued in connection with the Reverse Stock Split. Stockholders of record who were otherwise entitled to receive a fractional share received a whole share in lieu of the fractional share. All share amounts and per share prices in this Quarterly Report have been adjusted to reflect the Reverse Stock Split.

In July 2024, Mr. Lazar consummated a transaction pursuant to which he sold 550,000 shares of Series E Preferred Stock together with his rights to purchase the additional 2,450,000 shares of Series E Preferred Stock under the March 2024 Purchase Agreement to AEI Capital Ltd. Subsequently, AEI Capital Ltd. paid the Company \$2.45 million in August 2024 in exchange for the remaining 2,450,000 shares of Series E Preferred Stock under the terms of the March 2024 Purchase Agreement. All 3,000,000 shares of Series E Preferred Stock were converted into 7,200,000 shares of the Company’s common stock in August 2024. As of September 30, 2024, no shares of Series E Preferred Stock remain outstanding. Upon conversion, such shares of Series E Preferred Stock resumed the status of authorized but unissued shares of undesignated preferred stock of the Company.

Under the ownership of AEI Capital Ltd., the Company plans to continue scaling down legacy operations and selling the remaining Unyvero assets in inventory with the intention of exiting the Unyvero business. Going forward, the Company is planning to reposition itself and will launch a new business in the financial technology industry supporting digital investment banking activities. The Company also contemplates engaging in the provision of listing consultancy services to international companies seeking to list their securities on securities exchanges.

The Company’s headquarters and principal operations were located at 9717 Key West Avenue, Suite 100, in Rockville, Maryland, through the end of the first quarter of 2024. Upon assignment of the Company’s lease, the Company operates virtually. The Company operates in one business segment.

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. Historically, the Company has funded its operations primarily through external investor financing arrangements and significant actions taken by the Company, but going forward, the Company anticipates funding its operations primarily through financing arrangements with AEI Capital Ltd. Through the Company’s financing efforts, which include, among others, securities purchase agreements, warrant inducement agreements, and public offerings, the Company has received gross proceeds of approximately \$13.3 million and \$5.0 million in 2023 and 2024, respectively.

Although the Company only has cash and cash equivalents of \$1.6 million as of September 30, 2024, in August 2024, the Company and AEI Capital Ltd. entered into a Securities Purchase Agreement (the “August 2024 Securities Purchase Agreement”), pursuant to which the Company has the right, in its discretion, to sell to AEI Capital Ltd. shares of common stock having an aggregate value of up to \$3.0 million. The purchase price for any shares sold under the August 2024 Securities Purchase Agreement is the closing sales price on the Nasdaq Capital Market of the Company’s common stock as of the date immediately prior to the date of sale. In addition, in October 2024, the Company and AEI Capital Ltd. entered into a First Amendment (the “Amendment”) to the August 2024 Securities Purchase Agreement. The Amendment amended the August 2024 Securities Purchase Agreement by: (1) granting the Company the right to sell two additional tranches of common stock to AEI Capital Ltd. of \$3.0 million each, for an aggregate amount of \$9.0 million under the Purchase Agreement; and (2) extending the Company’s ability to sell shares of common stock to AEI Capital Ltd. under the Purchase Agreement until December 31, 2025. As of September 30, 2024, the Company sold 1,079,109 shares of common stock to AEI Capital Ltd. for gross proceeds of \$2.0 million before deducting offering expenses. Accordingly, the Company has the right, in its discretion, to sell to AEI Capital Ltd., at any time prior to December 31, 2025, shares of common stock, par value \$0.01 per share (the “Shares”), of the Company having an aggregate value of up to an additional \$7.0 million. As a result, the Company believes that its current cash and its access to additional cash under the August 2024 Securities Purchase Agreement will allow the Company to fund operations in excess of 12 months from the issuance date of these financial statements.

On June 5, 2024, the Company received a letter from the listing staff of The Nasdaq Stock Market LLC (“Nasdaq”) that the Company was no longer in compliance with the minimum stockholders’ equity requirement for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(b)(1) (the “Stockholders’ Equity Rule”). The Stockholders’ Equity Rule requires companies listed on the Nasdaq Capital Market to maintain stockholders’ equity of at least \$2,500,000 or to meet alternatives of market value of listed securities or net income from continuing operations, which the Company does not currently meet. In response to the letter, the Company submitted its plan to regain compliance with the Stockholders’ Equity Rule to the Nasdaq Hearings Panel (the “Panel”) and requested additional time to regain compliance with such rule. On August 16, 2024, following the Panel’s review of the Company’s plan to regain compliance, the Company received a letter (the “Notice”) indicating that the Panel had determined to deny the Company’s request for continued listing on Nasdaq. Pursuant to the Notice, based on the preliminary nature of the Company’s plan, the Panel determined that the Company did not provide a definitive plan evidencing its ability to achieve near- and long-term compliance with the Stockholders’ Equity Requirement. The Notice also provided that the Company’s securities will be suspended from trading on the Nasdaq Capital Market at the opening of business on August 20, 2024. The Company submitted its appeal regarding the Panel’s determination on September 13, 2024 and requested that the Nasdaq Listing and Hearing Review Council review the decision of the Panel. Such appeal stayed the delisting of the Company’s securities with Nasdaq and the filing of the Form 25 pending the Nasdaq Listing and Hearing Review Council’s decision until the resolution of such review. There can be no assurance that the Nasdaq Listing and Hearing Review Council will grant the Company’s request for continued listing on Nasdaq.

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, 2023 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 as of and for the three and nine months ended September 30, 2024. All intercompany transactions and balances have been eliminated.

Foreign currency

In prior years, the Company had foreign operating subsidiaries, 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 were translated into U.S. dollars based on exchange rates at the end of the reporting period. Income and expense items were translated at the average exchange rates prevailing during the reporting period. Translation adjustments were reported in accumulated other comprehensive income (loss), a component of stockholders' equity. Foreign currency translation adjustments were the sole component of accumulated other comprehensive income (loss) at December 31, 2023.

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 income (loss). Unless otherwise noted, all references to "\$" or "dollar" refer to the United States dollar.

Immaterial Out of Period Adjustments

During the three months ended March 31, 2024, the Company identified an immaterial error related to the calculation of preferred stock par value and additional paid-in capital for the Company's Series D convertible preferred stock that impacted the Company's previously issued 2023 consolidated financial statements. Management evaluated the effect of the error on the 2023 and current period consolidated financial statements and concluded the error was not material. As a result, in the three months ended March 31, 2024, the Company recorded an out of period adjustment to decrease preferred stock par value and increase additional paid-in capital, each by approximately \$2.5 thousand.

During the three months ended March 31, 2024, the Company identified an immaterial error related to the inclusion of balances of accumulated other comprehensive loss representing historic translation adjustments of previously dissolved subsidiaries that impacted the Company's previously issued 2023 and 2022 consolidated financial statements. Management evaluated the effect of the error on the 2023, 2022, and current period consolidated financial statements and concluded the error was not material. As a result, in the three months ended March 31, 2024, the Company recorded an out of period adjustment to increase the loss on deconsolidation of subsidiaries and decrease accumulated other comprehensive loss, each by approximately \$75.1 thousand.

Restatement of Prior Period Financial Statements

Subsequent to the filing of the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024, the Company identified an error relating to the accounting treatment of an indemnification asset in the Company's previously issued unaudited condensed consolidated financial statements included in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 (the "Affected Period"). As a result, the Company filed an amended Form 10-Q for the quarterly period ended March 31, 2024 to correct the error in the Affected Period by adjusting the following information for the three months ended March 31, 2024: (i) removing the previously recorded indemnification asset and gain on lease indemnification; and (ii) changing the accounting estimates related to the Company's operating lease right-of-use asset and leasehold improvement property and equipment and recording a gain on impairment adjustment associated with the Rockville, Maryland office due to the identification of a subtenant in the three months ended March 31, 2024. In total, the restatement and associated change in accounting estimates resulted in an incremental loss of approximately \$0.1 million.

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, stock-based compensation, allowances for doubtful accounts and inventory obsolescence, property and equipment, lease right-of-use assets, discount rates used to discount unpaid lease payments to present values, valuation of derivative financial instruments measured at fair value on a recurring basis, and deferred tax assets and liabilities and related valuation allowance. 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, and deferred revenue) are carried at cost, which approximates fair value, because of the short-term maturities of those instruments.

Cash and cash equivalents and restricted cash

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. The Company has cash and cash equivalents deposited in financial institutions in which the balances occasionally exceed the Federal Deposit Insurance Corporation (“FDIC”) insured limit of \$250,000. The Company also holds a portion of its cash and cash equivalents in accounts with foreign financial institutions that are not federally insured. While the Company has not experienced any losses related to its cash concentrations, the Company may be subject to risks relating to its cash held in U.S. financial institutions in excess of the FDIC limit or in financial institutions that are not FDIC-insured.

At September 30, 2024 and December 31, 2023, the Company had funds totaling \$302,262 that are required as collateral for letters of credit benefiting its landlords and technology vendors. 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:

	September 30, 2024	December 31, 2023
Cash and cash equivalents	\$ 1,633,166	\$ 1,151,823
Restricted cash	302,262	302,262
Total cash and cash equivalents and restricted cash in the condensed consolidated statements of cash flows	<u>\$ 1,935,428</u>	<u>\$ 1,454,085</u>

Accounts receivable

The Company’s accounts receivable result from amounts invoiced 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 September 30, 2024 and December 31, 2023.

At September 30, 2024, the Company had accounts receivable from one customer that individually represented 92% of total accounts receivable. At December 31, 2023, the Company had accounts receivable from three customers which individually represented 39%, 26%, and 10% of total accounts receivable. The Company did not generate revenue during the three months ended September 30, 2024. For the three months ended September 30, 2023, revenue earned from four customers represented 21%, 15%, 12%, and 11% of total revenues. For the nine months ended September 30, 2024, revenue earned from two customers represented 48% and 14% of total revenues. For the nine months ended September 30, 2023, revenue earned from three customers represented 28%, 17%, and 10% of total revenues.

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:

	September 30, 2024	December 31, 2023
Finished goods	\$ 1,225,975	\$ 1,280,805
Total, gross	1,225,975	1,280,805
Less inventory reserve	(1,225,975)	(1,280,805)
Total, net of inventory reserve	\$ -	\$ -

Inventory is entirely made up of Unyvero system instruments and components.

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 \$1,225,975 and \$1,280,805 at September 30, 2024 and December 31, 2023, respectively. Due to the insolvency proceedings and deconsolidation of the Company's subsidiaries for the year ended December 31, 2023, the Company reserved for the full value of its inventory at September 30, 2024 and December 31, 2023 given the uncertainty surrounding the net realizable value and future demand for the Company's products.

Long-lived assets

Property and equipment

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the three and nine months ended September 30, 2024 and 2023, the Company determined that its property and equipment was 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 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 are measured by a comparison of the carrying amount of the 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 the assets exceeds the fair value of the assets. The Company did not identify any impaired ROU assets for the nine months ended September 30, 2024 and 2023.

Intangible assets

Intangible assets consist of finite-lived and indefinite-lived intangible assets.

Intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If any indicators were present, the Company would test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (i.e., the asset is not recoverable), the Company would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any. All the Company’s finite-lived intangible assets with net balances were held by Curetis and Ares Genetics. As a result of the insolvency filings for Curetis and Ares Genetics and the associated deconsolidation of all balance sheet balances related to these entities in 2023, the Company does not have any finite-lived or indefinite-lived intangible asset balances as of September 30, 2024.

Total amortization expense of intangible assets was \$0 and \$187,255 for the three months ended September 30, 2024 and 2023, respectively. Due to the removal of the intangible assets of Curetis and Ares Genetics in 2023 and the Company’s absence of intangible assets as of September 30, 2024, the Company does not currently anticipate any future amortization of intangible assets.

Revenue recognition

During the nine months ended September 30, 2024 and 2023, the Company derived revenues from (i) the sale of Unyvero Application cartridges, Unyvero Systems, Acuitas AMR Gene Panel systems and test products, and SARS CoV-2 tests, (ii) providing laboratory services, and (iii) providing collaboration services including funded software arrangements, license arrangements, and its NGO collaboration with the Foundation for Innovative New Diagnostics (FIND) on our Unyvero A30 platform.

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 recognized 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 and nine months ended September 30, 2023, the Company recognized \$78,752 and \$301,229, respectively, as a reduction of research and development expense related to government grant arrangements. As of September 30, 2024, the Company does not have any active grants.

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 fair value. The fair value of stock-based compensation to employees and directors is estimated, on the date of grant, using the Black-Scholes model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the award. 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 \$241,110,447 and \$232,682,072 at December 31, 2023 and 2022, respectively. Despite the NOL carryforwards, which started 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.

Net income (loss) per share

In periods of net loss, 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. The Company's Series D and Series E convertible preferred stock contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; in periods of net income, the calculation of basic earnings per share excludes from the numerator net income attributable to the preferred stock and excludes the impact of those shares from the denominator.

In periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all potential dilutive common shares is anti-dilutive. In periods of net income, diluted earnings per share is computed using the more dilutive of the "two class method" or the "treasury method." Dilutive earnings per share under the "two class method" is calculated by dividing net income available to common stockholders as adjusted for the participating impacts of the preferred stock, by the weighted-average number of shares outstanding plus the dilutive impact of all other potential dilutive common shares, consisting primarily of common shares underlying common stock options and stock purchase warrants using the treasury stock method. Dilutive earnings per share under the "treasury stock method" are calculated by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the dilutive impact of all potential dilutive common shares, consisting primarily of common shares underlying common stock options and stock purchase warrants using the treasury stock method, and preferred stock using the if-converted method.

The Company has calculated basic and diluted earnings (loss) per share for the three months ended September 30, 2024 and 2023 as follows:

	Basic		Diluted	
	Three months ended September 30, 2024	Three months ended September 30, 2023	Three months ended September 30, 2024	Three months ended September 30, 2023
Net income (loss)	\$ 8,931,078	\$ (4,062,957)	\$ 8,931,078	\$ (4,062,957)
Net income allocated to preferred stockholders	(690,467)	-	-	-
Net income (loss) available to common stockholders	<u>\$ 8,240,611</u>	<u>\$ (4,062,957)</u>	<u>\$ 8,931,078</u>	<u>\$ (4,062,957)</u>
Basic weighted average shares outstanding	5,760,214	877,815	5,760,214	877,815
Dilutive effect of preferred stock			843,590	-
Dilutive weighted average shares outstanding			<u>6,603,804</u>	<u>877,815</u>
Earnings (loss) per share	<u>\$ 1.43</u>	<u>\$ (4.63)</u>	<u>\$ 1.35</u>	<u>\$ (4.63)</u>

The Company has calculated basic and diluted earnings (loss) per share for the nine months ended September 30, 2024 and 2023 as follows:

	Basic		Diluted	
	Nine months ended		Nine months ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Net income (loss)	\$ 7,642,696	\$ (15,626,883)	\$ 7,642,696	\$ (15,626,883)
Net income allocated to preferred stockholders	(519,161)	-	-	-
Net income (loss) available to common stockholders	<u>\$ 7,123,535</u>	<u>\$ (15,626,883)</u>	<u>\$ 7,642,696</u>	<u>\$ (15,626,883)</u>
Basic weighted average shares outstanding	2,837,744	656,585	2,837,744	656,585
Dilutive effect of preferred stock			733,761	-
Dilutive weighted average shares outstanding			<u>3,571,505</u>	<u>656,585</u>
Earnings (loss) per share	<u>\$ 2.51</u>	<u>\$ (23.80)</u>	<u>\$ 2.14</u>	<u>\$ (23.80)</u>

The number of anti-dilutive shares for the three and nine months ended September 30, 2024 and 2023, consisting of shares of common stock underlying (i) common stock options, (ii) restricted stock units, (iii) preferred stock, and (iv) stock purchase warrants, which have been excluded from the computation of diluted income per share was 1.2 million and 1.1 million for the three and nine months ended September 30, 2024 and 2023, respectively.

Recently issued accounting standards

The Company has evaluated all 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 provided diagnostic test products and laboratory services to hospitals, clinical laboratories and other healthcare providing customers, and entered 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		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Product sales	\$ -	\$ 558,965	\$ 169,373	\$ 1,409,534
Laboratory services	-	47,135	26,776	112,810
Collaboration revenue	-	92,922	-	826,257
Total revenue	<u>\$ -</u>	<u>\$ 699,022</u>	<u>\$ 196,149</u>	<u>\$ 2,348,601</u>

Revenues by geography are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Domestic	\$ -	\$ 142,716	\$ 196,149	\$ 523,978
International	-	556,306	-	1,824,623
Total revenue	\$ -	\$ 699,022	\$ 196,149	\$ 2,348,601

Deferred revenue

Changes to deferred revenue for the periods were as follows:

Balance at December 31, 2022	\$ 142,061
Contracts with customers	74,109
Recognized in the current period	(144,196)
Currency translation adjustment	(46,048)
Balance at December 31, 2023	25,926
Recognized in the current period	(21,096)
Refunded to customers in the current period	(4,830)
Balance at September 30, 2024	\$ -

Note 5 – Fair value measurements

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

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

For the three and nine months ended September 30, 2024, 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 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 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. In May 2022, the Company entered into a Waiver and Amendment Letter which increased the PPI to 0.75% upon maturity. This right constituted 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.

Following Curetis’ insolvency filing, in November 2023, Curetis received a termination notice from the EIB terminating the Standstill Agreement, pursuant to which the EIB had agreed that the EIB would not take any action or exercise any right with respect to an event of default under the Finance Contract, effective as of November 20, 2023. In December 2023, the Company received a notice from the EIB stating that Curetis was in default of the Finance Contract as a result of, among other things, Curetis’ failure to repay when due certain outstanding indebtedness under the Finance Contract. Pursuant to that certain Guarantee and Indemnity Agreement, dated July 9, 2020, between the EIB and the Company, the EIB demanded that the Company, as guarantor, immediately repay the EIB all amounts owed to the EIB under the Finance Contract and reserved all its other rights and remedies in connection with the Finance Contract. The Company determined the fair value of the PPI using the Monte Carlo simulation model as of August 19, 2024, the date in which the Company paid and settled its outstanding indebtedness with the EIB. Upon settlement of such indebtedness, the Company recorded a gain on extinguishment of debt of approximately \$9.7 million, which represents the excess of the fair value of the outstanding principal, accumulated and deferred interest, and the PPI over the settlement amount.

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 and nine months ended September 30, 2024, the Company did not record any such impairment expenses.

Note 6 – Debt

The following table summarizes the Company’s EIB loan guaranty as of September 30, 2024 and December 31, 2023, which loan was paid off and settled in August 2024:

	September 30, 2024	December 31, 2023
EIB	\$ -	\$ 10,873,867
Total obligations	-	10,873,867
Unamortized discount	-	-
Carrying value of EIB loan guaranty	-	10,873,867
Less EIB loan guaranty (current portion)	-	(10,873,867)
Long-term EIB loan guaranty	\$ -	\$ -

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, and each tranche was 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 was deferred and payable at maturity together with the principal. In June 2018, a second tranche of €3.0 million was drawn down. The terms and conditions were 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 was also deferred until repayment upon maturity. In return for the EIB waiving the condition precedent of minimum cumulative equity capital raised of €15.0 million to disburse this €5.0 million third tranche, the parties agreed on a 2.1% PPI. Upon maturity of the tranche, the EIB would be entitled to an additional payment that was 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 constituted an embedded derivative, which was 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 €14.4 million (approximately \$15.8 million) as of the acquisition date. The resulting debt discount was to be amortized over the life of the EIB debt as an increase to interest expense.

In May 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 2022 EIB Amendment also provided for an increase of the PPI applicable to the third tranche under the loan facility from 0.3% to 0.75%. 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, remained unchanged pursuant to the 2022 EIB Amendment. The second tranche became due and payable by the Company to the EIB in June 2023, and the third tranche would have become due and payable in June 2024. As the effective borrowing rate under the amended agreement was 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 was 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 exceeded the carrying value of the debt immediately prior to the amendment.

In June 2023, the Company announced that its subsidiary Curetis and the European Investment Bank (“EIB”) agreed in principle to certain terms relating to the repayment of the second tranche of Curetis’ loan from the EIB pursuant to that certain Finance Contract, dated December 12, 2016, as amended, by and between Curetis and the EIB (the “Finance Contract”). The second tranche had a principal balance of €3 million plus accumulated and deferred interest. The second tranche was drawn down in June 2018 and matured in June 2023. In July 2023, the EIB and Curetis entered into a Standstill Agreement pursuant to which the EIB agreed that, with respect to each default or event of default relating to such second tranche, the EIB would not take any action or exercise any right under the Finance Contract until the earlier of a restructuring of the second tranche and November 30, 2023. As a condition to entering into the Standstill Agreement, Curetis paid the EIB a partial payment of interest on the second tranche of €1 million in June 2023. In addition, Curetis agreed to certain undertakings during the standstill period, including the delivery of a rolling cash flow forecast and to cause a third-party restructuring expert to prepare and deliver a restructuring opinion to the EIB. EIB could terminate the Standstill Agreement upon notice to Curetis if, among other customary termination rights, Curetis or the guarantors failed to comply with any undertakings in the Standstill Agreement, the third party expert determined that there were no prospects for a successful restructuring of the second tranche and that it therefore will be unable to issue a restructuring opinion, or the cash flow forecast showed a negative liquidity shortfall during the specified period.

In November 2023, Curetis received a termination notice from the EIB terminating the Standstill Agreement effective as of November 20, 2023. The EIB’s termination notice stated that the termination of the Standstill Agreement was as a result of and in connection with certain defaults of the Standstill Agreement arising from, among other related reasons, Curetis’ and Ares’ entry into insolvency proceedings. In December 2023, the Company received a notice from the EIB stating that Curetis was in default of the Finance Contract as a result of, among other things, Curetis’ failure to repay when due certain outstanding indebtedness under the Finance Contract. In its notice, the EIB stated that, as of November 16, 2023, the aggregate amount of principal, accrued interest and all other amounts owed by Curetis to the EIB under the Finance Contract was approximately €9.66 million and that interest will continue to accrue in accordance with the Finance Contract until all amounts owed are paid in full. Pursuant to that certain Guarantee and Indemnity Agreement, dated July 9, 2020 (the “Guaranty”), between the EIB and the Company, the EIB demanded that the Company, as guarantor, immediately repay the EIB all amounts owed to the EIB under the Finance Contract and reserved all of its other rights and remedies in connection with the Finance Contract.

In connection with the Company’s entry into the March 2024 Purchase Agreement with David E. Lazar in March 2024, the Company entered into settlement agreements with each of the EIB and Curetis and Curetis’ trustee in insolvency, pursuant to which the Company agreed to pay a total of \$2.0 million to settle all outstanding debt and liabilities of the Company to EIB and Curetis. The settlement agreement with EIB also provided for the termination of that certain Guarantee and Indemnity Agreement, dated as of July 9, 2020, by and between the EIB and the Company, pursuant to which the Company had guaranteed all of Curetis’ debt to EIB. On August 19, 2024, the Company paid and settled its outstanding indebtedness with the EIB and Curetis, which terminated the Guarantee and Indemnity Agreement. Accordingly, upon termination of such Guarantee and Indemnity Agreement, the Company recorded a gain on extinguishment of debt in excess of \$9.7 million.

Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was \$3,238 and \$396,768 for the three months ended September 30, 2024 and 2023, respectively. Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was \$4,317 and \$1,698,564 for the nine months ended September 30, 2024 and 2023, respectively. Upon deconsolidation of the Company’s subsidiaries in 2023, the Company reclassified the EIB liability from a loan to a loan guaranty which is recorded based on its fair value with changes being recognized as part of net income at each reporting date.

In May 2024, the Company entered into an agreement to finance a portion of the premium for its Directors and Officers Insurance. The agreement provides for financing of \$300,926 of the premium, repayments in 10 equal monthly installments of \$31,172 each through March 2025 and accrued interest at 7.75%.

Note 7 – Stockholders' equity

As of September 30, 2024, the Company had 100,000,000 shares of authorized common stock and 10,068,111 shares issued and outstanding, and 10,000,000 shares of authorized preferred stock, of which 6,999,000 shares remain undesignated and unissued.

Following receipt of approval from stockholders at a special meeting of stockholders held in November 2022, 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 shares, and the 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 split.

Following receipt of approval from stockholders at a special meeting of stockholders held in May 2024, 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 ten shares, and the reverse stock split was effective May 20, 2024. All share amounts and per share prices in this Quarterly Report have been adjusted to reflect the reverse stock split.

In January 2023, the Company closed a best-efforts public offering pursuant to a securities purchase agreement with a certain institutional investor for the purchase of (i) 32,121 shares of the Company's common stock, par value \$0.01 per share, (ii) pre-funded warrants to purchase up to an aggregate of 226,500 shares of common stock, (iii) Series A-1 common warrants to purchase an aggregate of 258,621 shares of common stock, and (iv) Series A-2 common warrants to purchase an aggregate of 258,621 shares of common stock. Each share of common stock and accompanying Series A-1 and Series A-2 common warrant were sold at a price of \$29.00 per share and accompanying Series A-1 and Series A-2 common warrant, and each pre-funded warrant and accompanying Series A-1 and Series A-2 common warrant were sold at an offering price of \$28.90 per share underlying such pre-funded warrant and accompanying Series A-1 and Series A-2 common warrant, 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 Series A-1 and Series A-2 common warrants have an exercise price of \$26.50 per share. The Series A-1 common warrants were immediately exercisable upon issuance and will expire five years following the issuance date. The Series A-2 common 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 \$0.10 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 2023. In connection with the Company's best-efforts public offering consummated in May 2023, the Company amended the exercise price of the Series A-1 and Series A-2 common warrants to \$7.785 per share.

In May 2023, the Company closed a best-efforts public offering pursuant to a securities purchase agreement with a certain institutional investor, pursuant to which the Company issued and sold to the investor (i) 60,500 shares of the Company's common stock, par value \$0.01 per share, (ii) pre-funded warrants to purchase up to an aggregate of 389,083 shares of common stock, and (iii) common warrants to purchase up to an aggregate of 449,583 shares of common stock. Each share of common stock and accompanying common warrant was sold at a price of \$7.785 per share and accompanying common warrant, and each pre-funded warrant and accompanying common warrant was sold at an offering price of \$7.685 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 \$7.785 per share and will be exercisable beginning on the date of stockholder approval of the exercisability of the warrants under Nasdaq rules or may be exercised through October 26, 2023, pursuant to the Warrant Inducement Agreement entered into on October 12, 2023. Pursuant to amendment agreements entered into by the Company and holder on October 26, 2023 and February 7, 2024, the Company agreed to initially extend the offer period until December 31, 2023, and subsequently extend the offer period until April 30, 2024. In order to permit the exercise of the Existing Warrants pursuant to the rules of the Nasdaq Capital Market, the holder agreed to pay as additional consideration \$0.25 per share of common stock issued upon exercise of the Existing Warrants. The common warrants not exercised as part of the Inducement Agreement 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 \$0.10 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 amended certain existing warrants to purchase up to 639,691 shares of common stock that were previously issued in 2018, 2021, 2022 and 2023 to the investor, with exercise prices ranging from \$26.50 to \$75.40 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 \$7.785 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. In October 2023, the holder exercised 200,000 shares of Common Stock under the existing warrants pursuant to the Inducement Agreement for aggregate gross proceeds to the Company of \$2.057 million before deducting financial advisory fees and other expenses payable by the Company. The holder did not exercise any additional Existing Warrants prior to the termination of the April 30, 2024 extended offer period. Except for the extension of the offer period pursuant to the amendment agreements, the terms and conditions of the Inducement Agreement remained unchanged.

In October 2023, the Company entered into a Preferred Stock Purchase Agreement (the “October 2023 Purchase Agreement”) with a single investor, pursuant to which the Company agreed to issue and sell to the investor in a private placement (the “Private Placement”) 1,000 shares of the Company’s Series D Preferred Stock, par value \$0.01 per share (the “Preferred Stock”). Each share of preferred stock was agreed to sell at a price of \$1,000 per share for expected aggregate gross proceeds of \$1.0 million before deducting offering expenses. The Private Placement was conducted in connection with the negotiation of a potential strategic transaction involving the Company and the investor. The Company intended to use the proceeds from the Private Placement to fund the Company’s operations while it pursued a potential strategic transaction with the investor. Pursuant to the October 2023 Purchase Agreement, the Company filed a certificate of designation (the “Series D Certificate of Designation”) with the Secretary of State of the State of Delaware designating the rights, preferences and limitations of the shares of preferred stock in October 2023. The Series D Certificate of Designation provides that the shares of preferred stock have a stated value of \$1,000 per share and are convertible into shares of common stock, par value \$0.01 per share of the Company at a price of \$4.09 per share, subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications, or similar events affecting the common stock. The preferred stock may be converted at any time at the option of the holder. Notwithstanding the foregoing, the Series D Certificate of Designation provides that in no event will the preferred stock be convertible into common stock in a manner that would result in the holder, its permitted transferees and affiliates holding more than 19.99% (together with any shares of common stock otherwise held by the investor, its permitted transferees and their affiliates) of the then issued and outstanding common stock (the “Ownership Limitation”), prior to the date that the Company’s stockholders approve the issuance of shares of common stock to the holder upon conversion of the preferred stock (the “stockholder approval”). Upon receipt of stockholder approval, the shares of preferred stock will automatically be converted into shares of common stock without further action of the holder thereof. The investor funded \$250,000 of the expected aggregate gross proceeds of \$1.0 million before deducting offering expenses in November 2023. In December 2023, in coordination with the investor, the Company issued 250 shares of Series D Preferred Stock to the investor in consideration for the partial payment. As of September 30, 2024, all 250 Series D Preferred Shares remain outstanding and the remaining \$750,000 of the purchase price remains unpaid. The Company reserves all rights and remedies arising from the investor’s failure to close the transaction and the investor will continue to be in breach of the Purchase Agreement until the remaining amount is paid in full.

In October 2023, the Company entered into a warrant inducement agreement (the “Inducement Agreement”) with a holder (the “Holder”) of certain existing warrants (the “Existing Warrants”) to purchase shares of common stock, par value \$0.01 per share, of the Company. Pursuant to the Inducement Agreement, the Holder agreed to exercise for cash their Existing Warrants to purchase up to 1,089,274 shares of the Company’s common stock at an exercise price of \$7.785 per share, the exercise price per share of the Existing Warrants, during the period from the date of the Inducement Agreement until 7:30 a.m., Eastern Time, on October 26, 2023. Pursuant to amendment agreements entered into by the Company and Holder on October 26, 2023 and February 7, 2024, the Company agreed to initially extend the offer period until December 31, 2023, and subsequently extend the offer period until April 30, 2024. In order to permit the exercise of the Existing Warrants pursuant to the rules of the Nasdaq Capital Market, the Holder agreed to pay as additional consideration \$0.25 per share of common stock issued upon exercise of the Existing Warrants. In consideration of the Holder’s agreement to exercise the Existing Warrants in accordance with the Inducement Agreement, the Company agreed to issue new warrants (the “Inducement Warrants”) to purchase shares of common stock equal to 100% of the number of shares of common stock issued upon exercise of the Existing Warrants (the “Inducement Warrant Shares”). The Inducement Warrants will have an exercise price of \$3.36 per share and will be exercisable on the six-month anniversary of the date of issuance and expire on the five-year anniversary of the Inducement Warrant’s first becoming exercisable. In October 2023, the Holder exercised 200,000 shares of Common Stock under the existing warrants pursuant to the Inducement Agreement for aggregate gross proceeds to the Company of \$2.057 million before deducting financial advisory fees and other expenses payable by the Company. The Holder did not exercise any additional Existing Warrants prior to the termination of the April 30, 2024 extended offer period. Except for the extension of the offer period pursuant to the amendment agreements, the terms and conditions of the Inducement Agreement remained unchanged.

In March 2024, the Company entered into a securities purchase agreement (the “March 2024 Purchase Agreement”) with David E. Lazar, pursuant to which the Company agreed to sell 3,000,000 shares of Series E Convertible Preferred Stock (“Series E Preferred Stock”) to Mr. Lazar at a price of \$1.00 per share for aggregate gross proceeds of \$3.0 million. In connection with the transactions contemplated by the March 2024 Purchase Agreement, the members of the Board of Directors, prior to the closing of such transactions, resigned and a new Board of Directors was appointed, of which Mr. Lazar was appointed Chairman. In March 2024, Mr. Lazar paid \$200,000 at the initial closing of the transactions under the March 2024 Purchase Agreement in exchange for 200,000 shares of Series E Preferred Stock. Mr. Lazar subsequently paid \$350,000 in exchange for an additional 350,000 shares of Series E Preferred Stock in April 2024. Each share of Series E Preferred Stock was convertible into 2.4 shares of the Company’s common stock, and following stockholder approval of the issuance of shares of common stock to Mr. Lazar upon conversion of the Series E Preferred Stock at the Company’s special meeting of stockholders held in May 2024, Mr. Lazar or his transferees or their affiliates could convert the Series E Preferred Stock into common stock and hold in excess of applicable beneficial ownership limitations. In connection with the transactions contemplated by the March 2024 Purchase Agreement, the Company entered into settlement agreements (the “Settlement Agreements”) with each of the European Investment Bank (“EIB”) and Curetis GmbH, the Company’s subsidiary (“Curetis”), and Curetis’ trustee in insolvency, pursuant to which the parties agreed to settle outstanding liabilities amongst the parties. Additionally, in connection with the transactions contemplated by the March 2024 Purchase Agreement, in March 2024, the Company entered into an Inducement Offer to Amend Common Stock Purchase Warrants (the “Offer”) with the holder of such warrants. Pursuant to the Offer, the holder agreed to waive certain rights that would otherwise have been triggered under their warrants as a result of the transactions contemplated by the March 2024 Purchase Agreement, in exchange for the Company entering into the March 2024 Purchase Agreement.

In July 2024, Mr. Lazar consummated a transaction pursuant to which he sold 550,000 shares of Series E Preferred Stock together with his rights to purchase the additional 2,450,000 shares of Series E Preferred Stock under the March 2024 Purchase Agreement to AEI Capital Ltd. Subsequently, AEI Capital Ltd. paid the Company \$2.45 million in August 2024 in exchange for the remaining 2,450,000 shares of Series E Preferred Stock under the terms of the March 2024 Purchase Agreement. All 3,000,000 shares of Series E Preferred Stock were converted into 7,200,000 shares of the Company’s common stock in August 2024. As of September 30, 2024, no shares of Series E Preferred Stock remain outstanding. Upon conversion, such shares of Series E Preferred Stock resumed the status of authorized but unissued shares of undesignated preferred stock of the Company. Upon receipt of the funding from AEI Capital Ltd. and pursuant to the Settlement Agreements with the EIB and Curetis and the March 2024 Purchase Agreement, the Company paid and settled its outstanding indebtedness with the EIB and Curetis. Settlement with EIB also terminated that certain Guarantee and Indemnity Agreement, dated as of July 9, 2020, by and between the EIB and the Company, pursuant to which the Company had guaranteed all of Curetis’ debt to EIB.

In August 2024, the Company entered into a Securities Purchase Agreement (the “August 2024 Securities Purchase Agreement”) with AEI Capital Ltd., pursuant to which the Company had the right, in its discretion, to sell to AEI Capital Ltd., at any time prior to September 30, 2024, shares of common stock, par value \$0.01 per share (the “Shares”), of the Company having an aggregate value of up to \$3.0 million (the “Financing”). The Company will control the timing and amount of any sales of Shares pursuant to the August 2024 Securities Purchase Agreement. As of September 30, 2024, the Company sold 1,079,109 shares of common stock to AEI Capital Ltd. for gross proceeds of \$2.0 million before deducting offering expenses. In October 2024, the Company and AEI Capital Ltd. entered into a First Amendment to the August 2024 Securities Purchase Agreement (the “Amendment”). The Amendment amended the August 2024 Securities Purchase Agreement by: (1) granting the Company the right to sell two additional tranches of common stock to AEI Capital Ltd. of \$3.0 million each, for an aggregate amount of \$9.0 million under the August 2024 Securities Purchase Agreement; and (2) extending the Company’s ability to sell shares of common stock to AEI Capital Ltd. under the August 2024 Securities Purchase Agreement until December 31, 2025 (see Note 11).

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) 271 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, 48,058 shares were automatically added to the 2015 Plan in 2024. 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 September 30, 2024, 12,506 shares remain available for issuance under the 2015 Plan.

For the three and nine months ended September 30, 2024 and 2023, the Company recognized share-based compensation expense as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Cost of services	\$ -	\$ (442)	\$ -	\$ (442)
Research and development	-	(159,742)	48,820	(41,914)
General and administrative	1,530	74,411	504,941	259,452
Sales and marketing	-	(143,710)	4,397	(78,928)
	<u>\$ 1,530</u>	<u>\$ (229,483)</u>	<u>\$ 558,158</u>	<u>\$ 138,168</u>

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 anticipated net taxable loss position for the year ended December 31, 2024.

The Company did not grant any options during the three and nine months ended September 30, 2024. During the three months ended September 30, 2024, no options were forfeited, and 5,813 options expired. During the nine months ended September 30, 2024, 892 options were forfeited, and 8,594 options expired.

The Company had total stock options to acquire 138 shares of common stock outstanding at September 30, 2024 under all of its equity compensation plans.

Restricted stock units

During the three months ended September 30, 2024, no restricted stock units were granted, no restricted stock units vested, and no restricted stock units were forfeited. During the nine months ended September 30, 2024, the Company granted 61,053 restricted stock units, 61,053 restricted stock units vested, and 4,163 were forfeited. The Company had 4,163 total restricted stock units outstanding at September 30, 2024.

Stock purchase warrants

At September 30, 2024 and December 31, 2023, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at	
			September 30, 2024	December 31, 2023
February 2015	\$ 660,000.00	February 2025	3	3
October 2019	\$ 400.00	October 2024	1,770	1,770
October 2019	\$ 520.00	October 2024	1,175	1,175
November 2020	\$ 504.40	May 2026	1,211	1,211
February 2021	\$ 780.00	August 2026	2,084	2,084
May 2023	\$ 7.785	(1)	889,274	889,274
October 2023	\$ 3.36	April 2029	200,000	200,000
			<u>1,095,517</u>	<u>1,095,517</u>

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

- (1) Warrants will be exercisable beginning on the date of stockholder approval of the exercisability of the warrants under Nasdaq rules. Once exercisable, the warrants will expire on the five-year anniversary of the date of such stockholder approval.

Note 8 – Commitments and Contingencies

Registration and other stockholder rights

In connection with 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.

Note 9 – Leases

The following table presents the Company’s ROU assets and lease liabilities as of September 30, 2024 and December 31, 2023:

Lease Classification	September 30, 2024	December 31, 2023
ROU Assets:		
Operating	\$ 832,966	\$ -
Financing	-	138
Total ROU assets	<u>\$ 832,966</u>	<u>\$ 138</u>
Liabilities		
Current:		
Operating	\$ 167,021	\$ 147,943
Finance	-	280
Noncurrent:		
Operating	1,893,794	2,021,616
Finance	-	-
Total lease liabilities	<u>\$ 2,060,815</u>	<u>\$ 2,169,839</u>

Maturities of lease liabilities as of September 30, 2024 by fiscal year are as follows:

Maturity of Lease Liabilities	Operating	Finance	Total
2024 (October to December)	\$ 90,395	\$ -	\$ 90,395
2025	368,179	-	368,179
2026	378,279	-	378,279
2027	388,682	-	388,682
2028	399,388	-	399,388
Thereafter	1,338,299	-	1,338,299
Total lease payments	<u>2,963,222</u>	<u>-</u>	<u>2,963,222</u>
Less: Interest	(902,407)	-	(902,407)
Present value of lease liabilities	<u>\$ 2,060,815</u>	<u>\$ -</u>	<u>\$ 2,060,815</u>

Condensed consolidated statements of operations classification of lease costs as of the three and nine months ended September 30, 2024 and 2023 are as follows:

Lease Cost	Classification	Three months ended September 30,		Nine months ended September 30,	
		2024	2023	2024	2023
Operating	Operating expenses	\$ 58,496	\$ 175,243	\$ 175,488	\$ 484,546
Finance:					
Amortization	Operating expenses	-	847	138	2,514
Interest expense	Other expenses	-	-	-	-
Total lease costs		<u>\$ 58,496</u>	<u>\$ 176,090</u>	<u>\$ 175,626</u>	<u>\$ 487,060</u>

Other lease information as of September 30, 2024 is as follows:

Other Information	Total
Weighted average remaining lease term (in years)	
Operating leases	7.4
Finance leases	-
Weighted average discount rate:	
Operating leases	10.0%
Finance leases	-%

Supplemental cash flow information as of the nine months ended September 30, 2024 and 2023 is as follows:

Supplemental Cash Flow Information	2024	2023
Cash paid for amounts included in the measurement of lease liabilities		
Cash used in operating activities		
Operating leases	\$ 175,488	\$ 484,546
Finance leases	\$ -	\$ -
Cash used in financing activities		
Finance leases	\$ 280	\$ 2,523
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 through January 2025, Ares Genetics and Sandoz intended 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, aimed 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 was 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. Following Ares Genetics’ insolvency filing in 2023, the Company will no longer benefit from this framework agreement.

Qiagen

In February 2019, Ares Genetics and Qiagen GmbH, or Qiagen, entered into a strategic licensing agreement for ARESdb and AREStools in the area of AMR research. The agreement had a term of 20 years and could have been terminated by Qiagen for convenience with 180 days written notice.

Under the terms of the original agreement, Qiagen, in exchange for a moderate six figure up-front licensing payment, 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. Following the insolvency filings of Curetis and Ares Genetics in 2023, the Company will no longer benefit from this strategic licensing agreement.

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 incurred royalties on revenues from licensed product sales or sublicensing proceeds. Royalty rates under the Siemens agreement ranged 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 \$0 and \$3,102 for the three months ended September 30, 2024 and 2023, respectively. The total net royalty expense related to this agreement was \$0 and \$7,309 for the nine months ended September 30, 2024 and 2023, respectively. Following Ares Genetics' insolvency filing in 2023, the Company will no longer generate licensed product sales or sublicense revenues nor incur royalty expenses related to the Siemens GEAR assets.

Foundation for Innovative New Diagnostics (FIND)

In September 2022, Curetis GmbH and FIND entered into a research and development collaboration agreement for €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"). In April 2023, the Company entered into an amendment to its research and development collaboration agreement with FIND to expand the deliverables in exchange for an additional €0.13 million in milestone payments ("Amendment 1"). The additional deliverables were completed in June 2023. Following successful completion of the feasibility phase of the collaboration, including the additional deliverables, FIND and Curetis, in August 2023, extended the research and development collaboration agreement through May 2024, to include AMR assay and cartridge development, analytical testing, and software development for an additional €0.5 million ("Amendment 2"). The Company did not recognize any revenues related to the FIND collaboration during the three and nine months ended September 30, 2024. The agreement-to-date revenue recognized by the Company related to the FIND collaboration was \$0.9 million. Following Curetis' insolvency filing in 2023, the Company will no longer benefit from this collaboration agreement.

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.

In October 2024, the Company and AEI Capital Ltd. entered into a First Amendment (the "Amendment") to the August 2024 Securities Purchase Agreement. The Amendment amended the August 2024 Securities Purchase Agreement by: (1) granting the Company the right to sell two additional tranches of common stock to AEI Capital Ltd. of \$3.0 million each, for an aggregate amount of \$9.0 million under the August 2024 Securities Purchase Agreement; and (2) extending the Company's ability to sell shares of common stock to AEI Capital Ltd. under the August 2024 Securities Purchase Agreement until December 31, 2025.

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 I, Item 1A of our annual report on Form 10-K for the year ended December 31, 2023.

Overview

OpGen, Inc. (“OpGen” or the “Company”) was incorporated in Delaware in 2001. In April 2020, OpGen completed a business combination transaction with Curetis N.V., a public company with limited liability under the laws of the Netherlands, pursuant to which the Company 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 Curetis N.V., including Ares Genetics GmbH (“Ares Genetics”), a wholly owned subsidiary of Curetis GmbH (together, “Curetis”).

From inception until November 2023, OpGen operated as a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. The Company, along with its subsidiaries, Curetis and Ares Genetics, developed and commercialized 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. In November 2023, Curetis filed a petition for insolvency with the district court of Stuttgart, Germany, and Ares Genetics filed a petition for insolvency with the commercial court in Vienna, Austria. The insolvency proceedings of Curetis and Ares Genetics were adjudicated under the insolvency laws of Germany and Austria, respectively.

The insolvency administrators assumed control over the assets and liabilities of Curetis and Ares Genetics, respectively, which eliminated the authority and power of the Company and its officers to act on behalf of the subsidiaries. The loss of control required that the Company no longer include Curetis and Ares Genetics in its consolidated financial statements. Prior to the insolvency filings, Curetis and Ares Genetics had been included in the Company’s consolidated financial statements. As part of the insolvency proceedings, in April 2024, the insolvency administrator for Curetis notified the Company that all of Curetis’ assets were sold to Camtech Pte Ltd., a Singaporean family office (“Camtech”). In April 2024, the insolvency administrator for Ares Genetics notified the Company that all of Ares Genetics’ assets were sold to bioMerieux S.A.

In March 2024, the Company entered into a securities purchase agreement (the “March 2024 Purchase Agreement”) with David E. Lazar, pursuant to which the Company agreed to sell 3,000,000 shares of Series E Convertible Preferred Stock (“Series E Preferred Stock”) to Mr. Lazar at a price of \$1.00 per share for aggregate gross proceeds of \$3.0 million. In connection with the transactions contemplated by the March 2024 Purchase Agreement, the members of the Board of Directors, prior to the closing of such transactions, resigned and a new Board of Directors was appointed, of which Mr. Lazar was appointed Chairman. Furthermore, in April 2024, the Company entered into an employment agreement with David E. Lazar, pursuant to which the Company engaged Mr. Lazar to act as its Chief Executive Officer (“CEO”).

In April 2024, the Company entered into a lease assignment agreement where the Company assigned the lease of its Rockville, Maryland headquarters to a third party. The Company's security deposit remains with the landlord and will be repaid over time as agreed upon with the third party assignee. The Company has a continuing liability under the lease; however, within the lease assignment agreement, the new tenant indemnifies the Company from and against any liabilities resulting from obligations arising on or after the lease assignment date.

In July 2024, Mr. Lazar consummated a transaction pursuant to which he sold 550,000 shares of Series E Preferred Stock together with his rights to purchase the additional 2,450,000 shares of Series E Preferred Stock under the March 2024 Purchase Agreement to AEI Capital Ltd. Subsequently, AEI Capital Ltd. paid the Company \$2.45 million in August 2024 in exchange for the remaining 2,450,000 shares of Series E Preferred Stock under the terms of the March 2024 Purchase Agreement. All 3,000,000 shares of Series E Preferred Stock were converted into 7,200,000 shares of the Company's common stock in August 2024. As of September 30, 2024, no shares of Series E Preferred Stock remain outstanding. Upon conversion, such shares of Series E Preferred Stock resumed the status of authorized but unissued shares of undesignated preferred stock of the Company.

Under the ownership of AEI Capital Ltd., the Company plans to continue scaling down legacy operations and selling the remaining Unyvero assets in inventory with the intention of exiting the Unyvero business. Going forward, the Company is planning to reposition itself and will launch a new business in the financial technology industry supporting digital investment banking activities. The Company also contemplates engaging in the provision of listing consultancy services to international companies seeking to list their securities on securities exchanges.

In November 2022, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to effect a one-for-twenty reverse stock split of the issued and outstanding shares of common stock on January 5, 2023. In addition, in May 2024, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to effect a one-for-ten reverse stock split of the issued and outstanding shares of common stock on May 20, 2024. All share amounts and per share prices in this Quarterly Report have been adjusted to reflect such reverse stock splits.

The Company's headquarters were located at 9717 Key West Avenue, Suite 100, in Rockville, Maryland, through the end of the first quarter of 2024. Upon assignment of the Company's lease, the Company operates virtually. The Company operates in one business segment.

Financial Overview

Revenue

We recognize three types of revenues: product sales, laboratory services and collaboration revenue. Prior to the repositioning of our business in July 2024, we generated product revenues from sales of our products, including through our distribution partners, such as our Unyvero instruments and consumables. We also generated revenue from sales by Ares Genetics of its AI-powered prediction models and solutions. Revenues generated from our laboratory services related to services that we and our subsidiaries provided to customers. Lastly, our collaboration revenues consisted of revenue received from research and development collaborations that we 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 consisted primarily of expenses incurred in connection with our clinical and pre-clinical research activities. Selling, general and administrative expenses consist of public company costs, salaries, and related costs for administrative, sales, and business development personnel.

Results of operations for the three months ended September 30, 2024 and 2023

Revenues

	Three months ended September 30,	
	2024	2023
Product sales	\$ -	\$ 558,965
Laboratory services	-	47,135
Collaboration revenue	-	92,922
Total revenue	<u>\$ -</u>	<u>\$ 699,022</u>

Total revenue for the three months ended September 30, 2024 decreased 100% when compared to the same period in 2023 since we did not generate any revenue during the three months ended September 30, 2024. This decrease is primarily attributable to:

- Product Sales: the decrease of 100% in the 2024 period compared to the 2023 period is attributable to the exclusion of Curetis' and Ares Genetics' product sales in the 2024 period following their insolvency filings in November 2023 and the resulting deconsolidation of the subsidiaries as well as the scaling down of legacy operations at the Company in connection with the Company repositioning its business;
- Laboratory Services: the decrease of 100% in the 2024 period compared to the 2023 period is attributable to the discontinuance of Ares Genetics' related products and services during the first quarter of 2024 due to the sale of the Ares Genetics assets to a strategic acquiror by its insolvency administrator in Austria; and
- Collaboration Revenue: the decrease of 100% in the 2024 period compared to the 2023 period is due to the Company no longer receiving revenues under the collaboration agreement with FIND as a result of the deconsolidation following Curetis' insolvency filing in 2023.

Operating expenses

	Three months ended September 30,	
	2024	2023
Cost of products sold	\$ -	\$ 618,796
Cost of services	-	73,174
Research and development	488	1,201,865
General and administrative	768,551	2,034,628
Sales and marketing	14,846	336,184
Total operating expenses	<u>\$ 783,885</u>	<u>\$ 4,264,647</u>

Our total operating expenses for the three months ended September 30, 2024 decreased approximately 82% when compared to the same period in 2023. Operating expenses changed as follows:

- Cost of products sold: cost of products sold for the three months ended September 30, 2024 decreased 100% when compared to the same period in 2023. The decrease in cost of products sold aligns with the decrease in product sales during such three-month period of 2024. In addition, cost of products sold was greater in the third quarter of 2023 due to increases in inventory reserves for obsolescence, expirations, and slow-moving inventory, whereas in the third quarter of 2024, all inventory had already been fully reserved;
- Cost of services: cost of services for the three months ended September 30, 2024 decreased 100% when compared to the same period in 2023. The decrease in cost of services aligns with the decrease in laboratory services and collaboration revenue during such three-month period of 2024, which is due to the sale of Ares Genetics' business in the first quarter of 2024 as part of Ares Genetics' insolvency proceedings and the Company no longer incurring expenses under the collaboration agreement with FIND as a result of the deconsolidation following Ares Genetics' and Curetis' insolvency filings in 2023; and
- Research and development, general and administrative, and sales and marketing: research and development, general and administrative, and sales and marketing expenses decreased approximately 100%, 62%, and 96%, respectively, for the three months ended September 30, 2024 compared to the same period in 2023. The decreases are primarily attributable to the Company no longer including expenses related to Curetis and Ares Genetics in the consolidated figures as a result of the deconsolidation following their insolvency filings in November 2023, and the scaling down of legacy operations at the Company in connection with the Company repositioning its business.

Other income (expense)

	Three months ended September 30,	
	2024	2023
Interest expense	\$ (3,238)	\$ (396,768)
Foreign currency transaction gains (losses)	(2)	(135,930)
Interest and other income, net	92,131	24,977
Gain on extinguishment of debt	9,738,487	-
Gain on settlement of compensation expenses	570,785	-
Change in fair value of derivative financial instruments	-	10,389
Change in fair value of EIB loan guaranty	(683,200)	-
Total other income (expense)	<u>\$ 9,714,963</u>	<u>\$ (497,332)</u>

Our total other income (expense) for the three months ended September 30, 2024 increased to a net income of \$9.7 million from a net expense of \$0.5 million in the same period in 2023 primarily due to the Company recognizing a gain on extinguishment of debt following the Company's settlement of the EIB loan guaranty in August 2024 and the Company recognizing a gain on settlement of compensation expenses following the Company's settlement of deferred and accrued compensation and severance expenses with the Company's former CEO, David E. Lazar.

Results of operations for the nine months ended September 30, 2024 and 2023

Revenues

	Nine months ended September 30,	
	2024	2023
Product sales	\$ 169,373	\$ 1,409,534
Laboratory services	26,776	112,810
Collaboration revenue	-	826,257
Total revenue	<u>\$ 196,149</u>	<u>\$ 2,348,601</u>

Total revenue for the nine months ended September 30, 2024 decreased approximately 92% when compared to the same period in 2023. This decrease is primarily attributable to:

- **Product Sales:** the decrease of approximately 88% during the nine months ended September 30, 2024 compared to the same period in 2023 is primarily attributable to the exclusion of Curetis' and Ares Genetics' product sales in the 2024 period following their insolvency filings in November 2023 and the resulting deconsolidation of the subsidiaries as well as the scaling down of legacy operations at the Company in connection with the Company repositioning its business;
- **Laboratory Services:** the decrease of approximately 76% during the nine months ended September 30, 2024 compared to the same period in 2023 is primarily attributable to the discontinuance of Ares Genetics' related products and services during the first quarter of 2024 due to the sale of the Ares Genetics assets to a strategic acquiror by its insolvency administrator in Austria; and
- **Collaboration Revenue:** the decrease of 100% during the nine months ended September 30, 2024 compared to the same period in 2023 is due to the Company no longer receiving revenues under the collaboration agreement with FIND as a result of the deconsolidation following Curetis' insolvency filing in 2023.

Operating expenses

	Nine months ended September 30,	
	2024	2023
Cost of products sold	\$ 31,636	\$ 1,925,566
Cost of services	1,575	405,582
Research and development	49,308	4,403,488
General and administrative	4,021,321	6,883,588
Sales and marketing	168,819	2,522,471
Total operating expenses	<u>\$ 4,272,659</u>	<u>\$ 16,140,695</u>

Our total operating expenses for the nine months ended September 30, 2024 decreased approximately 74% when compared to the same period in 2023. Operating expenses changed as follows:

- **Cost of products sold:** cost of products sold for the nine months ended September 30, 2024 decreased approximately 98% when compared to the same period in 2023. The decrease in cost of products sold aligns with the decrease in product sales for the same period in 2024. Additionally, cost of products sold was greater in the first nine months of 2023 due to increases in inventory reserves for obsolescence, expirations, and slow-moving inventory, whereas in the first nine months of 2024, all inventory had already been fully reserved;

- Cost of services: cost of services for the nine months ended September 30, 2024 decreased approximately 100% when compared to the same period in 2023. The decrease in cost of services aligns with the decrease in laboratory services and collaboration revenue in the same period in 2024, which is due to the sale of Ares Genetics' business in the first quarter of 2024 as part of Ares Genetics' insolvency proceedings and the Company no longer being a party to the collaboration agreement with FIND as a result of the deconsolidation following Ares Genetics' and Curetis' insolvency filings in 2023; and
- Research and development, general and administrative, and sales and marketing: research and development, general and administrative, and sales and marketing expenses decreased approximately 99%, 42%, and 93%, respectively, for the nine months ended September 30, 2024 compared to the same period in 2023. The decreases are primarily attributable to the Company no longer including expenses related to Curetis and Ares Genetics in the consolidated figures as a result of the deconsolidation following their insolvency filings in November 2023, plus the scaling down of legacy operations at the Company in connection with the Company repositioning its business.

Other income (expense)

	Nine months ended September 30,	
	2024	2023
Interest expense	\$ (4,317)	\$ (1,698,564)
Foreign currency transaction gains (losses)	463	(288,326)
Interest and other income, net	242,799	86,301
Gain on impairment adjustment	2,079,575	-
Gain on extinguishment of debt	9,738,487	-
Gain on settlement of compensation expenses	570,785	-
Change in fair value of derivative financial instruments	-	65,800
Change in fair value of EIB loan guaranty	(908,586)	-
Total other income (expense)	\$ 11,719,206	\$ (1,834,789)

Our total other income (expense) for the nine months ended September 30, 2024 increased to a net income of \$11.7 million from a net expense of \$1.8 million in the same period in 2023 primarily due to the Company recognizing a gain on extinguishment of debt following the Company's settlement of the EIB loan guaranty in August 2024, the Company recognizing a gain on settlement of compensation expenses following the Company's settlement of deferred and accrued compensation and severance expenses with the Company's former CEO, David E. Lazar, and the Company recording a gain on impairment adjustment of \$2.1 million. In addition, the Company did not recognize interest expense on the Company's EIB liability for the nine months ended September 30, 2024 because, upon deconsolidation of the Company's subsidiaries in the fourth quarter of 2023, the Company reclassified the EIB liability from a loan to a loan guaranty, which is recorded based on its fair value with changes being recognized as part of net income (loss) at each reporting date.

Liquidity and capital resources

As of September 30, 2024, we had cash and cash equivalents of \$1.6 million compared to \$1.2 million at December 31, 2023. Historically, we have funded our operations primarily through external investor financing arrangements and have raised funds in 2024 and 2023, including:

- In January 2023, we closed a best-efforts public offering for the purchase of (i) 32,121 shares of common stock, (ii) pre-funded warrants to purchase up to an aggregate of 226,500 shares of common stock, (iii) Series A-1 common warrants to purchase an aggregate of 258,621 shares of common stock, and (iv) Series A-2 common warrants to purchase an aggregate of 258,621 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 May 2023, we closed a best-efforts public offering for the purchase of (i) 60,500 shares of the Company's common stock, par value \$0.01 per share, (ii) pre-funded warrants to purchase up to an aggregate of 389,083 shares of common stock, and (iii) common warrants to purchase up to an aggregate of 449,583 shares of common stock. The offering raised aggregate gross proceeds of approximately \$3.5 million and net proceeds of approximately \$3.0 million.
- In October 2023, Curetis received a payment of €0.75 million related to the sale of certain Unyvero A50 systems by Curetis to a strategic partner. Such purchase of systems and payment was made in connection with the negotiation of a potential strategic transaction involving Curetis and the Company's subsidiary, Ares Genetics, with such strategic partner; however, the potential strategic transaction was unsuccessful.
- In October 2023, we entered into a Preferred Stock Purchase Agreement with a single investor for 1,000 shares of the Company's Series D Preferred Stock, par value \$0.01 per share, where each share of preferred stock was agreed to sell at a price of \$1,000 per share for aggregate gross proceeds of \$1.0 million before deducting offering expenses. The investor funded \$250,000 of the expected aggregate gross proceeds of \$1.0 million before deducting offering expenses in November 2023. In December 2023, in coordination with the investor, the Company issued 250 shares of Series D Preferred Stock to the investor in consideration for the partial payment. As of September 30, 2024, all 250 Series D Preferred Shares remain outstanding and the remaining \$750,000 of the purchase price remains unpaid. The private placement was conducted in connection with the negotiation of a potential strategic transaction involving the Company and the investor. The Company's discussions with this investor have ceased.
- In October 2023, we entered into a warrant inducement agreement with a holder of certain existing warrants to purchase shares of common stock, par value \$0.01 per share, of the Company. Pursuant to the Inducement Agreement, the holder agreed to exercise for cash their existing warrants to purchase up to 1,089,274 shares of the Company's common stock at an exercise price of \$7.785 per share, the exercise price per share of the existing warrants, during the period from the date of the Inducement Agreement until 7:30 a.m., Eastern Time, on October 26, 2023; however, on October 26, 2023, and subsequently on February 7, 2024, the Company and the holder agreed to initially extend the offer period through December 31, 2023, and later through April 30, 2024. In October 2023, the Holder exercised 200,000 shares of Common Stock under the existing warrants pursuant to the Inducement Agreement for aggregate gross proceeds to the Company of \$2.057 million before deducting financial advisory fees and other expenses payable by the Company. The Holder did not exercise any additional Existing Warrants prior to the termination of the April 30, 2024 extended offer period.
- In November 2023, Curetis filed a petition for insolvency with the district court of Stuttgart, Germany, and Ares Genetics filed a petition for insolvency with the commercial court in Vienna, Austria, Reference Number 38 S 175/23x. The insolvency proceedings of Curetis and Ares Genetics were adjudicated under the insolvency laws of Germany and Austria, respectively. The insolvency administrators assumed control over the assets and liabilities of Curetis and Ares Genetics, respectively, which eliminated the authority and power of the Company and its officers to act on behalf of the subsidiaries. The German and Austrian insolvency administrators both successfully completed asset sales of the assets of Curetis and Ares Genetics, but the Company does not anticipate receiving any proceeds from such sales as the proceeds will be allocated amongst each entity's creditors.
- In March 2024, we entered into a securities purchase agreement with David E. Lazar, pursuant to which we agreed to sell 3,000,000 shares of Series E Convertible Preferred Stock to Mr. Lazar at a price of \$1.00 per share for aggregate gross proceeds of \$3.0 million. In March 2024, Mr. Lazar paid \$200,000 at the initial closing in exchange for 200,000 shares of Series E Preferred Stock. Mr. Lazar subsequently paid \$350,000 in exchange for an additional 350,000 shares of Series E Preferred Stock in April 2024. In July 2024, Mr. Lazar consummated a transaction pursuant to which he sold 550,000 shares of Series E Preferred Stock together with his rights to purchase the additional 2,450,000 shares of Series E Preferred Stock under the March 2024 Purchase Agreement to AEI Capital Ltd. Subsequently, AEI Capital Ltd. paid the Company \$2.45 million in August 2024 in exchange for the remaining 2,450,000 shares of Series E Preferred Stock under the terms of the March 2024 Purchase Agreement.

- In August 2024, we entered into a securities purchase agreement (the “August 2024 Securities Purchase Agreement”) with AEI Capital Ltd., pursuant to which we have the right, in our discretion, to sell to AEI Capital Ltd., at any time prior to September 30, 2024, shares of common stock, par value \$0.01 per share, of the Company having an aggregate value of up to \$3.0 million. As of September 30, 2024, the Company sold 1,079,109 shares of common stock to AEI Capital Ltd. for gross proceeds of \$2.0 million before deducting offering expenses. In October 2024, we entered into a First Amendment (the “Amendment”) to the securities purchase agreement with AEI Capital Ltd. whereby we were: (1) granted the right to sell two additional tranches of common stock to AEI Capital Ltd. of \$3.0 million each, for an aggregate amount of \$9.0 million under the securities purchase agreement; and (2) our ability to sell shares of common stock to AEI Capital Ltd. under the securities purchase agreement was extended until December 31, 2025.

Although the Company only has cash and cash equivalents of \$1.6 million as of September 30, 2024, in October 2024, pursuant to the Amendment, which granted the Company the right to sell two additional tranches of common stock to AEI Capital Ltd. of \$3.0 million each, for an aggregate amount of \$9.0 million under the August 2024 Securities Purchase Agreement until December 31, 2025, the Company currently has the right, in its discretion, to sell to AEI Capital Ltd. shares of common stock of the Company having an aggregate value of up to an additional \$7.0 million. As a result, the Company believes that its current cash and its access to additional cash under the August 2024 Securities Purchase Agreement will allow the Company to fund operations in excess of 12 months from the issuance date of these financial statements.

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 (used in) provided by operating activities, investing activities and financing activities for the periods indicated:

	Nine months ended	
	September 30,	
	2024	2023
Net cash used in operating activities	\$ (4,637,508)	\$ (12,643,099)
Net cash used in investing activities	-	(799,498)
Net cash provided by financing activities	5,118,851	6,275,625

Net cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2024 consisted primarily of our net income of \$7.6 million adjusted for certain noncash items, including share-based compensation expense of \$0.6 million and changes in operating assets and liabilities of \$0.5 million, reduced by certain non-cash items, including gain on change in fair value of EIB loan guaranty of \$10.9 million, gain on impairment adjustment of \$2.1 million, and gain on settlement of compensation expenses of \$0.6 million. Net cash used in operating activities for the nine months ended September 30, 2023 consisted primarily of our net loss of \$15.6 million, reduced by certain noncash items, including depreciation and amortization expense of \$1.1 million, noncash interest expense of \$1.3 million, change in inventory reserve of \$0.5 million, and share-based compensation expense of \$0.1 million.

Net cash used in investing activities

Net cash used in investing activities for the nine months ended September 30, 2023 consisted of purchases of property and equipment.

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2024 consisted primarily of proceeds from the issuance of preferred stock in connection with the March 2024 Purchase Agreement with David E. Lazar and, subsequently, AEI Capital Ltd., as assignee from Mr. Lazar, and proceeds from the issuance of common stock in connection with the August 2024 Securities Purchase Agreement with AEI Capital Ltd. Net cash provided by financing activities for the nine months ended September 30, 2023 consisted of proceeds from the issuance of common stock and warrants, net of issuance costs, in connection with the Company's financings in January and May 2023, partially offset by payments on the Company's debt with the EIB.

Contractual Commitments

Subsequent to the insolvency filings of Curetis and Ares Genetics in November 2023 and the resulting deconsolidation, and following the Company's settlements with EIB and Curetis in August 2024, other than the continuing liability under our former headquarters' office lease, which lease was assigned to a third party in April 2024, the Company has no other material contractual commitments as of September 30, 2024.

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, stock-based compensation, allowances for doubtful accounts and inventory obsolescence, property and equipment, lease right-of-use assets, discount rates used to discount unpaid lease payments to present values, valuation of derivative financial instruments measured at fair value on a recurring basis, and deferred tax assets and liabilities and related valuation allowance. 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, 2023.

Off-balance sheet arrangements

As of September 30, 2024 and December 31, 2023, 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 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 September 30, 2024. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, due to the material weakness in our internal control over financial reporting noted in our amended quarterly report on Form 10-Q for the quarter ended March 31, 2024, our disclosure controls and procedures were not effective as of September 30, 2024.

Previously Identified Material Weakness in Internal Control over Financial Reporting

A material weakness is a significant deficiency, or combination of significant deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. As previously reported in the Company's amended Form 10-Q for the three months ended March 31, 2024, the Company concluded it did not design and maintain effective controls over the completeness and accuracy of the accounting for, and disclosure of, a complex accounting transaction as of March 31, 2024. This material weakness resulted in a material error in the Company's originally issued unaudited condensed consolidated financial statements included in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024.

Management's Remediation Efforts for Previously Identified Material Weakness in Internal Control over Financial Reporting

In response to the material weakness described above, with the oversight of the Audit Committee of our Board of Directors, the Company is conducting and will continue to conduct more thorough and diligent accounting research and will engage third-party consultants and accounting experts to assist with complex accounting transactions.

The remediation efforts are intended both to address the identified material weakness and to enhance our overall financial control environment. The Company is committed to continuous improvement of its internal control over financial reporting and will continue to diligently review its internal control over financial reporting. The Company cannot assure you that the measures we have taken to date, or that we may take in the future, will be sufficient to remediate the material weakness we identified or avoid potential future material weaknesses. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

Changes in Internal Control over Financial Reporting

For the quarter ended September 30, 2024, other than the ongoing remediation efforts discussed above, 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

From time to time, we may be a party to litigation or subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation; the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources and other factors.

There were no material changes in litigation from that reported in our Form 10-Q for the period ended June 30, 2024 and Form 10-K for the year ended December 31, 2023.

Item 1A. Risk Factors

Except as set forth below, there have been no other material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2023.

We cannot assure you that we will be able to continue to comply with the Nasdaq minimum stockholders' equity requirement or other continued listing standards of the Nasdaq Capital Market. If we are unable to maintain compliance with such standards, we could be subject to delisting or other adverse action, which could negatively impact the trading of our common stock.

On June 5, 2024, the Company received a letter from the listing staff of The Nasdaq Stock Market LLC ("Nasdaq") that the Company was no longer in compliance with the minimum stockholders' equity requirement for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(b)(1) (the "Stockholders' Equity Rule"). The Stockholders' Equity Rule requires companies listed on the Nasdaq Capital Market to maintain stockholders' equity of at least \$2,500,000 or to meet alternatives of market value of listed securities or net income from continuing operations, which the Company does not currently meet. In response to the letter, the Company submitted its plan to regain compliance with the Stockholders' Equity Rule to the Nasdaq Hearings Panel (the "Panel") and requested additional time to regain compliance with such rule. On August 16, 2024, following the Panel's review of the Company's plan to regain compliance, the Company received a letter (the "Notice") indicating that the Panel had determined to deny the Company's request for continued listing on Nasdaq. Pursuant to the Notice, based on the preliminary nature of the Company's plan, the Panel determined that the Company did not provide a definitive plan evidencing its ability to achieve near- and long-term compliance with the Stockholders' Equity Requirement. The Notice also provided that the Company's securities will be suspended from trading on the Nasdaq Capital Market at the opening of business on August 20, 2024. The Company submitted its appeal regarding the Panel's determination on September 13, 2024 and requested that the Nasdaq Listing and Hearing Review Council review the decision of the Panel. Such appeal stayed the delisting of the Company's securities with Nasdaq and the filing of the Form 25 pending the Nasdaq Listing and Hearing Review Council's decision until the resolution of such review.

While the Company intends to comply with such conditions and rules, there can be no assurance that the Company will be able to regain or remain in compliance with the Stockholders' Equity Rule or other applicable Nasdaq listing requirements on an ongoing and long-term basis or that the Nasdaq Listing and Hearing Review Council will grant the Company additional time to achieve compliance. If we are unable to satisfy these requirements or standards, we could be subject to delisting, which could have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so.

Adverse conditions affecting foreign financial institutions and credit markets could impair our liquidity or interrupt our access to our cash and cash equivalents, which could adversely affect our operations.

As of September 30, 2024, we had approximately \$1.6 million of cash and cash equivalents. Our cash and cash equivalents are held in bank demand deposit accounts with a significant portion held in foreign bank accounts with foreign institutions. Disruptions in the foreign financial markets or with such foreign financial institutions may, in some cases, result in an inability for us to access our cash or cash equivalents, such as cash held in money market funds that traditionally have been viewed as highly liquid. Any failure of our counterparty financial institutions in which we have deposits may adversely impact our cash and cash equivalent positions and, in turn, our financial position and operations.

In addition, our cash and cash equivalents held in foreign institutions are not insured by the Federal Deposit Insurance Corporation ("FDIC"). Accordingly, in the event of any loss by such foreign institutions or if any such institutions experience financial difficulties, our cash and cash equivalents may not be insured, and we may not be able to recover the full amount of our assets, which could result in material financial losses.

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

None other than as disclosed in the Company's Current Reports on Form 8-K.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description
10.1	Securities Purchase Agreement, dated August 22, 2024, by and between the Company and AEI Capital Ltd. (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on August 22, 2024).
10.2	First Amendment to Securities Purchase Agreement, dated October 3, 2024, by and between the Company and AEI Capital Ltd. (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on October 9, 2024).
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer and Principal Accounting Officer pursuant to Rule 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted 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/ John Tan Honjian
John Tan Honjian
Chairman and CEO (principal executive officer)

Date: November 15, 2024

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

I, John Tan Honjian, 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 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 is made known to us by others, 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 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: November 15, 2024

/s/ John Tan Honjian

John Tan Honjian

Chairman and CEO (principal executive officer)

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

I, David E. Lazar, 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 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 is made known to us by others, 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 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: November 15, 2024

/s/ David E. Lazar

David E. Lazar

President (principal financial officer and principal accounting officer)

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 September 30, 2024 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Principal Executive Officer and Principal 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: November 15, 2024

By: /s/ John Tan Honjian
John Tan Honjian
Chairman and CEO
(principal executive officer)

Date: November 15, 2024

By: /s/ David E. Lazar
David E. Lazar
President
(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.
