

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 March 31, 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

1,348,974 shares of the Company's common stock, par value \$0.01 per share, were outstanding as of July 5, 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 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[®] and Acuitas[®]. All other trademarks, servicemarks or trade names referred to in this quarterly report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this quarterly report are sometimes referred to without the [®] and [™] symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies, products or services.

Part I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

OpGen, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	\$ 267,493	\$ 1,151,823
Accounts receivable, net	37,968	103,316
Prepaid expenses and other current assets	227,112	324,735
Total current assets	532,573	1,579,874
Finance lease right-of-use assets, net	-	138
Indemnification assets	2,135,545	-
Other noncurrent assets	302,262	302,262
Total assets	\$ 2,970,380	\$ 1,882,274
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	\$ 191,575	\$ 111,149
Accrued compensation and benefits	47,828	127,601
Accrued liabilities	378,586	135,476
Deferred revenue	8,571	25,926
EIB loan guaranty	10,920,451	10,873,867
Short-term finance lease liabilities	-	280
Short-term operating lease liabilities	154,117	147,943
Total current liabilities	11,701,128	11,422,242
Long-term operating lease liabilities, net of short-term amount	1,981,428	2,021,616
Total liabilities	13,682,556	13,443,858
Commitments and contingencies (Note 8)		
Stockholders' deficit		
Series D convertible preferred stock, \$0.01 par value; 1,000 shares authorized; 250 shares issued and outstanding at March 31, 2024 and December 31, 2023	2	2,500
Series E convertible preferred stock, \$0.01 par value; 3,000,000 shares authorized; 200,000 and 0 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	2,000	-
Common stock, \$0.01 par value; 100,000,000 shares authorized; 1,303,739 and 1,282,686 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	13,037	12,827
Additional paid-in capital	294,380,054	293,991,529
Accumulated deficit	(305,107,269)	(305,493,302)
Accumulated other comprehensive loss	-	(75,138)
Total stockholders' deficit	(10,712,176)	(11,561,584)
Total liabilities and stockholders' deficit	\$ 2,970,380	\$ 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	
	March 31,	
	2024	2023
Revenue		
Product sales	\$ 141,373	\$ 410,897
Laboratory services	26,776	21,673
Collaboration revenue	-	480,874
Total revenue	168,149	913,444
Operating expenses		
Cost of products sold	73,236	592,378
Cost of services	1,575	128,306
Research and development, net	25,856	1,812,831
General and administrative	1,642,054	2,423,953
Sales and marketing	128,646	1,026,087
Total operating expenses	1,871,367	5,983,555
Operating loss	(1,703,218)	(5,070,111)
Other income (expense)		
Interest and other income	9	30,106
Gain on lease indemnification	2,135,545	-
Interest expense	-	(617,298)
Foreign currency transaction gains (losses)	281	(91,994)
Change in fair value of derivative financial instruments	-	12,694
Change in fair value of EIB loan guaranty	(46,584)	-
Total other income (expense)	2,089,251	(666,492)
Income (loss) before income taxes	386,033	(5,736,603)
Provision for income taxes	-	-
Net income (loss)	\$ 386,033	\$ (5,736,603)
Net income (loss) allocated to preferred stockholders	(113,225)	-
Net income (loss) available to common stockholders	\$ 272,808	\$ (5,736,603)
Earnings (loss) per share attributable to common stockholders		
Basic	\$ 0.212	\$ (12.53)
Diluted	\$ 0.207	\$ (12.53)
Weighted average shares outstanding		
Basic	1,284,305	457,727
Diluted	1,331,578	457,727
Net income (loss)	\$ 386,033	\$ (5,736,603)
Other comprehensive income - foreign currency translation	-	153,067
Comprehensive income (loss)	\$ 386,033	\$ (5,583,536)

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' (Deficit) 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
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	-	-	-	-	-	-	386,033	386,033
Balances at March 31, 2024	1,303,739	\$ 13,037	200,250	\$ 2,002	\$ 294,380,054	\$ -	\$ (305,107,269)	\$ (10,712,176)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three months ended	
	March 31,	
	2024	2023
Cash flows from operating activities		
Net income (loss)	\$ 386,033	\$ (5,736,603)
Adjustments to reconcile net income (loss) to net cash used in operating activities		
Depreciation and amortization	138	350,452
Non-cash interest expense	-	456,679
Gain on lease indemnification	(2,135,545)	-
Stock compensation expense	188,237	211,122
Change in inventory reserve	(13,240)	256,814
Loss on deconsolidation of subsidiaries	75,138	-
Change in fair value of derivative liabilities	-	(12,694)
Change in fair value of EIB loan guaranty	46,584	-
Changes in operating assets and liabilities		
Accounts receivable	65,348	(142,177)
Inventory	13,240	(195,029)
Other assets	97,623	3,498
Accounts payable	80,426	(157,139)
Accrued compensation and other liabilities	129,323	100,388
Deferred revenue	(17,355)	(97,929)
Net cash used in operating activities	(1,084,050)	(4,962,618)
Cash flows from investing activities		
Purchases of property and equipment	-	(330,446)
Net cash used in investing activities	-	(330,446)
Cash flows from financing activities		
Proceeds from issuance of common stock and pre-funded warrants, net of issuance costs	-	6,974,050
Proceeds from issuance of preferred stock	200,000	-
Payments on debt	-	(2,229,560)
Payments on finance lease obligations	(280)	(841)
Net cash provided by financing activities	199,720	4,743,649
Effects of exchange rates on cash	-	150,186
Net decrease in cash and cash equivalents and restricted cash	(884,330)	(399,229)
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	\$ 569,755	\$ 7,536,430
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ -	\$ 56,320
Supplemental disclosures of noncash investing and financing activities		
Right-of-use assets acquired through operating leases	\$ -	\$ 801,321

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc. and Subsidiaries
Notes to Unaudited Condensed Consolidated Financial Statements
March 31, 2024

Note 1 – Organization

OpGen, Inc. (“OpGen” or the “Company”) was incorporated in Delaware in 2001. On April 1, 2020, OpGen completed its business combination transaction (the “Transaction”) with Curetis N.V., a public company with limited liability under the laws of the Netherlands (the “Seller” or “Curetis N.V.”), as contemplated by the Implementation Agreement, dated as of September 4, 2019 (the “Implementation Agreement”) by and among the Company, the Seller, and Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and wholly owned subsidiary of the Company (the “Purchaser”). Pursuant to the Implementation Agreement, the Purchaser acquired all the shares of Curetis GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany (“Curetis GmbH”), and certain other assets and liabilities of the Seller (together, “Curetis”). As of December 31, 2022, Crystal GmbH has been dissolved and merged into Curetis GmbH. On November 6, 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, and insolvency administrators in the respective jurisdictions assumed control over the assets and liabilities of these entities. 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.

OpGen Overview

From inception through 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.

During the year ended December 31, 2023, the Company implemented certain cash management initiatives, including restructuring its U.S. operations by reducing headcount from 24 to 5 and has since continued scaling down operations at OpGen’s U.S. headquarters to the core functions of a U.S. Nasdaq listed company with only minimal distribution, marketing, and sales support, allowing the Company to conserve cash and focus on the functions needed to pursue potential strategic alternatives. However, on November 6, 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. In April 2024, the insolvency administrator for Ares Genetics notified the Company that all of Ares Genetics’ assets were sold to bioMerieux S.A.

Since the insolvency filings and through the three months ended March 31, 2024, the Company continues to sell the Curetis Unyvero products to its existing customers in the United States via drop shipments from Curetis directly to customer locations. The Unyvero tests are sold to hospitals, laboratories, and public health organizations as products and on a fee-for-service basis. When hospital and health system clients purchase our products, we bill them directly for the purchase of test kits and consumables. As of March 31, 2024, OpGen had an installed base of approximately 28 Unyvero A50 Analyzers across the United States in different types of hospitals and laboratories, including installations for clinical studies. The sale of Ares Genetics’ related products and services was discontinued 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.

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. The focus of OpGen going forward under new leadership and a new Board of Directors will be on the sale of the Company or the identification of a privately held company to complete a reverse merger or similar strategic transaction.

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, including the following:

- On March 26, 2024, the Company entered into an Inducement Offer to Amend Common Stock Purchase Warrants (the “Offer”) with an investor (the “Investor”). Pursuant to the Offer, the investor 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.
- On March 25, 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. On March 25, 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 \$200,000 and \$150,000 on April 5, 2024 and April 23, 2024, respectively, in exchange for an additional 350,000 shares of Series E Preferred Stock. Mr. Lazar is expected to fund the remaining \$2.45 million in the third quarter of 2024, at which time he will receive the remaining 2.45 million shares of Series E Preferred Stock. Each share of Series E Preferred Stock is convertible into 2.4 shares of the Company’s common stock (“Common Stock”); provided, that, in no event, will the Series E Preferred Stock be convertible into Common Stock in a manner that would result in Mr. Lazar or his transferees or their affiliates holding more than the lesser of (i) 19.99% (together with any other shares of Common Stock otherwise held by them or their affiliates) and (ii) such lower percentage as may be required by applicable stock exchange rules 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 Mr. Lazar upon conversion of the Series E Preferred Stock. Such stockholder approval was obtained at the Company’s special meeting of stockholders held on May 9, 2024 (see Note 11). 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 Company settled outstanding liabilities amongst the parties. Pursuant to the settlement agreements and the March 2024 Purchase Agreement, following the final closing of transactions contemplated by the March 2024 Purchase Agreement, the Company will pay a total of \$2.0 million of the proceeds to settle all outstanding debt of the Company to EIB and Curetis. The settlement agreement 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. Upon termination of the Guarantee and Indemnity Agreement, the Company anticipates recording a gain on extinguishment of debt in excess of \$8 million.

- On October 12, 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. As of March 31, 2024, 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 after March 31, 2024. Except for the extension of the offer period pursuant to the amendment agreements, the terms and conditions of the Inducement Agreement remain unchanged. Since the warrant inducement period was not extended beyond April 30, 2024, the Company is required to hold a stockholders’ meeting to obtain approval for the exercisability of the existing common warrants within 70 days of the end of the extension period.
- On October 11, 2023, the Company entered into a Preferred Stock Purchase Agreement (the “Purchase Agreement”) with a single investor (the “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 of the Private Placement to fund the Company’s operations while it pursued a potential strategic transaction with the Investor. Pursuant to the Purchase Agreement, the Company filed a certificate of designation (the “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 on October 11, 2023. The 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 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 on November 14, 2023. On December 13, 2023, in coordination with the Investor, the Company issued to the Investor 250 shares of Series D Preferred Stock in consideration for the partial payment. As of March 31, 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.

- On June 26, 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 on June 22, 2023. On July 4, 2023, the EIB and Curetis entered into a Standstill Agreement (the “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 on June 22, 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. On November 20, 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. On December 4, 2023, the Company received a notice from the EIB stating that Curetis is 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 euro 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. As of the three months ended March 31, 2024, the Guaranty remained unpaid and outstanding, with the liability reflected on the Company’s financial statements, which was previously on Curetis’ balance sheet. In connection with the Company’s entry into the March 2024 Purchase Agreement with David E. Lazar on March 25, 2024, the Company entered into settlement agreements with each of the EIB and Curetis and Curetis’ trustee in insolvency, pursuant to which the parties agreed to settle outstanding liabilities amongst the parties. Pursuant to the settlement agreements, following the final closing of the transactions contemplated by the March 2024 Purchase Agreement, the Company will pay a total of \$2.0 million of the proceeds to settle all outstanding debt of the Company to EIB and Curetis. The settlement agreement with EIB also terminated the Guaranty. Upon termination of the Guaranty, the Company anticipates recording a gain on extinguishment of debt in excess of \$8 million.
- On May 4, 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. As of March 31, 2024, 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 after March 31, 2024. Except for the extension of the offer period pursuant to the amendment agreements, the terms and conditions of the Inducement Agreement remain unchanged. Since the warrant inducement period was not extended beyond April 30, 2024, the Company is required to hold a stockholders’ meeting to obtain approval for the exercisability of the existing common warrants within 70 days of the end of the extension period.

- On January 11, 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 (the "Pre-funded Warrants"), (iii) Series A-1 common warrants to purchase an aggregate of 258,621 shares of common stock (the "Series A-1 Warrants"), and (iv) Series A-2 common warrants to purchase an aggregate of 258,621 shares of common stock (the "Series A-2 Warrants," and together with the Series A-1 Warrants, the "Common Warrants"). Each share of common stock and accompanying Common Warrants were sold at a price of \$29.00 per share and accompanying Common Warrants, and each Pre-funded Warrant and accompanying Common Warrants were sold at an offering price of \$28.90 per share underlying such Pre-funded Warrants and accompanying Common Warrants, for aggregate gross proceeds of approximately \$7.5 million before deducting the placement agent's fees and the offering expenses, and net proceeds of approximately \$6.9 million. The Common Warrants have an exercise price of \$26.50 per share. The Series A-1 Warrants were immediately exercisable upon issuance, and will expire five years following the issuance date. The Series A-2 Warrants were immediately exercisable upon issuance, and will expire eighteen months following the issuance date. Subject to certain ownership limitations described in the Pre-funded Warrants, the Pre-funded Warrants were immediately exercisable and could be exercised at a nominal consideration of \$0.10 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 15, 2023. In connection with the Company's best-efforts public offering consummated in May 2023, the Company amended the exercise price of the Common Warrants to \$7.785 per share.

Although Mr. Lazar is expected to provide the Company with \$3.0 million in total funding, the Company believes that current cash will only be sufficient to fund operations into the third quarter of 2024. This has led management to conclude that there is substantial doubt about the Company's ability to continue as a going concern. In the event the Company does not receive additional funding from David E. Lazar or other investors or find a reverse merger partner or other strategic transaction partner before or during the third quarter of 2024, the Company will not have sufficient cash flows and liquidity to finance its business operations. Accordingly, in such circumstances, the Company would be compelled to immediately reduce general and administrative expenses until it is able to obtain sufficient financing. If such sufficient financing is not received on a timely basis, the Company would then need to pursue a plan to seek to be acquired by another entity, cease operations and/or seek bankruptcy protection. There can be no assurance that the Company will be able to identify or execute on any of these alternatives on acceptable terms or that any of these alternatives will be successful.

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 months ended March 31, 2024; all intercompany transactions and balances have been eliminated.

Foreign currency

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

Additionally, 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.

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, 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.

At March 31, 2024 and December 31, 2023, the Company had funds totaling \$302,262 which are required as collateral for letters of credit benefiting its landlords and for credit card processors. These funds are reflected in other noncurrent assets on the accompanying unaudited condensed consolidated balance sheets.

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the condensed consolidated balance sheets:

	March 31, 2024	December 31, 2023	March 31, 2023	December 31, 2022
Cash and cash equivalents	\$ 267,493	\$ 1,151,823	\$ 7,039,375	\$ 7,440,030
Restricted cash	302,262	302,262	497,055	495,629
Total cash and cash equivalents and restricted cash in the condensed consolidated statements of cash flows	<u>\$ 569,755</u>	<u>\$ 1,454,085</u>	<u>\$ 7,536,430</u>	<u>\$ 7,935,659</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 March 31, 2024 and December 31, 2023.

At March 31, 2024, the Company had accounts receivable from four customers which individually represented 40%, 29%, 15% and 14% 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. For the three months ended March 31, 2024, revenue earned from two customers represented 56% and 11% of total revenues. For the three months ended March 31, 2023, revenue earned from two customers represented 46% and 19% 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:

	March 31, 2024	December 31, 2023
Raw materials and supplies	\$ -	\$ -
Work-in-process	-	-
Finished goods	1,267,565	1,280,805
Total, gross	1,267,565	1,280,805
Less inventory reserve	(1,267,565)	(1,280,805)
Total, net of inventory reserve	<u>\$ -</u>	<u>\$ -</u>

Inventory includes Unyvero system instruments and components and systems related to the Acuitas business.

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 \$1,267,565 and \$1,280,805 at March 31, 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 March 31, 2024 and December 31, 2023 given the uncertainty surrounding the net realizable value and future demand for the Company's products.

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

Long-lived assets

Property and equipment

Property and equipment 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 year ended December 31, 2023, the Company determined that all of its property and equipment, including leasehold improvements and computer and networking equipment, at its Rockville, MD office was impaired due to the Company's financial condition and the impairment of the Company's ROU lease asset. As a result, the Company recorded an impairment charge in the amount of \$1,231,874. During the three months ended March 31, 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 is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which the Company can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the year ended December 31, 2023, the Company determined that its operating right-of-use lease asset for its Rockville, MD office was impaired due to the Company's inability to support the lease given its financial position. As a result, the Company recorded an impairment charge in the amount of \$849,243. The Company did not identify any impaired ROU assets for three months ended March 31, 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 March 31, 2024.

Total amortization expense of intangible assets was \$0 and \$186,377 for the three months ended March 31, 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 March 31, 2024, the Company does not currently anticipate any future amortization of intangible assets.

Revenue recognition

During the three months ended March 31, 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 the FIND NGO collaboration 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 recognizes funding from grants and research incentives received from Austrian government agencies in the condensed consolidated statements of operations and comprehensive loss in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants or incentives were provided have been met. For grants under funding agreements and for proceeds under research incentive programs, the Company recognizes grant and incentive income in an amount equal to the estimated qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage. The Company classifies government grants received under these arrangements as a reduction to the related research and development expense incurred. The Company analyzes each arrangement on a case-by-case basis. For the three months ended March 31, 2023, the Company recognized \$133,938 as a reduction of research and development expense related to government grant arrangements. As of March 31, 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 E convertible preferred stock contains 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” is 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 March 31, 2024 and 2023 as follows:

	Basic		Diluted	
	March 31, 2024	March 31, 2023	March 31, 2024	March 31, 2023
Net income (loss)	\$ 386,033	\$ (5,736,603)	\$ 386,033	\$ (5,736,603)
Net income allocated to preferred stock	(113,225)	-	(110,396)	-
Net income (loss) available to common stockholders	<u>\$ 272,808</u>	<u>\$ (5,736,603)</u>	<u>\$ 275,637</u>	<u>\$ (5,736,603)</u>
Basic weighted average shares outstanding	1,284,305	457,727	1,284,305	457,727
Dilutive effect of stock purchase warrants			47,273	-
Dilutive weighted average shares outstanding			<u>1,331,578</u>	<u>457,727</u>
Earnings (loss) per share	<u>\$ 0.212</u>	<u>\$ (12.53)</u>	<u>\$ 0.207</u>	<u>\$ (12.53)</u>

None of the potential dilutive securities had a dilutive impact during the three months ended March 31, 2023 due to the Company's net loss.

The number of anti-dilutive shares for the three months ended March 31, 2024 and 2023 consisting of common shares underlying (i) common stock options, (ii) restricted stock units, and (iii) stock purchase warrants which have been excluded from the computation of diluted income per share, was 1.1 million and 0.7 million shares, 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 March 31,	
	2024	2023
Product sales	\$ 141,373	\$ 410,897
Laboratory services	26,776	21,673
Collaboration revenue	-	480,874
Total revenue	<u>\$ 168,149</u>	<u>\$ 913,444</u>

Revenues by geography are as follows:

	Three Months Ended March 31,	
	2024	2023
Domestic	\$ 168,149	\$ 114,949
International	-	798,495
Total revenue	<u>\$ 168,149</u>	<u>\$ 913,444</u>

Deferred revenue

Changes in deferred revenue for the period 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		(12,525)
Refunded to customers in the current period		(4,830)
Balance at March 31, 2024	\$	8,571

Note 5 – Fair value measurements

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

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

For the three months ended March 31, 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 a minimum cumulative equity capital raised of €15.0 million to disburse this €5.0 million tranche, the parties agreed on a 2.1% participation percentage interest (“PPI”). Upon maturity of the tranche, the EIB would be entitled to an additional payment that is equity-linked and equivalent to 2.1% of the then total valuation of Curetis N.V. On July 9, 2020, the Company negotiated an amendment to the EIB debt financing facility. As part of the amendment, the parties adjusted the PPI percentage applicable to the previous EIB tranche of €5.0 million which was funded in June 2019 from its original 2.1% PPI in Curetis N.V.’s equity value upon maturity to a new 0.3% PPI in OpGen’s equity. On May 23, 2022, the Company entered into a Waiver and Amendment Letter which increased the PPI to 0.75% upon maturity. 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, on November 20, 2023, Curetis received a termination notice from the EIB terminating the Standstill Agreement effective as of November 20, 2023. On December 4, 2023, the Company received a notice from the EIB stating that Curetis is 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 March 31, 2024. 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. As a result, the Company included the PPI component along with the principal and interest in the EIB loan guaranty as of March 31, 2024.

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

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

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

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

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

The Company measures its long-lived assets, including property and equipment and intangible assets (including goodwill), at fair value on a non-recurring basis when a triggering event requires such evaluation. During the three months ended March 31, 2024, the Company did not record any such impairment expenses. During the year ended December 31, 2023, the Company recorded impairment expense of \$1,231,874 related to its property and equipment (see Note 3) and \$849,243 related to its right-of-use lease asset (see Note 3).

Note 6 – EIB loan guaranty

The following table summarizes the Company's EIB loan guaranty as of March 31, 2024 and December 31, 2023:

	March 31, 2024	December 31, 2023
EIB	\$ 10,920,451	\$ 10,873,867
Total obligations	10,920,451	10,873,867
Unamortized discount	-	-
Carrying value of EIB loan guaranty	10,920,451	10,873,867
Less EIB loan guaranty (current portion)	(10,920,451)	(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, under the EIB amendment, 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 is deferred and payable at maturity together with the principal. In June 2018, a second tranche of €3.0 million was drawn down. The terms and conditions are analogous to the first one. In June 2019, Curetis drew down a third tranche of €5.0 million from the EIB. In line with all prior tranches, the majority of interest is also deferred until repayment upon maturity. In return for the EIB waiving the condition precedent of a minimum cumulative equity capital raised of €15.0 million to disburse this €5.0 million 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 is equity-linked and equivalent to 2.1% of the then total valuation of Curetis N.V. As part of the amendment between the Company and the EIB on July 9, 2020, the parties adjusted the PPI percentage applicable to the third EIB tranche of €5.0 million, which was funded in June 2019, from its original 2.1% PPI in Curetis N.V.'s equity value upon maturity to a new 0.3% PPI in OpGen's equity value upon maturity. This right constituted an embedded derivative, which is separated and measured at fair value with changes being accounted for through income or loss. The EIB debt was measured and recognized at fair value as of the acquisition date. The fair value of the EIB debt was approximately €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.

On May 23, 2022, the Company and the EIB entered into a Waiver and Amendment Letter (the "2022 EIB Amendment") relating to the amendment of the EIB loan facility, between the EIB and Curetis, pursuant to which Curetis borrowed an aggregate amount of €18.0 million in three tranches. The 2022 EIB Amendment restructured the first tranche of approximately €13.4 million (including accumulated and deferred interest) of the Company's outstanding indebtedness with the EIB. Pursuant to the 2022 EIB Amendment, the Company repaid €5.0 million to the EIB in April 2022. The Company also agreed, among other things, to amortize the remainder of the debt tranche over the twelve-month period beginning in May 2022. Accordingly, the Company agreed to pay a monthly amount of approximately €0.7 million through April 2023. The Amendment also 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 is less than the effective borrowing rate under the previous agreement, a concession is deemed to have been granted under ASC 470-60. As a concession has been granted, the agreement was accounted for as a troubled debt restructuring under ASC 470-60. The amendment did not result in a gain on restructuring as the future undiscounted cash outflows required under the amended agreement exceed the carrying value of the debt immediately prior to the amendment.

On June 26, 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 on June 22, 2023. On July 4, 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 on June 22, 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 fail to comply with any undertakings in the Standstill Agreement, the third party expert determines that there are 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 shows a negative liquidity shortfall during the specified period.

On November 20, 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. On December 4, 2023, the Company received a notice from the EIB stating that Curetis is 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 euro 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. As of the three months ended March 31, 2024, the Guaranty remained unpaid and outstanding, with the liability reflected on the Company's financial statements, which was previously on Curetis' balance sheet.

In connection with the Company's entry into the March 2024 Purchase Agreement with David E. Lazar on March 25, 2024, the Company entered into settlement agreements with each of the EIB and Curetis and Curetis' trustee in insolvency, pursuant to which the parties agreed to settle outstanding liabilities amongst the parties. Pursuant to the settlement agreements, following the final closing of the transactions contemplated by the March 2024 Purchase Agreement, the Company will pay a total of \$2.0 million of the proceeds to settle all outstanding debt of the Company to EIB and Curetis. The settlement agreement with EIB also terminated the Guaranty. Upon termination of the Guaranty, the Company anticipates recording a gain on extinguishment of debt in excess of \$8 million.

As of March 31, 2024, the outstanding borrowings under all tranches were €10.1 million (approximately \$10.9 million), including deferred interest payable at maturity of €1.6 million (approximately \$1.8 million).

Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was \$0 and \$617,298 for the three months ended March 31, 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.

Note 7 – Stockholders' equity

As of March 31, 2024, the Company had 100,000,000 shares of authorized common stock and 1,303,739 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 on November 30, 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 on May 9, 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 (see Note 11).

On January 11, 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 (the "Pre-funded Warrants"), (iii) Series A-1 common warrants to purchase an aggregate of 258,621 shares of common stock (the "Series A-1 Warrants"), and (iv) Series A-2 common warrants to purchase an aggregate of 258,621 shares of common stock (the "Series A-2 Warrants," and together with the Series A-1 Warrants, the "Common Warrants"). Each share of common stock and accompanying Common Warrants were sold at a price of \$29.00 per share and accompanying Common Warrants, and each Pre-funded Warrant and accompanying Common Warrants were sold at an offering price of \$28.90 per share underlying such Pre-funded Warrants and accompanying Common Warrants, for aggregate gross proceeds of approximately \$7.5 million before deducting the placement agent's fees and the offering expenses, and net proceeds of approximately \$6.9 million. The Common Warrants have an exercise price of \$26.50 per share. The Series A-1 Warrants were immediately exercisable upon issuance, and will expire five years following the issuance date. The Series A-2 Warrants were immediately exercisable upon issuance, and will expire eighteen months following the issuance date. Subject to certain ownership limitations described in the Pre-funded Warrants, the Pre-funded Warrants were immediately exercisable and could be exercised at a nominal consideration of \$0.10 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 15, 2023. In connection with the Company's best-efforts public offering consummated in May 2023, the Company amended the exercise price of the Common Warrants to \$7.785 per share.

On May 4, 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. As of March 31, 2024, 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 after March 31, 2024. Except for the extension of the offer period pursuant to the amendment agreements, the terms and conditions of the Inducement Agreement remain unchanged. Since the warrant inducement period was not extended beyond April 30, 2024, the Company is required to hold a stockholders' meeting to obtain approval for the exercisability of the existing common warrants within 70 days of the end of the extension period.

On October 11, 2023, the Company entered into a Preferred Stock Purchase Agreement (the “Purchase Agreement”) with a single investor (the “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 of the Private Placement to fund the Company’s operations while it pursued a potential strategic transaction with the Investor. Pursuant to the Purchase Agreement, the Company filed a certificate of designation (the “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 on October 11, 2023. The 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 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 on November 14, 2023. On December 13, 2023, in coordination with the Investor, the Company issued to the Investor 250 shares of Series D Preferred Stock in consideration for the partial payment. As of March 31, 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.

On October 12, 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. As of March 31, 2024, 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 after March 31, 2024. Except for the extension of the offer period pursuant to the amendment agreements, the terms and conditions of the Inducement Agreement remain unchanged. Since the warrant inducement period was not extended beyond April 30, 2024, the Company is required to hold a stockholders’ meeting to obtain approval for the exercisability of the existing common warrants within 70 days of the end of the extension period.

On March 25, 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. On March 25, 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 \$200,000 and \$150,000 on April 5, 2024 and April 23, 2024, respectively, in exchange for an additional 350,000 shares of Series E Preferred Stock. Mr. Lazar is expected to fund the remaining \$2.45 million in the third quarter of 2024, at which time he will receive the remaining 2.45 million shares of Series E Preferred Stock. Each share of Series E Preferred Stock is convertible into 2.4 shares of the Company’s common stock (“Common Stock”); provided, that, in no event, will the Series E Preferred Stock be convertible into Common Stock in a manner that would result in Mr. Lazar or his transferees or their affiliates holding more than the lesser of (i) 19.99% (together with any other shares of Common Stock otherwise held by them or their affiliates) and (ii) such lower percentage as may be required by applicable stock exchange rules 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 Mr. Lazar upon conversion of the Series E Preferred Stock. Such stockholder approval was obtained at the Company’s special meeting of stockholders held on May 9, 2024 (see Note 11). 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 Company settled outstanding liabilities amongst the parties. Pursuant to the settlement agreements and the March 2024 Purchase Agreement, following the final closing of transactions contemplated by the March 2024 Purchase Agreement, the Company will pay a total of \$2.0 million of the proceeds to settle all outstanding debt of the Company to EIB and Curetis. The settlement agreement 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. Upon termination of the Guarantee and Indemnity Agreement, the Company anticipates recording a gain on extinguishment of debt in excess of \$8 million.

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 March 31, 2024, 40,441 shares remain available for issuance under the 2015 Plan.

For the three months ended March 31, 2024 and 2023, the Company recognized share-based compensation expense as follows:

	Three months ended March 31,	
	2024	2023
Cost of services	\$ -	\$ -
Research and development	25,856	70,364
General and administrative	157,984	105,832
Sales and marketing	4,397	34,926
	<u>\$ 188,237</u>	<u>\$ 211,122</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 months ended March 31, 2024. During the three months ended March 31, 2024, 83 options were forfeited, and 88 options expired.

The Company had total stock options to acquire 9,453 shares of common stock outstanding at March 31, 2024 under all of its equity compensation plans.

Restricted stock units

The Company granted 21,053 restricted stock units during the three months ended March 31, 2024, 21,053 restricted stock units vested and 1,413 restricted stock units were forfeited. The Company had 6,913 total restricted stock units outstanding at March 31, 2024.

Stock purchase warrants

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

Issuance	Exercise Price	Expiration	Outstanding at	
			March 31, 2024 (1)	December 31, 2023 (1)
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	(2)	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 to purchase fractional shares of common stock resulting from the reverse stock splits effected on January 5, 2023 and May 20, 2024 were rounded up to the next whole share of common stock on a holder by holder basis.
- (2) 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 the various investment transactions, the Company entered into registration rights agreements with stockholders, pursuant to which the investors were granted certain demand registration rights and/or piggyback and/or resale registration rights in connection with subsequent registered offerings of the Company's common stock.

Note 9 – Leases

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

Lease Classification	March 31, 2024	December 31, 2023
ROU Assets:		
Operating	\$ -	\$ -
Financing	-	138
Total ROU assets	<u>\$ -</u>	<u>\$ 138</u>
Liabilities		
Current:		
Operating	\$ 154,117	\$ 147,943
Finance	-	280
Noncurrent:		
Operating	1,981,428	2,021,616
Finance	-	-
Total lease liabilities	<u>\$ 2,135,545</u>	<u>\$ 2,169,839</u>

Maturities of lease liabilities as of March 31, 2024 by fiscal year are as follows:

Maturity of Lease Liabilities	Operating	Finance	Total
2024 (April to December)	\$ 270,377	\$ -	\$ 270,377
2025	368,179	-	368,179
2026	378,279	-	378,279
2027	388,682	-	388,682
2028	399,388	-	399,388
Thereafter	1,338,300	-	1,338,300
Total lease payments	<u>3,143,205</u>	<u>-</u>	<u>3,143,205</u>
Less: Interest	(1,007,660)	-	(1,007,660)
Present value of lease liabilities	<u>\$ 2,135,545</u>	<u>\$ -</u>	<u>\$ 2,135,545</u>

Condensed consolidated statements of operations classification of lease costs as of the three months ended March 31, 2024 and 2023 are as follows:

Lease Cost	Classification	Three months ended March 31,	
		2024	2023
Operating	Operating expenses	\$ 58,496	\$ 137,797
Finance:			
Amortization	Operating expenses	138	829
Interest expense	Other expenses	-	-
Total lease costs		\$ 58,634	\$ 138,626

Other lease information as of March 31, 2024 is as follows:

Other Information	Total
Weighted average remaining lease term (in years)	
Operating leases	7.9
Finance leases	-
Weighted average discount rate:	
Operating leases	10.0%
Finance leases	-%

Supplemental cash flow information as of the three months ended March 31, 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	\$ 58,496	\$ 137,797
Finance leases	\$ -	\$ -
Cash used in financing activities		
Finance leases	\$ 280	\$ 841
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’ anti-infective portfolio.

Under the terms of the framework agreement, which had an initial term of 36 months and was subsequently extended to January 31, 2025, Ares Genetics and Sandoz 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

On February 18, 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 \$1,943 for the three months ended March 31, 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.

On September 20, 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”). On April 4, 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 by June 30, 2023. Following successful completion of the feasibility phase of the collaboration, including the additional deliverables, FIND and Curetis, on August 1, 2023, extended the research and development collaboration agreement through May 31, 2024, to include AMR assay and cartridge development, analytical testing, and software development for an additional €0.5 million (“Amendment 2”). During the three months ended March 31, 2024, the Company recognized \$0 related to the collaboration, bringing the total amount recognized through March 31, 2024 to \$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.

Effective April 1, 2024, the Company entered into a lease assignment agreement where the Company assigned, transferred, set over and conveyed to an assignee all its estate, right, title and interest in and to the lease at its Rockville, Maryland headquarters. The Company’s security deposit will remain with the landlord and be repaid over time as agreed upon with the 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.

On April 11, 2024, the Company entered into an Employment Agreement with David E. Lazar. Pursuant to the Employment Agreement, the Company engaged Mr. Lazar to act as its Chief Executive Officer (“CEO”). Mr. Lazar will have the customary powers and responsibilities of a CEO of a corporation of the size and type of the Company. Effective April 1, 2024, Mr. Lazar shall be paid a base salary of \$406,000 per annum, which shall be deferred and accrued until the Company’s compensation committee determines that the Company is sufficiently liquid to pay the accrued salary. Under the Agreement, Mr. Lazar will also be eligible for certain annual bonuses, annual incentive bonuses, and special bonuses. The Agreement has a three (3) year term. Mr. Lazar also serves as the Chairman of the Board of Directors of the Company.

On April 18, 2024, the Company received a notice from The Nasdaq Stock Market LLC (“Nasdaq”) stating that the Company was delinquent in filing its Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the “Form 10-K”) and was therefore not in compliance with Nasdaq Listing Rule 5250(c)(1). The notice indicated that such delinquency serves as an additional basis for delisting the Company’s securities in addition to the failure to comply with the Minimum Bid Price Rule described previously. In accordance with the notice, the Company submitted its response to the Nasdaq Hearings Panel regarding such delinquency and the Company’s plan to cure such delinquency by June 3, 2024, the additional period to regain compliance granted by such Nasdaq Hearings Panel. The Company filed its Form 10-K on June 3, 2024; however, no assurance can be given as to the final decision of the Nasdaq Hearings Panel regarding a delisting of the Company’s securities.

On April 22, 2024, UHY LLP (“UHY”), the Company’s then-current independent public accounting firm, notified the Company that UHY would resign as the Company’s auditor effective as of April 22, 2024. During the period of UHY’s engagement, which commenced in March 2023, UHY did not provide any report on the financial statements of the Company. During the fiscal years ended December 31, 2023 and 2022 and the subsequent interim period through April 22, 2024, there were no: (1) disagreements with UHY on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements, if not resolved to their satisfaction, would have caused them to make reference in connection with their opinion to the subject matter of the disagreement, or (2) reportable events under Item 304(a)(1)(v) of Regulation S-K. In light of such resignation, on April 23, 2024, the Company engaged Beckles & Co., Inc. (“Beckles”) to serve as the Company’s independent registered public accounting firm for the fiscal year ending December 31, 2023 and the three months ended March 31, 2024. The appointment of Beckles as the Company’s independent registered public accounting firm was approved by the Company’s Board of Directors.

On April 23, 2024, the Company entered into a letter agreement with Camtech Pte Ltd, a Singaporean family office (“Camtech”), for the sale of certain of the Company’s inventory and customer contracts for its Unyvero products. The transaction was entered into following the prior acquisition by Camtech in April 2024 of the assets from the Company’s subsidiary, Curetis GmbH (“Curetis”), as part of Curetis’ insolvency proceedings. The purchase price for the transaction is \$218,000, and the transaction closed in May 2024. As part of such letter agreement, the Company also offered Camtech the opportunity to purchase its remaining Unyvero inventory and assets for up to an additional \$176,000. Until such sale for the remaining inventory is completed, the Company will maintain commercial operations and service support for the Unyvero systems. The foregoing transactions are part of the Company’s planned exit from its Unyvero business, as the Company continues to seek strategic alternatives.

On May 9, 2024, the Company held a special meeting of stockholders (the “Special Meeting”). The Company’s stockholders voted on three proposals, each of which was described in the Company’s proxy statement for the Special Meeting dated May 9, 2024. At the Special Meeting, shares of the Company’s capital stock representing 14,795,642 votes out of a total of 26,435,902 votes of the Company’s capital stock, as of April 26, 2024, the record date for the Special Meeting, were represented in person or by proxy at the Special Meeting. All three of the following proposals were voted upon and approved at the Special Meeting. Proposal 1 approved (i) the issuance to David E. Lazar of the common stock issuable upon the conversion of the Company’s Series E Preferred Stock in excess of applicable beneficial ownership limitations, the issuance of which would result in a “change of control” under the rules of The Nasdaq Capital Market and (ii) an amendment of the Certificate of Designation for the Series E Preferred Stock removing such ownership limitations. Proposal 2 approved the amendment to the Company’s Amended and Restated Certificate of Incorporation, as amended (the “Charter”), to effect a reverse stock split at a ratio not less than two-to-one and not more than ten-to-one, such ratio and the implementation and timing of such reverse stock split to be determined in the discretion of our Board of Directors. Proposal 3 approved of an adjournment of the Special Meeting to a later date, if necessary or appropriate, to permit further solicitation and vote of proxies in the event that there are insufficient votes for, or otherwise in connection with, Proposals 1 and 2. Following the approval of the amendment of the Certificate of Designation, the Company filed the amendment with the Secretary of State of the State of Delaware on May 9, 2024. Except for the removal of the Ownership Limitation, the amendment does not make any other changes to the Certificate of Designation.

On May 16, 2024, the Company entered into an Amendment Agreement (the “Amendment Agreement”) with the European Investment Bank (the “EIB”) relating to the previously disclosed settlement agreement, dated March 25, 2024, by and between the Company and the EIB (the “Settlement Agreement”). As previously disclosed, in connection with the sale and issuance of shares of preferred stock of the Company to David E. Lazar (the “Private Placement”), the Company entered into the Settlement Agreement with the EIB, which provided, among other things, for the settlement of outstanding liabilities between the EIB, the Company and the Company’s subsidiary, Curetis GmbH (“Curetis”), and the termination of the Company’s guarantee of Curetis’ debt to EIB. Pursuant to the Settlement Agreement, the Company agreed to pay a portion of the proceeds (the “Settlement Amount”) of the Private Placement to the EIB upon the final closing of the Private Placement. As a result of the delay of the final closing of the Private Placement due to the delay in filing the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2023, the Company and the EIB entered into the Amendment Agreement in order to extend the timing for the payment of the Settlement Amount to June 3, 2024. As of the filing of this quarterly report on Form 10-Q for the three months ended March 31, 2024, the Settlement Amount remains unpaid. However, the Company and the EIB are in ongoing discussions and the Company anticipates paying the Settlement Amount in the third quarter of 2024.

On May 16, 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 will continue 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 Company filed an Amendment to the Company’s Amended and Restated Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware on May 17, 2024, and the Reverse Stock Split became effective in accordance with the terms of the Amendment on May 20, 2024 (the “Effective Time”). The Reverse Stock Split impacts all holders of OpGen’s common stock proportionally and will not impact any stockholders’ percentage ownership of common stock (except to the extent the Reverse Stock Split results in any stockholder owning a fractional share). No fractional shares will be issued in connection with the Reverse Stock Split. Stockholders of record who would otherwise be entitled to receive a fractional share will receive a whole share in lieu of the fractional share.

On May 20, 2024, the Company received a notice from The Nasdaq Stock Market LLC (“Nasdaq”) stating that the Company was delinquent in filing its Quarterly Report on Form 10-Q for the period ended March 31, 2024 (the “Form 10-Q”) and was therefore not in compliance with Nasdaq Listing Rule 5250(c)(1). The notice indicated that such delinquency serves as an additional basis for delisting the Company’s securities in addition to the failure to comply with the Minimum Bid Price Rule as well as the failure to timely file its Annual Report on Form 10-K for the fiscal year ended December 31, 2023. In accordance with the notice, the Company submitted its response to the Nasdaq Hearings Panel regarding such delinquency and the Company’s plan to cure such delinquency. On May 29, 2024, the Nasdaq Hearings Panel granted the Company’s request for continued listing subject to the Company filing its quarterly report on Form 10-Q by July 8, 2024. With the filing of this quarterly report on Form 10-Q on July 8, 2024, the Company believes it is in compliance with Nasdaq Listing Rule 5250(c)(1); however, no assurance can be given as to the final decision of the Nasdaq Hearings Panel regarding a delisting of the Company’s securities.

On June 5, 2024, the Nasdaq Hearings Panel notified the Company that it had regained compliance with the Minimum Bid Price Rule. As previously disclosed, the listing staff of The Nasdaq Stock Market LLC (“Nasdaq”) notified the Company on June 5, 2023 that the Company’s common stock had failed to maintain a minimum bid price of \$1.00 per share for the 30 consecutive business days preceding the date of such notice as required by Nasdaq Listing Rule 5550(a)(2) (the “Minimum Bid Price Rule”). In December 2023, the Company appealed such determination to a Nasdaq Hearings Panel, which in February 2024, granted the Company’s request for an additional period to regain compliance with the Minimum Bid Price Rule.

On June 5, 2024, the Company received a notice from Nasdaq stating that the Company is not in compliance with the minimum stockholders’ equity requirement for continued listing on Nasdaq. Nasdaq Listing Rule 5550(b)(1) requires companies listed on the Nasdaq Capital Market to maintain stockholders’ equity of at least \$2,500,000 or to meet the alternatives of market value of listed securities or net income from continuing operations. The notice indicated that such delinquency serves as an additional basis for delisting the Company’s securities from Nasdaq. In accordance with the notice, the Company submitted its response to the Nasdaq Hearings Panel on June 11, 2024 regarding such delinquency and the Company’s plan to cure such delinquency. As with the prior notices received by the Company, the most recent notice from Nasdaq has no immediate effect on the listing of the Company’s securities on The Nasdaq Capital Market. There can be no assurance that the Nasdaq Hearings Panel will grant the Company additional time to cure such deficiency or, if additional time is granted, that the Company will be able to regain compliance with the requirements for continued listing.

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. On April 1, 2020, OpGen completed its business combination transaction with Curetis N.V., a public company with limited liability under the laws of the Netherlands. As part of the transaction, 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”), and certain other assets and liabilities of Curetis GmbH including all its shares of Ares Genetics GmbH (“Ares Genetics”). From inception through November 2023, the Company 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.

During the year ended December 31, 2023, the Company implemented certain cash management initiatives, including restructuring its U.S. operations by reducing headcount from 24 to 5 and has since continued scaling down operations at OpGen’s U.S. headquarters to the core functions of a U.S. Nasdaq listed company with only minimal distribution, marketing, and sales support, allowing the Company to conserve cash and focus on the functions needed to pursue potential strategic alternatives. However, on November 6, 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. In April 2024, the insolvency administrator for Ares Genetics notified the Company that all of Ares Genetics’ assets were sold to bioMerieux S.A.

Since the insolvency filings and through the three months ended March 31, 2024, the Company continues to sell the Curetis Unyvero products to its existing customers in the United States via drop shipments from Curetis directly to customer locations. The Unyvero tests are sold to hospitals, laboratories, and public health organizations as products and on a fee-for-service basis. When hospital and health system clients purchase our products, we bill them directly for the purchase of test kits and consumables. As of March 31, 2024, OpGen had an installed base of approximately 28 Unyvero A50 Analyzers across the United States in different types of hospitals and laboratories, including installations for clinical studies. The sale of Ares Genetics’ related products and services was discontinued 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.

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. The focus of OpGen going forward under new leadership and a new Board of Directors will be on the sale of the Company or the identification of a privately held company to complete a reverse merger or similar strategic transaction.

On May 9, 2024, the Company held a special meeting of stockholders to vote on certain matters, including the removal of certain restrictions applicable to the voting of Mr. Lazar’s shares of Series E Preferred Stock. Following approval of the proposals at such special meeting, subject to limited exceptions, Mr. Lazar may vote his shares without restrictions.

Following receipt of approval from stockholders at a special meeting of stockholders held on November 30, 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. 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 on May 9, 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 the reverse stock split.

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. We generate product revenues from sales of our products, including through our distribution partners, such as our Unyvero instruments and consumables. We also generate revenue from sales by Ares Genetics of its AI-powered prediction models and solutions. Revenues generated from our laboratory services relate to services that we and our subsidiaries provide to customers. Lastly, our collaboration revenues consist of revenue received from research and development collaborations that we enter into with third parties, such as our collaboration agreement with FIND.

Cost of Products, Cost of Services, and Operating Expenses

Our cost of products consists 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 consist 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 March 31, 2024 and 2023

Revenues

	Three months ended March 31,	
	2024	2023
Product sales	\$ 141,373	\$ 410,897
Laboratory services	26,776	21,673
Collaboration revenue	-	480,874
Total revenue	<u>\$ 168,149</u>	<u>\$ 913,444</u>

Total revenue for the three months ended March 31, 2024 decreased approximately 82% when compared to the same period in 2023. This decrease is primarily attributable to:

- Product Sales: the decrease of approximately 66% in the 2024 period compared to the 2023 period 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;
- Laboratory Services: the increase of approximately 24% in the 2024 period compared to the 2023 period is primarily attributable to an increase in the number of AREScLOUD subscriptions sold by the Company in the 2024 period; and
- Collaboration Revenue: the decrease of 100% in the 2024 period compared to the 2023 period is due to the Company no longer being a party to the collaboration agreement with FIND as a result of the deconsolidation following Curetis' insolvency filing in 2023.

Operating expenses

	Three months ended March 31,	
	2024	2023
Cost of products sold	\$ 73,236	\$ 592,378
Cost of services	1,575	128,306
Research and development	25,856	1,812,831
General and administrative	1,642,054	2,423,953
Sales and marketing	128,646	1,026,087
Total operating expenses	<u>\$ 1,871,367</u>	<u>\$ 5,983,555</u>

Our total operating expenses for the three months ended March 31, 2024 decreased approximately 69% 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 March 31, 2024 decreased approximately 88% when compared to the same period in 2023. The decrease in cost of products sold aligns with the decrease in product sales in the first quarter of 2024. Additionally, cost of products sold was greater in the first quarter of 2023 due to increases in inventory reserves for obsolescence, expirations, and slow-moving inventory, whereas in the first quarter of 2024, all inventory had already been fully reserved;

- Cost of services: cost of services for the three months ended March 31, 2024 decreased approximately 99% when compared to the same period in 2023. The decrease in cost of services aligns with the decrease in collaboration revenue in the first quarter of 2024, which is due to the Company no longer being a party to the collaboration agreement with FIND as a result of the deconsolidation following Curetis' insolvency filing 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%, 32%, and 87%, respectively, for the three months ended March 31, 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 operations at the Company while it pursues a strategic transaction.

Other income (expense)

	Three months ended March 31,	
	2024	2023
Interest expense	\$ -	\$ (617,298)
Foreign currency transaction gains (losses)	281	(91,994)
Interest and other income, net	9	30,106
Gain on lease indemnification	2,135,545	-
Change in fair value of derivative financial instruments	-	12,694
Change in fair value of EIB loan guaranty	(46,584)	-
Total other income (expense)	\$ 2,089,251	\$ (666,492)

Our total other income (expense) for the three months ended March 31, 2024 increased to a net income of \$2.1 million from a net expense of \$0.7 million in the same period in 2023 primarily due to the Company's recording of a gain on lease indemnification of \$2.1 million in the first quarter of 2024. Effective April 1, 2024, the Company entered into a lease assignment agreement where the Company assigned the lease at its Rockville, Maryland headquarters to another tenant. 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 addition, the Company did not recognize interest expense for the three months ended March 31, 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 at each reporting date.

Liquidity and capital resources

As of March 31, 2024, we had cash and cash equivalents of \$0.3 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:

- On January 11, 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.

- On May 4, 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.
- On October 6, 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.
- On October 11, 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 on November 14, 2023. On December 13, 2023, in coordination with the investor, the Company issued to the investor 250 shares of Series D Preferred Stock in consideration for the partial payment. As of March 31, 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.
- On October 12, 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. As of March 31, 2024, 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 after March 31, 2024.
- On November 6, 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.
- On March 25, 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. On March 25, 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 \$200,000 and \$150,000 on April 5, 2024 and April 23, 2024, respectively, in exchange for an additional 350,000 shares of Series E Preferred Stock. Mr. Lazar is expected to fund the remaining \$2.45 million in the third quarter of 2024, at which time he will receive the remaining 2.45 million shares of Series E Preferred Stock.

Although Mr. Lazar is expected to provide the Company with \$3.0 million in total funding, the Company believes that current cash will only be sufficient to fund operations into the third quarter of 2024. This has led management to conclude that there is substantial doubt about the Company’s ability to continue as a going concern. In the event the Company does not receive additional funding from David E. Lazar or other investors or find a reverse merger partner or other strategic transaction partner before or during the third quarter of 2024, the Company will not have sufficient cash flows and liquidity to finance its business operations. Accordingly, in such circumstances, the Company would be compelled to immediately reduce general and administrative expenses until it is able to obtain sufficient financing. If such sufficient financing is not received on a timely basis, the Company would then need to pursue a plan to seek to be acquired by another entity, cease operations and/or seek bankruptcy protection. There can be no assurance that the Company will be able to identify or execute on any of these alternatives on acceptable terms or that any of these alternatives will be successful.

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

Sources and uses of cash

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

	Three months ended	
	March 31,	
	2024	2023
Net cash used in operating activities	\$ (1,084,050)	\$ (4,962,618)
Net cash used in investing activities	-	(330,446)
Net cash provided by financing activities	199,720	4,743,649

Net cash used in operating activities

Net cash used in operating activities for the three months ended March 31, 2024 consists primarily of our net income of \$0.4 million, noncash share-based compensation expense of \$0.2 million, and changes in operating assets and liabilities of \$0.4 million, reduced by certain other noncash items including gain on lease indemnification of \$2.1 million. Net cash used in operating activities for the three months ended March 31, 2023 consists primarily of our net loss of \$5.7 million, reduced by certain noncash items, including depreciation and amortization expense of \$0.4 million, noncash interest expense of \$0.5 million, change in inventory reserve of \$0.3 million, and share-based compensation expense of \$0.2 million.

Net cash used in investing activities

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

Net cash provided by financing activities

Net cash provided by financing activities for the three months ended March 31, 2024 consists of proceeds from the issuance of preferred stock in connection with the March 2024 Purchase Agreement with David E. Lazar, net of payments on the Company's finance lease obligations. Net cash provided by financing activities for the three months ended March 31, 2023 consists of proceeds from the issuance of common stock and warrants, net of issuance costs, in connection with the best-efforts public offering closed in January 2023, net of payments on the Company's debt to the EIB.

Contractual Commitments

Curetis has contractual commitments under its 2016 senior, unsecured loan financing facility of up to €25.0 million with the European Investment Bank ("EIB"). Following the consummation of the Company's business combination with Curetis in April 2020, the Company guaranteed Curetis' obligations under the loan financing facility. Curetis drew down three tranches under the facility: €10.0 million in April 2017, €3.0 million in June 2018, and €5.0 million in June 2019. The first tranche had, and second tranche has, a floating interest rate of EURIBOR plus 4% payable after each 12-month-period from the draw-down-date and an additional 6% interest per annum that is deferred and payable at maturity together with the principal. The third tranche originally had a 2.1% PPI. Upon maturity of the third tranche, the EIB would have been entitled to an additional payment that is equity-linked and equivalent to 2.1% of the then total valuation of Curetis N.V. As part of an amendment between the Company and the EIB on July 9, 2020, the parties adjusted the PPI percentage applicable to the third EIB tranche of €5.0 million, which was funded in June 2019, from its original 2.1% PPI in Curetis N.V.'s equity value upon maturity to a new 0.3% PPI in OpGen's equity value upon maturity. This right constitutes an embedded derivative, which is separated and measured at fair value with changes being accounted for through income or loss.

As of March 31, 2024, the outstanding borrowings under all tranches were €10.1 million (approximately \$10.9 million), including deferred interest payable at maturity of €1.6 million (approximately \$1.8 million).

On May 23, 2022, the Company and the EIB entered into a Waiver and Amendment Letter (the "2022 EIB Amendment"), which amended the EIB loan facility. The 2022 EIB Amendment restructured the first tranche of approximately €13.4 million (including accumulated and deferred interest) of the Company's indebtedness with the EIB. Pursuant to the 2022 EIB Amendment, the Company repaid €5.0 million to the EIB in April 2022. The Company also agreed, among other things, to amortize the remainder of the debt tranche over a twelve-month period beginning in May 2022. As a result, the Company paid twelve monthly installments totaling approximately €8.4 million through April 2023, at which point the first tranche was repaid in full. The 2022 EIB Amendment also provided for the increase of the PPI of the third tranche under the loan facility from 0.3% to 0.75% beginning in June 2024.

On July 4, 2023, the Company entered into a Standstill Agreement, by and among Curetis, as borrower, the Company and Ares Genetics, as guarantors, and the EIB, as lender, relating to that certain Finance Contract, originally dated December 12, 2016, as amended, by and between Curetis and EIB. Pursuant to the Standstill Agreement, the EIB agreed that, with respect to each default or event of default relating to €3 million in principal plus accumulated interest that (i) was due and payable on June 22, 2023 under the Finance Contract and (ii) continues to exist as of the date of the Standstill Agreement, the EIB would not take any action or exercise any right under the Finance Contract, including, but not limited to, any right of acceleration or termination, until the earlier of the entry into a definitive agreement for the restructuring of the second tranche and November 30, 2023. As a condition of entering into such standstill agreement, Curetis paid the EIB a partial payment of interest on the second tranche of €1 million on June 22, 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. On November 20, 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.

On December 4, 2023, the Company received a notice from the EIB stating that Curetis is 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 euro 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.

On March 25, 2024, in connection with the Company's entry into the March 2024 Purchase Agreement with David E. Lazar, the Company entered into settlement agreements with each of the EIB and Curetis' trustee in insolvency, pursuant to which the parties agreed to settle outstanding liabilities amongst the parties. Pursuant to the settlement agreements, following the final closing of the transactions contemplated by the March 2024 Purchase Agreement, the Company will pay a total of \$2.0 million of the proceeds to settle all outstanding debt of the Company to EIB and Curetis. The settlement agreement with the EIB also terminated the Guaranty. Upon termination of the Guaranty, the Company anticipates recording a gain on extinguishment of debt in excess of \$8 million.

On May 16, 2024, the Company entered into an Amendment Agreement with the EIB relating to the previously disclosed settlement agreement, dated March 25, 2024. As a result of the delay of the final closing of the Private Placement due to the delay in filing the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, the Company and the EIB entered into the Amendment Agreement in order to extend the timing for the payment of the Settlement Amount to June 3, 2024. As of the filing of this quarterly report on Form 10-Q for the three months ended March 31, 2024, the Settlement Amount remains unpaid. However, the Company and the EIB are in ongoing discussions and the Company anticipates paying the Settlement Amount in the third quarter of 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, share-based compensation, allowances for doubtful accounts and inventory obsolescence, 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.

Recently issued accounting pronouncements

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

Off-balance sheet arrangements

As of March 31, 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 has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of March 31, 2024. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

For the quarter ended March 31, 2024, 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.

On November 6, 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 administrator for each entity 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. 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. In April 2024, the insolvency administrator for Ares Genetics notified the Company that all of Ares Genetics' assets were sold to bioMerieux S.A.

Item 1A. Risk Factors

Reference is made to the Risk Factors included in our Annual Report on Form 10-K for the year ended December 31, 2023.

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
3.1	<u>Certificate of Designation of Preferences, Rights and Limitations of Series E Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 29, 2024).</u>
10.1	<u>Consulting Agreement, dated January 8, 2024, by and between OpGen, Inc. and Albert Weber (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 9, 2024).</u>
10.2	<u>Consulting Agreement, dated January 8, 2024, by and between OpGen, Inc. and Johannes Bacher (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on January 9, 2024).</u>
10.3	<u>Form of Second Amendment Agreement to Warrant Inducement Agreement, by and between the Company and the Holder (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 8, 2024).</u>
10.4	<u>Form of Securities Purchase Agreement, dated as of March 25, 2024, by and between the Company and David Lazar (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 29, 2024).</u>
10.5	<u>Settlement Agreement, dated March 25, 2024, by and between the European Investment Bank and the Company (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on March 29, 2024).</u>
10.6	<u>Agreement, dated March 25, 2024, by and between Insolvency Administrator for Curetis GmbH and the Company (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on March 29, 2024).</u>
10.7	<u>Form of Director Agreement (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on March 29, 2024).</u>
10.8	<u>Form of Inducement Offer to Amend Common Stock Purchase Warrants, dated March 26, 2024 (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed on March 29, 2024).</u>
31.1*	<u>Certification 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</u>
32.1*	<u>Certification pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
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 Income (Loss), (iii) the Unaudited Condensed Consolidated Statements of Stockholders' (Deficit) Equity, (iv) the Unaudited Condensed Consolidated Statements of Cash Flows and (v) 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/ David E. Lazar
David E. Lazar
Chief Executive Officer and Chairman
(principal executive officer, principal financial officer, and principal
accounting officer)

Date: July 8, 2024

**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. I am 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 my supervision, to ensure that material information relating to the registrant is made known to me 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 my 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 my 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. I have disclosed, based on my 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: July 8, 2024

/s/ David E. Lazar

David E. Lazar

Chief Executive Officer and Chairman (principal executive officer, 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 March 31, 2024 (the “Report”) as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer of the Company hereby certifies 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: July 8, 2024

By: /s/ David E. Lazar
David E. Lazar
Chief Executive Officer and Chairman
(principal executive officer, principal financial officer, and principal accounting officer)

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