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

FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 2020

or

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

For the transition period from _____ to _____

Commission File Number 001-37367

OPGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware	**06-1614015**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. employer identification no.)**
708 Quince Orchard Road, Suite 205, Gaithersburg, MD	**20878**
(Address of principal executive offices)	**(Zip code)**

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

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

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

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

15,070,107 shares of the Company's common stock, par value $0.01 per share, were outstanding as of May 7, 2020.

OPGEN, INC.

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

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

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part 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 liquidity and working capital requirements, including our cash requirements over the next 12 months;
- our ability to maintain compliance with the ongoing listing requirements for the Nasdaq Capital Market;
- receipt of regulatory clearance of our submitted 510(k) pre-market submission for our Acuitas AMR Gene Panel test for use with bacterial isolates;
- the impact of the coronavirus pandemic on our business and operations;
- the completion of our development efforts for the Acuitas AMR Gene Panel Urine test and Acuitas Lighthouse Software, Unyvero IJI and SHR panels, Unyvero A30 RQ platform and Ares*db* and the timing of regulatory submissions;
- our ability to sustain or grow our customer base for our current research use only and rapid pathogen ID testing products;
- regulations and changes in laws or regulations applicable to our business, including regulation by the FDA;
- anticipated trends and challenges in our business and the competition that we face;
- the execution of our business plan and our growth strategy;
- our expectations regarding the size of and growth in potential markets;
- our opportunity to successfully enter into new collaborative or strategic agreements;
- compliance with the U.S. and international regulations applicable to our business; and
- our expectations regarding future revenue and expenses.

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

NOTE REGARDING TRADEMARKS

We own various U.S. federal trademark registrations and applications and unregistered trademarks and servicemarks, including 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)

	March 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 11,469,455	$ 2,708,223
Accounts receivable, net	165,931	567,811
Inventory, net	436,683	473,030
Note receivable	4,808,712	2,521,479
Prepaid expenses and other current assets	264,013	396,760
Total current assets	**17,144,794**	**6,667,303**
Property and equipment, net	102,579	130,759
Finance lease right-of-use assets, net	826,243	958,590
Operating lease right-of-use assets	885,882	1,043,537
Goodwill	600,814	600,814
Intangible assets, net	—	817,550
Other noncurrent assets	203,212	203,271
Total assets	**$ 19,763,524**	**$ 10,421,824**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,054,261	$ 1,056,035
Accrued compensation and benefits	988,291	855,994
Accrued liabilities	1,047,019	1,046,661
Deferred revenue	9,808	9,808
Short-term notes payable	348,494	373,599
Short-term finance lease liabilities	517,042	579,030
Short-term operating lease liabilities	947,610	1,017,414
Total current liabilities	**4,912,525**	**4,938,541**
Note payable	163,401	329,456
Long-term finance lease liabilities	212,798	313,263
Long-term operating lease liabilities	392,106	547,225
Total liabilities	**5,680,830**	**6,128,485**
Commitments (Note 9)		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at March 31, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.01 par value; 50,000,000 shares authorized; 12,468,214 and 5,582,280 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	124,682	55,823
Additional paid-in capital	192,410,127	178,779,814
Accumulated deficit	(178,474,277)	(174,524,983)
Accumulated other comprehensive income (loss)	22,162	(17,315)
Total stockholders' equity	**14,082,694**	**4,293,339**
Total liabilities and stockholders' equity	**$ 19,763,524**	**$ 10,421,824**

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31, 2020	2019
Revenue		
Product sales	$ 366,933	$ 520,177
Collaboration revenue	250,000	500,000
Total revenue	**616,933**	**1,020,177**
Operating expenses		
Cost of products sold	276,554	220,702
Cost of services	137,666	144,482
Research and development	1,217,556	1,776,382
General and administrative	1,701,448	1,747,585
Sales and marketing	282,277	372,233
Transaction costs	245,322	—
Impairment of right-of-use asset	—	520,759
Impairment of intangibles assets	750,596	—
Total operating expenses	**4,611,419**	**4,782,143**
Operating loss	**(3,994,486)**	**(3,761,966)**
Other income (expense)		
Interest and other income (expense)	87,335	(24,422)
Interest expense	(38,267)	(56,444)
Foreign currency transaction losses	(3,876)	(10,351)
Change in fair value of derivative financial instruments	—	67
Total other income (expense)	**45,192**	**(91,150)**
Loss before income taxes	**(3,949,294)**	**(3,853,116)**
Provision for income taxes	—	—
Net loss	**(3,949,294)**	**(3,853,116)**
Net loss available to common stockholders	**$ (3,949,294)**	**$ (3,853,116)**
Net loss per common share - basic and diluted	**$ (0.53)**	**$ (8.25)**
Weighted average shares outstanding - basic and diluted	7,393,232	467,286
Net loss	$ (3,949,294)	$ (3,853,116)
Other comprehensive income - foreign currency translations	39,477	2,826
Comprehensive loss	**$ (3,909,817)**	**$ (3,850,290)**

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Common Stock		Preferred Stock					
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total
Balances at December 31, 2018	432,286	$ 4,323	**—**	**$ —**	**$ 165,396,036**	**$ (13,093)**	**$ (162,078,525)**	**$ 3,308,741**
Public offering of common stock and warrants, net of issuance costs	450,000	4,500	—	—	4,778,009	—	—	4,782,509
Stock compensation expense	—	—	—	—	98,033	—	—	98,033
Foreign currency translation	—	—	—	—	—	2,826	—	2,826
Net loss	—	—	—	—	—	—	(3,853,116)	(3,853,116)
Balances at March 31, 2019	**882,286**	**$ 8,823**	**—**	**$ —**	**$ 170,272,078**	**$ (10,267)**	**$ (165,931,641)**	**$ 4,338,993**
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**

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (3,949,294)	$ (3,853,116)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	228,538	223,115
Noncash interest expense	4,397	29,265
Noncash interest income	(87,233)	—
Stock compensation expense	79,740	98,033
Loss on sale of equipment	—	24,439
Change in fair value of warrant liability	—	(67)
Impairment of right-of-use asset	—	520,759
Impairment of intangible assets	750,596	—
Changes in operating assets and liabilities:		
Accounts receivable	401,532	(440,475)
Inventory	36,257	44,545
Other assets	283,180	285,070
Accounts payable	(627)	(31,531)
Accrued compensation and other liabilities	(91,828)	120,015
Deferred revenue	—	(5,831)
Net cash used in operating activities	**(2,344,742)**	**(2,985,779)**
Cash flows from investing activities		
Note receivable	(2,200,000)	—
Purchases of property and equipment	(1,057)	(8,493)
Proceeds from sale of equipment	—	1,250
Net cash used in investing activities	**(2,201,057)**	**(7,243)**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	5,477,432	4,782,509
Proceeds from the exercise of common stock warrants	8,142,000	—
Payments on debt	(191,772)	(217,484)
Payments on finance lease obligations	(162,453)	(116,538)
Net cash provided by financing activities	**13,265,207**	**4,448,487**
Effects of exchange rates on cash	41,824	4,216
Net increase in cash, cash equivalents and restricted cash	8,761,232	1,459,681
Cash, cash equivalents and restricted cash at beginning of period	2,893,603	4,737,207
Cash, cash equivalents and restricted cash at end of period	**$ 11,654,835**	**$ 6,196,888**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 55,011	$ 73,754
Supplemental disclosures of noncash investing and financing activities:		
Right-of-use assets acquired through finance leases	$ —	$ 161,116
Conversion of accounts payable to finance lease	$ —	$ 63,600

See accompanying notes to unaudited condensed consolidated financial statements.

Note 1 – Organization

OpGen, Inc. ("OpGen" or the "Company") was incorporated in Delaware in 2001. References in this report to the "Company" include OpGen and its wholly-owned subsidiaries. The Company's headquarters are in Gaithersburg, Maryland, and its principal operations are in Gaithersburg, Maryland. The Company also has operations in Copenhagen, Denmark and Bogota, Colombia. The Company operates in one business segment.

Business Combination Transaction with Curetis N.V.

On April 1, 2020 (the "Closing Date"), the Company 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"), 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, as further described below, and paid, as the sole consideration, 2,028,208 shares of the Company's common stock, par value $0.01 per share (the "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, of which 265,002 shares have been issued as of May 8, 2020, in satisfaction of approximately $543,000 of outstanding principal and indebtedness under the assumed convertible notes. The 2,028,208 shares of Common Stock issued to the Seller represented approximately 13.8% of the outstanding Common Stock of the Company as of the Closing Date.

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 patient (the "Curetis Business"). 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 (the "Assignment Agreement"), and entered into pursuant to the Implementation Agreement. In this Quarterly Report we refer to the combined business following the consummation of the Transaction as "Newco".

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 molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. Its proprietary DNA tests and informatics address the rising threat of antibiotic resistance by helping physicians and other healthcare providers optimize care decisions for patients with acute infections.

The Company's molecular diagnostics and informatics products, product candidates and services combine its Acuitas molecular diagnostics and Acuitas Lighthouse informatics platform for use with its proprietary, curated MDRO knowledgebase. The Company is working to deliver products and services, some in development, to a global network of customers and partners.

- The Company's Acuitas molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include its Acuitas antimicrobial resistance, or AMR, Gene Panel Urine test in development for patients at risk for complicated urinary tract infection, or cUTI, and its Acuitas AMR Gene Panel test for use with bacterial isolates in development for testing bacterial isolates, and its QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures. Each of the Acuitas AMR Gene Panel tests is available for sale for research use only, or RUO and is not for use in diagnostic procedures.

- The Company's Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that combine clinical lab test results with patient and hospital information to provide analytics and actionable insights to help manage MDROs in the hospital and patient care environment. Components of the informatics systems include the Acuitas Lighthouse Knowledgebase and the Acuitas Lighthouse Software. The Acuitas Lighthouse Knowledgebase is a relational database management system and a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens. The Acuitas Lighthouse Software system includes the Acuitas Lighthouse Portal, a suite of web applications and dashboards, the Acuitas Lighthouse Prediction Engine, which is a data analysis software, and other supporting software components. The Acuitas Lighthouse Software can be customized and made specific to a healthcare facility or collaborator, such as a pharmaceutical company. The Acuitas Lighthouse Software is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

The Company's operations are subject to certain risks and uncertainties. The risks include the risk that the Company will not receive 510(k) clearance for its Acuitas AMR Gene Panel test for use with bacterial isolates on a timely basis, or at all, the timing and ultimate success of future 510(k) and *De Novo* submissions for additional Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software, rapid technology changes, the need to retain key personnel, the need to protect intellectual property and the need to raise additional capital financing on terms acceptable to the Company. The Company's success depends, in part, on its ability to develop, obtain regulatory approval for and commercialize its proprietary technology as well as raise additional capital.

Overview of the Curetis Business

The Curetis Business develops, manufactures and commercializes innovative solutions for molecular microbiology.

The Curetis business is based on two complementary business pillars:

- The Unyvero A50 is a high-plex polymerase chain reaction, or PCR, platform for comprehensive and rapid diagnosis of severe infectious diseases in hospitalized patients. The platform is based on proven, intelligently integrated technologies, allowing for the testing of broad panels of pathogens and antibiotic resistance markers and the processing of a large variety of native patient samples with an intuitive workflow. The Unyvero A50 high-plex PCR platform's advantage is the timely access to comprehensive, actionable and reliable data. Curetis' molecular tests for different indications are commercially available in Europe, the United States, Asia and the Middle East. The Curetis Group is also developing the Unyvero A30 RQ Analyzer, which is designed to serve as a platform with low-to medium-plex capabilities that it ultimately intends to commercially leverage predominantly in collaborations with one or more diagnostics industry partners.

- The ARES AMR database, or ARES*db*, is a comprehensive database of the genetics of antimicrobial resistance, or AMR, which permits Curetis to increasingly utilize the proprietary biomarker content in its own assay and cartridge development, as well as to build an independent business in next-generation sequencing, or NGS, based offerings for AMR research and diagnostics in collaboration with partners in the life science, pharmaceutical and diagnostics industries. ARES*db* is not commercially available in the United States for diagnostic use, as it has not been cleared by the FDA. In September 2019, Ares Genetics, a wholly owned subsidiary of Curetis, or Ares Genetics, signed a technology evaluation agreement with an undisclosed global IVD corporation. In the first phase of the collaboration, expected to take about 10 months, Ares Genetics expects to further enrich ARES*db* with a focus on certain pathogens relevant in a first, undisclosed infectious disease indication.

Curetis GmbH's offices and R&D laboratories are based in Holzgerlingen, near Stuttgart with its cartridge manufacturing facility in Bodelshausen also in southern Germany, in addition to subsidiaries located in San Diego, California, USA and Vienna, Austria.

Overview of Newco

We anticipate that the focus of Newco will be on its combined broad portfolio of products, which include high impact rapid diagnostics and bioinformatics to interpret AMR genetic data. The products we expect Newco to focus on are for lower respiratory infection and urinary tract infection:

- The Unyvero Lower Respiratory Tract, or LRT, test is the first FDA cleared test that can be used for more than 90% of infection cases of hospitalized pneumonia patients. According to the National Center for Health Statistics (2018), pneumonia is a leading cause of admissions to the hospital and is associated with substantial morbidity and mortality. 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 are also commercializing the Unyvero LRT test for testing bronchoalveolar lavage, or BAL, specimens of U.S. patients with lower respiratory tract infections following FDA clearance received by Curetis in December 2019. We believe the Unyvero LRT test has 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.

- The Acuitas AMR Gene Panel (Urine)) test is being developed for patients at risk for cUTI, and is designed to test for up to five pathogens and up to 47 antimicrobial resistance genes. When paired with the Acuitas Lighthouse software, we believe the test will be able to help improve management of the more than one million patients in the United States with cUTI. The AMR Gene Panel (Urine) is in testing for preparation of a *De Novo* submission with the FDA. We are pursuing a Class I designation through a De Novo Request for the test in connection with an initial clinical indication to test bacterial isolates.

Newco will have an extensive offering of additional *in vitro* diagnostic tests including CE-marked Unyvero tests for implant and tissue infections, intra-abdominal infections, cUTI, and blood stream infections, and the QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures, which we believe have an established market position in the United States.

Newco's combined AMR informatics offerings, once all such products are cleared for marketing, if ever, will offer important new tools to clinicians treating patients with AMR infections. OpGen has 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 Curetis ARES*db* is a comprehensive database of genetic and phenotypic information. ARES*db* was originally designed based on the SIEMENS microbiology strain collection covering resistant pathogens over the last 30 years and its development has significantly expanded to now include approximately 55,000 sequenced isolate strains and phenotypic correlation data against over 100 antibiotics. In September 2019, Ares Genetics signed a technology evaluation agreement with an undisclosed global IVD corporation. In the first phase of the collaboration, expected to take about 10 months, Ares Genetics expects to further enrich ARES*db* with a focus on certain pathogens relevant in a first, undisclosed infectious disease indication. We anticipate that Newco will 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 partners in the life science, pharmaceutical and diagnostics industries.

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 Marked in 2012 and was FDA cleared in 2018 along with the LRT test through *De Novo* process. As of December 31, 2019, there is an installed base of 173 Unyvero A50 Analyzers globally. 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 45 to 90 minutes with 2-5 minutes of hands on time. The Unyvero A30 has a small laboratory footprint and has an attractive cost of goods profile. Curetis has been following a partnering strategy for the Unyvero A30.

Newco has extensive partner and distribution relationships to help accelerate the establishment of a global infectious disease diagnostic testing and informatics business. Partners will include A. Menarini Diagnostics for pan-European distribution to currently 11 countries; MGI/BGI for NGS-based molecular microbiology applications in China; and Beijing Clear Biotech Co. Ltd. for Unyvero A50 product distribution in China. Newco has a network currently consisting of 18 distributors covering 43 countries.

Newco will continue to develop and seek FDA and other regulatory clearances or approvals, as applicable, for the Acuitas AMR Gene Panel (Urine) diagnostic test and the Acuitas Lighthouse Software products. Newco will continue to offer the Acuitas AMR Gene Panel (Isolates) and Acuitas Lighthouse Software as well as the Unyvero UTI Panel as RUO products to hospitals, public health departments, clinical laboratories, pharmaceutical companies and contract research organizations, or CROs.

Note 2 – Liquidity 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 transactions, including the following in 2019 and 2020 to date:

- On February 11, 2020, the Company entered into an At the Market Common Offering (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), 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 $15.7 million of shares of the Company's common stock through Wainwright, as sales agent, (the "2020 ATM Offering"). During the three months ended March 31, 2020, the Company sold 2,814,934 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately $5.5 million, and gross proceeds of $5.8 million.
- On October 28, 2019, the Company closed a public offering (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, raising gross proceeds of approximately $9.4 million and net proceeds of approximately $8.3 million. Each unit included one share of common stock and one common warrant to purchase one share of common stock at an exercise price of $2.00 per share. Each pre-funded unit included one pre-funded warrant to purchase one share of common stock for an exercise price of $0.01 per share, and one common warrant to purchase one share of common stock at an exercise price of $2.00 per share. The common warrants are exercisable immediately and have a five-year term from the date of issuance. As of March 31, 2020, all 2,109,830 pre-funded warrants issued in the October 2019 Public Offering have been exercised. Additionally during the three months ended March 31, 2020, 4,071,000 common warrants issued in the October 2019 Public Offering were exercised for net proceeds of approximately $8.1 million.
- On March 29, 2019, the Company closed a public offering (the "March 2019 Public Offering") of 450,000 shares of its common stock at a public offering price of $12.00 per share. The offering raised gross proceeds of $5.4 million and net proceeds of approximately $4.8 million.

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 and business combination transactions. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. The Company believes that current cash will be sufficient to fund operations into the fourth quarter of 2020. This has led management to conclude that substantial doubt about the Company's ability to continue as a going concern exists. In the event the Company is unable to successfully raise additional capital during or before the end of the fourth quarter of 2020, 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, 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 following 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, 2019 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 March 31, 2020 and excludes the Curetis Business which was acquired on April 1, 2020; all intercompany transactions and balances have been eliminated.

Foreign currency

The Company has subsidiaries located in Copenhagen, Denmark, and Bogota, Colombia, both 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 (loss)/income, a component of stockholders' equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive (loss)/income at March 31, 2020 and 2019.

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, 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, the estimated useful lives of long-lived assets, and the recoverability of long-lived assets. Actual results could differ from those estimates.

Fair value of financial instruments

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

Cash, cash equivalents and restricted cash

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. The Company has cash and cash equivalents deposited in financial institutions in which the balances occasionally exceed the federal government agency ("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 March 31, 2020 and December 31, 2019, the Company has funds totaling $185,380, 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, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the statements of cash flows:

	March 31, 2020	December 31, 2019	March 31, 2019	December 31, 2018
Cash and cash equivalents	$ 11,469,455	$ 2,708,223	$ 6,011,508	$ 4,572,487
Restricted cash	185,380	185,380	185,380	164,720
Total cash, cash equivalents and restricted cash in the condensed consolidated statement of cash flows	$ 11,654,835	$ 2,893,603	$ 6,196,888	$ 4,737,207

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 60 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 $20,753 as of March 31, 2020 and December 31, 2019.

At March 31, 2020, the Company had accounts receivable from one customer which individually represented 31% of total accounts receivable. At March 31, 2019, one individual customer represented 61% of total accounts receivable. For the three months ended March 31, 2020, revenue earned from one customer represented 41% of total revenues. For the three months ended March 31, 2019, revenue earned from one customer represented 49% of total revenues.

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:

	March 31, 2020	December 31, 2019
Raw materials and supplies	$ 266,444	$ 315,542
Work-in-process	22,291	35,080
Finished goods	147,948	122,408
Total	$ 436,683	$ 473,030

Inventory includes reagents and components for QuickFISH and PNA FISH kit products, and reagents and supplies used for the Company's laboratory services. Inventory reserves for obsolescence and expirations were $132,260 and $92,454 at March 31, 2020 and December 31, 2019, respectively.

Long-lived assets

Property and equipment

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the three months ended March 31, 2020 and 2019, the Company determined that its property and equipment was not impaired.

Leases

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

Lease expense for operating leases is recognized on a straight-line basis over the lease term as an operating expense while expense for financing leases is recognized as depreciation expense and interest expense using the accelerated 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. In conjunction with adoption of Accounting Standards Update ("ASU") 2016-02, *Leases* (Topic 842) ("ASC 842"), the Company determined that the ROU asset associated with its Woburn, Massachusetts office lease may not be recoverable. As a result, the Company recorded an impairment charge of $520,759 during the three months ended March 31, 2019.

Intangible assets and goodwill

Intangible assets and goodwill as of March 31, 2020 consist of finite-lived intangible assets and goodwill.

Finite-lived intangible assets

Finite-lived intangible assets include trademarks, developed technology and customer relationships and consisted of the following as of March 31, 2020 and December 31, 2019:

	March 31, 2020				December 31, 2019	
	Cost	Accumulated Amortization	Impairment	Net Balance	Accumulated Amortization	Net Balance
Trademarks and tradenames	$ 461,000	(217,413)	$ (243,587)	$ —	$ (205,887)	$ 255,113
Developed technology	458,000	(308,526)	(149,474)	—	(292,170)	165,830
Customer relationships	1,094,000	(736,465)	(357,535)	—	(697,393)	396,607
	$ 2,013,000	(1,262,404)	$ (750,596)	$ —	$ (1,195,450)	$ 817,550

Finite-lived intangible assets are amortized over their estimated useful lives. The estimated useful life of trademarks is 10 years, developed technology is 7 years, and customer relationships is 7 years. 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 $66,954 for each of the three months ended March 31, 2020 and 2019.

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

In accordance with ASC 360-10, *Property, Plant and Equipment*, the Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that long-lived assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. During the three months ended March 31, 2020, events and circumstances indicated the Company's 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 intangible assets were impaired. The Company's analysis determined that the fair value of the assets was $0 and the Company recorded and impairment loss of $750,596.

Goodwill

Goodwill represents the excess of the purchase price paid in a July 2015 merger transaction in which the Company acquired AdvanDx, Inc. and its subsidiary (the "Merger") 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 March 31, 2020 and December 31, 2019 was $600,814.

The Company conducts an impairment test of goodwill on an annual basis, and will also conduct tests if events occur or circumstances change that would, more likely than not, reduce the Company's fair value below its net equity value. During the three months ended March 31, 2020 and 2019, the Company determined that its goodwill was not impaired.

Revenue recognition

The Company derives revenues from (i) the sale of QuickFISH and PNA FISH diagnostic test products and Acuitas AMR Gene Panel RUO 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.

Stock-based compensation

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

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

Income taxes

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

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

The Company had federal net operating loss (“NOL”) carryforwards of $188,282,298 at December 31, 2019. Despite the NOL carryforwards, which begin to expire in 2022, the Company may have future tax liability due to alternative minimum tax or 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.

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 1.1 million shares and 0.2 million shares as of March 31, 2020 and 2019, respectively.

Adopted accounting pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* (“ASC 842”), which amended the existing accounting standards for leases. The new standard requires lessees to record a right-of-use (“ROU”) asset and a corresponding lease liability on the balance sheet (with the exception of short-term leases), whereas under previous accounting standards, the Company’s lease portfolio consisting of operating leases were not recognized on its consolidated balance sheets. The new standard required expanded disclosures regarding leasing arrangements. The new standard was effective for the Company beginning January 1, 2019.

The Company adopted this guidance effective January 1, 2019 using the modified retrospective transition method and the following practical expedients:

- The Company did not reassess if any expired or existing contracts are or contain leases.
- The Company did not reassess the classification of any expired or existing leases.

Additionally, the Company made ongoing 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.

Upon adoption of the new guidance on January 1, 2019, the Company recorded an operating lease right of use asset of approximately $2.2 million (net of existing deferred rent) and recognized a lease liability of approximately $2.5 million.

Prior to the adoption of ASC 842, deferred rent was recorded and amortized to the extent the total minimum rental payments allocated to the period on a straight-line basis exceeded or were less than the cash payments required.

The Company adopted Accounting Standards Update 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), as of January 1, 2020. ASU 2016-13 requires an entity to measure and recognize expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded through net income instead of directly reducing the amortized cost of the investment under the previous other-than-temporary impairment model. The adoption of this standard did not have a material impact on our 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 – 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 March 31,	
	2020	2019
Product sales	$ 366,933	$ 520,177
Collaboration revenue	250,000	500,000
Total revenue	$ 616,933	$ 1,020,177

Deferred revenue

Changes in deferred revenue for the period were as follows:

Balance at December 31, 2019	$ 9,808
Revenue recognized in the current period from the amounts in the beginning balance	—
New deferrals, net of amounts recognized in the current period	—
Balance at March 31, 2020	$ 9,808

Contract assets

The Company had no contract assets as of March 31, 2020, which are generated when contractual billing schedules differ from revenue recognition timing. Contract assets represent a conditional right to consideration for satisfied performance obligations that becomes a billed receivable when the conditions are satisfied.

Unsatisfied performance obligations

The Company had no unsatisfied performance obligations related to its contracts with customers at March 31, 2020.

Note 5 – 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 are secured by a lien on all of the Company’s assets.

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 Note to six semi-annual payments of $166,667 plus accrued and unpaid interest beginning on January 2, 2019 and ending on July 1, 2021. The Allonge to the MGHIF Note was treated as a debt modification and as such the unamortized issuance costs of approximately $7,000 as of June 11, 2018 is deferred and amortized as incremental expense over the term of the MGHIF Note.

On July 30, 2018, the Company issued 7,212 shares of common stock to MGHIF in a private placement transaction in payment of the $285,512 of accrued and unpaid interest due as of July 14, 2018 under the MGHIF Note.

The Company’s outstanding debt under the MGHIF Note, net of discounts and financing costs as of March 31, 2020 was approximately $497,000.

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 three months ended March 31, 2020, 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.

As part of the Company's bridge financing and amendment to the MGHIF Note, the Company issued stock purchase warrants that the Company considers to be mark-to-market liabilities due to certain put features that allow the holder to put the warrant back to the Company for cash equal to the Black-Scholes value of the warrant upon a change of control or fundamental transaction. The Company determines the fair value of the warrant liabilities using the Black-Scholes option pricing model. Using this model, level 3 unobservable inputs include the estimated volatility of the Company's common stock, estimated terms of the instruments, and estimated risk-free interest rates. The fair value of level 3 liabilities measured at fair value on a recurring basis for the three months ended March 31, 2020 and December 31, 2019 was $0.

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 they are deemed to be impaired. During the three months ended March 31, 2020 the Company recorded impairment expense of $750,596 related to its intangible assets (See Note – 3).

Note 7 – Debt

As of March 31, 2020, the Company's outstanding short-term debt consisted of approximately $333,000 due under the MGHIF Note, as well as the financing arrangements for the Company's insurance with note balances of approximately $15,000 with a final payment scheduled for May 2020. The Company's outstanding long-term debt as of March 31, 2020 consisted of approximately $163,000 due under the MGHIF Note (see Note 5 "MGHIF financing") net of discounts and financing costs. As of December 31, 2019, the Company's outstanding short-term debt consisted of approximately $333,000 due under the MGHIF Note, as well as the financing arrangements for the Company's insurance with note balances of approximately $40,000. The Company's outstanding long-term debt as of December 31, 2019 consisted of approximately $329,000 due under the MGHIF Note, net of discounts and financing costs. Total principal payments of approximately $333,000 are due annually in 2020 and 2021.

Total interest expense (including amortization of debt discounts and financing fees) on all debt instruments was $38,267 and $56,444 for the three months ended March 31, 2020 and 2019, respectively.

Note 8 – Stockholders' equity

As of March 31, 2020, the Company has 50,000,000 shares of authorized common shares and 12,468,214 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 March 29, 2019, the Company closed the March 2019 Public Offering of 450,000 shares of its common stock at a public offering price of $12.00 per share. The offering raised gross proceeds of $5.4 million and net proceeds of approximately $4.8 million.

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. As of March 31, 2020, the 2,109,830 pre-funded warrants issued in the October 2019 Public Offering have been exercised. Additionally, during the three months ended March 31, 2020, 4,071,000 common warrants were exercised raising net proceeds of approximately $8.1 million.

In connection with the October 2019 Public Offering, the Company issued to its placement agent warrants to purchase 235,000 shares of common stock. The warrants issued to the placement agent have an exercise price of $2.60 per share and are exercisable for five years.

On February 11, 2020, the Company entered into an ATM Agreement with Wainwright, 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 $15.7 million of shares of the Company's common stock through Wainwright, as sales agent. During the three months ended March 31, 2020, the Company sold 2,814,934 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately $5.5 million, and gross proceeds of $5.8 million. As of March 31, 2020, remaining availability under the at the market offering is $9.9 million.

Stock options

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

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

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 54,200 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. Shares subject to awards granted under the 2015 Plan that are forfeited or terminated before being exercised or settled, or are not delivered to the participant because such award is settled in cash, will again become available for issuance under the 2015 Plan. However, shares that have actually been issued shall not again become available unless forfeited. As of March 31, 2020, 229,533 shares remain available for issuance under the 2015 Plan, which includes 223,291 shares automatically added to the 2015 Plan on January 1, 2020.

For the three months ended March 31, 2020 and 2019, the Company recognized share-based compensation expense as follows:

	Three Months Ended March 31,	
	2020	2019
Cost of services	$ 728	$ 38
Research and development	13,986	17,127
General and administrative	61,488	76,013
Sales and marketing	3,538	4,855
	$ 79,740	$ 98,033

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

The Company did not grant any stock options during the three months ended March 31, 2020. During the three months ended March 31, 2020, 28 options were forfeited and 230 options expired. The Company had total stock options to acquire 9,396 shares of common stock outstanding at March 31, 2020.

Restricted stock units

During the three months ended March 31, 2020, no restricted stock units vested and 200 restricted stock units were forfeited. The Company had 14,775 total restricted stock units outstanding at March 31, 2020.

Stock purchase warrants

At March 31, 2020 and December 31, 2019, the following warrants to purchase shares of common stock were outstanding:

Issuance	Exercise Price	Expiration	Outstanding at March 31, 2020	Outstanding at December 31, 2019
January 2010	$ 3,955.00	January 2020	—	17
March 2010	$ 3,955.00	March 2020	—	7
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 2015	$ 3,300.00	May 2020	6,697	6,697
May 2016	$ 656.20	May 2021	9,483	9,483
June 2016	$ 656.20	May 2021	4,102	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	$ 212.60	July 2022	50,006	50,006
February 2018	$ 81.25	February 2023	9,232	9,232
February 2018	$ 65.00	February 2023	92,338	92,338
October 2019	$ 2.00	October 2024	629,000	4,700,000
October 2019	$ 2.60	October 2024	235,000	235,000
			1,040,083	5,111,107

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

Note 9 – Commitments and Contingencies

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 March 31, 2020, the Company has acquired twenty-four QuantStudio 5s including none during the three months ended March 31, 2020. As of March 31, 2020, the Company has not committed to acquiring additional QuantStudio 5s in the next three months.

Contingencies

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic, which continues to spread throughout the United States and around the world. As of March 31, 2020, the Company is aware of changes in its business as a result of COVID-19 but uncertain of the impact of those changes on its financial position, results of operations or cash flows. Management believes any disruption, when and if experienced, could be temporary; however, there is uncertainty around when any disruption might occur, the duration and hence the potential impact. As a result, we are unable to estimate the potential impact on our business as of the date of this filing.

Note 10 – Leases

The following table presents the Company's ROU assets and lease liabilities as of March 31, 2020 and December 31, 2019:

Lease Classification	March 31, 2020	December 31, 2019
ROU Assets:		
Operating	$ 885,882	$ 1,043,537
Financing	826,243	958,590
Total ROU assets	$ 1,712,125	$ 2,002,127
Liabilities		
Current:		
Operating	$ 947,610	$ 1,017,414
Finance	517,042	579,030
Noncurrent:		
Operating	392,106	547,225
Finance	212,798	313,263
Total lease liabilities	$ 2,069,556	$ 2,456,932

Maturities of lease liabilities as of March 31, 2020 by fiscal year are as follows:

Maturity of Lease Liabilities	Operating	Finance	Total
2020	$ 856,889	$ 452,206	$ 1,309,095
2021	547,019	281,914	828,933
2022	40,930	45,374	86,304
2023	—	3,364	3,364
2024	—	280	280
Thereafter	—	—	—
Total lease payments	1,444,838	783,138	2,227,976
Less: Interest	(105,122)	(53,298)	(158,420)
Present value of lease liabilities	$ 1,339,716	$ 729,840	$ 2,069,556

Statement of operations classification of lease costs as of the three months ended March 31, 2020, and 2019 are as follows:

Lease Cost	Classification	2020	2019
Operating	Operating expenses	$ 214,336	$ 220,922
Finance:			
Amortization	Operating expenses	132,348	97,193
Interest expense	Other expenses	18,470	22,480
Total lease costs		$ 365,154	$ 340,595

Other lease information as of March 31, 2020 is as follows:

Other Information	Total
Weighted average remaining lease term (in years)	
Operating leases	1.5
Finance leases	1.4
Weighted average discount rate:	
Operating leases	10.0%
Finance leases	9.4%

Supplemental cash flow information as of the three months ended March 31, 2020, and 2019 is as follows:

Supplemental Cash Flow Information	2020	2019
Cash paid for amounts included in the measurement of lease liabilities		
Cash used in operating activities		
Operating leases	$ 214,336	$ 214,622
Finance leases	$ 18,470	$ 22,480
Cash used in financing activities		
Finance leases	$ 162,455	$ 116,538
ROU assets obtained in exchange for lease obligations:		
Finance leases	$ —	$ 224,716

Note 11 – License agreements, research collaborations and development agreements

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. The Company is working together with DOH's Wadsworth Center and ILÚM to develop 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. During the three months ended March 31, 2020 and 2019, the Company recognized $250,000 and $500,000 of revenue related to the contract, respectively.

The Company is a party to one license agreement to acquire certain patent rights and technologies related to its FISH product line. Royalties are incurred upon the sale of a product or service which utilizes the licensed technology. The Company recognized net royalty expense of $62,500 for each of the three months ended March 31, 2020 and 2019. Annual future minimum royalty fees are $250,000 under this agreement.

Note 12 – Related party transactions

In October 2016, the Company entered into an agreement with Merck Sharp & Dohme Corp. ("MSD"), a wholly-owned subsidiary of Merck, and an affiliate of MGHIF, a principal stockholder of the Company and a related party to the Company. Under the agreement, MSD provided access to its archive of over 200,000 bacterial pathogens. The Company is initially performing molecular analyses on up to 10,000 pathogens to identify markers of resistance to support rapid decision making using the Acuitas Lighthouse, and to speed development of its rapid diagnostic products. MSD gains access to the high-resolution genotype data for the isolates as well as access to the Acuitas Lighthouse informatics to support internal research and development programs. The Company is required to expend up to $175,000 for the procurement of materials related to the activities contemplated by the agreement. Contract life-to-date, the Company has incurred $171,646 of procurement costs which have been recognized as research and development expense. The Company did not recognize any research and development expense related to the agreement in the three months ended March 31, 2020 and 2019.

Note 13 – Interim Facility

On September 4, 2019, OpGen entered into the Implementation Agreement. Under the Implementation Agreement, OpGen agreed to purchase, through Crystal GmbH, all of the outstanding shares and acquire all of the related business assets of Curetis GmbH to create a combined business within OpGen. The Implementation Agreement required OpGen to enter into an interim facility with Curetis GmbH to support Curetis GmbH's operations prior to the closing of the transaction under the Implementation Agreement.

On November 12, 2019, Crystal GmbH, OpGen's subsidiary, as Lender, and Curetis GmbH, as Borrower, entered into the Interim Facility Agreement. The Interim Facility was amended and restated by the parties on March 18, 2020, or the Interim Facility. Under the Interim Facility, the Lender has lent to the Borrower committed capital of $4.7 million between November 18, 2019 and the closing of the transaction. The purpose of the loans was to provide capital to fund the operations of Curetis GmbH, including the discharge of current liabilities when due. Each loan under the Interim Facility bears interest at 10% per annum and is due to be repaid on the first anniversary of the loan. The Interim Facility loans are subordinated to the current and future indebtedness of the Borrower. As of March 31, 2020, Curetis GmbH had borrowed approximately $4.7 million, and OpGen had recognized approximately $109,000 of interest income under the Interim Facility including approximately $87,000 during the three months ended March 31, 2020.

On April 1, 2020, the Company completed the transaction with Curetis N.V. and acquired all of the assets and liabilities of Curetis GmbH (see Note 1). The Company will include the Interim Facility in the consideration transferred in the business combination and will account for the Interim Facility under ASC 805 as part of the opening balance sheet and purchase price allocation.

Note 14– Subsequent Events

On April 1, 2020, the Company completed the transaction with Curetis N.V. and acquired all of the assets and liabilities of Curetis GmbH (see Note 1).

Subsequent to March 31, 2020, the Company sold 358,452 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately $942,000, and gross proceeds of $974,000.

On April 22, 2020, OpGen, Inc. (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 is $879,630, and the principal amount of the Subsidiary Note is $259,353.

In accordance with the requirements of the CARES Act, the Borrowers will use 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 amount 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 eight weeks following disbursement under the Notes. The Borrowers intend to use the entire proceeds under the Notes for such qualifying expenses.

Subject to any forgiveness under the PPP, the Notes mature two years following the date of issuance of the Notes and includes a period for the first six months during which time required payments of interest and principal are deferred. Beginning on the seventh month following the date of the Notes, the Borrowers are required to make 18 monthly payments of principal and interest. The Notes may be prepaid at any time prior to maturity with no prepayment penalties. The Notes provide for customary events of default, including, among others, those relating to breaches of their obligations under the Notes, including a failure to make payments, any bankruptcy or similar proceedings involving the Borrowers, and certain material effects on the Borrowers' ability to repay the Notes. The Borrowers did not provide any collateral or guarantees for the Notes.

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, 2019.

Overview

OpGen was incorporated in Delaware in 2001. On July 14, 2015, OpGen completed the Merger with AdvanDx. Pursuant to the terms of a Merger Agreement, Velox Acquisition Corp., OpGen's wholly-owned subsidiary formed for the express purpose of effecting the Merger, merged with and into AdvanDx with AdvanDx surviving as OpGen's wholly-owned subsidiary. OpGen and AdvanDx are collectively referred to hereinafter as the "Company." The Company's headquarters and principal operations are in Gaithersburg, Maryland. The Company also has operations in Copenhagen, Denmark. The Company operates in one business segment.

Business Combination Transaction with Curetis N.V.

On April 1, 2020 (the "Closing Date"), the Company 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"), 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, as further described below, and paid, as the sole consideration, 2,028,208 shares of the Company's common stock, par value $0.01 per share (the "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, of which 265,002 shares have been issued as of May 8, 2020, in satisfaction of approximately $543,000 of outstanding principal and indebtedness under the assumed convertible notes. The 2,028,208 shares of Common Stock issued to the Seller represented approximately 13.8% of the outstanding Common Stock of the Company as of the Closing Date.

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 patient (the "Curetis Business"). 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 (the "Assignment Agreement"), and entered into pursuant to the Implementation Agreement. We refer to the combined business within OpGen, in this Quarterly Report as "Newco"

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 molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. Its proprietary DNA tests and informatics address the rising threat of antibiotic resistance by helping physicians and other healthcare providers optimize care decisions for patients with acute infections.

The Company's molecular diagnostics and informatics products, product candidates and services combine its Acuitas molecular diagnostics and Acuitas Lighthouse informatics platform for use with its proprietary, curated MDRO knowledgebase. The Company is working to deliver products and services, some in development, to a global network of customers and partners.

- The Company's Acuitas molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include its Acuitas antimicrobial resistance, or AMR, Gene Panel Urine test in development for patients at risk for complicated urinary tract infection, or cUTI, and its Acuitas AMR Gene Panel test for use with bacterial isolates in development for testing bacterial isolates, and its QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures. Each of the Acuitas AMR Gene Panel tests is available for sale for research use only, or RUO and is not for use in diagnostic procedures.
- The Company's Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that combine clinical lab test results with patient and hospital information to provide analytics and actionable insights to help manage MDROs in the hospital and patient care environment. Components of the informatics systems include the Acuitas Lighthouse Knowledgebase and the Acuitas Lighthouse Software. The Acuitas Lighthouse Knowledgebase is a relational database management system and a proprietary data warehouse of genomic data matched with antibiotic susceptibility information for bacterial pathogens. The Acuitas Lighthouse Software system includes the Acuitas Lighthouse Portal, a suite of web applications and dashboards, the Acuitas Lighthouse Prediction Engine, which is a data analysis software, and other supporting software components. The Acuitas Lighthouse Software can be customized and made specific to a healthcare facility or collaborator, such as a pharmaceutical company. The Acuitas Lighthouse Software is not distributed commercially for antibiotic resistance prediction and is not for use in diagnostic procedures.

The Company's operations are subject to certain risks and uncertainties. The risks include the risk that the Company will not receive 510(k) clearance for its Acuitas AMR Gene Panel test for use with bacterial isolates on a timely basis, or at all, the timing and ultimate success of future 510(k) and *De Novo* submissions for additional Acuitas AMR Gene Panel tests and Acuitas Lighthouse Software, rapid technology changes, the need to retain key personnel, the need to protect intellectual property and the need to raise additional capital financing on terms acceptable to the Company. The Company's success depends, in part, on its ability to develop, obtain regulatory approval for and commercialize its proprietary technology as well as raise additional capital.

Overview of the Curetis Business

The Curetis Business develops, manufactures and commercializes innovative solutions for molecular microbiology.

The Curetis business is based on two complementary business pillars:

- The Unyvero A50 is a high-plex polymerase chain reaction, or PCR, platform for comprehensive and rapid diagnosis of severe infectious diseases in hospitalized patients. The platform is based on proven, intelligently integrated technologies, allowing for the testing of broad panels of pathogens and antibiotic resistance markers and the processing of a large variety of native patient samples with an intuitive workflow. The Unyvero A50 high-plex PCR platform's advantage is the timely access to comprehensive, actionable and reliable data. Curetis' molecular tests for different indications are commercially available in Europe, the United States, Asia and the Middle East. The Curetis Group is also developing the Unyvero A30 RQ Analyzer, which is designed to serve as a platform with low-to medium-plex capabilities that it ultimately intends to commercially leverage predominantly in collaborations with one or more diagnostics industry partners.
- The ARES AMR database, or ARES*db*, is a comprehensive database of the genetics of antimicrobial resistance, or AMR, which permits Curetis to increasingly utilize the proprietary biomarker content in its own assay and cartridge development, as well as to build an independent business in next-generation sequencing, or NGS, based offerings for AMR research and diagnostics in collaboration with partners in the life science, pharmaceutical and diagnostics industries. ARES*db* is not commercially available in the United States for diagnostic use, as it has not been cleared by the FDA. In September 2019, Ares Genetics, a wholly owned subsidiary of Curetis, or Ares Genetics, signed a technology evaluation agreement with an undisclosed global IVD corporation. In the first phase of the collaboration, expected to take about 10 months, Ares Genetics expects to further enrich ARES*db* with a focus on certain pathogens relevant in a first, undisclosed infectious disease indication.

Curetis GmbH's offices and R&D laboratories are based in Holzgerlingen, near Stuttgart with its cartridge manufacturing facility in Bodelshausen also in southern Germany, in addition to subsidiaries located in San Diego, California, USA and Vienna, Austria.

Overview of Newco

We anticipate that the focus of Newco will be on its combined broad portfolio of products, which include high impact rapid diagnostics and bioinformatics to interpret AMR genetic data. The products we expect Newco to focus on are for lower respiratory infection and urinary tract infection:

- The Unyvero Lower Respiratory Tract, or LRT, test is the first FDA cleared test that can be used for more than 90% of infection cases of hospitalized pneumonia patients. According to the National Center for Health Statistics (2018), pneumonia is a leading cause of admissions to the hospital and is associated with substantial morbidity and mortality. 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 are also commercializing the Unyvero LRT test for testing bronchoalveolar lavage, or BAL, specimens of U.S. patients with lower respiratory tract infections following FDA clearance received by Curetis in December 2019. We believe the Unyvero LRT test has 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.

- The Acuitas AMR Gene Panel (Urine) test is being developed for patients at risk for cUTI, and is designed to test for up to five pathogens and up to 47 antimicrobial resistance genes. When paired with the Acuitas Lighthouse software, we believe the test will be able to help improve management of the more than one million patients in the United States with cUTI. The AMR Gene Panel (Urine) is in testing for preparation of a *De Novo* submission with the FDA. We are pursuing a Class I designation through a De Novo Request for the test in connection with an initial clinical indication to test bacterial isolates.

Newco will have an extensive offering of additional *in vitro* diagnostic tests including CE-marked Unyvero tests for implant and tissue infections, intra-abdominal infections, cUTI, and blood stream infections, and the QuickFISH and PNA FISH FDA-cleared and CE-marked diagnostics used to rapidly detect pathogens in positive blood cultures, which we believe have an established market position in the United States.

Newco's combined AMR informatics offerings, once all such products are cleared for marketing, if ever, will offer important new tools to clinicians treating patients with AMR infections. OpGen has 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 Curetis ARES*db* is a comprehensive database of genetic and phenotypic information. ARES*db* was originally designed based on the SIEMENS microbiology strain collection covering resistant pathogens over the last 30 years and its development has significantly expanded to now include approximately 55,000 sequenced isolate strains and phenotypic correlation data against over 100 antibiotics. In September 2019, Ares Genetics signed a technology evaluation agreement with an undisclosed global IVD corporation. In the first phase of the collaboration, expected to take about 10 months, Ares Genetics expects to further enrich ARES*db* with a focus on certain pathogens relevant in a first, undisclosed infectious disease indication. We anticipate that Newco will 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 partners in the life science, pharmaceutical and diagnostics industries.

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 Marked in 2012 and was FDA cleared in 2018 along with the LRT test through *De Novo* process. As of December 31, 2019, there is an installed base of 173 Unyvero A50 Analyzers globally. 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 45 to 90 minutes with 2-5 minutes of hands on time. The Unyvero A30 has a small laboratory footprint and has an attractive cost of goods profile. Curetis has been following a partnering strategy for the Unyvero A30.

Newco has extensive partner and distribution relationships to help accelerate the establishment of a global infectious disease diagnostic testing and informatics business. Partners will include A. Menarini Diagnostics for pan-European distribution to currently 11 countries; MGI/BGI for NGS-based molecular microbiology applications in China; and Beijing Clear Biotech Co. Ltd. for Unyvero A50 product distribution in China. Newco has a network currently consisting of 18 distributors covering 43 countries.

Newco will continue to develop and seek FDA and other regulatory clearances or approvals, as applicable, for the Acuitas AMR Gene Panel (Urine) diagnostic test and the Acuitas Lighthouse Software products. Newco will continue to offer the Acuitas AMR Gene Panel (Isolates) and Acuitas Lighthouse Software as well as the Unyvero UTI Panel as RUO products to hospitals, public health departments, clinical laboratories, pharmaceutical companies and contract research organizations, or CROs.

Recent developments

COVID-19

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

As a result, we have experienced a material impact on our business, financial condition or results of operations for the three months ended March 31, 2020 and significant business disruptions as a result of the outbreak. For example, most of our employees are currently working remotely from home, we have suspended all business travel, and we are unable to physically meet with future and current customers to sell and market our products. In addition, the COVID-19 pandemic has interrupted many of our clinical activities, which will delay our ability to complete clinical trials and obtain regulatory approval for new 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, the Company has incurred, and continues to incur, significant losses from operations. The Company has funded its operations primarily through external investor financing arrangements. During 2019, the Company raised net proceeds of approximately $13.1 million. On February 11, 2020, the Company entered into an ATM Agreement with Wainwright, 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 $15.7 million of shares of the Company's common stock through Wainwright, as sales agent. During the three months ended March 31, 2020, the Company sold 2,814,934 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately $5.5 million, and gross proceeds of $5.8 million. Additionally, during the three months ended March 31, 2020, approximately 4.1 million common warrants issued in our October 2019 Public Offering were exercised raising net proceeds of approximately $8.1 million. See Note 2 ("Liquidity and management's plan") to the Notes to Unaudited Condensed Consolidated Financial Statements elsewhere in this quarterly report on Form 10-Q.

Results of operations for the three months ended March 31, 2020 and 2019

Revenues

	Three Months Ended March 31,	
	2020	2019
Product sales	$ 366,933	$ 520,177
Collaboration revenue	250,000	500,000
Total revenue	$ 616,933	$ 1,020,177

Total revenue for the three months ended March 31, 2020 decreased approximately 40%, with a change in the mix of revenue, as follows:

- Product Sales: a decrease in revenue of approximately 29% in the 2020 period compared to the 2019 period is primarily attributable to a reduction in the sale of our rapid pathogen ID testing products due to the loss of two large customers and COVID-19; and
- Collaboration Revenue: a decrease in revenue of approximately 50% in the 2020 period compared to the 2019 period is primarily the result of revenue from our contract with the New York State Department of Health.

Operating expenses

	Three Months Ended March 31,	
	2020	2019
Cost of products sold	$ 276,554	$ 220,702
Cost of services	137,666	144,482
Research and development	1,217,556	1,776,382
General and administrative	1,701,448	1,747,585
Sales and marketing	282,277	372,233
Transaction costs	245,322	—
Impairment of intangible assets	750,596	—
Impairment of right-of-use asset	—	520,759
Total operating expenses	$ 4,611,419	$ 4,782,143

The Company's total operating expenses for the three months ended March 31, 2020 decreased approximately 4% when compared to the same period in 2019. Operating expenses changed as follows:

- Costs of products sold: cost of products sold for the three months ended March 31, 2020 increased approximately 25% when compared to the same period in 2019. The change in costs of products sold is primarily attributable to increased regulatory costs and an increase in the Company's inventory reserve;
- Costs of services: cost of services for the three months ended March 31, 2020 decreased approximately 5% when compared to the same period in 2019. The change in costs of services is primarily attributable to a decrease in costs associated with our collaboration contracts;
- Research and development: research and development expenses for the three months ended March 31, 2020 decreased approximately 31% when compared to the same period in 2019, primarily due to the clinical trials needed to support the 510(k) submission for the Acuitas AMR Gene Panel (Isolates);
- General and administrative: general and administrative expenses for the three months ended March 31, 2020 decreased approximately 3% when compared to the same period in 2019, primarily due to decreased payroll related costs;
- Sales and marketing: sales and marketing expenses for the three months ended March 31, 2020 decreased approximately 24% when compared to the same period in 2019, primarily due to the reduced headcount of our international sales team;
- Transaction costs: transaction costs for the three months ended March 31, 2020 represent one-time costs incurred as part of the business combination with Curetis;
- Impairment of intangible assets: impairment of intangible assets for the three months ended March 31, 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 three months ended March 31, 2019 represents the impairment of our Woburn, Massachusetts ROU asset recorded as part of the Company's adoption of ASU 2016-02, *Leases (Topic 842)* in 2019.

Other income (expense)

	Three Months Ended March 31,	
	2020	2019
Interest expense	$ (38,267)	$ (56,444)
Foreign currency transaction losses	(3,876)	(10,351)
Other income (expense)	87,335	(24,422)
Change in fair value of derivative financial instruments	—	67
Total other income (expense)	$ 45,192	$ (91,150)

The Company's total other income (expense) for the three months ended March 31, 2020 increased primarily due to an increase in other income related to interest income earned under the Interim Facility with Curetis.

Liquidity and capital resources

As of March 31, 2020, the Company had cash and cash equivalents of $11.5 million compared to $2.7 million at December 31, 2019. The Company has funded its operations primarily through external investor financing arrangements and has raised funds in 2020 and 2019, including:

During the three months ended March 31, 2020, the Company sold 2,814,934 shares of its common stock in its 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately $5.5 million, and gross proceeds of $5.8 million.

During the three months ended March 31, 2020, approximately 4.1 million common warrants issued in our October 2019 Public Offering were exercised for net proceeds of approximately $8.1 million.

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.

On March 29, 2019, the Company closed the March 2019 Public Offering of 450,000 shares of its common stock at a public offering price of $12.00 per share. The offering raised gross proceeds of $5.4 million and net proceeds of approximately $4.8 million.

To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings, debt financings and other funding transactions, licensing and/or partnering arrangements and business combination transactions. 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 on hand will be sufficient to fund operations into the fourth quarter of 2020. 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 2020, 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, 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.

Sources and uses of cash

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

	Three Months Ended March 31,	
	2020	2019
Net cash used in operating activities	$ (2,344,742)	$ (2,985,779)
Net cash (used in) provided by investing activities	(2,201,057)	(7,243)
Net cash provided by financing activities	13,265,207	4,448,487

Net cash used in operating activities

Net cash used in operating activities for the three months ended March 31, 2020 consists primarily of our net loss of $3.9 million, reduced by certain noncash items, including impairment of intangible assets of $0.7 million, depreciation and amortization expense of $0.2 million, and share-based compensation expense of $0.1 million. Net cash used in operating activities for the three months ended March 31, 2019 consists primarily of our net loss of $3.9 million, reduced by certain noncash items, including impairment of ROU asset of $0.5 million, depreciation and amortization expense of $0.2 million, and share-based compensation expense of $0.1 million.

Net cash (used in) provided by investing activities

Net cash used in investing activities for the three months ended March 31, 2020 consisted primarily of funds provided to Curetis GmbH as part of the Interim Facility. Net cash used in operating activities for the three months ended March 31, 2019 consisted of the purchase of property and equipment offset by proceeds from the sale of equipment.

Net cash provided by financing activities

Net cash provided by financing activities for the three months ended March 31, 2020 of $13.3 million consisted primarily of the net proceeds from the 2020 ATM Offering and exercises of common stock warrants. Net cash provided by financing activities for the three months ended March 31, 2019 of $4.4 million consisted primarily of the net proceeds from the March 2019 Public Offering.

Critical accounting policies and use of estimates

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

A summary of our significant accounting policies is included in Note 3 "Summary of significant accounting policies" to the accompanying unaudited condensed consolidated financial statements. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain. Our critical policies are summarized in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2019.

Recently issued accounting pronouncements

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

Off-balance sheet arrangements

As of March 31, 2020 and December 31, 2019, we did not have any off-balance sheet arrangements.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows it to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, the Company's financial statements may not be comparable to companies that comply with public company effective dates.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," the Company intends to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. The Company will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which it has total annual gross revenues of $1.07 billion or more; (ii) December 31, 2020; (iii) the date on which the Company has issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which the Company is deemed to be a large accelerated filer under the rules of the SEC.

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 March 31, 2020. 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

There were no changes in the Company's internal control over financial reporting during the quarter ended March 31, 2020 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, 2019, as supplemented by the following:

We have a history of losses, and we expect to incur losses for the next several years. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2019 and 2018 contains explanatory language that substantial doubt exists about our ability to continue as a going concern.

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the years ended December 31, 2019 and 2018, we had net losses of $12.4 million and $13.4 million, respectively. From our inception through March 31, 2020, we had an accumulated deficit of $178.5 million. The reports of our independent registered public accounting firm on our financial statements for the years ended December 31, 2019 and 2018 each contain explanatory language that substantial doubt exists about our ability to continue as a going concern. We completed a number of financings in 2019 and 2020 to date, including the October 2019 Public Offering, March 2019 Public Offering, and 2020 ATM Offering. The net proceeds from such financings were approximately $26.7 million. We believe we can fund our operations into the fourth quarter of 2020, but cannot assure you that we can continue to raise the capital necessary to fund our business.

We need to raise equity capital to support our business. If we cannot do so successfully, we will not be able to continue as a going concern.

We need to raise equity capital to support our business. If we cannot do so successfully, we will not be able to continue as a going concern. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, the 2020 ATM Offering, additional equity financings, debt financings and other funding transactions, licensing and/or partnering arrangements and business combination transactions. We believe that additional equity financings are the most likely source of capital. There can be no assurance that we will be able to complete any such financing transaction on acceptable terms or otherwise.

We believe that current cash on hand will be sufficient to fund operations into the fourth quarter of 2020. In the event we are unable to successfully raise additional capital during or before the fourth quarter of 2020, 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 timely, we would then need to pursue a plan to license or sell assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

In July 2015, in connection with our acquisition of our subsidiary, AdvanDx, MGHIF made investments in the Company, including the $1 million MGHIF Note, secured by a security interest in substantially all of our assets, including our intellectual property assets. The debt is due to be paid in six semi-annual payments of $166,667 which began on January 2, 2019 and will end on July 1, 2021. Such secured creditor rights could negatively impact our ability to raise money in the future. If we default on payments under the MGHIF Note, MGHIF has the rights of a secured creditor. If those rights are exercised, it could have a material adverse effect on our financial condition.

The COVID-19 pandemic could adversely impact our business, financial condition and results of operations.

The COVID-19 pandemic has impacted the global economy and has impacted our operations in the United States and abroad, including by negatively impacting our sales and revenue. As a result, our total revenues have decreased significantly and we have implemented certain operational changes in order to address the evolving challenges presented by the global pandemic. We have experienced significant reductions in the demand for certain of our products, particularly due to the decline in elective medical procedures and medical treatment unrelated to COVID-19, which negatively impacted our revenues in the first quarter of fiscal year 2020. As the pandemic continues, we expect to continue to experience weakened demand for these products as a result of the reduction in elective and non-essential procedures, lower utilization of routine testing and related specimen collection, reduced spend by customers and reduced demand from research laboratories.

Healthcare providers, including our strategic partners, are focused almost exclusively on dealing with COVID-19, and may be unable to continue to participate in our clinical activities. For example, some clinical trial sites have imposed restrictions on site visits by sponsors and CROs, the initiation of new trials, and new patient enrollment to protect both site staff and patients from possible COVID-19 exposure and to focus medical resources on patients suffering from COVID-19. The pandemic will therefore likely delay enrollment in and completion of our clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Moreover, due to site and participant availability during the pandemic and in the interest of patient safety, many of our partners have paused new subject enrollment for most clinical trials.

For ongoing trials, we have seen an increasing number of clinical trial sites imposing restrictions on patient visits to limit risks of possible COVID-19 exposure, and we may experience issues with participant compliance with clinical trial protocols as a result of quarantines, travel restrictions and interruptions to healthcare services. The current pressures on medical systems and the prioritization of healthcare resources toward the COVID-19 pandemic have also resulted in interruptions in data collection and submissions for certain clinical trials and delayed starts for certain planned studies. Further, health regulatory agencies globally may also experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced, which could significantly delay the FDA's ability to timely review and process any submissions we or our partners have filed or may file.

As a result of the outbreak, we and certain of our suppliers may also be affected and could experience closures and labor shortages, which could disrupt activities. We could therefore face difficulty sourcing key components necessary to produce our product candidates, which may negatively affect our clinical development activities. Even if we are able to find alternate sources for some of these components, they may cost more, which could affect our results of operations and financial position.

At this point in time, there remains significant uncertainty relating to the potential effect of the novel coronavirus on our business and results of operations. As coronavirus becomes more widespread each day manufacturing closures and travel restrictions may remain or worsen, all of which would have a negative impact on our ability to operate our business, financial condition and results of operations.

We and our wholly-owned subsidiary, Curetis USA, accepted loans under the CARES Act pursuant to the Paycheck Protection Program, or the PPP, which loan may not be forgiven or may subject us to challenges and investigations regarding qualification for the loan.

We have secured loans under the CARES Act Paycheck Protection Program ("PPP") in the aggregate amount of approximately $1.1 million. We intend to use such funds for the intended purposes to maintain our employee base and pay rent and utility expenses. There has been significant negative publicity regarding the receipt of PPP loans by publicly traded companies and there is a risk that our receipt of PPP loans will be closely scrutinized and additional requirements will be imposed on us by the lender and the Small Business Association, or the SBA.

The PPP loan application required us to certify, among other things, that the current economic uncertainty made the PPP loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP loan and that our receipt of the PPP loans is consistent with the broad objectives of the PPP of the CARES Act, the certification described above does not contain any objective criteria and is subject to interpretation.

In addition, the SBA has stated that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the PPP has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good faith belief that we satisfied all eligibility requirements for the PPP loans, we are found to have been ineligible to receive the PPP loans or in violation of any of the laws or governmental regulations that apply to us in connection with the PPP loans, including the False Claims Act, we may be subject to penalties, including significant civil, criminal and administrative penalties and could be required to repay the PPP loans. In the event that we seek forgiveness of all or a portion of the PPP loans, we will also be required to make certain certifications which will be subject to audit and review by governmental entities and could subject us to significant penalties and liabilities if found to be inaccurate, including under the False Claims Act. In addition, our receipt of the PPP loans may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. Any of these events could harm our business, results of operations and financial condition.

Customer demand for and our ability to sell and market our products may be adversely affected by the COVID-19 pandemic and the legislative and regulatory responses thereto.

U.S. state and local governments have imposed orders, restrictions and recommendations resulting in closures of businesses, work stoppages, travel restrictions, social distancing practices and cancellations of gatherings and events. Such orders, restrictions and recommendations, combined with fears of the spreading of COVID-19, has and may continue to cause certain of our customers to delay, cancel or reduce orders of our products and makes it difficult to facilitate meetings with current and potential customers, as our sales personnel often rely on in-person meetings and interaction with our customers. COVID-19 related restrictions have thus harmed our sales efforts, and continued restrictions could have a negative impact on our sales and results of operations. We are unable to accurately predict how these factors will reduce our sales going forward and when these orders, restrictions and recommendations will be relaxed or lifted. There can be no assurances that our customers will resume purchases of our products upon termination of these governmental orders, restrictions and recommendations, particularly if there remains any continued community outbreak of COVID-19. A prolonged economic contraction or recession may also result in our customers seeking to reduce their costs and expenditures, which could result in lower demand for our products. If our sales decline, or if such lost sales are not recoverable in the future, our revenues, business and results of operations will be significantly adversely affected.

It is not possible to predict the future of the emerging COVID-19 global pandemic or the development of potential tests or treatments. No assurance can be given that OpGen's products will aid in the testing or the treatment of this virus.

The combined businesses offers products for the testing for SARS-CoV-2, the causal pathogen of COVID-19. OpGen may offer other products for testing or treatment of coronavirus. There can be no assurance that the existing test or any such future tests will be broadly adopted for use. OpGen is among many companies that are trying to develop tests for coronavirus, most of whom have far greater resources than us. If one of these companies develops an effective test, our development of such tests may not significantly increase our revenues and results of operations.

We incurred significant indebtedness as a result of the combination with Curetis, which could have a material adverse effect on our financial condition.

On April 1, 2020, we assumed the indebtedness of Curetis N.V. and Curetis. As of December 31, 2019, Curetis N.V. owed indebtedness of $1.4 million to lenders under the Curetis Convertible Notes with maturity in June 2020 and owed indebtedness of $20.3 million of principal (plus interest of $2.6 million) under a loan provided by the European Investment Bank with maturity in 2024. In addition, OpGen has secured indebtedness to MGHIF under the MGHIF Note. OpGen may not be able to generate sufficient cash to service all of its indebtedness and may be forced to take other actions to satisfy its obligations under indebtedness that may not be successful. The inability in the future to repay such indebtedness when due would have a material adverse effect on us.

We have incurred significant transaction costs as a result of the business combination transaction with Curetis, which could have a material adverse effect on our financial condition.

We have incurred significant one-time transaction costs related to the business combination with Curetis. These transaction costs include legal and accounting fees and expenses and filing fees, printing expenses, banking advisory fees, and other related charges. Additional costs will be incurred in connection with integrating the two companies' businesses. Costs in connection with the transaction and integration may be higher than expected. These costs could adversely affect OpGen's financial condition, operating results or prospects.

The business combination transaction with Curetis significantly changed the business and operations of OpGen. We may face challenges integrating the businesses.

Following the consummation of the combination with Curetis, OpGen will continue as the operating entity and both the size and geographic scope of OpGen's business will significantly increase. Most of the Curetis business is currently conducted in Europe, Asia and other countries outside of the United States, and many of the Curetis employees are located outside of the United States. In addition, the majority of the initial board of directors consist of individuals appointed by Curetis N.V., and we expect that the focus of OpGen may shift to Curetis operations. We may face challenges integrating such geographically diverse businesses and implementing a smooth transition of business focus and governance in a timely or efficient manner. In particular, if the effort we devote to the integration of our businesses diverts more management time or other resources from carrying out our operations than we originally planned, our ability to maintain and increase revenues as well as manage our costs could be impaired. Furthermore, our capacity to expand other parts of our existing businesses may be impaired. We also cannot assure you that the combination of the OpGen and Curetis businesses will function as we anticipate, or that significant synergies will result from the business combination. Any of the above could have a material adverse effect on our business.

Management and the board of directors of OpGen changed upon the consummation of the transaction. We cannot assure you that this will not have a material impact on OpGen.

Oliver Schacht, Ph.D., the prior chief executive officer of Curetis N.V. became the chief executive officer of OpGen at the closing of the Transaction. Under the Implementation Agreement, four members of the board of directors of OpGen following the closing were appointed by Curetis N.V. and two by OpGen. Any new members of management or new directors are likely to have different backgrounds, experiences and perspectives from those individuals who previously served as executive officers or directors and, thus, may have different views on the issues that will determine our future. Additionally, the ability of our new directors to quickly expand their knowledge of our operations will be critical to their ability to make informed decisions about our business and strategies, particularly given the competitive environment in which we operate. As a result, our future strategy and plans may differ materially from those of the past.

The combination of the OpGen and Curetis businesses may not lead to the growth and success of the combined business that we believe will occur.

Although we believe the combination of the OpGen and Curetis businesses provides a significant commercial opportunity for growth, we may not realize all of the synergies that we anticipate and may not be successful in implementing our commercialization strategy. Our combined business will be subject to all of the risks and uncertainties inherent in the pursuit of growth in our industry and we may not be able to successfully sell our products, obtain the regulatory clearances and approvals we apply for or, or realize the anticipated benefits from our distribution, collaboration and other commercial partners. If we are not able to grow the business of OpGen as a commercial enterprise, our financial condition will be negatively impacted.

Integrating the businesses of OpGen and Curetis may disrupt or have a negative impact on OpGen.

We could have difficulty integrating the assets, personnel and business of OpGen and Curetis. The proposed transaction is complex and we will need to devote significant time and resources to integrating the businesses. Risks that could impact us negatively include:

- the difficulty of integrating the acquired companies, and their concepts and operations;
- the difficulty in combining our financial operations and reporting;
- the potential disruption of the ongoing businesses and distraction of our management;
- changes in our business focus and/or management;
- risks related to international operations;
- the potential impairment of relationships with employees and partners as a result of any integration of new management personnel; and
- the potential inability to manage an increased number of locations and employees.

If we are not successful in addressing these risks effectively, our business could be severely impaired.

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
2.1	Implementation Agreement, dated as of September 4, 2019, by and among Curetis N.V., Crystal GmbH, and OpGen (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on September 4, 2019).
10.1	At the Market Offering Agreement, by and between OpGen, Inc. and H.C. Wainwright & Co., LLC dated February 11, 2020 (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K, filed on February 12, 2020).
10.2	Assignment of the Agreement for the Issuance of and Subscription to Notes Convertible into Shares, dated February 24, 2020, among OpGen, Inc., YA II PN, LTD, and Curetis N.V. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on February 28, 2020).
10.3	Amended and Restated Interim Facility Agreement, dated as of March 18, 2020, by and among Curetis GmbH, as Borrower, Crystal GmbH, a wholly owned subsidiary of the Registrant, as Lender and Curetis N.V. (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K filed on March 24, 2020).
10.4	Amended and Restated Management Services Agreement, dated April 2, 2020, by and between OpGen, Inc. and Oliver Schacht (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed on April 2, 2020).
10.5	Amended and Restated Stock Option Plan, dated April 1, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 2, 2020).
10.6	Term Note between OpGen, Inc. and Silicon Valley Bank, dated April 22, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 28, 2020).
10.7	Term Note between Curetis USA Inc. and Silicon Valley Bank, dated April 22, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 28, 2020).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the 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/ Timothy C. Dec
Timothy C. Dec
Chief Financial Officer

Date: May 8, 2020

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13A-14(A)/15D-14(A)

I, Oliver Schacht, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 8, 2020

/s/ Oliver Schacht

Oliver Schacht
Chief Executive Officer (principal executive officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13A-14(A)/15D-14(A)

I, Timothy C. Dec, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 8, 2020

/s/ Timothy C. Dec

Timothy C. Dec
Chief Financial Officer (principal financial officer and principal accounting officer)

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of OpGen, Inc. (the "Company") for the quarterly period ended March 31, 2020 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

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

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

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

Date: May 8, 2020

By: /s/ Oliver Schacht
Oliver Schacht
Chief Executive Officer
(principal executive officer)

Date: May 8, 2020

By: /s/ Timothy C. Dec
Timothy C. Dec
Chief Financial Officer
(principal financial officer and principal accounting officer)

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