

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

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2021

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.)

9717 Key West Avenue, Suite 100, Rockville, MD
(Address of principal executive offices)

20850
(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

38,950,250 shares of the Company's common stock, par value \$0.01 per share, were outstanding as of November 11, 2021.

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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 II Item 1A “Risk Factors.” In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances included herein may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to integrate the OpGen, Curetis, and Ares Genetics businesses;
- our ability to obtain the approval of our stockholders to increase the number of authorized shares of our common stock;
- the impact of COVID-19 on our business and operations;
- our liquidity and working capital requirements, including our cash requirements over the next 12 months;
- our use of proceeds from capital financing transactions;
- the completion of our development efforts for our Unyvero UTI and IJI panels, Unyvero A30 RQ platform and ARESdb and the timing of regulatory submissions;
- our ability to obtain regulatory clearance for and commercialize our product and services offerings;
- our ability to establish a market for and sell our Acuitas AMR Gene Panel test for use with bacterial isolates;
- our ability to sustain or grow our customer base for our Unyvero IVD products as well as our current research use only products;
- regulations and changes in laws or regulations applicable to our business, including regulation by the FDA, European Union, including pending IVDR requirements, and China’s NMPA;
- anticipated trends and challenges in our business and the competition that we face;
- the execution of our business plan and our growth strategy;
- our expectations regarding the size of and growth in potential markets;
- our opportunity to successfully enter into new collaborative or strategic agreements;
- our ability to maintain compliance with the ongoing listing requirements for the Nasdaq Capital Market;
- compliance with the U.S. and international regulations applicable to our business; and
- our expectations regarding future revenue and expenses.

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

NOTE REGARDING TRADEMARKS

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

Part I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

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

	September 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 25,352,337	\$ 13,360,463
Accounts receivable, net	751,065	653,104
Inventory, net	1,356,912	1,485,986
Prepaid expenses and other current assets	2,319,939	1,388,090
Total current assets	29,780,253	16,887,643
Property and equipment, net	4,290,204	3,259,487
Finance lease right-of-use assets, net	141,387	449,628
Operating lease right-of-use assets	1,885,025	2,082,300
Goodwill	7,606,071	8,024,729
Intangible assets, net	15,050,387	16,580,963
Strategic inventory	2,974,992	1,686,342
Other noncurrent assets	560,599	779,953
Total assets	\$ 62,288,918	\$ 49,751,045
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,146,895	\$ 1,868,666
Accrued compensation and benefits	1,342,013	2,126,511
Accrued liabilities	1,329,983	1,437,141
Deferred revenue	—	9,808
Current maturities of long-term debt	14,668,424	699,000
Short-term finance lease liabilities	68,831	266,470
Short-term operating lease liabilities	610,336	964,434
Total current liabilities	19,166,482	7,372,030
Long-term debt, net	6,484,300	19,378,935
Long-term finance lease liabilities	7,869	46,794
Long-term operating lease liabilities	2,953,615	1,492,544
Derivative liabilities	225,395	112,852
Other long-term liabilities	152,405	156,635
Total liabilities	28,990,066	28,559,790
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, \$0.01 par value; 10,000,000 shares authorized; none issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.01 par value; 50,000,000 shares authorized; 38,270,250 and 25,085,534 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	382,703	250,855
Additional paid-in capital	260,244,997	219,129,045
Accumulated deficit	(228,729,675)	(200,735,827)
Accumulated other comprehensive income	1,400,827	2,547,182
Total stockholders' equity	33,298,852	21,191,255
Total liabilities and stockholders' equity	\$ 62,288,918	\$ 49,751,045

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenue				
Product sales	\$ 643,887	\$ 601,562	\$ 1,479,270	\$ 1,569,799
Laboratory services	192,753	112,892	643,602	138,884
Collaboration revenue	402,492	342,311	757,591	1,153,400
Total revenue	1,239,132	1,056,765	2,880,463	2,862,083
Operating expenses				
Cost of products sold	648,298	1,350,296	1,544,932	2,340,766
Cost of services	203,314	159,794	446,232	550,115
Research and development	2,382,303	2,433,553	8,055,384	6,630,134
General and administrative	2,088,226	2,356,413	7,444,138	6,549,432
Sales and marketing	1,003,577	932,671	2,705,378	2,258,980
Transaction costs	—	—	—	470,322
Impairment of right-of-use asset	—	—	170,714	—
Impairment of intangibles assets	—	—	—	750,596
Total operating expenses	6,325,718	7,232,727	20,366,778	19,550,345
Operating loss	(5,086,586)	(6,175,962)	(17,486,315)	(16,688,262)
Other (expense) income				
Gain on extinguishment of debt	—	—	259,353	—
Warrant inducement expense	—	—	(7,755,541)	—
Interest and other income, net	31,844	19,965	41,471	101,644
Interest expense	(1,222,867)	(1,183,927)	(3,586,018)	(2,267,085)
Foreign currency transaction (losses) gains	229,074	(501,168)	655,774	(794,832)
Change in fair value of derivative financial instruments	(8,161)	165,497	(122,572)	548,008
Total other (expense) income	(970,110)	(1,499,633)	(10,507,533)	(2,412,265)
Loss before income taxes	(6,056,696)	(7,675,595)	(27,993,848)	(19,100,527)
Provision for income taxes	—	—	—	—
Net loss	\$ (6,056,696)	\$ (7,675,595)	\$ (27,993,848)	\$ (19,100,527)
Net loss available to common stockholders	\$ (6,056,696)	\$ (7,675,595)	\$ (27,993,848)	\$ (19,100,527)
Net loss per common share - basic and diluted	\$ (0.16)	\$ (0.40)	\$ (0.79)	\$ (1.36)
Weighted average shares outstanding - basic and diluted	38,270,250	19,116,864	35,373,397	14,016,896
Net loss	\$ (6,056,696)	\$ (7,675,595)	\$ (27,993,848)	\$ (19,100,527)
Other comprehensive income (loss) - foreign currency translation	(597,527)	1,266,901	(1,146,355)	1,631,317
Comprehensive loss	\$ (6,654,223)	\$ (6,408,694)	\$ (29,140,203)	\$ (17,469,210)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Common Stock		Preferred Stock		Additional Paid- in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount				
Balances at December 31, 2019	5,582,280	\$ 55,823	—	\$ —	\$ 178,779,814	\$ (17,315)	\$ (174,524,983)	\$ 4,293,339
At the market offering, net of offering costs	2,814,934	28,149	—	—	5,449,283	—	—	5,477,432
Common stock warrant exercises	4,071,000	40,710	—	—	8,101,290	—	—	8,142,000
Stock compensation expense	—	—	—	—	79,740	—	—	79,740
Foreign currency translation	—	—	—	—	—	39,477	—	39,477
Net loss	—	—	—	—	—	—	(3,949,294)	(3,949,294)
Balances at March 31, 2020	12,468,214	124,682	—	—	192,410,127	22,162	(178,474,277)	14,082,694
At the market offering, net of offering costs	2,739,442	27,394	—	—	5,870,807	—	—	5,898,201
Shares issued in business combination	2,028,208	20,282	—	—	4,827,135	—	—	4,847,417
Value of equity awards assumed in business combination	—	—	—	—	136,912	—	—	136,912
Issuance of RSUs	5,166	52	—	—	(52)	—	—	—
Shares issued to settle convertible notes	452,902	4,529	—	—	875,903	—	—	880,432
Stock compensation expense	—	—	—	—	33,587	—	—	33,587
Foreign currency translation	—	—	—	—	—	324,939	—	324,939
Net loss	—	—	—	—	—	—	(7,475,638)	(7,475,638)
Balances at June 30, 2020	17,693,932	176,939	—	—	204,154,419	347,101	(185,949,915)	18,728,544
At the market offering, net of offering costs	1,523,663	15,237	—	—	3,591,793	—	—	3,607,030
Common stock warrant exercises	270,000	2,700	—	—	537,000	—	—	540,000
Issuance of RSUs	750	7	—	—	(7)	—	—	—
Shares issued to settle convertible notes	311,003	3,110	—	—	567,255	—	—	570,365
Stock compensation expense	—	—	—	—	41,703	—	—	41,703
Foreign currency translation	—	—	—	—	—	1,266,901	—	1,266,901
Net loss	—	—	—	—	—	—	(7,675,595)	(7,675,595)
Balances at September 30, 2020	19,799,438	\$ 197,993	—	\$ —	\$ 208,892,463	\$ 1,614,002	\$ (193,625,510)	\$ 17,078,948
Balances at December 31, 2020	25,085,534	\$ 250,855	—	\$ —	\$ 219,129,045	\$ 2,547,182	\$ (200,735,827)	\$ 21,191,255
Offering of common stock and warrants, net of issuance costs	8,333,333	83,334	—	—	23,390,628	—	—	23,473,962
Inducement expense related to warrant reprice	—	—	—	—	7,755,541	—	—	7,755,541
Common stock warrant exercises, net of issuance costs	4,847,615	48,476	—	—	9,045,696	—	—	9,094,172
Proceeds from issuance of common stock warrants	—	—	—	—	255,751	—	—	255,751
Stock compensation expense	—	—	—	—	189,670	—	—	189,670
Foreign currency translation	—	—	—	—	—	(1,078,479)	—	(1,078,479)
Net loss	—	—	—	—	—	—	(14,850,591)	(14,850,591)
Balances at March 31, 2021	38,266,482	382,665	—	—	259,766,331	1,468,703	(215,586,418)	46,031,281
Issuance of RSUs	3,768	38	—	—	(38)	—	—	—
Stock compensation expense	—	—	—	—	261,548	—	—	261,548
Foreign currency translation	—	—	—	—	—	529,651	—	529,651
Net loss	—	—	—	—	—	—	(7,086,561)	(7,086,561)
Balances at June 30, 2021	38,270,250	382,703	—	—	260,027,841	1,998,354	(222,672,979)	39,735,919
Stock compensation expense	—	—	—	—	217,156	—	—	217,156
Foreign currency translation	—	—	—	—	—	(597,527)	—	(597,527)
Net loss	—	—	—	—	—	—	(6,056,696)	(6,056,696)
Balances at September 30, 2021	38,270,250	\$ 382,703	—	\$ —	\$ 260,244,997	\$ 1,400,827	\$ (228,729,675)	\$ 33,298,852

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine months ended September 30,	
	2021	2020
Cash flows from operating activities		
Net loss	\$ (27,993,848)	\$ (19,100,527)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	2,107,323	1,622,922
Noncash interest expense	2,967,775	1,714,543
Noncash interest income	—	(87,233)
Stock compensation expense	668,374	155,030
Gain on extinguishment of debt	(259,353)	—
Inducement expense related to warrant reprice	7,755,541	—
Change in fair value of derivative liabilities	122,572	(548,008)
Impairment of right-of-use asset	170,714	—
Impairment of intangible assets	—	750,596
Changes in operating assets and liabilities, net of acquisition		
Accounts receivable	(118,755)	649,079
Inventory	(1,891,760)	(348,484)
Other assets	(353,371)	754,484
Accounts payable	(667,480)	(1,037,810)
Accrued compensation and other liabilities	(188,322)	(166,753)
Deferred revenue	(9,808)	(816,006)
Net cash used in operating activities	(17,690,398)	(16,458,167)
Cash flows from investing activities		
Acquisition of business, net of cash acquired of \$1,266,849	—	1,266,849
Note receivable	—	(2,200,000)
Purchases of property and equipment	(1,824,765)	(2,455)
Net cash used in investing activities	(1,824,765)	(935,606)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	—	14,982,663
Proceeds from issuance of common stock warrants	255,751	—
Proceeds from issuance of common stock and pre-funded warrants in registered offering, net of selling costs	23,473,962	—
Proceeds from the exercise of common stock warrants, net of issuance costs	9,094,172	8,682,000
Proceeds from debt, net of issuance costs	—	1,871,308
Payment of deferred offering costs	(108,794)	—
Payments on debt	(441,076)	(853,063)
Payments on finance lease obligations	(236,563)	(467,592)
Net cash provided by financing activities	32,037,452	24,215,316
Effects of exchange rates on cash	(727,477)	1,066,898
Net increase in cash and cash equivalents and restricted cash	11,794,812	7,888,441
Cash and cash equivalents and restricted cash at beginning of period	14,107,255	2,893,603
Cash and cash equivalents and restricted cash at end of period	\$ 25,902,067	\$ 10,782,044
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 886,796	\$ 118,540
Supplemental disclosures of noncash operating, investing, and financing activities		
Right-of-use assets acquired through operating leases	\$ 748,294	\$ —
Inventory transferred to property and equipment	\$ 559,230	\$ —
Shares issued in business combination	\$ —	\$ 4,847,417
Shares issued to settle convertible notes	\$ —	\$ 1,450,797

See accompanying notes to unaudited condensed consolidated financial statements.

OpGen, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements
September 30, 2021

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 (“Purchaser”). Pursuant to the Implementation Agreement, the Purchaser acquired all of the shares of Curetis GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany (“Curetis GmbH”), and certain other assets and liabilities of the Seller (together, “Curetis”) (see Note 4). References in this report to the “Company” include OpGen and its wholly-owned subsidiaries. The Company’s headquarters are in Rockville, Maryland and the Company’s principal operations are in Rockville, Maryland; Holzgerlingen and Bodelshausen, Germany; and Vienna, Austria. The Company operates in one business segment.

OpGen Overview

OpGen is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. The Company is developing and commercializing molecular microbiology solutions helping to guide clinicians with more rapid and actionable information about life threatening infections to improve patient outcomes and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. OpGen’s current product portfolio includes Unyvero, Acuitas AMR Gene Panel and Acuitas Lighthouse, and the ARES Technology Platform including ARESdb, using NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit.

Following its initial announcement in October 2020, the Company discontinued its QuickFISH and PNA FISH product portfolio in its entirety as of June 30, 2021 (see Note 11). The Company’s FISH customers and distribution partners have been informed accordingly and last orders were received and processed in the first quarter of 2021. The discontinuance of these product lines did not qualify for discontinued operations reporting.

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

Note 2 – Going Concern and Management’s Plans

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

- On October 18, 2021, the Company closed a registered direct offering (the “October 2021 Offering”) with a single healthcare-focused institutional investor of 150,000 shares of convertible preferred stock and warrants to purchase up to an aggregate of 7,500,000 shares of common stock. The shares of preferred stock have a stated value of \$100 per share and are convertible into an aggregate of 7,500,000 shares of common stock at a conversion price of \$2.00 per share at any time after the Company has received stockholder approval to increase the number of authorized shares of common stock of the Company. The warrants have an exercise price of \$2.05 per share, will become exercisable on the later of the date of such stockholder approval and six months following the date of issuance, and will expire five years following the initial exercise date. The October 2021 Offering raised aggregate net proceeds of \$13.9 million, and gross proceeds of \$15.0 million.

- On March 9, 2021, the Company entered into a Warrant Exercise Agreement (the “Exercise Agreement”) with the institutional investor (the “Holder”) from our 2020 PIPE financing (see discussion below for a description of the 2020 PIPE). Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of the remaining 4,842,615 outstanding warrants acquired in the 2020 PIPE (the “Existing Warrants”) for cash, pursuant to the terms of and subject to beneficial ownership limitations contained in the Existing Warrants, the Company agreed to issue to the Holder new warrants (the “New Warrants”) to purchase 0.65 shares of common stock for each share of common stock issued upon such exercise of the Existing Warrants pursuant to the Exercise Agreement or an aggregate of 3,147,700 New Warrants. The terms of the New Warrants are substantially similar to those of the Existing Warrants, except that the New Warrants have an exercise price of \$3.56. The New Warrants are immediately exercisable and will expire five years from the date of the Exercise Agreement. The Holder paid an aggregate of \$255,751 to the Company for the purchase of the New Warrants. The Company received aggregate gross proceeds before expenses of approximately \$9.65 million from the exercise of the remaining Existing Warrants held by the Holder and the payment of the purchase price for the New Warrants (together, the “2021 Warrant Exercise”). As additional compensation, A.G.P./Alliance Global Partners, the Company’s placement agent for such warrant exchange, will receive a cash fee equal to \$200,000 upon the cash exercise in full of the New Warrants.
- On February 11, 2021, the Company closed a registered direct offering (the “February 2021 Offering”) with a single U.S.-based, healthcare-focused institutional investor for the purchase of (i) 2,784,184 shares of common stock and (ii) 5,549,149 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock. The Company also issued to the investor, in a concurrent private placement, unregistered common share purchase warrants to purchase 4,166,666 shares of the Company’s common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of \$3.00, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of \$2.99. The pre-funded warrants were immediately exercisable, at an exercise price of \$0.01, and could be exercised at any time until all of the pre-funded warrants are exercised in full. The common warrants have an exercise price of \$3.55 per share, are exercisable commencing on the six-month anniversary of the date of issuance, and will expire five and one-half (5.5) years from the date of issuance. The February 2021 Offering raised aggregate net proceeds of \$23.5 million, and gross proceeds of \$25.0 million. As of September 30, 2021, all 5,549,149 pre-funded warrants issued in the February 2021 Offering have been exercised.
- On November 25, 2020, the Company closed a private placement (the “2020 PIPE”) with one healthcare-focused U.S. institutional investor for the purchase of (i) 2,245,400 shares of common stock, (ii) 4,842,615 warrants to purchase shares of common stock and (iii) 2,597,215 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of \$2.065, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of \$2.055. The common warrants have an exercise price of \$1.94 per share, and are exercisable commencing on the six-month anniversary of the date of issuance, and will expire five and one-half (5.5) years from the date of issuance. The 2020 PIPE raised aggregate net proceeds of \$9.3 million, and gross proceeds of \$10.0 million. As of December 31, 2020, all 2,597,215 pre-funded warrants issued in the 2020 PIPE have been exercised.
- On February 11, 2020, the Company entered into an At the Market Common Offering (the “ATM Agreement”) with H.C. Wainwright & Co., LLC (“Wainwright”), which was amended and restated on November 13, 2020 to add BTIG, LLC (“BTIG”), pursuant to which the Company may offer and sell from time to time in an “at the market offering”, at its option, up to an aggregate of \$22.1 million of shares of the Company’s common stock through the sales agents (the “2020 ATM Offering”). During the year ended December 31, 2020, the Company sold 7,521,610 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately \$15.8 million, and gross proceeds of \$16.7 million. Since January 1, 2021, the Company sold 680,000 shares of its common stock under the 2020 ATM Offering, all of which were sold subsequent to September 30, 2021, resulting in aggregate net proceeds to the Company of approximately \$1,500,000, and gross proceeds of approximately \$1,548,000.

To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, strategic financings or other transactions, additional equity financings, debt financings and other funding transactions, licensing and/or partnering arrangements. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. The Company believes that current cash, including the October 2021 Offering, will be sufficient to repay or refinance the current portion of the Company’s debt and fund operations into the fourth quarter of 2022. This has led management to conclude that there is substantial doubt about the Company’s ability to continue as a going concern. In the event the Company is unable to successfully raise additional capital during or before the end of the fourth quarter of 2022, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances, the Company would be compelled to immediately reduce general and administrative expenses and delay research and development projects, pause or abort clinical trials including the purchase of scientific equipment and supplies, until it is able to obtain sufficient financing. If such sufficient financing is not received on a timely basis, the Company would then need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

Note 3 – Summary of Significant Accounting Policies

Basis of presentation and consolidation

The Company has prepared the accompanying unaudited condensed consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”) and the standards of accounting measurement set forth in the Interim Reporting Topic of the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”). Certain information and note disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) have been condensed or omitted, although the Company believes that the disclosures made are adequate to make the information not misleading. The Company recommends that the unaudited condensed consolidated financial statements be read in conjunction with the audited consolidated financial statements and the notes thereto included in the Company’s latest Annual Report on Form 10-K. In the opinion of management, all adjustments that are necessary for a fair presentation of the Company’s financial position for the periods presented have been reflected. All adjustments are of a normal, recurring nature, unless otherwise stated. The interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2020 consolidated balance sheet included herein was derived from the audited consolidated financial statements, but does not include all disclosures including notes required by GAAP for complete financial statements.

The accompanying unaudited condensed consolidated financial statements include the accounts of OpGen and its wholly-owned subsidiaries as of September 30, 2021 including Curetis GmbH and subsidiaries acquired on April 1, 2020; all intercompany transactions and balances have been eliminated.

Foreign currency

The Company has subsidiaries located in Holzgerlingen, Germany; Vienna, Austria; and Copenhagen, Denmark, each of which use currencies other than the U.S. dollar as their functional currency. As a result, all assets and liabilities are translated into U.S. dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at the average exchange rates prevailing during the reporting period. Translation adjustments are reported in accumulated other comprehensive income, a component of stockholders’ equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive income at September 30, 2021 and December 31, 2020.

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

Use of estimates

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

Fair value of financial instruments

Financial instruments classified as current assets and liabilities (including cash and cash equivalents, receivables, accounts payable, 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 exceed the Federal Deposit Insurance Corporation (“FDIC”) insured limit of \$250,000. The Company has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk.

At September 30, 2021 and December 31, 2020, the Company had funds totaling \$549,730 and \$746,792, respectively, which are required as collateral for letters of credit benefiting its landlords and for credit card processors. These funds are reflected in other noncurrent assets on the accompanying unaudited condensed consolidated balance sheets.

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Cash and cash equivalents	\$ 25,352,337	\$ 13,360,463	\$ 10,488,072	\$ 2,708,223
Restricted cash	549,730	746,792	293,972	185,380
Total cash and cash equivalents and restricted cash in the condensed consolidated statements of cash flows	<u>\$ 25,902,067</u>	<u>\$ 14,107,255</u>	<u>\$ 10,782,044</u>	<u>\$ 2,893,603</u>

Accounts receivable

The Company's accounts receivable result from revenues earned but not yet collected from customers. Credit is extended based on an evaluation of a customer's financial condition and, generally, collateral is not required. Accounts receivable are due within 30 to 90 days and are stated at amounts due from customers. The Company evaluates if an allowance is necessary by considering a number of factors, including the length of time accounts receivable are past due, the Company's previous loss history and the customer's current ability to pay its obligation. If amounts become uncollectible, they are charged to operations when that determination is made. The allowance for doubtful accounts was \$0 and \$20,753 as of September 30, 2021 and December 31, 2020, respectively.

At September 30, 2021, the Company had accounts receivable from three customers which individually represented 28%, 15% and 11% of total accounts receivable, respectively. At December 31, 2020, the Company had accounts receivable from one customer which individually represented 20% of total accounts receivable. For the three months ended September 30, 2021, revenue earned from two customers represented 20% and 17% of total revenues, respectively. For the three months ended September 30, 2020, revenue earned from one customer represented 33% of total revenues. For the nine months ended September 30, 2021, revenue earned from three customers represented 19%, 15%, and 10% of total revenues, respectively. For the nine months ended September 30, 2020, revenue earned from two customers represented 29% and 11% of total revenues, respectively.

Inventory

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Raw materials and supplies	\$ 850,402	\$ 773,021
Work-in-process	58,217	87,159
Finished goods	3,423,285	2,312,148
Total	<u>\$ 4,331,904</u>	<u>\$ 3,172,328</u>

Inventory includes Unyvero instrument systems, Unyvero cartridges, reagents and components for Unyvero, Acuitas, Curetis SARS-CoV-2 test kits, and reagents and supplies used for the Company's laboratory services. Inventory reserves for obsolescence and expirations were \$67,248 and \$288,378 at September 30, 2021 and December 31, 2020, respectively.

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

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

Long-lived assets

Property and equipment

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the three and nine months ended September 30, 2021 and 2020, the Company determined that its property and equipment were not impaired.

Leases

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

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

ROU assets

ROU assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which the Company can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the nine months ended September 30, 2021, the Company determined that the ROU asset associated with its San Diego, California office lease may not be recoverable. As a result, during the three and nine months ended September 30, 2021, the Company recorded an impairment charge of \$0 and \$170,714, respectively.

Intangible assets and goodwill

Intangible assets and goodwill as of September 30, 2021 consist of finite-lived and indefinite-lived intangible assets and goodwill.

Finite-lived and indefinite-lived intangible assets

Intangible assets include trademarks, developed technology, In-Process Research & Development, software and customer relationships and consisted of the following as of September 30, 2021 and December 31, 2020:

	Subsidiary	Cost	September 30, 2021			December 31, 2020			
			Accumulated Amortization	Effect of Foreign Exchange Rates	Net Balance	Accumulated Amortization	Impairment	Effect of Foreign Exchange Rates	Net Balance
Trademarks and tradenames	AdvanDx	\$ 461,000	\$ —	\$ —	\$ —	\$ (217,413)	\$ (243,587)	\$ —	\$ —
Developed technology	AdvanDx	458,000	—	—	—	(308,526)	(149,474)	—	—
Customer relationships	AdvanDx	1,094,000	—	—	—	(736,465)	(357,535)	—	—
Trademarks and tradenames	Curetis	1,768,000	(277,723)	83,469	1,573,746	(147,161)	—	194,119	1,814,958
Distributor relationships	Curetis	2,362,000	(247,356)	111,511	2,226,155	(131,070)	—	259,336	2,490,266
A50 - Developed technology	Curetis	349,000	(78,326)	16,477	287,151	(41,504)	—	38,319	345,815
Ares - Developed technology	Curetis	5,333,000	(598,360)	251,772	4,986,412	(317,060)	—	585,536	5,601,476
A30 - In-Process Research & Development	Curetis	5,706,000	—	270,923	5,976,923	—	—	622,448	6,328,448
		<u>\$17,531,000</u>	<u>\$(1,201,765)</u>	<u>\$ 734,152</u>	<u>\$15,050,387</u>	<u>\$(1,899,199)</u>	<u>\$(750,596)</u>	<u>\$1,699,758</u>	<u>\$16,580,963</u>

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

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

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

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

Total amortization expense of intangible assets was \$212,829 and \$205,026 for the three months ended September 30, 2021 and 2020, respectively. Total amortization expense of intangible assets was \$615,471 and \$464,689 for the nine months ended September 30, 2021 and 2020, respectively. Expected future amortization of intangible assets is as follows:

Year Ending December 31,	
2021 (Three months)	\$ 200,294
2022	801,174
2023	801,174
2024	801,174
2025	801,174
2026	801,174
Thereafter	4,867,300
Total	<u>\$ 9,073,464</u>

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

In accordance with ASC 360-10, *Property, Plant and Equipment*, the Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that long-lived assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. During the nine months ended September 30, 2021, the Company determined that its finite-lived intangible assets were not impaired. During the nine months ended September 30, 2020, events and circumstances indicated the Company’s FISH intangible assets might be impaired. These circumstances included decreased product sales related to the COVID-19 pandemic and the loss of significant customers. Management’s updated estimate of undiscounted cash flows indicated that such carrying amounts were no longer expected to be recovered and that the

FISH intangible assets were impaired. The Company's analysis determined that the fair value of the assets was \$0 and the Company recorded an impairment loss of \$750,596.

Goodwill

Goodwill represents the excess of the purchase price paid when the Company acquired AdvanDx, Inc. in July 2015 and Curetis in April 2020, over the fair values of the acquired tangible or intangible assets and assumed liabilities. Goodwill is not tax deductible in any relevant jurisdictions. The Company's goodwill balance as of September 30, 2021 and December 31, 2020 was \$7,606,071 and \$8,024,729, respectively.

The changes in the carrying amount of goodwill as of September 30, 2021, and since December 31, 2020, were as follows:

Balance as of December 31, 2020	\$	8,024,729
Changes in currency translation		(418,658)
Balance as of September 30, 2021	\$	<u>7,606,071</u>

The Company conducts an impairment test of goodwill on an annual basis, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company's fair value below its net equity value. During the nine months ended September 30, 2021 and 2020, the Company determined that its goodwill was not impaired.

Revenue recognition

The Company derives revenues from (i) the sale of diagnostic test products, Unyvero Application cartridges, Unyvero Systems, SARS-CoV-2 tests, Acuitas AMR Gene Panel test products, (ii) providing laboratory services, and (iii) providing collaboration services including funded software arrangements, and license arrangements.

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

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

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

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

Research and development costs

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

Government grant agreements and research incentives

From time to time, the Company may enter into arrangements with governmental entities for the purposes of obtaining funding for research and development activities. The Company recognizes funding from grants and research incentives received from Austrian government agencies in the condensed consolidated statements of operations and comprehensive loss in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants or incentives were provided have been met. For grants under funding agreements and for proceeds under research incentive programs, the Company recognizes grant and incentive income in an amount equal to the estimated qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage. The Company classifies government grants received under these arrangements as a reduction to the related research and development expense incurred. The Company analyzes each arrangement on a case-by-case basis. For the three months ended September 30, 2021, the Company recognized \$190,911 as a reduction of research and development expense related to government grant arrangements. For the nine months ended September 30, 2021, the Company recognized \$564,983 as a reduction of research and development expense related to government grant arrangements. There were no grant proceeds recognized for the three and nine months ended September 30, 2020. The Company had earned but not yet received \$896,799 and \$413,530 related to these agreements and incentives included in prepaid expenses and other current assets, as of September 30, 2021 and December 31, 2020, respectively.

Stock-based compensation

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

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

Income taxes

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

Tax benefits are initially recognized in the condensed consolidated financial statements when it is more likely than not that 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 \$196,511,928 and \$188,282,298 at December 31, 2020 and 2019, respectively. Despite the NOL carryforwards, which begin to expire in 2022, the Company may have state tax requirements. Also, use of the NOL carryforwards may be subject to an annual limitation as provided by Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”). To date, the Company has not performed a formal study to determine if any of its remaining NOL and credit attributes might be further limited due to the ownership change rules of Section 382 or Section 383 of the Code. The Company will continue to monitor this matter going forward. There can be no assurance that the NOL carryforwards will ever be fully utilized.

The Company also has foreign NOL carryforwards of \$160,540,528 at December 31, 2020 from its foreign subsidiaries. \$138,576,755 of those foreign NOL carryforwards are from the Company’s operations in Germany. Despite the NOL carryforwards, the Company may have a current and future tax liability due to the nuances of German tax law around the use of NOL’s within a consolidated group. There is no assurance that these foreign NOL carryforwards will ever be fully utilized.

Loss per share

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

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

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. The number of anti-dilutive shares, consisting of (i) common stock options, (ii) stock purchase warrants, and (iii) restricted stock units representing the right to acquire shares of common stock which have been excluded from the computation of diluted loss per share, was 10.7 million shares and 2.2 million shares as of September 30, 2021 and 2020, respectively.

Adopted accounting pronouncements

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*, which removes certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period, the recognition of deferred tax liabilities for outside basis differences and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The Company adopted ASU 2019-12 on January 1, 2021. The impact of adopting ASU 2019-12 did not have a material impact on the Company's condensed consolidated financial statements.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. The new guidance under ASU 2020-04 provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships and other transactions affected by reference rate reform if certain criteria are met. The amendments apply only to contracts and hedging relationships that reference LIBOR or another reference rate expected to be discontinued due to reference rate reform. These amendments are effective immediately and may be applied prospectively to contract modifications made and hedging relationships entered into or evaluated on or before December 31, 2022. The impact of adopting ASU 2020-04 did not have a material impact on the Company's condensed consolidated financial statements.

Recently issued accounting standards

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

Note 4 – Business Combination

On April 1, 2020, the Company completed its business combination transaction with Curetis N.V., a public company with limited liability under the laws of the Netherlands, as contemplated by the Implementation Agreement, dated as of September 4, 2019, 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. Pursuant to the Implementation Agreement, the Purchaser acquired all of the shares of Curetis GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany, and certain other assets and liabilities of the Seller, as further described below, and paid, as the sole consideration, 2,028,208 shares of the Company's common stock to the Seller, and reserved for future issuance (a) 134,356 shares of Common Stock, in connection with its assumption of the Seller's 2016 Stock Option Plan, as amended (the "Seller Stock Option Plan"), and the outstanding awards thereunder, and (b) 500,000 shares of common stock to be issued upon the conversion, if any, of certain convertible notes issued by the Seller.

At the closing, the Company assumed all of the liabilities of the Seller solely and exclusively related to the acquired business, which is providing innovative solutions, through development of proprietary platforms, diagnostic content, applied bioinformatics, lab services, research services and commercial collaborations and agreements, for molecular microbiology, diagnostics designed to address the global challenge of detecting severe infectious diseases and identifying antibiotic resistances in hospitalized patients. Pursuant to the Implementation Agreement, the Company also assumed and adopted the Seller Stock Option Plan as an Amended and Restated Stock Option Plan of the Company. In connection with the foregoing, the Company assumed all awards thereunder that were outstanding as of the Closing Date and converted such awards into options to purchase shares of the Company's Common Stock pursuant to the terms of the applicable award. In addition, the Company assumed, at the closing, all of the outstanding convertible notes issued by Seller in favor of YA II PN, LTD, pursuant to the previously disclosed Assignment of the Agreement for the Issuance of and Subscription to Notes Convertible into Shares, dated February 24, 2020, and entered into pursuant to the Implementation Agreement.

Curetis' assets and liabilities were measured and recognized at their fair values as of the transaction date and combined with the assets, liabilities, and results of operations of OpGen after the consummation of the business combination. The allocation of the purchase price to acquired assets and assumed liabilities based on their underlying fair values requires the extensive use of significant estimates and management's judgment. The allocation of the purchase price is final at this time.

The components of the purchase price and net assets acquired are as follows:

Purchase Price

Number of shares issued to Curetis N.V	2,028,208
Multiplied by the market value per share of OpGen's common stock (i)	\$ 2.39
Total fair value of common stock issued to Curetis N.V shareholders	4,847,417
Fair value of replacement stock awards related to pre combination service (ii)	136,912
Fair value of convertible notes assumed (iii)	1,323,750
Fair value of EIB debt assumed (iv)	15,784,892
Funds advanced to Curetis GmbH under Interim Facility	4,808,712
Cash and cash equivalents and restricted cash acquired	(1,266,849)
	\$ 25,634,834

(i) The price per share of OpGen's common stock was based on the closing price as reported on the Nasdaq Capital Market on April 1, 2020.

(ii) The fair value of the stock options assumed was determined using the Black-Scholes option pricing model.

(iii) To derive the fair value of the convertible notes, the Company estimated the fair value of the convertible notes with and without the derivative liability using a scenario analysis and Monte Carlo simulation.

(iv) The fair value of the EIB debt is determined using a discounted cash flow analysis with current applicable rates for similar instruments.

Net Assets Acquired

Assets acquired	
Receivables	\$ 482,876
Inventory	2,022,577
Property and equipment	3,802,431
Right of use assets	1,090,812
Other current assets	925,364
Finite-lived intangible assets	
Trade names/trademarks	1,768,000
Customer/distributor relationships	2,362,000
A50 - Developed technology	349,000
Ares - Developed technology	5,333,000
Indefinite-lived intangible assets	
A30 - In-process research & development	5,706,000
Goodwill	6,688,652
Liabilities assumed	
Accounts payable	(1,168,839)
Accrued expenses and other current liabilities	(1,953,927)
Derivative liabilities	(615,831)
Lease liabilities	(1,108,193)
Other long-term liabilities	(49,088)
Net assets acquired	\$ 25,634,834

The fair value of identifiable intangible assets has been determined using the income approach, which involves significant unobservable inputs (Level 3 inputs). These inputs include projected sales, margin, required rate of return and tax rate, as well as an estimated royalty rate in the case of the trade names/trademarks intangibles. The trade names/trademarks intangibles are valued using a relief-from-royalty method. The customer/distributor relationships are valued using the with and without method. The developed technology intangibles are valued using a multi-period earnings method.

The Company determined the fair value of an IPR&D asset resulting from the acquisition of Curetis using the multi-period earnings method under the income approach. This method reflects the present value of the projected cash flows that are expected to be generated by the IPR&D, less charges representing the required return on other assets to sustain those cash flows.

The weighted-average amortization periods for finite-lived intangible assets acquired are 15 years for customer/distributor relationships, 10 years for developed technology and 10 years for trade names/trademarks.

The total consideration paid in the acquisition exceeded the estimated fair value of the tangible and identifiable intangible assets acquired and liabilities assumed, resulting in approximately \$6.7 million of goodwill. Goodwill, primarily related to expected synergies gained from combining operations, sales growth from future product offerings and customers, together with certain intangible assets that do not qualify for separate recognition, including assembled workforce, is not tax deductible in all relevant taxing jurisdictions.

The following unaudited pro forma financial information summarizes the results of operations for the periods indicated as if the Transaction had been completed as of January 1, 2020. Pro forma information primarily reflects adjustments relating to the amortization of intangibles acquired and elimination of interest expense due under the interim facility. The pro forma amounts do not purport to be indicative of the results that would have actually been obtained if the acquisition had occurred as of January 1, 2020 or that may be obtained in the future.

Unaudited pro forma results	Nine months ended September 30, 2020
Revenues	\$ 3,886,834
Net loss	(22,340,822)
Net loss per share	(1.59)

Note 5 – Revenue from contracts with customers

Disaggregated revenue

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Product sales	\$ 643,887	\$ 601,562	\$ 1,479,270	\$ 1,569,799
Laboratory services	192,753	112,892	643,602	138,884
Collaboration revenue	402,492	342,311	757,591	1,153,400
Total revenue	<u>\$ 1,239,132</u>	<u>\$ 1,056,765</u>	<u>\$ 2,880,463</u>	<u>\$ 2,862,083</u>

Revenues by geography are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Domestic	\$ 372,902	\$ 309,119	\$ 1,036,662	\$ 1,202,244
International	866,230	747,646	1,843,801	1,659,839
Total revenue	<u>\$ 1,239,132</u>	<u>\$ 1,056,765</u>	<u>\$ 2,880,463</u>	<u>\$ 2,862,083</u>

Deferred revenue

Changes in deferred revenue for the period were as follows:

Balance at December 31, 2020	\$ 9,808
New deferrals, net of amounts recognized in the current period	—
Amounts returned to customers	(9,808)
Effect of foreign exchange rates	—
Balance at September 30, 2021	<u>\$ —</u>

Contract assets

The Company had contract assets of \$109,444 as of September 30, 2021, which are generated when contractual billing schedules differ from revenue recognition timing. The Company had approximately \$18,000 of contract assets as of December 31, 2020. Contract assets represent a conditional right to consideration for satisfied performance obligations that becomes a billed receivable when the conditions are satisfied.

Unsatisfied performance obligations

The Company had no unsatisfied performance obligations related to its contracts with customers at September 30, 2021 and December 31, 2020.

Note 6 – 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 nine months ended September 30, 2021, the Company has not transferred any assets between fair value measurement levels.

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

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

In June 2019, Curetis drew down a third tranche of EUR 5.0 million from the EIB (“European Investment Bank”). In return for EIB waiving the condition precedent of a minimum cumulative equity capital raised of EUR 15 million to disburse this EUR 5.0 million tranche, the parties agreed on a 2.1% participation percentage interest (“PPI”). Upon maturity of the tranche, 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 EUR 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 between mid-2024 and mid-2025. This right constitutes an embedded derivative, which is separated and measured at fair value with changes being accounted for through profit or loss. The Company determines the fair value of the derivative using a Monte Carlo simulation model. Using this model, level 3 unobservable inputs include estimated discount rates and estimated risk-free interest rates.

The fair value of level 3 liabilities measured at fair value on a recurring basis for the nine months ended September 30, 2021 was as follows:

Description	Balance at December 31, 2020	Change in Fair Value	Effect of Foreign Exchange Rates	Balance at September 30, 2021
Participation percentage interest liability	\$ 112,852	\$ 122,572	\$ (10,029)	\$ 225,395
Total	\$ 112,852	\$ 122,572	\$ (10,029)	\$ 225,395

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 nine months ended September 30, 2021, the Company recorded impairment expense of \$170,714 related to its ROU assets. During the three and nine months ended September 30, 2020, the Company recorded impairment expense of \$0 and \$750,596 related to its intangible assets, respectively (see Note 3).

Note 7 – Debt

The following table summarizes the Company’s long-term debt and short-term borrowings as of September 30, 2021 and December 31, 2020:

	September 30, 2021	December 31, 2020
EIB	\$ 25,408,938	\$ 25,936,928
PPP	—	259,353
MGHIF	—	331,904
Insurance financings	—	107,742
Total debt obligations	25,408,938	26,635,927
Unamortized debt discount	(4,256,214)	(6,557,992)
Carrying value of debt	21,152,724	20,077,935
Less current portion	(14,668,424)	(699,000)
Long-term debt	\$ 6,484,300	\$ 19,378,935

MGHIF financing

In July 2015, the Company entered into a Purchase Agreement with MGHIF, pursuant to which MGHIF purchased 2,273 shares of common stock of the Company at \$2,200 per share for gross proceeds of \$5.0 million. Pursuant to the Purchase Agreement, the Company also issued to MGHIF an 8% Senior Secured Promissory Note (the “MGHIF Note”) in the principal amount of \$1.0 million with a two-year maturity date from the date of issuance. The Company’s obligations under the MGHIF Note were secured by a lien on all of OpGen’s assets excluding the assets of Curetis GmbH, Curetis USA, and Ares Genetics.

On June 28, 2017, the MGHIF Note was amended and restated, and the maturity date of the MGHIF Note was extended by one year to July 14, 2018. As consideration for the agreement to extend the maturity date, the Company issued an amended and restated secured promissory note to MGHIF that (1) increased the interest rate to ten percent (10%) per annum and (2) provided for the issuance of common stock warrants to purchase 656 shares of its common stock to MGHIF.

On June 11, 2018, the Company executed an Allonge to the MGHIF Note. The Allonge provided that accrued and unpaid interest of \$285,512 due as of July 14, 2018, the original maturity date, be paid through the issuance of shares of OpGen’s common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the MGHIF Note to six semi-annual payments of \$166,667 plus accrued and unpaid interest beginning on January 2, 2019. During the nine months ended September 30, 2021, the Company made the final payment under the MGHIF Note and the lien on the Company’s assets was released.

Yorkville Convertible Notes

The Company agreed to assume, as a condition to closing the business combination with Curetis, all of the outstanding convertible notes (the “Convertible Notes”) issued by Curetis N.V. in favor of YA II PN, LTD (“Yorkville”), pursuant to that certain Agreement for the Issuance of and Subscription to Notes Convertible into Shares and Share Subscription Warrants, dated October 2, 2018, by and between Curetis N.V. and Yorkville.

On February 24, 2020, the Company entered into an Assignment of the Agreement for the Issuance of and Subscription to Notes Convertible into Shares (the “Assignment Agreement”) with Curetis N.V. and Yorkville. Pursuant to the Assignment Agreement, upon assumption of the Convertible Notes by the Company, the Convertible Notes ceased to be convertible into shares of Curetis N.V. and are instead convertible into shares of the Company’s common stock, par value \$0.01. The Assignment Agreement provided that an amount of 500,000 shares of the Company’s common stock that comprise a portion of the consideration payable by the Company under the Implementation Agreement be reserved for issuance under the Convertible Notes. On June 17, 2020, the Company registered for resale an additional 450,000 shares of Company common stock issuable upon conversion of the Convertible Notes.

At closing of the Transaction, an aggregate amount of €1.3 million of unconverted Convertible Notes was assumed by the Company. The Convertible Notes were measured and recognized at fair value at the acquisition date. The fair value of the Convertible Notes as of the closing of the Transaction was approximately \$1.3 million. The resulting debt discount was amortized over the life of the Convertible Notes as an increase in interest expense. During year ended December 31, 2020, the Company issued 763,905 shares of common stock in satisfaction of approximately \$1,451,000 of Convertible Notes. As of December 31, 2020, all notes have been converted.

EIB Loan Facility

In 2016, Curetis entered into a contract for an up to €25 million senior, unsecured loan financing facility from the European Investment Bank (“EIB”). The financing is in the first growth capital loan under the European Growth Finance Facility (“EGFF”), launched in November 2016. It is backed by a guarantee from the European Fund for Strategic Investment (“EFSI”). EFSI is an essential pillar of the Investment Plan for Europe (“IPE”), under which the EIB and the European Commission are working as strategic partners to support investments and bring back jobs and growth to Europe.

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

In April 2017, Curetis drew down a first tranche of €10 million from this facility. This tranche has a floating interest rate of EURIBOR plus 4% payable after each 12-month-period from the draw-down-date and another additional 6% interest per annum that is deferred and payable at maturity together with the principal. In June 2018, another tranche of €3 million was drawn down. The terms and conditions are analogous to the first one.

In June 2019, Curetis drew down a third tranche of €5 million from the EIB. In line with all prior tranches, the majority of interest is also deferred into the bullet repayment structure upon maturity. In return for EIB waiving the condition precedent of a minimum cumulative equity capital raised of €15 million to disburse this €5 million tranche, the parties agreed on a 2.1% PPI. Upon maturity of the tranche, not before approximately mid-2024 (and no later than mid-2025) 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 EIB on July 9, 2020, the parties adjusted the PPI percentage applicable to the previous EIB tranche of €5 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.

On July 10, 2020, EIB agreed to defer total interest payments of €720 thousand due in April and June 2020 under the first three tranches of the debt financing facility until December 31, 2020. The Company made these interest payments in December 2020.

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

As of September 30, 2021, the outstanding borrowings under all tranches were €21,943,983 (USD \$25,408,938), including deferred interest payable at maturity of €3,943,983 (USD \$4,566,738).

PPP

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

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

Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was \$1,222,867 and \$1,183,927 for the three months ended September 30, 2021 and 2020, respectively. Total interest expense (including accretion of fair value to book value and amortization of debt discounts and financing fees) on all debt instruments was \$3,586,018 and \$2,267,085 for the nine months ended September 30, 2021 and 2020, respectively.

Note 8 – Stockholders' equity

As of September 30, 2021, the Company had 50,000,000 shares of authorized common shares and 38,270,250 shares issued and outstanding, and 10,000,000 shares of authorized preferred shares, of which none were issued or outstanding.

Following receipt of approval from stockholders at a special meeting of stockholders held on January 17, 2018, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to effect a reverse stock split of the issued and outstanding shares of common stock, at a ratio of one share for twenty-five shares, and to reduce the authorized shares of common stock from 200,000,000 to 50,000,000 shares. Additionally, following receipt of approval from stockholders at a special meeting of stockholders held on August 22, 2019, the Company filed an additional amendment to its Amended and Restated Certificate of Incorporation to effect a reverse stock split of the issued and outstanding shares of common stock, at a ratio of one share for twenty shares. All share amounts and per share prices in this Quarterly Report have been adjusted to reflect the reverse stock splits.

On October 28, 2019, the Company closed the October 2019 Public Offering of 2,590,170 units at \$2.00 per unit and 2,109,830 pre-funded units at \$1.99 per pre-funded unit. The offering raised gross proceeds of approximately \$9.4 million and net proceeds of approximately \$8.3 million. During the nine months ended September 30, 2021, 5,000 common warrants were exercised raising net proceeds of \$10,000. During the year ended December 31, 2020, 4,341,000 common warrants were exercised raising net proceeds of approximately \$8.7 million.

On February 11, 2020, the Company entered into an ATM Agreement with Wainwright, which we amended and restated on November 13, 2020 to add BTIG, LLC pursuant to which the Company may offer and sell from time to time in an "at the market offering," at its option, up to an aggregate of \$22.1 million of shares of the Company's common stock through the sales agents. The Company did not sell any shares under the 2020 ATM Offering during the three or nine months ended September 30, 2021. During the year ended December 31, 2020, the Company sold 7,521,610 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately \$15.8 million, and gross proceeds of \$16.7 million. As of September 30, 2021, remaining availability under the ATM Agreement is \$5.4 million.

On April 1, 2020, the Company acquired all of the shares of Curetis GmbH, and certain other assets and liabilities of Curetis N.V., as further described in Notes 1 and 4, and paid, as the sole consideration, 2,028,208 shares of the Company's common stock to the Seller.

On November 25, 2020, the Company closed a private placement with one healthcare-focused U.S. institutional investor of (i) 2,245,400 shares of common stock together with 2,245,400 common warrants to purchase up to 2,245,400 shares of common stock and (ii) 2,597,215 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock, together with 2,597,215 common warrants to purchase up to 2,597,215 shares of common stock (the "2020 PIPE"). Each share of common stock and accompanying common warrant were sold together at a combined offering price of \$2.065, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of \$2.055. The common warrants have an exercise price of \$1.94 per share, and are exercisable commencing on the six month anniversary of the date of issuance, and will expire five and one half (5.5) years from the date of issuance. The 2020 PIPE raised aggregate net proceeds of \$9.3 million, and gross proceeds of \$10.0 million. As of December 31, 2020, all 2,597,215 pre-funded warrants issued in the 2020 PIPE have been exercised.

On February 11, 2021, the Company closed the February 2021 Offering with a single U.S.-based, healthcare-focused institutional investor for the purchase of (i) 2,784,184 shares of common stock and (ii) 5,549,149 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock. The Company also issued to the investor, in a concurrent private placement, unregistered common warrants to purchase 4,166,666 shares of the Company's common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of \$3.00, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of \$2.99. The pre-funded warrants are immediately exercisable, at an exercise price of \$0.01, and may be exercised at any time until all of the pre-funded warrants are exercised in full. The common warrants will have an exercise price of \$3.55 per share, will be exercisable commencing on the six-month anniversary of the date of issuance, and will expire five and one-half (5.5) years from the date of issuance. The February 2021 Offering raised aggregate net proceeds of \$23.5 million, and gross proceeds of \$25.0 million. As of September 30, 2021, all pre-funded warrants issued in the February 2021 Offering have been exercised.

On March 9, 2021, the Company entered into an Exercise Agreement with the Holder from our 2020 PIPE financing. Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of the remaining 4,842,615 Existing Warrants for cash, pursuant to the terms of and subject to beneficial ownership limitations contained in the Existing Warrants, the Company agreed to issue to the Holder, New Warrants to purchase 0.65 shares of common stock for each share of common stock issued upon such exercise of the remaining Existing Warrants pursuant to the Exercise Agreement or an aggregate of 3,147,700 New Warrants. The terms of the New Warrants are substantially similar to those of the Existing Warrants, except that the New Warrants have an exercise price of \$3.56. The New Warrants are immediately exercisable and will expire five years from the date of the Exercise Agreement. The Holder paid an aggregate of \$255,751 to the Company for the purchase of the New Warrants. The Company received aggregate gross proceeds before expenses of approximately \$9.65 million from the exercise of the remaining Existing Warrants held by the Holder and the payment of the purchase price for the New Warrants. The Company recognized approximately \$7.8 million of non-cash warrant inducement expense during the nine months ended September 30, 2021 related to this transaction representing the fair value of the New Warrants issued to induce the exercise. The fair values were calculated using the Black-Scholes option pricing model.

Stock options

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

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

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 2,710 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan’s effective date, that are subsequently forfeited or terminated for any reason before being exercised or settled, plus (3) the number of shares subject to vesting restrictions under the 2008 Plan as of the 2015 Plan’s effective date that are subsequently forfeited. In addition, the number of shares that have been authorized for issuance under the 2015 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to the lesser of (1) 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (2) another lesser amount determined by the Company’s Board of Directors. Following Board of Director approval, 1,003,421 shares were automatically added to the 2015 Plan. Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled, or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited. As of September 30, 2021, 647,968 shares remain available for issuance under the 2015 Plan.

On September 30, 2020, the Company held its 2020 Annual Meeting of Stockholders (the “Annual Meeting”). At the Annual Meeting, stockholders of the Company voted to approve, among other things, a plan under which stock options to purchase an aggregate of 1,300,000 shares of the Company’s common stock would be made by the Board of Directors of the Company outside of the stockholder-approved equity incentive plan to its executive officers and non-employee directors (the “2020 Stock Options Plan”). The 2020 Stock Options Plan and the grant made thereunder were approved by the Board of Directors on August 6, 2020, subject to receipt of stockholder approval at the Annual Meeting. The aggregate number of shares of the Company’s common stock authorized for issuance is 1,300,000 shares of common stock and all 1,300,000 stock options were issued on September 30, 2020. Shares subject to awards granted under the 2020 Stock Options Plan that are forfeited or terminated before being exercised will not be available for re-issuance under the 2020 Stock Options Plan.

Replacement awards

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

For the three and nine months ended September 30, 2021 and 2020, the Company recognized share-based compensation expense as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Cost of services	\$ 2,977	\$ 736	\$ 7,323	\$ 2,191
Research and development	65,836	12,259	168,592	38,322
General and administrative	112,706	24,100	427,487	102,810
Sales and marketing	35,637	4,608	64,972	11,707
	<u>\$ 217,156</u>	<u>\$ 41,703</u>	<u>\$ 668,374</u>	<u>\$ 155,030</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 net loss position.

The Company granted 60,000 options during the three months ended September 30, 2021. During the three months ended September 30, 2021, 252,625 options were forfeited, and 199 options expired. The Company granted 415,000 options during the nine months ended September 30, 2021. During the nine months ended September 30, 2021, 351,001 options were forfeited, and 672 options expired.

The Company had total stock options to acquire 1,727,849 shares of common stock outstanding at September 30, 2021 under all of its equity compensation plans.

Restricted stock units

The Company granted no restricted stock units during the three months ended September 30, 2021, no restricted stock units vested, and 43,500 were forfeited. The Company granted 360,000 restricted stock units during the nine months ended September 30, 2021, and 3,768 restricted stock units vested and 64,967 were forfeited. The Company had 299,383 total restricted stock units outstanding at September 30, 2021.

Stock purchase warrants

At September 30, 2021 and December 31, 2020, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at	
			September 30, 2021 (1)	December 31, 2020 (1)
November 2011	\$ 3,955.00	November 2021	15	15
December 2011	\$ 3,955.00	December 2021	2	2
February 2015	\$ 3,300.00	February 2025	451	451
May 2016	\$ 656.20	May 2021	—	9,483
June 2016	\$ 656.20	May 2021	—	4,102
June 2017	\$ 390.00	June 2022	938	938
July 2017	\$ 345.00	July 2022	318	318
July 2017	\$ 250.00	July 2022	2,501	2,501
July 2017	\$ 212.50	July 2022	50,006	50,006
February 2018	\$ 81.25	February 2023	9,232	9,232
February 2018	\$ 65.00	February 2023	92,338	92,338
October 2019	\$ 2.00	October 2024	354,000	359,000
October 2019	\$ 2.60	October 2024	235,000	235,000
November 2020	\$ 1.94	May 2026	—	4,842,615
November 2020	\$ 2.68	May 2026	242,130	242,130
February 2021	\$ 3.55	August 2026	4,166,666	—
February 2021	\$ 3.90	August 2026	416,666	—
March 2021	\$ 3.56	March 2026	3,147,700	—
			<u>8,717,963</u>	<u>5,848,131</u>

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

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

Note 9 – Commitments and Contingencies

Registration and other stockholder rights

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

Supply agreements

In June 2017, the Company entered into an agreement with Life Technologies Corporation, a subsidiary of Thermo Fisher Scientific ("LTC"), to supply the Company with Thermo Fisher Scientific's QuantStudio 5 Real-Time PCR Systems ("QuantStudio 5") to be used to run OpGen's Acuitas AMR Gene Panel tests. Under the terms of the agreement, the Company must notify LTC of the number of QuantStudio 5s that it commits to purchase in the following quarter. As of September 30, 2021, the Company had acquired twenty-four QuantStudio 5s including none during the three and nine months ended September 30, 2021. As of September 30, 2021, the Company has not committed to acquiring additional QuantStudio 5s in the next three months.

Curetis places frame-work orders for Unyvero Systems and for raw materials for its cartridge manufacturing to ensure availability during commercial ramp-up-phase and also to gain volume-scale-effects with regards to purchase prices. Some of the electronic parts used for the production of Unyvero Systems have lead times of several months, hence it is necessary to order such systems with long-term framework-orders to ensure the demands from the market are covered. The aggregate purchase commitments over the next twelve months are approximately \$1.5 million.

COVID-19 Impact

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

Note 10 – Leases

The following table presents the Company's ROU assets and lease liabilities as of September 30, 2021 and December 31, 2020:

Lease Classification	September 30, 2021	December 31, 2020
ROU Assets:		
Operating	\$ 1,885,025	\$ 2,082,300
Financing	141,387	449,628
Total ROU assets	<u>\$ 2,026,412</u>	<u>\$ 2,531,928</u>
Liabilities		
Current:		
Operating	\$ 610,336	\$ 964,434
Finance	68,831	266,470
Noncurrent:		
Operating	2,953,615	1,492,544
Finance	7,869	46,794
Total lease liabilities	<u>\$ 3,640,651</u>	<u>\$ 2,770,242</u>

Maturities of lease liabilities as of September 30, 2021 by fiscal year are as follows:

Maturity of Lease Liabilities	Operating	Finance	Total
2021	\$ 255,767	\$ 31,397	\$ 287,164
2022	731,523	44,850	776,373
2023	617,829	3,364	621,193
2024	627,424	280	627,704
2025	541,023	—	541,023
Thereafter	2,504,648	—	2,504,648
Total lease payments	5,278,214	79,891	5,358,105
Less: Interest	(1,714,263)	(3,191)	(1,717,454)
Present value of lease liabilities	\$ 3,563,951	\$ 76,700	\$ 3,640,651

Condensed consolidated statements of operations classification of lease costs as of the three and nine months ended September 30, 2021 and 2020 are as follows:

Lease Cost	Classification	Three months ended September 30,		Nine months ended September 30,	
		2021	2020	2021	2020
Operating	Operating expenses	\$ 188,945	\$ 332,241	\$ 835,314	\$ 882,659
Finance:					
Amortization	Operating expenses	85,822	125,005	308,242	387,262
Interest expense	Other expenses	2,640	15,806	13,991	49,326
Total lease costs		\$ 277,407	\$ 473,052	\$ 1,157,547	\$ 1,319,247

Other lease information as of September 30, 2021 is as follows:

Other Information	Total
Weighted average remaining lease term (in years)	
Operating leases	7.4
Finance leases	0.9
Weighted average discount rate:	
Operating leases	8.9%
Finance leases	9.2%

Supplemental cash flow information as of the nine months ended September 30, 2021 and 2020 is as follows:

Supplemental Cash Flow Information	2021	2020
Cash paid for amounts included in the measurement of lease liabilities		
Cash used in operating activities		
Operating leases	\$ 835,314	\$ 882,659
Finance leases	\$ 13,991	\$ 45,185
Cash used in financing activities		
Finance leases	\$ 236,563	\$ 467,592
ROU assets obtained in exchange for lease obligations:		
Operating leases	\$ 748,294	\$ —

Note 11 – License agreements, research collaborations and development agreements

NYSDOH

In 2018, the Company announced a collaboration with the New York State Department of Health (“DOH”) and ILÚM Health Solutions, LLC (“ILÚM”), a wholly-owned subsidiary of Merck’s Healthcare Services and Solutions division, to develop a state-of-the-art research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions statewide. ILÚM has since been acquired by Infectious Disease Connect, Inc. (“IDC”), a University of Pittsburgh Medical Center (“UPMC”) Enterprise company. The Company is working together with DOH’s Wadsworth Center and IDC to continue development of an infectious disease digital health and precision medicine platform that connects healthcare institutions to DOH and uses genomic microbiology for statewide surveillance and control of antimicrobial resistance. As part of the collaboration, the Company received approximately \$1.6 million over the 15-month demonstration portion of the project. The demonstration project began in early 2019 and was completed in the first quarter of 2020. In April 2020, the Company began a second-year expansion phase to build on the successes and experience of the first-year pilot phase while focusing on accomplishing the goal of the effort to improve patient outcomes and save healthcare dollars by integrating real-time epidemiologic surveillance with rapid delivery of antibiotic resistance results to care-givers via web-based and mobile platforms. The second-year contract included a quarterly retainer-based project fee as well as volume-dependent per test fees for a total contract value of up to \$450,000 to OpGen. In April 2021, the Company extended its second-year expansion phase by another six months through September 30, 2021 at which point the project was completed and has ended. The six-month extension and expansion contract included a quarterly retainer-based project fee as well as volume-dependent per test fees for a total contract value of up to an additional \$540,000. During the three months ended September 30, 2021 and 2020, the Company recognized \$213,000 and \$43,000 of revenue related to the contract, respectively. During the nine months ended September 30, 2021 and 2020, the Company recognized \$558,000 and \$323,000 of revenue related to the contract, respectively. The project has been successfully completed and all revenues thereunder have been fully recognized.

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 frame agreement, which has an initial term of 36 months and is currently scheduled to terminate December 13, 2021, Ares Genetics and Sandoz intend to develop a digital anti-infectives platform, combining established microbiology laboratory methods with advanced bioinformatics and artificial intelligence methods to support drug development and life-cycle management. The collaboration, in the short- to mid-term, aims to both rapidly and cost-effectively re-purpose existing antibiotics and design value-added medicines with the objective of expanding indication areas and to overcome antibiotic resistance, in particular with regards to infections with bacteria that has already developed resistance against multiple treatment options. In the longer-term, the platform is expected to enable surveillance for antimicrobial resistant pathogens to inform antimicrobial stewardship and the development of novel anti-infectives that are less prone to encounter resistance and thereby preserve antibiotics as an effective treatment option.

The agreement covers the first phases of the collaboration with Sandoz and provides certain moderate six-figure R&D funding to Ares Genetics. No milestones or royalties were agreed to as part of this first phase of the collaboration. The agreement may be terminated by Sandoz effective immediately at any time with written notice.

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 antimicrobial resistance (“AMR”) research. The agreement has a term of 20 years and may be terminated by Qiagen for convenience with 180 days written notice.

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

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

The Company was party to one license agreement with Life Technologies to acquire certain patent rights and technologies related to its FISH product line. Royalties were incurred upon the sale of a product or service which utilizes the licensed technology. The Company terminated this license agreement in October 2020 effective as of June 30, 2021 in conjunction with its announced exit of the FISH business in June 2021. The Company paid a one-time settlement fee of \$350,000 and paid a 10% royalty on the sale of eligible products through June 2021 but is no longer subject to any minimum royalty obligations. The Company recognized net royalty expense of \$2,725 and \$62,500 for the three months ended September 30, 2021 and 2020, respectively. The Company recognized net royalty expense of \$11,721 and \$187,500 for the nine months ended September 30, 2021 and 2020, respectively.

Note 12 – Related party transactions

On April 1, 2020, as part of the Transaction, Oliver Schacht, Ph.D., the former CEO of Curetis N.V., was appointed as the CEO of the Company, and Johannes Bacher, the former COO of Curetis N.V., was appointed as the COO of the Company. Effective April 1, 2020, Mr. Schacht and Mr. Bacher were appointed as liquidators of Curetis N.V. in liquidation and Curetis GmbH was designated as Custodian of the Books for Curetis N.V. During a portion of the year ended December 31, 2020, Curetis N.V. in liquidation processed payroll for Mr. Schacht and Mr. Bacher and invoiced OpGen and Curetis GmbH, respectively, in line with their signed management agreements.

Note 13 – Subsequent events

Subsequent to September 30, 2021, in October 2021, the Company sold 680,000 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately \$1,500,000, and gross proceeds of approximately \$1,548,000.

On October 18, 2021, the Company closed the October 2021 Offering with a single healthcare-focused institutional investor of 150,000 shares of convertible preferred stock and warrants to purchase up to an aggregate of 7,500,000 shares of common stock. The shares of preferred stock have a stated value of \$100 per share and are convertible into an aggregate of 7,500,000 shares of common stock at a conversion price of \$2.00 per share at any time after the Company has received stockholder approval to increase the number of authorized shares of common stock of the Company. The warrants have an exercise price of \$2.05 per share, will become exercisable on the later of the date of stockholder approval and six months following the date of issuance, and will expire five years following the initial exercise date. The October 2021 Offering raised aggregate net proceeds of \$13.9 million, and gross proceeds of \$15.0 million.

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

The following Management’s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited condensed consolidated financial statements and the accompanying notes thereto included in Part I, Item 1 of this quarterly report on Form 10-Q. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under Part II, Item 1A. “Risk Factors” of this quarterly report on Form 10-Q and Part 1, Item 1A of our annual report on Form 10-K for the year ended December 31, 2020.

Overview

OpGen is a precision medicine company harnessing the power of molecular diagnostics and informatics to help combat infectious disease. Along with our subsidiaries, Curetis GmbH and Ares Genetics GmbH, we are developing and commercializing molecular microbiology solutions helping to guide clinicians with more rapid and actionable information about life threatening infections to improve patient outcomes and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. Our current product portfolio includes Unyvero, Acuitas AMR Gene Panel, Acuitas Lighthouse, and the ARES Technology Platform including ARESdb, using NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction, as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit. On October 13, 2020, the Company announced its decision to exit the FISH business in its entirety by June 30, 2021, and the Company’s license agreement with Life Technologies, a subsidiary of ThermoFisher, was terminated as of such date.

On April 1, 2020, the Company completed a 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 (“Purchaser”). Pursuant to the Implementation Agreement, the Purchaser acquired all of the shares of Curetis GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany (“Curetis GmbH”), and certain other assets and liabilities of the Seller (together, “Curetis”). Curetis is an early commercial-stage molecular diagnostics (MDx) company focused on rapid infectious disease testing for hospitalized patients with the aim to improve the treatment of hospitalized, critically ill patients with suspected microbial infection and has developed the innovative Unyvero molecular diagnostic solution for comprehensive infectious disease testing. The Transaction was designed principally to leverage each company’s existing research and development and relationships with hospitals and clinical laboratories to accelerate the sales of both companies’ products and services.

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

- The Unyvero Lower Respiratory Tract, or LRT, test is the first U.S. Food and Drug Administration, or FDA, cleared test that can be used for the detection of more than 90% of common causative agents of hospitalized pneumonia. According to the National Center for Health Statistics (2018), pneumonia is a leading cause of admissions to the hospital and is associated with substantial morbidity and mortality. The Unyvero LRT automated test detects 19 pathogens within less than five hours, with approximately two minutes of hands-on time and provides clinicians with a comprehensive overview of 10 genetic antibiotic resistance markers. We have commercialized the Unyvero LRT BAL test for testing bronchoalveolar lavage, or BAL, specimens from patients with lower respiratory tract infections following FDA clearance received by Curetis in December 2019. The Unyvero LRT BAL automated test simultaneously detects 20 pathogens and 10 antibiotic resistance markers, and it is the first and only FDA-cleared panel that also includes *Pneumocystis jirovecii*, a key fungal pathogen often found in immunocompromised patients (such as AIDS and transplant patients) that can be difficult to diagnose, as the 20th pathogen on the panel. We believe the Unyvero LRT and LRT BAL tests have the ability to help address a significant, previously unmet medical need that causes over \$10 billion in annual costs for the U.S. healthcare system, according to the Centers for Disease Control, or CDC.
- Following registration of the Unyvero instrument system as an IVD for the Chinese market earlier in 2021, we are currently working with our strategic partner Beijing Clear Biotech towards execution of a supplemental clinical trial with the Unyvero HPN test. As requested by the Chinese regulatory authority NMPA, this study is geared towards generating additional data in China which will complement a larger data set with data from abroad compiled from other clinical and analytical studies performed in the past.

- The Unyvero Urinary Tract Infection, or UTI, test which is CE-IVD marked in Europe is currently being made available to laboratories in the U.S. as a research use only or RUO kit. The test detects a broad range of pathogens as well as antimicrobial resistance markers directly from native urine specimens. As part of our portfolio strategy update on October 13, 2020, we have decided to proceed with the analytical and clinical performance evaluation including clinical trials required for a subsequent U.S. FDA submission and initiated clinical trials in the third quarter of 2021.
- The Unyvero Invasive Joint Infection, or IJI, test, which is a variant developed for the U.S. market based on the CE-IVD-marked European Unyvero ITI test, has also been selected for analytical and clinical performance evaluation including clinical trials towards a future U.S. FDA submission. Microbial diagnosis of IJI is difficult because of challenges in sample collection, usually at surgery, and patients being on prior antibiotic therapy which minimizes the chances of recovering viable bacteria. We believe that Unyvero IJI could be useful in identifying pathogens as well as their AMR markers to help guide optimal antibiotic treatment for these patients.
- On September 30, 2021, we received clearance from the FDA for our Acuitas AMR Gene Panel for bacterial isolates. The Acuitas AMR Gene Panel detects 28 genetic antimicrobial resistance, or AMR, markers in isolated bacterial colonies from 26 different pathogens. We believe the panel provides clinicians with a valuable diagnostic tool that informs about potential antimicrobial resistance patterns early and supports appropriate antibiotic treatment decisions in this indication. We expect to commercialize the Acuitas AMR Gene Panel for isolates more broadly to customers in the U.S.
- We are also developing novel bioinformatics tools and solutions to accompany or augment our current and potential future IVD products and may seek regulatory clearance for such bioinformatics tools and solutions to the extent they would be required either as part of our portfolio of IVD products or even as a standalone bioinformatics product.

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

OpGen's combined AMR bioinformatics offerings, once such products are cleared for marketing, if ever, will offer important new tools to clinicians treating patients with AMR infections. We have collaborated with Merck, Inc. to establish the Acuitas Lighthouse Knowledgebase, which is currently commercially available in the United States for RUO. The Acuitas Lighthouse Knowledgebase includes approximately 15,000 bacterial isolates from the Merck SMART surveillance network of 192 hospitals in 52 countries and other sources. The relevant datasets from Lighthouse have successfully been integrated into Ares Genetics' ARESdb. Ares Genetics' ARESdb is a comprehensive database of genetic and phenotypic information. ARESdb was originally designed based on the SIEMENS microbiology strain collection covering resistant pathogens and its development has significantly expanded, also by transferring data from the Acuitas Lighthouse into ARESdb to now cover approximately 78,000 bacterial isolates that have been sequenced using NGS technology and tested for susceptibility with applicable antibiotics from a range of over 100 antimicrobial drugs. In September 2019, Ares Genetics had signed a technology evaluation agreement with an undisclosed global IVD corporation. In the collaboration, Ares Genetics further enriched ARESdb with a focus on certain pathogens relevant in a first, undisclosed infectious disease indication. Following the successful completion of this collaborative R&D project, the IVD partner exercised its option for a 90-day period of exclusive negotiations with Ares Genetics for a potential exclusive license to ARESdb in the field of human clinical diagnostics. Following the lapse of such 90-day period without any commercial deal being signed, Ares Genetics is now in multiple, nonexclusive parallel discussions with several interested parties and such discussions are ongoing. Additional partnerships with a U.S. CLIA lab and CRO as well as UPMC have been initiated and are ongoing.

In addition to potential future licensing and partnering, OpGen's subsidiary Ares Genetics intends to independently utilize the proprietary biomarker content in these databases, as well as to build an independent business in NGS and AI based offerings for AMR research and diagnostics in collaboration with its current and potential future partners in the life science, pharmaceutical and diagnostics industries. Ares Genetics signed up Siemens Technology Accelerator and AGES (Austrian Agency for Health and Food Safety), as well as several other national institutions from various European countries as new customers, as well as entered into another technology assessment and feasibility project with another undisclosed major global IVD corporation, which was also successfully completed.

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

The Company has extensive partner and distribution relationships to help accelerate the establishment of a global infectious disease diagnostic testing and informatics business. Partners include A. Menarini Diagnostics for pan-European distribution to currently 11 countries and Beijing Clear Biotech Co. Ltd. for Unyvero A50 product distribution in China. We have a network of distributors covering many countries in Europe, the Middle East and Africa, Asia Pacific and Latin America. With the discontinuation of our FISH products business in Europe, we have reduced our network of distributors to only those distributors actively commercializing our Unyvero line of products or CE-IVD-marked SARS-CoV-2 test kits.

OpGen will continue to develop and seek FDA and other regulatory clearances or approvals, as applicable, for our Unyvero UTI and IJI products. OpGen will continue to offer the FDA-cleared Unyvero LRT and LRT BAL Panels, and Acuitas AMR Gene Panel tests, as well as the Unyvero UTI Panel as a RUO product to hospitals, public health departments, clinical laboratories, pharmaceutical companies and contract research organizations (“CROs”). OpGen’s subsidiary, Curetis, continues its preparations for achieving compliance with the upcoming European Union’s In-Vitro-Diagnostic Device Regulation (IVDR), which officially will go into effect in May 2022. Given the lack of designated Notified Bodies at this time, and with the recent EU commission proposal to provide for generous multi-year grace periods for IVD products with current IVDD CE marking, it is currently unclear at what point in time which of our products will actually begin to fall under the new regulation.

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

Recent developments

COVID-19 Impact

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

As a result, we have experienced a material impact on our business, financial condition or results of operations for the three and nine months ended September 30, 2021, and significant business disruptions as a result of the outbreak. For example, some of our employees are currently still working remotely from home, we have continued to suspend most business travel, and we are still not always able to physically meet with future and current customers to sell and market our products.

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

Financings

Since inception, we have incurred, and continue to incur, significant losses from operations. We have funded our operations primarily through external investor financing arrangements. During 2020, we raised net proceeds of approximately \$33.8 million. The following financing transactions took place during 2021, raising combined net proceeds of approximately \$48.25 million:

- On February 11, 2021, the Company closed the February 2021 Offering raising net proceeds of \$23.5 million, and gross proceeds of \$25.0 million.
- On March 9, 2021, the Company entered into the Exercise Agreement to induce the warrant holders from our 2020 PIPE to exercise their warrants issued in the 2020 PIPE. The Company received aggregate gross proceeds before expenses of approximately \$9.65 million from the exercise of all of the remaining 4,842,615 outstanding Existing Warrants held by the Holder and the payment of the purchase price for the New Warrants.

- Subsequent to September 30, 2021, the Company sold 680,000 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately \$1,500,000, and gross proceeds of approximately \$1,548,000.
- On October 18, 2021, the Company closed the October 2021 Offering with a single healthcare-focused institutional investor of 150,000 shares of convertible preferred stock and warrants to purchase up to an aggregate of 7,500,000 shares of common stock. The shares of preferred stock have a stated value of \$100 per share and are convertible into an aggregate of 7,500,000 shares of common stock at a conversion price of \$2.00 per share at any time after the Company has received stockholder approval to increase the number of authorized shares of common stock of the Company. The warrants have an exercise price of \$2.05 per share, will become exercisable on the later of the date of stockholder approval and six months following the date of issuance, and will expire five years following the initial exercise date. The October 2021 Offering raised aggregate net proceeds of \$13.9 million, and gross proceeds of \$15.0 million.

Results of operations for the three months ended September 30, 2021 and 2020

Revenues

	Three months ended September 30,	
	2021	2020
Product sales	\$ 643,887	\$ 601,562
Laboratory services	192,753	112,892
Collaboration revenue	402,492	342,311
Total revenue	\$ 1,239,132	\$ 1,056,765

Total revenue for the three months ended September 30, 2021 increased approximately 17% when compared to the same period in 2020, with a change in the mix of revenue, as follows:

- Product Sales: an increase in revenue of approximately 7% in the 2021 period compared to the 2020 period is primarily attributable to an increase in the Company's Unyvero product sales offset, in part, by the loss of FISH products revenue following the discontinuation of the FISH business;
- Laboratory Services: an increase in revenue of approximately 71% in the 2021 period compared to the 2020 period is primarily attributable to an increase in Ares Genetics' laboratory services as well as COVID testing services performed by the Company's Curetis subsidiary; and
- Collaboration Revenue: an increase in revenue of approximately 18% in the 2021 period compared to the 2020 period is primarily attributable to an increase in Ares Genetics collaboration revenue.

Operating expenses

	Three months ended September 30,	
	2021	2020
Cost of products sold	\$ 648,298	\$ 1,350,296
Cost of services	203,314	159,794
Research and development	2,382,303	2,433,553
General and administrative	2,088,226	2,356,413
Sales and marketing	1,003,577	932,671
Total operating expenses	\$ 6,325,718	\$ 7,232,727

Our total operating expenses for the three months ended September 30, 2021 decreased approximately 13% when compared to the same period in 2020. Operating expenses changed as follows:

- Cost of products sold: cost of products sold for the three months ended September 30, 2021 decreased approximately 52% when compared to the same period in 2020. The decrease in cost of products sold is primarily attributable to the discontinuation of the Company's FISH line of products;

- Cost of services: cost of services for the three months ended September 30, 2021 increased approximately 27% when compared to the same period in 2020. The increase in cost of services is primarily attributable to an increase in laboratory service and collaboration revenue by Ares Genetics;
- Research and development: research and development expenses for the three months ended September 30, 2021 decreased approximately 2% when compared to the same period in 2020, primarily due to reduced expenses related to our Acuitas AMR clinical trials;
- General and administrative: general and administrative expenses for the three months ended September 30, 2021 decreased approximately 11% when compared to the same period in 2020, primarily due to a decrease in payroll related expenses; and
- Sales and marketing: sales and marketing expenses for the three months ended September 30, 2021 increased approximately 8% when compared to the same period in 2020, primarily due to the expansion of our US sales team.

Other expense

	Three months ended September 30,	
	2021	2020
Interest expense	\$ (1,222,867)	\$ (1,183,927)
Foreign currency transaction gains (losses)	229,074	(501,168)
Other income	31,844	19,965
Change in fair value of derivative financial instruments	(8,161)	165,497
Total other expense	\$ (970,110)	\$ (1,499,633)

Our total other expense for the three months ended September 30, 2021 decreased when compared to the same period in 2020 primarily due to the change in foreign currency transaction gains (losses).

Results of operations for the nine months ended September 30, 2021 and 2020

The results of operations for the nine months ended September 30, 2020 exclude results from operations of Curetis and its subsidiaries for the three months ended March 31, 2020.

Revenues

	Nine months ended September 30,	
	2021	2020
Product sales	\$ 1,479,270	\$ 1,569,799
Laboratory services	643,602	138,884
Collaboration revenue	757,591	1,153,400
Total revenue	\$ 2,880,463	\$ 2,862,083

Total revenue for the nine months ended September 30, 2021 increased approximately 1% when compared to the same period in 2020, with a change in the mix of revenue, as follows:

- Product Sales: a decrease in revenue of approximately 6% in the 2021 period compared to the 2020 period is primarily attributable due to the Company's exit from the Company's FISH business, offset in part by the inclusion of Curetis' products sales subsequent to the Transaction;
- Laboratory Services: an increase in revenue of approximately 363% in the 2021 period compared to the 2020 period is primarily attributable to the inclusion of Curetis and Ares Genetics' laboratory services subsequent to the Transaction, including COVID testing services performed by the Company's Curetis subsidiary; and
- Collaboration Revenue: a decrease in revenue of approximately 34% in the 2021 period compared to the 2020 period is primarily attributable to the conclusion of non-recurring partnering revenues from a completed research and development collaboration with an IVD partner at Ares Genetics in 2020 and non-recurring milestone based revenue from the NYS project.

Operating expenses

	Nine months ended September 30,	
	2021	2020
Cost of products sold	\$ 1,544,932	\$ 2,340,766
Cost of services	446,232	550,115
Research and development	8,055,384	6,630,134
General and administrative	7,444,138	6,549,432
Sales and marketing	2,705,378	2,258,980
Transaction costs	—	470,322
Impairment of intangible assets	—	750,596
Impairment of right-of-use asset	170,714	—
Total operating expenses	\$ 20,366,778	\$ 19,550,345

Our total operating expenses for the nine months ended September 30, 2021 increased approximately 4% when compared to the same period in 2020. Operating expenses changed as follows:

- Cost of products sold: cost of products sold for the nine months ended September 30, 2021 decreased approximately 34% when compared to the same period in 2020. The decrease in cost of products sold is primarily attributable to the discontinuance of the Company's FISH line of products, partially offset by increased costs due to the sale of Curetis products;
- Cost of services: cost of services for the nine months ended September 30, 2021 decreased approximately 19% when compared to the same period in 2020. The decrease in cost of services is primarily attributable to lower Ares Genetics' collaboration revenue;
- Research and development: research and development expenses for the nine months ended September 30, 2021 increased approximately 21% when compared to the same period in 2020. The increase in research and development is primarily attributable to the inclusion of Curetis' and Ares Genetics' research and development expenses subsequent to the Transaction;
- General and administrative: general and administrative expenses for the nine months ended September 30, 2021 increased approximately 14% when compared to the same period in 2020, primarily due to the inclusion of Curetis' expenses subsequent to the Transaction;
- Sales and marketing: sales and marketing expenses for the nine months ended September 30, 2021 increased approximately 20% when compared to the same period in 2020, primarily due to the inclusion of Curetis' sales and marketing expenses subsequent to the Transaction, partially offset by lower travel costs;
- Transaction costs: transaction costs for the nine months ended September 30, 2020 represent one-time costs incurred as part of the business combination with Curetis;
- Impairment of intangible assets: impairment of intangible assets for the nine months ended September 30, 2020 represents the write down of intangible assets acquired from AdvanDx in 2015; and
- Impairment of right-of-use asset: impairment of right-of-use asset for the nine months ended September 30, 2021 represents the impairment of our San Diego, California ROU asset.

Other expense

	Nine months ended September 30,	
	2021	2020
Warrant inducement expense	\$ (7,755,541)	\$ —
Gain on extinguishment of debt	259,353	—
Interest expense	(3,586,018)	(2,267,085)
Foreign currency transaction gains (losses)	655,774	(794,832)
Other income	41,471	101,644
Change in fair value of derivative financial instruments	(122,572)	548,008
Total other expense	\$ (10,507,533)	\$ (2,412,265)

Our total other expense for the nine months ended September 30, 2021 increased when compared to the same period in 2020 primarily due to warrant inducement expense related to our 2021 Warrant Exercise and an increase in interest expense associated with the debt assumed as part of the Transaction with Curetis.

Liquidity and capital resources

As of September 30, 2021, we had cash and cash equivalents of \$25.4 million compared to \$13.4 million at December 31, 2020. We have funded our operations primarily through external investor financing arrangements and have raised funds in 2021 and 2020, including:

During the year ended December 31, 2020, we sold 7,521,610 shares of common stock under the 2020 ATM Offering resulting in aggregate net proceeds to us of approximately \$15.8 million, and gross proceeds of \$16.7 million.

During the year ended December 31, 2020, approximately 4.3 million common warrants issued in our October 2019 Public Offering were exercised for net proceeds of approximately \$8.7 million.

On November 25, 2020, we closed the 2020 PIPE of (i) 2,245,400 shares of common stock, (ii) 4,842,615 warrants to purchase shares of common stock and (iii) 2,597,215 pre-funded warrants. The offering raised gross proceeds of approximately \$10.0 million and net proceeds of approximately \$9.3 million.

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

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

Subsequent to September 30, 2021, we sold 680,000 shares of our common stock under the 2020 ATM Offering resulting in aggregate net proceeds to us of approximately \$1,500,000, and gross proceeds of approximately \$1,548,000.

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

To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions, and licensing and/or partnering arrangements. There can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise. We believe that our cash and cash equivalents as of September 30, 2021 and proceeds from the October 2021 Offering will be sufficient to repay or refinance the current portion of our debt and fund operations into the fourth quarter of 2022. This has led management to conclude that there is substantial doubt about our ability to continue as a going concern. In the event we are unable to successfully raise additional capital during or before the end of the fourth quarter of 2022, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to immediately reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until we are able to obtain sufficient financing. If such sufficient financing is not received on a timely basis, we would then need to pursue a plan to license or sell our assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

Sources and uses of cash

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

	Nine months ended September 30,	
	2021	2020
Net cash used in operating activities	\$ (17,690,398)	\$ (16,458,167)
Net cash used in investing activities	(1,824,765)	(935,606)
Net cash provided by financing activities	32,037,452	24,215,316

Net cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2021 consists primarily of our net loss of \$28.0 million, reduced by certain noncash items, including inducement expense related to warrant repricing of \$7.8 million, depreciation and amortization expense of \$2.1 million, noncash interest expense of \$3.0 million, and share-based compensation expense of \$0.7 million. Net cash used in operating activities for the nine months ended September 30, 2020 consists primarily of our net loss of \$19.1 million, reduced by certain noncash items, including impairment of intangible assets of \$0.8 million, depreciation and amortization expense of \$1.6 million, non-cash interest expense of \$1.7 million, and share-based compensation expense of \$0.2 million.

Net cash used in investing activities

Net cash used in investing activities for the nine months ended September 30, 2021 consists of the purchase of property and equipment. Net cash used in investing activities for the nine months ended September 30, 2020 consisted primarily of funds provided to Curetis GmbH as part of the Interim Facility offset by the acquisition of Curetis, net of cash acquired of \$1.3 million.

Net cash provided by financing activities

Net cash provided by financing activities for the nine months ended September 30, 2021 consists primarily of the net proceeds from the February 2021 Offering, 2021 Warrant Exercise, and other exercises of common stock warrants, net of payments on debt and insurance financings. Net cash provided by financing activities for the nine months ended September 30, 2020 consisted primarily of the net proceeds from the 2020 ATM Offering, exercises of common stock warrants, and issuance of debt.

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 unaudited condensed consolidated financial statements, estimates are used for, but not limited to, liquidity assumptions, revenue recognition, warrant inducement, share-based compensation, allowances for doubtful accounts and inventory obsolescence, valuation of derivative financial instruments measured at fair value on a recurring basis, deferred tax assets and liabilities and related valuation allowance, estimated useful lives of long-lived assets, and the recoverability of long-lived assets. Actual results could differ from those estimates.

A summary of our significant accounting policies is included in Note 3 "Summary of significant accounting policies" to the accompanying unaudited condensed consolidated financial statements. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain. Our critical policies are summarized in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2020.

Recently issued accounting pronouncements

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

Off-balance sheet arrangements

As of September 30, 2021 and December 31, 2020, we did not have any off-balance sheet arrangements.

JOBS Act

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of September 30, 2021. 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

On April 1, 2020, OpGen completed its business combination transaction of Curetis. The Company has not yet completed an assessment of the design and/or operating effectiveness of Curetis' internal control over financial reporting. There were no changes in the Company's internal control over financial reporting during the quarter ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

Reference is made to the Risk Factors included in our Annual Report on Form 10-K for the year ended December 31, 2020.

Our Board of Directors could issue one or more additional series of preferred stock without stockholder approval with the effect of diluting existing stockholders and impairing their voting and other rights.

Our Amended and Restated Certificate of Incorporation, as amended (the "Certificate"), authorizes the issuance of up to 10,000,000 shares of "blank check" preferred stock, of which only 150,000 shares were issued as Series B Convertible Preferred Stock to an investor in our October 2021 Offering, with designations, rights and preferences as may be determined from time to time by our Board of Directors. Our Board of Directors is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting or other rights which could dilute the interest of, or impair the voting power of, our common stockholders. The issuance of a series of preferred stock could be used as a method of discouraging, delaying or preventing a change in control. For example, it would be possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change in control of our company. In the event that we issue preferred stock in the future that has preferences over our common stock with respect to payment of dividends or upon our liquidation, dissolution, or winding up, or if we issue preferred stock that is convertible into our common stock at, or that has voting rights that are, greater than a one-to-one ratio, the voting and other rights of the holders of our common stock or the market price of our common stock could be adversely affected.

Holders of our preferred stock may have interests and rights that are different from our common stockholders.

In October 2021, we issued 150,000 shares of Series B Convertible Preferred Stock, with a stated value of \$100 per share, to an investor for aggregate gross proceeds of \$15 million. The holders of the Series B Convertible Preferred Stock generally participate in dividends and proceeds of any liquidation, on an as-if converted basis, in an equal amount and form as the holders of shares of our common stock and are convertible, upon the occurrence of certain events, at a rate of \$2.00 per share (subject to certain adjustments for stock dividends, stock splits or the occurrence of a fundamental transaction). The total number of shares of common stock issuable upon conversion of the outstanding shares of preferred stock is 7,500,000 shares (subject to adjustment), which if and when issued upon conversion will dilute the existing holders of common stock.

The shares of preferred stock have no voting rights, except that they have the right to vote, with the holders of common stock, as a single class, with each share of preferred stock entitled to 30,000 votes on: (i) any resolution to amend the Certificate to reduce the voting standard required for future amendments to a majority of the shares outstanding; and (ii) any resolution to amend the Certificate to increase the authorized shares of common stock to 100,000,000, provided, that the Company must count the votes of such preferred stock on such matter in proportion to the vote of the common stock on such resolution. The holders of preferred stock will therefore have a substantial number of votes in excess of the amount of shares of common stock underlying its shares of preferred stock on such proposals that will be considered at the Company's Special Meeting of Stockholders to be held on December 8, 2021 (provided, that, as noted above, the votes of the preferred stock on the proposal to increase the authorized shares of common stock must be counted in proportion to the vote of the common stock on such proposal). Unless the Company's number of authorized shares of common stock remaining available for issuance is increased, including by approval of the proposals at the Special Meeting by the requisite vote of the Company's stockholders, the shares of preferred stock cannot be converted into common stock of the Company. In addition, there is also no established public trading market for the preferred stock, and we do not expect one to develop. Accordingly, the interests of the holders of preferred stock may differ from those of our common stockholders, including, with respect to the approval of such amendments to the Certificate.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description
31.1*	Certification of Chief Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).
32.1*	Certification of Chief Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) the Unaudited Condensed Consolidated Balance Sheets, (ii) the Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Unaudited Condensed Consolidated Statements of Cash Flows and (iv) the Notes to Unaudited Condensed Consolidated Financial Statements.

* Filed or furnished herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OPGEN, INC.

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

Date: November 12, 2021

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER

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

I, Oliver Schacht, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OpGen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2021

/s/ Oliver Schacht

Oliver Schacht, Ph.D.

Chief Executive Officer

(principal executive officer and principal financial officer)

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

In connection with the quarterly report on Form 10-Q of OpGen, Inc. (the "Company") for the quarterly period ended September 30, 2021 (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: November 12, 2021

By: /s/ Oliver Schacht

Oliver Schacht, Ph.D.

Chief Executive Officer

(principal executive officer and principal financial 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.