2020

Annual Report

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

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2020

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

For the transition period from _____ to _____.

Commission file number 001-37367

OPGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware	**06-1614015**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
708 Quince Orchard Road Gaithersburg, Maryland	**20878**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

Securities registered or to be registered pursuant to Section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☐

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant as of June 30, 2020, was $35,998,374 (based upon the last reported sale price of $2.04 per share on June 30, 2020, on The Nasdaq Capital Market.

As of March 26, 2021, 38,266,482 shares of common stock of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with respect to its 2021 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. The proxy statement will be filed with the Securities and Exchange Commission within 120 days after the registrant's fiscal year ended December 31, 2020.

OPGEN, INC.

ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2020

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K for the year ended December 31, 2020 (the "Annual Report") 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 Annual Report, we refer to OpGen, Inc. as the "Company," "OpGen," "we," "our" or "us." All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect" or the negative version of these words and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A "Risk Factors." 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;
- 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 COVID-19 on our business and operations;
- our use of proceeds from capital financing transactions;
- the completion of our development efforts for our Acuitas Lighthouse Software, Unyvero UTI and IJI panels, Unyvero A30 *RQ* platform and ARESdb and the timing of regulatory submissions;
- our ability to sustain or grow our customer base for our Unyvero IVD products as well as our current research use only products;
- regulations and changes in laws or regulations applicable to our business, including regulation by the FDA and China's NMPA;
- anticipated trends and challenges in our business and the competition that we face;
- the execution of our business plan and our growth strategy;
- our expectations regarding the size of and growth in potential markets;
- our opportunity to successfully enter into new collaborative or strategic agreements;
- our ability to maintain compliance with the ongoing listing requirements for the Nasdaq Capital Market;
- compliance with the U.S. and international regulations applicable to our business; and
- our expectations regarding future revenue and expenses.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Any forward-looking statement made by us in this Annual Report speaks only as of the date on which it is made. We disclaim any duty to update any of these forward-looking statements after the date of this Annual Report to confirm these statements to actual results or revised expectations.

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to the risk factors described in Part I, Item 1A of this Annual 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 Annual 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.

RISK FACTOR SUMMARY

Investing in our securities involves a high degree of risk. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described under "Risk Factors" in Part I, Item 1A of this Annual Report.

- We have a history of losses, and we expect to incur losses for the next several years.
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to continue as a going concern.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- We may never successfully develop, receive regulatory clearance or approval for or commercialize our new products.
- Our products and services may never achieve significant commercial market acceptance.
- The COVID-19 pandemic has adversely impacted our business, financial condition and results of operations.
- Recent changes to our management and our board of directors may have a material impact on our business.
- Changes in healthcare laws policies, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and operations.
- We rely on collaborations with third parties to develop product and services candidates. If these collaborations are not successful, our business could be adversely affected.
- Our future success is dependent upon our ability to expand our customer base.
- If we are unable to protect our intellectual property effectively, our business will be harmed.

NOTE REGARDING TRADEMARKS

We own various U.S. federal trademark registrations and applications and unregistered trademarks and servicemarks, including but not limited to OpGen®, Curetis®, Unyvero®, ARES® and ARES GENETICS®, Acuitas®, Acuitas Lighthouse®, AdvanDx®, QuickFISH®, and PNA FISH®. All other trademarks, servicemarks or trade names referred to in this Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual 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

Item 1. Business

Please refer to the Glossary at the end of this Business section for definitions or descriptions of scientific, diagnostic, healthcare, regulatory, and OpGen-specific terms used in this Annual Report.

Overview

OpGen, Inc. (the "Company") 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 MDROs. OpGen's 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.

On April 1, 2020, we completed our business combination transaction (the "Transaction") with Curetis N.V., a public company with limited liability under the laws of the Netherlands (the "Seller" or "Curetis N.V."), as contemplated by the Implementation Agreement, dated as of September 4, 2019 (the "Implementation Agreement"), by and among the Company, the Seller, and Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and wholly-owned subsidiary of the Company ("Purchaser"). Pursuant to the Implementation Agreement, the Purchaser acquired all of the shares of Curetis GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany ("Curetis GmbH") and certain other assets and liabilities of the Seller (together, "Curetis"). Curetis is an early commercial-stage molecular diagnostics (MDx) company focused on rapid infectious disease testing for hospitalized patients with the aim to improve the treatment of hospitalized, critically ill patients with suspected microbial infection and has developed the innovative Unyvero molecular diagnostic solution for comprehensive infectious disease testing. The Transaction was designed principally to leverage each company's existing research and development and relationships with hospitals and clinical laboratories to accelerate the sales of both companies' products and services.

Our molecular diagnostics and informatics products, product candidates and services combine our Unyvero and Acuitas® molecular diagnostics and Ares Genetics' database and the Acuitas Lighthouse® informatics platform for use with our proprietary, curated MDRO knowledgebase. We are working to deliver our products and services, some in development, to a global network of customers and partners.

- Our molecular diagnostic tests provide rapid microbial identification and antibiotic resistance gene information. These products include the Unyvero platform and Unyvero application cartridges with five CE-IVD-marked tests (pneumonia, implant and tissue infection, urinary tract infection, blood culture, intra abdominal infection) and two FDA cleared cartridges (LRT and LRT BAL for lower respiratory tract infections such as pneumonia), the Acuitas AMR Gene Panel (Isolates) test pending FDA clearance for testing bacterial isolates, a proprietary CE-IVD-marked SARS CoV-2 PCR test kit including our PULB (PCR compatible universal lysis buffer), and the legacy QuickFISH and PNA FISH FDA-cleared and CE-IVD-marked diagnostics used to rapidly detect pathogens in positive blood cultures. The entire suite of FISH products will be discontinued by June 30, 2021 in the United States, Europe and rest of the world. Our ARESdb provides next generation sequencing (NGS) based and artificial intelligence (AI) powered, cloud-based bioinformatics solutions to generate comprehensive AMR profiles as well as predict AST results.

- Our Acuitas Lighthouse informatics systems are cloud-based HIPAA compliant informatics offerings that are designed to 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.

In May 2019, OpGen filed a 510(k) submission with the FDA seeking clearance of its Acuitas AMR Gene Panel (Isolates) diagnostic test. In July 2019, the Company received an Additional Information Request, or AI, Request from the FDA detailing a number of questions related to the submission. At the time, questions from the FDA focused on the intended use of the test including the correlation between marker detection and antibiotic resistance, the level of evidence to support resistance marker/organism claims, whole genome sequencing, or WGS, test validation and use as a comparator method, clinical performance of the test compared to WGS and further analysis of individual study results, in silico analysis to support test evaluations, further analysis of analytical study results, additional information regarding instrumentation for use with the test, and test reporting and labeling. On January 6, 2020, OpGen filed a formal response to the FDA's July 2019 AI Request. Subsequently, the FDA issued a second AI Request on January 17, 2020 to formalize additional questions and remaining requests for information from the earlier July 2019 AI Request. The issuance of the January 2020 AI letter effectively placed the Acuitas AMR Gene Panel (Isolates) 510(k) submission on hold until OpGen provided a formal response to the questions posed or a 180-day hold period ended, after which the Acuitas AMR Gene Panel (Isolates) 510(k) submission may be considered withdrawn and a second submission required. Following an extension of the response deadline from July 14, 2020 to October

13, 2020, OpGen submitted its formal response to the second AI letter to the FDA on October 13, 2020. We believe that the comprehensive formal response addresses all of the FDA's questions and feedbacks received to date. Following the FDA's announcement in November 2020 that it would suspend review activity for submissions other than those related to COVID-19, in late January 2021, the FDA informed OpGen that it has resumed the review of the AI letter responses filed by OpGen. However, due to the ongoing staffing surge related to COVID-19 towards EUAs, the FDA at this time is not committing to any MDUFA timelines for the completion of its review and any potential clearance decision.

We have established a number of commercial arrangements to support execution of our business strategy as we work to address the more than $2 billion potential market for precision medicine MDRO solutions. Our relationship with Merck & Co., Inc. includes a previous investment from Merck Global Health Innovation Fund, or MGHIF, and a research agreement with Merck Sharp & Dohme, or MSD, to provide access to MSD's 250,000 clinical isolate SMART bacterial surveillance archive. For our global Unyvero and FISH product distribution we have entered into exclusive contracts with more than 20 distributors covering more than 40 countries globally from EMEA to APAC and LatAm. Following the decision to exit the FISH business as part of our portfolio consolidation we do expect the number of distributors to decline in 2021.

In September 2018, OpGen announced a collaboration with The New York State DOH and ILÚM (now part of IDC) to develop a state-of-the-art research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions in New York State. The collaboration is called The New York State Infectious Disease Digital Health Initiative. The first stage of the collaboration is the completion of a demonstration project, which commenced in February of 2019 and was completed at the end of March 2020. Under the demonstration project, OpGen worked with DOH's Wadsworth Center and ILÚM (now IDC) 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. The DOH, ILÚM (now IDC) and OpGen are working collaboratively to build a sustainable, flexible infectious diseases reporting, tracking and surveillance tool for antimicrobial resistance that can be applied across New York State. The goal of this research project is to improve patient outcomes and save healthcare dollars by integrating real-time epidemiologic surveillance with rapid delivery of resistance results to care-givers via web-based and mobile platforms. ILÚM (now IDC) is leading the project with the implementation of its technology platform. OpGen is providing its Acuitas AMR Gene Panel (RUO) for rapid detection of multidrug-resistant bacterial pathogens along with its Acuitas Lighthouse Software (RUO) for high resolution pathogen tracking. Under the agreement, OpGen received approximately $1.6 million for the 15-month demonstration portion of the project, of which approximately $1.3 million was earned in 2019. Effective April 1, 2020, OpGen entered into a year two contract with the NYS DOH and the participating sites. During this second year which has a total volume of up to $450,000, OpGen is primarily providing Acuitas AMR Gene Panel (RUO) kits to the sites and except for a $100,000 retainer component gets compensated on a per test fee basis. OpGen and NYS DOH are currently discussing a possible extension and expansion of this second-year contract in 2021 to allow for completion of testing which had been suspended during the first phase of the COVID-19 pandemic in 2020.

In June 2017, OpGen entered into a supply agreement to use Thermo Fisher Scientific's technology in the United States and Europe to support the commercialization of its rapid molecular products for RUO. Under the terms of the agreement, OpGen provides customer access to Thermo Fisher Scientific's products to support the commercialization of our Acuitas AMR Gene Panel and Acuitas Lighthouse Software to combat MDROs. In January 2018, the Company entered into a second supply agreement to incorporate Thermo Fisher Scientific's real-time PCR technology in the Company's Acuitas AMR Gene Panel tests. Specific products covered under these agreements include the QuantStudio 5 Real-Time PCR System, TaqMan® Fast Advanced Master Mix and TaqMan® MGB Probes for quick, multiplexed gene detection.

OpGen's subsidiary Curetis has long-term strategic supply agreements for its Unyvero products in place for instrument systems (Zollner Elektronik), injection molding plastic parts (Scholz HTIK), as well as key reagents such as primers and probes (Microsynth). QIAGEN is a strategic collaboration and licensing partner to our Ares Genetics subsidiary and provides instruments as well as reagents for that part of the business also. Furthermore, Ares Genetics has entered into a number of strategic collaborations with partners, such as Sandoz, and is exploring R&D collaborations and potential licensing opportunities with some of the global leading IVD corporations.

OpGen's Products and Products in Development

Through the business combination with Curetis, OpGen maintains a comprehensive portfolio of molecular diagnostics for rapid infectious disease and AMR testing. At the core of the portfolio is the Unyvero platform and product family which is developed, manufacture and commercialized via the wholly owned Curetis GmbH subsidiary. On the bioinformatics side, OpGen has combined its Acuitas Lighthouse data with the Ares Genetics (Ares) data into the ARESdb. Ares develops and commercializes its NGS as well as

bioinformatics based, AI-powered prediction models and solutions to partners and customers in the pharma, biotech and diagnostics industries as well as to public research institutions.

OpGen is a molecular diagnostics company that focuses on the development and commercialization of reliable, fast and cost-effective products for diagnosing severe infectious diseases in hospitalized patients, an indication with a high unmet medical need and significant prevalence in developed countries. Our unique Unyvero Platform currently comprises the Unyvero System with the Unyvero A50 Analyzer at its core, proprietary software, and single use Application Cartridges. These Application Cartridges contain molecular tests addressing specific severe infectious diseases and detect a broad range of pathogens relevant in a given indication and associated toxin genes and genetic antimicrobial resistance markers.

The Unyvero Platform has been CE-IVD-marked since 2012 and is commercialized in Europe and certain other markets that accept CE-IVD-marking or where it has successfully passed the registration process (i.e. Kuwait, Qatar, Belarus, UAE, Israel, Singapore, Malaysia, Thailand), and has been rolled out commercially in the United States following De Novo clearance of the Unyvero System and the LRT Application Cartridge by the FDA in April 2018 and the 510(k) clearance of the LRT Application for BAL samples in December 2019.

Today, the diagnosis of infectious diseases in the hospital setting is still largely carried out through traditional culture-based microbiology methods. This process is labor-intensive and time-consuming, typically delivering results only after 24 to 72 hours or, in some cases, weeks. As a result, informed antibiotic therapy decisions may be delayed, which can lead to poor patient outcomes, including higher mortality rates for indications such as pneumonia and sepsis, longer hospital stays, increased hospital costs and overall spread of antibiotic resistance, a significant and increasing problem throughout the world. All of these factors pose clinical and economic challenges to hospitals and a significant threat to public health globally.

OpGen aims to improve on this standard-of-care by offering comprehensive test information in a timely manner that allows for early, efficacious treatment, which OpGen believes results in improved clinical and health economic outcomes. The Company's Unyvero Platform delivers results within four to five hours and can cover over 100 diagnostic targets. The broad Unyvero test panels also allow the identification of microorganisms that are difficult to culture and hence missed in culture-based test methods, as well as rare but critical pathogens not routinely tested for by standard methods, a conclusion confirmed by a number of clinical studies. The FDA clinical trial for the LRT Application Cartridge concluded that the Unyvero System identified 32 positive atypical pathogen results in 1,653 prospectively tested specimens, as opposed to only four confirmed positive atypical pathogen results identified in 116 specimens from this cohort using traditional culture-based diagnostic methods. The Company believes this allows clinicians to make early adjustments to the specific treatment of the patient, saving significant time and cost, in particular by reducing the duration of the patient's hospital stay.

The Unyvero Platform is intended to complement rather than replace traditional microbiology-based diagnostics testing. OpGen believes, however, that timely diagnosis of the underlying pathogens and their resistances could greatly improve outcomes for patients and is likely to provide net savings to hospitals.

The Unyvero Platform is marketed through a combination of direct sales in the United States and a growing network of distribution partners in Europe, Middle East, the ASEAN Region, Asia and Latin America. As of December 31, 2020, the distribution network

comprises over 20 distributors covering more than 40 countries in those regions with regulatory clearance for the Unyvero System and the Unyvero Application Cartridges in some of these countries still pending.

There are currently seven commercially available Application Cartridges, consisting of:

- the HPN Application Cartridge, which addresses severe forms of pneumonia and is CE-IVD-marked in Europe;
- the ITI Application Cartridge, which addresses severe cases of implant and tissue infections and is CE-IVD-marked in Europe;
- the BCU Application Cartridge, which addresses severe blood stream infections and is CE-IVD-marked in Europe;
- the IAI Application Cartridge, which addresses intra-abdominal infections and is CE-IVD-marked in Europe;
- the UTI Application Cartridge, which addresses severe urinary tract infections and is CE-IVD-marked in Europe;
- the LRT Application Cartridge, which is technically similar to the HPN Application Cartridge and also addresses severe forms of pneumonia, which was cleared by the FDA in April 2018 for use with tracheal aspirates and is now being marketed in the United States; and
- the LRT BAL Application Cartridge which was cleared on December 20, 2019 by the FDA for use with BAL specimens and has been launched in the Unites States in the first quarter of 2020;

The HPN and BCU Application Cartridges have also been approved by the Singaporean HAS as well as regulatory authorities in Malaysia and Thailand.

In addition to the current Unyvero System, the Company through its subsidiary Curetis also develops its Unyvero A30 *RQ* Analyzer module designed to offer a rapid time-to-result (potentially as fast as 45 to 90 minutes), qualitative and, where needed, quantitative real-time PCR testing in a cartridge format that can provide up to 11 parallel multiplex (i.e. simultaneously running multiple assays in one reaction) PCR reactions from one sample, with up to three assays per reaction (for a total of up to 33 assays per cartridge). It is expected to be operated on a stand-alone basis or fully integrated into the Unyvero System suite of products with respect to system architecture, design, software and handling, thereby expanding the Unyvero Platform to include low- and mid-plex capabilities. We expect that the costs of the Unyvero A30 *RQ* Analyzer and cartridges will be lower than those for the current Unyvero System and Application Cartridges, potentially opening up commercial opportunities in the medium multiplexing infectious disease testing market segment. Initially developed as an expansion of the Unyvero platform, complementing the Unyvero A50 high-plex Application Cartridges with low- to mid-plex Unyvero A30 *RQ* Application Cartridges for infectious diseases, OpGen adjusted its strategy and now also seeks partners in the global IVD industry that may want to license the Unyvero A30 *RQ* for commercialization of their own assays on this platform, potentially even as legal manufacturer under their own branding.

The Unyvero Platform

Curetis launched its CE-IVD-marked Unyvero Platform with a first disposable Application Cartridge for pneumonia in 2012. The FDA cleared the Unyvero System and LRT Application Cartridge in April 2018 and the LRT BAL Application Cartridge in December 2019. The Chinese authorities National Medical Products Administration ("NMPA") cleared the Unyvero System in early 2021.

The Unyvero Platform is a highly automated sample-to-answer molecular diagnostics platform, based on multiplexed end-point PCR with an array-based detection process. It integrates fully automated sample preparation, analysis and identification of disease relevant pathogens and antibiotic resistance markers to provide timely high-quality information to its end-users. The scalable system is designed to be either placed in laboratory settings or directly in hospital wards or intensive care units. Time-to-result is four to five hours for the different Application Cartridges commercially available today Application Cartridges, including 30 minutes of automated sample preparation (lysis) and total hands-on time of no more than five minutes. The Unyvero Platform's intuitive workflow with only minimal hands-on time enables untrained hospital staff to perform molecular tests at the point of need, such as ICUs.

Unyvero Platform, System Components and Workflow

The Unyvero System consists of three devices, the Unyvero L4 Lysator, the Unyvero C8 Cockpit and the Unyvero A50 Analyzer. The Unyvero L4 Lysator is used for sample pre-processing and pathogen lysis. The Unyvero C8 Cockpit is the control panel for the Unyvero L4 Lysator and Unyvero A50 Analyzer and displays the results of patient sample analysis. The Unyvero A50 Analyzer consists of mechanical, electronic, pneumatic and optical elements and enables a fully automatic random-access processing of the Application

Cartridges. The Application Cartridges are single-use, disposable and disease specific. The Unyvero System, together with proprietary software and the Application Cartridges, comprise the Unyvero Platform.

Figure 1: Unyvero Platform

The Unyvero L4 Lysator

This instrument is used for sample pre-processing and pathogen lysis. It performs proprietary software-controlled lysis of up to four samples, simultaneously within 30 minutes, combining mechanical, thermal, enzymatic and chemical lysis steps and allows the use of a wide range of native sample types due to a proprietary sample processing method (in respect of which several patents have been granted or are currently pending). Biofilm-forming pathogens can be detected by the Unyvero Platform. In addition, the Unyvero Platform is CE-IVD-marked for a broad variety of native patient sample types including sputum, (mini) BAL, tracheal aspirates, aspirates and exudates, catheter tips, pus, sonication fluid, synovial fluid, swabs and tissue. The lysis of further sample types such as blood, urine, stool and formalin-fixed paraffin embedded tissues is also possible with the proprietary Unyvero lysis method. Up to two Unyvero L4 Lysators can be attached to a single Unyvero C8 Cockpit to allow processing of up to eight samples simultaneously within 30 minutes.

The Unyvero C8 Cockpit

This device is the control panel for the Unyvero L4 Lysator and Unyvero A50 Analyzer. It has a touchscreen and built-in bar code reader and runs on proprietary in-house developed Unyvero software. Step-by-step instructions guide the user from preparing a test to executing the fully automated process in the Unyvero A50 Analyzer in just a few minutes. The results display, storage of results and data storage, as well as information about the performed tests including the Application Cartridges' shelf-life and lot numbers, are generated automatically. Data can be exported as PDF files via a USB key or to a connected printer. It also features built-in interfaces for possible future connectivity to standard hospital and laboratory information systems.

The Unyvero A50 Analyzer

This instrument consists of mechanical, electronic, pneumatic and optical elements and enables a fully-automatic random-access processing of the Application Cartridges. Once a run is started, the Unyvero A50 Analyzer automatically executes and controls all sample processing and analysis steps (including DNA extraction, DNA purification, PCR set-up, highly multiplexed end-point PCR amplification and a hybridization array-based fluorescence detection) inside the Application Cartridge. For safety and equipment longevity, and to avoid issues of calibration or waste-removal, the Unyvero A50 Analyzer contains neither reagents nor waste. All fluids are handled within the sealed Application Cartridge. Up to four Unyvero A50 Analyzers can be attached to a single Unyvero C8 Cockpit and each Unyvero A50 Analyzer includes the two available slots that provide full random access per Unyvero A50 Analyzer, allowing

the processing of up to eight patient samples simultaneously within four to five hours. In the future, OpGen believes a further expansion to up to eight Unyvero A50 Analyzers will also be possible.

Figure 2: Unyvero sample tube, sample tube cap, sample pre-treatment tool and Master Mix tube

Workflow

The Unyvero Platform is a modular, flexible easy-to-use platform, which substantially reduces turnaround time from up to 24 hours or even weeks for traditional microbiology culture-based tests to approximately four to five hours. This allows physicians to adjust treatment at a much earlier stage than with the traditional microbiology culture-based test, which is the current clinical standard of care. OpGen believes that the reduced hands-on time of no more than five minutes and the intuitive workflow make the system operable by non-specialty trained laboratory personnel and reduce the risks of errors.

Unyvero A50 Application Cartridge Portfolio

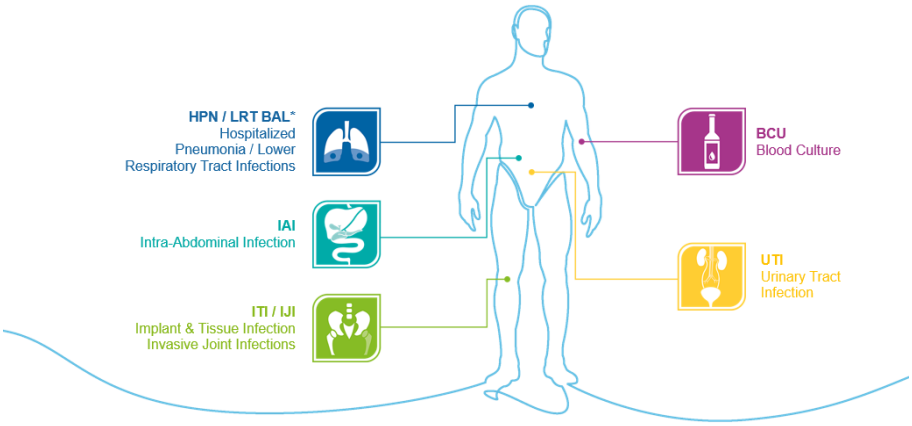

Figure 3: Currently available Application Cartridges

The HPN and LRT Application Cartridges

The HPN Application Cartridge was commercially launched in April 2015 and is the second-generation version of the P50 Application Cartridge, the Pneumonia Application Cartridge originally launched in 2012. It is a CE-IVD-marked Application Cartridge for the fully automated performance of currently 21 PCR assays for microorganisms and 19 PCR assays for antibiotic resistance markers combined in a total of eight multiplex PCR reactions on native respiratory samples, such as sputum, tracheal aspirates and BAL fluids with no pre-culturing required. This Application Cartridge combines the necessary detection of bacteria, fungus and resistance markers into a single

test to aid diagnosing pneumonia. With the HPN Application Cartridge, the Company aims to detect the vast majority of pneumonia-causing pathogens and antibiotic resistance markers in hospitalized patients.

The HPN Application Cartridge of microorganisms and resistance gene markers was designed based on feedback of clinical experts and international and national guidelines. It aims to detect at least 90% of healthcare-associated pneumonia-causing pathogens and clinically relevant resistances against antimicrobials. The Application Cartridge is primarily designed to capture patients at risks for:

- microorganisms causing severe, and complicated to treat, forms of pneumonia, e.g. *Pseudomonas aeruginosa*;
- microorganisms carrying antibiotic resistance and where patients may need isolation (MRSA, *Klebsiella*);
- infections with multidrug-resistant bacteria that might not be targeted by empiric treatment schemes; and
- rare and difficult to detect pathogens like Legionella sp.

The Application Cartridge composition takes pathogen incidences into account. It includes those microorganisms showing an incidence of above 1%. The Application Cartridge is completed by adding pathogens with lower incidence but a high clinical need, such as Legionella sp.

The HPN Application Cartridge covers 19 antibiotic resistance markers, including: (i) ß-Lactam resistance, including ESBL; (ii) kpc resistance; (iii) macrolide resistance; (iv) quinolone resistance; and (v) multi-drug resistance.

The LRT Application Cartridge was launched in the United States in April 2018. It is an FDA-cleared Application Cartridge for the fully automated detection of 46 targets, covering 36 microorganisms and 10 antibiotic resistance markers, for lower respiratory tract infections with a total of 29 PCR assays combined in eight multiplexed PCR reactions. Although similar in most respects to the HPN Application Cartridge, the LRT differs from the HPN in its pathogen reporting due to FDA reporting requirements. In accordance with a De Novo request that was granted by the FDA in April 2018, the initial label claim covers the use of LRT with tracheal aspirate samples only and has cleared 19 pathogen assays as well as 10 antibiotic resistance marker assays.

The LRT BAL Application Cartridge that was 510(k)-cleared by the U.S. FDA in December 2019 and launched in the United States in January 2020, is a version of the LRT Application Cartridge that is optimized for use with commonly obtained BAL specimens. The Unyvero LRT BAL application is the first and only U.S. FDA-cleared molecular diagnostic panel that detects *Pneumocystis jirovecii* in addition to a broad spectrum of clinically relevant bacterial pathogens and antibiotic resistance markers associated with pneumonia.

The ITI Application Cartridge

The ITI Application Cartridge was launched in May 2016 and is the second-generation version of the ITI Application Cartridge originally launched in the second quarter of 2014. Improvements were made to the panel and analytical performance as well as clinical sensitivity and specificity. It is a CE-IVD-marked Application Cartridge for the fully automated detection of currently 102 targets, covering 85 microorganisms and 17 antibiotic resistance markers for eight different clinical indications within the areas of prosthetic joint infections, surgical site infections, diabetic foot ulcers, catheter-associated infections, deep skin and tissue infections, cardiology-related infections, burn wounds and other implant infections. CE performance evaluation has demonstrated sensitivity of 86.9% at specificity of 99.2%. A diverse range of sample types such as aspirates and exudates, pus, sonication fluid, swabs, synovial fluid and tissue can be used on this Application Cartridge. Moreover, biofilm-forming pathogens can be identified by the Unyvero Platform. The ITI Application Cartridge was jointly developed and co-funded with a worldwide market leader in orthopedic bone cement, which offers comprehensive infection management solutions. The Company pays a customer referral commission but has retained full control on product commercialization.

The BCU Application Cartridge

The BCU Application Cartridge was launched in Europe in April 2016. It is a CE-IVD-marked and Singapore HSA-cleared Application Cartridge for the fully automated detection of 103 targets, covering 87 microorganisms and 16 antibiotic resistance markers relevant in the area of blood stream infections. The CE-IVD performance evaluation has demonstrated a weighted average sensitivity for all pathogens of 96.2%, and a weighted average specificity of 99.4%. Unlike other Unyvero Application Cartridges, BCU uses samples from positive blood cultures rather than native patient samples. Such blood cultures are started in cases of suspected blood stream infections.

The IAI Application Cartridge

The IAI Application Cartridge was launched in April 2017. It is a CE-IVD-marked Application Cartridge for the fully automated detection of 130 targets, covering 105 pathogens, three toxins and 22 resistance markers for several different clinical indications within the areas of severe intra-abdominal infections such as symptoms of peritonitis, appendicitis, acute abdomen, acute pancreatitis, and

megacolon. Overall weighted average sensitivity for the pathogens specifically targeted by the test panel was 93.8% at an overall weighted average specificity of 99.7% following discrepant result resolution.

The UTI Application Cartridge

The UTI Application Cartridge was launched in April 2018. It is a CE-IVD-marked Application Cartridge for the fully automated detection of up to 103 diagnostic targets, covering 88 microorganisms and 15 genetic resistance markers for the areas of severe urinary tract infections in patients with anatomical, structural and functional alterations, renal impairments, impaired immune status, catheter-associated UTI, patients failing to respond to therapy and suffering from severe manifestations, urosepsis. OpGen estimates that the addressable market for the UTI Application Cartridge is 1.6 million cases eligible for testing per year in the EU and the United States. The UTI Application Cartridge is also available as RUO in the USA since 2020.

Ares Genetics' NGS and Bioinformatics Services for Molecular Microbiology

OpGen's other core business in NGS and Bioinformatics based solutions for molecular microbiology is operated by its wholly-owned subsidiary Ares Genetics GmbH, or Ares Genetics, founded in 2017 and based in Vienna, Austria. This business is based on the proprietary ARES Technology Platform and Ares Genetics' proprietary genetic database on AMR, ARESdb. The ARES Technology Platform and ARESdb build and expand upon the GEAR assets acquired from Siemens Technology Accelerator GmbH in 2016. On the bioinformatics side, OpGen has combined its Acuitas Lighthouse data with the Ares Genetics (Ares) data into the ARESdb. Ares Genetics believes ARESdb is a unique comprehensive database on the genetics of antibiotic resistance. Ares Genetics also pursues an active out-licensing and collaboration strategy with suitable partners in the life science, pharmaceutical, and diagnostic industry to jointly develop solutions for microbiology relying on the database and/or the Ares Technology Platform. Ares Genetics entered into its first partnering and strategic collaborations with QIAGEN, Sandoz, and undisclosed global IVD corporations in 2018, 2019, and 2020, respectively.

In addition to its out-licensing strategy, Ares Genetics offers next-generation molecular AMR testing services out of its NGS service lab opened in mid-2019 in Vienna, Austria, with initial focus on infection control, AMR epidemiology and surveillance, clinical research and pharmaceutical anti-infectives R&D.

Ares Genetics has also developed its ARESupa Universal Pathogenome Assay, which is based on the ARES Technology Platform and ARESdb. ARESupa is intended to cover nearly any pathogen in a broad array of sample types and to predict antimicrobial drug response to a wide variety of treatment options using a single NGS laboratory workflow.

In August 2019, Ares Genetics opened a specialized service laboratory offering next-generation AMR testing services with an initial focus on infection control, AMR epidemiology and surveillance, clinical research and pharmaceutical anti-infectives R&D. All services are based on NGS and Ares Genetics' proprietary, AI-powered antimicrobial resistance database ARESdb and the ARES Technology Platform for data interpretation.

Initial services focused on the molecular identification of bacterial species and the detection of mutations and genes conferring antibiotic resistance with Ares Genetics Universal Pathogenome Assay, ARESupa. A second generation of ARESupa predicting antibiotics susceptibility based on complex genetic signatures was launched in an early access program October 2019. The launch followed the successful completion of a blinded feasibility study in which Ares Genetics correctly identified 100% of the pathogen species and successfully predicted antibiotic susceptibility for over 50 drug/pathogen combinations in line with FDA requirements (<1.5% very major error, i.e. misclassification of resistant isolates as susceptible and <3 % major error, i.e., misclassification of susceptible isolates as resistant).

OpGen's Rapid Diagnostics and Acuitas Lighthouse Software

We believe more rapid genetic identification methods will reduce morbidity from MDROs, reduce healthcare costs through reduced length of stay, and assist in the identification of targeted antibiotic therapy. Current conventional microbiology, largely unchanged in 50 years, requires one to two days for growth and phenotypic analysis and often leads to the use of broad spectrum antibiotic therapy in the early stages of infection.

OpGen has developed the Acuitas AMR Gene Panel (Isolates) test for testing bacterial isolates. This test has been available in the United States for RUO and is being used in such capacity in connection with The New York State Infectious Disease Digital Health Initiative for testing of bacterial isolates. A version of this product is currently pending FDA clearance. In the pilot phase of the Initiative, the test is contributing to the research mission by genotyping carbapenem resistant isolates from four health systems in the New York City

Metro Area. Results are subsequently analyzed by the Acuitas Lighthouse Software (RUO) to support a series of infection control tracking capabilities that are of interest to The New York State Department of Health and healthcare providers.

FISH Products

We have commercialized 12 QuickFISH and PNA FISH diagnostic test products in the United States and Europe for the identification of various infectious pathogens. The pathogens identified and differentiated by our FISH products are:

QuickFISH	PNA FISH
Staphylococcus	Staphylococcus
Enterococcus	Enterococcus
Gram-negative bacteria	Gram-negative bacteria

Our FISH products can provide pathogen identification and differentiation within 20 to 90 minutes of positive blood culture results. The tests provide actionable information that can be used by the healthcare provider to determine appropriate antibiotic therapy.

OpGen's FDA-cleared and CE-IVD-marked QuickFISH and PNA FISH products are powered by PNA technology and provide rapid pathogen identification, typically in less than 30 minutes from a positive blood culture result.

The product line is planned to be discontinued effective June 30, 2021. All customers and distributors have been informed of such discontinuation and submitted final purchase orders in the fourth quarter of 2020. All final purchase orders have been fulfilled or shipped, and OpGen does not plan to either manufacture or distribute any further FISH products going forward.

Market Overview

Antibiotic Resistance – An Urgent Global Issue

We believe that antimicrobial resistance is an urgent global healthcare issue. MDROs have been prioritized as an urgent national and global threat by the CDC, the executive branch of the federal government and the World Health Organization. In September 2020, The White House released the National Action Plan 2020-2025, which is an update to the September 2014 Strategy for Combating Antibiotic-Resistant Bacteria issued a National Strategy for Combating Antibiotic-Resistant Bacteria. This strategy calls for the strengthening of surveillance efforts to combat resistance, the development and use of innovative diagnostic tests for identification and characterization of resistant bacteria and antibiotic stewardship and development.

The CDC estimates that in the United States more than two million people are sickened every year with antibiotic-resistant infections, with at least 23,000 dying as a result. Antibiotic-resistant infections add considerable but often avoidable costs to the U.S. healthcare system. In most cases, these infections require prolonged and/or costlier treatments, extended hospital stays, additional doctor visits and healthcare facilities use, and result in greater disability and death compared with infections that are treatable with antibiotics. Estimates for the total economic cost to the U.S. economy are difficult to calculate but have been estimated to be as high as $20 billion in excess direct healthcare costs annually. As described in a December 2014 report issued by the Review on Antimicrobial Resistance commissioned by the U.K. Prime Minister, titled "Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations," 300 million people are expected to die prematurely because of drug resistance over the next 35 years, which could result in $60 to $100 trillion worth of lost economic output if the problem of antimicrobial drug resistance is not resolved.

Over the last decade, multidrug-resistant Gram-negative bacteria, frequently referred to as Superbugs, have been implicated in severe HAIs and their occurrence has increased steadily. For example, Klebsiella pneumoniae, or K. pneumoniae, is responsible for roughly 15% of Gram-negative infections in hospital intensive care units. Infections caused by KPC strains have few treatment options and are associated with a mortality rate upwards of 50%.

Exacerbating the problems associated with the emergence of these highly resistant KPC strains is their propensity to cause outbreaks in healthcare institutions. These pathogens persist both in the flora of hospitalized patients and in the hospital environment, and they have the capacity to silently colonize patients or hospital personnel by establishing residence in the gastrointestinal tract without causing any signs of infection. Individuals can be silently colonized or become asymptomatic carriers for long periods of time, with detection of these carriers often proving difficult. These silent carriers act as reservoirs for continued transmission, which makes subsequent spread difficult to control and outbreaks difficult to stop. In addition, KPC strains can survive for several hours on the hands of hospital personnel, which likely facilitates the spread of organisms from patient to patient. Effective control of KPC outbreaks requires a detailed understanding of how transmission occurs, but current technologies do not allow healthcare providers to routinely perform these investigations on a timely basis.

The lack of currently available treatment options and scarcity of new treatment options in development are compounding the emerging Superbug problem. It has been close to 30 years since a new class of antibiotics was developed and successfully introduced. As a result, we believe that rapid, accurate identification of the pathogen and its genetic make-up, screening, infection control and antibiotic stewardship have become one of the most powerful weapons in the fight to contain this threat.

The emergence of multidrug resistant pathogens has made the treatment of patients with UTIs a growing problem in the United States and internationally. There are approximately 10 million patients each year in the United States with UTIs and more than one million of these patients have cUTI often requiring hospitalization with intravenous antibiotic therapy. Among these patients *E. coli* represents the most common pathogen, and recent data indicate that 18.3% of U.S. *E. coli* isolates are extended spectrum β-lactamase (ESBL) resistant. These patients present complicated therapeutic choices for clinicians and often require last resort carbapenem antibiotics. The rate of ESBL resistant *E. coli* increased 34% annually between 2010 and 2014. Therapy with carbapenem antibiotics has contributed to growing Carbapenem resistance (CRE) rates and high patient treatment costs. A large outcomes study recently completed by the Company indicated that average cost to treat an ESBL *E. coli* patient was $25,000 while patients with ESBL *K. pneumoniae* infections cost over $60,000.

Based on industry analyses, we believe the global HAI market is a $2 billion dollar market with the molecular diagnostic segment representing a fast growing segment of such market with multiple high acuity patients and significant infectious sites, including UTIs, surgical site infections, pneumonia and bloodstream infections.

Commercial Sales

We currently sell and market our products and services directly in the United States through a dedicated sales and marketing support team. Internationally, we sell our products through a network of over 20 distributors covering more than 40 countries. Support for our European FISH product customers had been handed over to Curetis in 2020 from our subsidiary in Denmark, which is in the process of being liquidated. In 2018, we established OpGen Colombia SAS to commercialize our products in Colombia and to support sales on a direct basis and through distributors in South America and Central America, however we discontinued these efforts and began the process to dissolve the subsidiary in 2019. On completion of the business combination with Curetis, our strategy is to commercialize the Acuitas AMR Gene Panel and the Curetis products in the United States through our direct commercial organization.

In the first quarter of 2018, we introduced the Acuitas AMR Gene Panel (RUO) for infection control purposes and pharmaceutical surveillance research as research use only tests. The Acuitas AMR Gene Panel (RUO) tests will remain available while the Company completes its regulatory submission to support FDA clearance to commercialize such product for broader clinical use. We anticipate that customers who use the products as RUO tests for infection control and clinical research will serve as a potential installed base for the FDA cleared products.

We operate in one segment. Our operations are located in the United States, Germany, and Austria.

Competition

We are developing a molecular information business focused on leading a transformation in microbiology and infectious disease through precision medicine products and services that combine genomic data and informatics. Our approach combines proprietary, FDA cleared and CE-IVD-marked DNA tests such as Unyvero as well as our Acuitas AMR Gene Panel (isolates). Our competitors include rapid diagnostic testing, next-generation sequencing testing, and traditional microbiology companies, commercial laboratories, information technology companies, and hospital laboratories who may internally develop testing capabilities. Principal competitive factors in our target market include: organizational size, scale, and breadth of product offerings; rapidity of test results; quality and strength of clinical and analytical validation data and confidence in diagnostic results; cost effectiveness; ease of use; and regulatory approval status.

Our principal competition comes from traditional methods used by healthcare providers to diagnose and screen for MDROs and from other molecular diagnostic companies creating screening and diagnostic products such as Cepheid, Becton-Dickinson, bioMérieux, Accelerate Diagnostics, T2 Biosystems, GenMark (currently being acquired by Roche), Qiagen, and Luminex. We believe our focus on identifying antibiotic-resistant genes in addition to broad panels of organisms from a wide variety of native clinical sample types, and our Ares Genetics and Acuitas Lighthouse bioinformatics offerings distinguish us from such competitors.

Competitors may develop their own versions of our product offerings in countries where we do not have patents or where our intellectual property rights are not recognized.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical, research and development and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by hospitals, physicians and payers as functionally equivalent to our products and services, or offer products and services at prices designed to promote market penetration, which could force us to lower our list prices and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully against current and future competitors, we may

be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

Competition to the Unyvero System

The Unyvero Platform is a sample-to-answer MDx solution. There are several other companies who develop and commercialize similar systems. In terms of devices and assays, OpGen believes its key competitors include bioMérieux (BioFire with its FilmArray® platform) and GenMark with its ePlex® platform as well as Accelerate Diagnostics with its Pheno™. Taking into consideration the broader market, devices of other key competitors can be extended to include Cepheid (GeneXpert®), T2 Biosystems (T2DX®), Luminex Corporation (formerly known as Nanoshphere) (Verigene System® and Aries®), Atlas Genetics (with io™ System), Roche (Cobas® with the Liat® and GeneWEAVE platform), Qiagen (QIAstat-Dx™) and Biocartis N.V (Idylla™), Bosch with the Vivalytic platform and the Meridian Bioscience (formerly GenePOC) Revogene® system. Disease-related assay competitors including those providing reagent kits only (e.g. Seegene, Fast-Track Diagnostics/Siemens Healthineers, Genetic Signatures) and LDT developers have to be separately assessed by each application. OpGen believes that its Unyvero Platform has certain key characteristics that clearly differentiate it from other sample-to-answer systems:

Based on its corporate market analysis, OpGen believes that due to the proprietary lysis technology its Unyvero Platform is able to process a broader variety of sample types than competing platforms. In most cases, no labor or time intensive manual sample preparation is necessary and even difficult and blood-contaminated native samples can be processed. Furthermore, the Unyvero Platform is CE-IVD-marked for a variety of samples including sputum, bronchoalveolar lavage, tracheal aspirate, exudate, catheter tip, pus, sonication fluid, synovial fluid, swab and tissue. Further samples such as blood, urine, stool and formalin-fixed paraffin embedded tissues present further options for extending the variety of samples for future applications. Fresh or frozen samples and also samples that have been stored in different media can be processed easily on the Unyvero Platform. As the lysis is integrated into the workflow, hands-on time and potential handling errors are significantly reduced.

The Unyvero Platform is also differentiated from competing products by its high multiplexing capability based on end-point PCR, which allows for the execution of eight independent multiplex PCR reactions simultaneously. Therefore, Unyvero can identify a broad range of microorganisms and in addition a large variety of antibiotic resistance markers in a single run.

Focusing on severe infectious diseases and having developed a HPN Application Cartridge, an ITI Application Cartridge, a BCU Application Cartridge, an IAI Application Cartridge and a UTI Application Cartridge and planning to develop further Application Cartridges in the severe infectious disease area, Unyvero has a highly differentiated positioning in the market.

Although several direct competitors have in the past three years started to develop or commercialize their own infectious disease tests, OpGen believes that the variety and breadth of its menu of cartridges targeting different infection areas positions it favorably to answer patient and customer needs.

Competition to the Unyvero Application Cartridges

Considering its panel design, the Company believes that there are currently very few assays directly comparable to the Company's HPN / LRT / LRT BAL, ITI, IAI, and UTI Unyvero Application Cartridges that are commercially available to date. With its BCU Unyvero Application Cartridge, the Company has entered a competitive indication area for which the Company believes it can offer a more comprehensive panel compared to its competitors. Various competitors offer testing in some, but not all, of the infections targeted by Unyvero Application Cartridges. For example, for the HPN and LRT Application Cartridges, currently only two companies (OpGen and bioMérieux/BioFire) offer an FDA-cleared IVD automated molecular panel for lower respiratory tract infections / pneumonia. According to publicly available sources, Accelerate Diagnostics has a CE-IVD pneumonia assay and it is believed to be in clinical trials for future U.S. FDA submission of this application. Other companies, such as, Luminex (formerly Nanosphere), GenMark, Seegene, Genomica, Miacom, PathoFinder, Fast-Track Diagnostics (now a Siemens Healthineers company), Randox, ArcDia, Qiagen, and iCubate are primarily targeting the upper respiratory tract with their panels. Their panels mainly cover viruses and a few bacteria, and in some occasions a limited number of antibiotic resistance markers only. Diatherix offers a manual test claiming to cover both upper and lower respiratory infections. OpGen believes that it offers the most comprehensive panel for severe bacterial pneumonia for critically ill patients that require hospitalization, as the panel includes unique and differentiated bacterial targets and the broadest coverage of carbapenem resistance markers, while BioFire's panel has a limited range of resistance markers and viral targets.

Competition by Conventional Microbiology

The conventional microbiology market consists of culture and MALDI-TOF based testing and is largely shared by well-established players including BD, bioMérieux, Bio-Rad Laboratories, Danaher (Cepheid, Beckman Coulter), Thermo Fisher Scientific. Culture-based testing is usually performed in the central laboratory at TATs of 48 to 72 h and it is yet to be seen whether it can robustly be accelerated by miniaturization, an approach pursued by the company Accelerate Diagnostics. While TATs for MALDI-TOF based testing is much faster, overall TATs from sample to report are still greater than 24 hours as MALDI-TOF generally depends on an initial

culturing step for pathogen isolation and cannot be performed from native patient samples. Generally, providers of conventional microbiology solutions are focusing on reducing TAT, use of labor and lab space, as well as overall costs by automatic specimen processing and pathogen identification.

Competition by Molecular Diagnostics – PCR

Key competitors in the PCR-based molecular diagnostics market include bioMérieux, BD, Danaher, Roche, Qiagen, Abbott, Hologic, OpGen and, amongst others, Ares Genetics' parent company, Curetis. PCR-based microbiology testing is usually performed at the point of need or in the central laboratory at rapidly reduced TAT compared to conventional microbiology. Generally, providers of PCR-based molecular diagnostics are focusing on further reducing TAT to less than 30 minutes to one hour and/or increasing multi-plexing degree as well as reducing use of labor, lab space, and overall costs. The Company believes that its ability to quantitatively predict antibiotic susceptibility based on the pathogen's genetic profile complements PCR-based approaches detecting panels of genes and mutations as indicators of resistance.

Competition to Ares Genetics

Ares Genetics' peers and competitors include companies providing conventional microbiology, PCR- and NGS based molecular diagnostics, as well as AMR databases and bioinformatics solutions. In general, many peers and competitors are at the same time also considered potential ARESdb licensing partners due to the unique content and positioning of ARES' artificial intelligence curated reference database, ARESdb.

Competition by Molecular Diagnostics – NGS

The emerging NGS-based molecular diagnostics market is shared by start-up-like companies such as IDbyDNA, Karius, CosmosID, Noscendo, Day Zero Diagnostics, or ArcBio aiming at disrupting the molecular microbiology by pathogen detection via direct sequencing from patient samples, as well as established players such as bioMérieux focusing on isolate sequencing to monitor outbreaks in hospitals (in partnership with Illumina). NGS-based testing is currently performed as a service and companies mostly focus on reducing TAT as well as increasing the NGS market share in molecular microbiology. NGS-based molecular diagnostics companies are considered as Ares Genetics' closest competitors, while Ares Genetics believes to have a competitive advantage by its ability to predict antibiotic susceptibility based on the pathogen's genetic profile with a performance meeting FDA requirements for functional testing of AST by culture.

Competing AMR Databases & Bioinformatics Solutions

To date, several AMR databases exist (e.g. CARD, PATRIC, etc.) but they are purely designed for academic research applications as they neither represent IVD-grade reference databases, nor systematically cover high-resolution resistance profiles including confidence levels and diagnostic performance parameters for associated AMR markers. The commercial microbial bioinformatics solution market on the other hand, is largely covered by QIAGEN, a strategic licensing partner of ARES for co-marketing bioinformatics research solutions based on ARESdb.

Research and Development

We intend to continue to invest in the development of additional Unyvero panels such as UTI and IJI for the Unyvero A50 platform, we intend to invest in the further development of the Unyvero A30 *RQ* platform, as well as the Ares Genetics bioinformatics solutions such as ARESdb and ares-genetics.cloud.

Our ongoing and anticipated research and development efforts include:

- Expanding the Ares Genetics bioinformatics and NGS offerings such as ARESdb, ares-genetics.cloud, ARESupa etc.
- Development of Unyvero A30 *RQ* platform
- Clinical trials and regulatory filings for Unyvero UTI in the USA (expect as De Novo with clinical trial at a minimum of 3 trial sites and minimum of 1,500 samples tested)
- Clinical trials and regulatory filings for Unyvero IJI in the USA (expect as De Novo with clinical trial at a minimum of 3 trial sites and minimum of 1,500 samples tested)

Sales and Marketing

We currently sell and market our products and services directly in the United States through a dedicated sales and marketing support team. Internationally, we sell our products through over 20 distributors covering more than 40 countries.

Our strategy to build demand for our products following receipt of such regulatory clearance includes completing clinical verification studies, customer driven evaluations and studies, sales of our tests for RUO.

Customers

OpGen's commercial teams have identified several stakeholder groups: treating clinicians, doctors of pharmacy (PharmDs), antibiotic stewardship programs, microbiologists, molecular biologists and laboratory managers as well as hospital administration, all of whom will be actively involved in the purchase decision at varying levels and stages. In terms of product benefits, OpGen believes that clinicians and physicians seek timely diagnostic results that can be used to better inform or confirm a treatment decision and improve patient outcomes, while microbiology laboratory managers, who have to contend with the steadily decreasing availability of trained lab technicians and the need to perform testing during off-shifts, need simple-to-use, robust technologies. Ultimately, however, the decision whether a proposed new testing solution is cost effective and affordable on a routine basis must be made by the payer, which in the case of hospitalized in-patients under the DRG-reimbursement system is typically the hospital's purchasing and finance departments. OpGen's key account management ensures that all stakeholders are targeted early in the sales process.

Sales Process

The typical sales process starts with an introductory visit to the microbiology laboratory director and senior microbiology staff. The goal is to introduce Unyvero or Acuitas and assess general interest in evaluating the Unyvero or Acuitas Platform during a demonstration phase. However, the goal is also to initiate contact to any new hospital customer via the gatekeeping microbiology laboratory function. The primary objective apart from getting a demo phase agreed upon is to seek joint introductory meetings with the senior microbiology staff and the various intensive care units, or ICUs, and clinicians in any relevant ICU. Since the latter can be multiple ICUs (sometimes over a dozen in major university hospitals) with multiple 24/7 rotating shift operations each, it is paramount to identify one or a few key ICUs as internal product champions. The clinicians are ultimately the end-customers of Application Cartridge results for use in treatment assessment and optimizing medical care for their patients. They will also be the ones routinely requesting a test to be done. At this stage a discussion about the ideal placement of the Unyvero System during a demonstration usually takes place. In the United States, the Unyvero System is placed in the core laboratory. In the EU and the rest of world, or RoW, central location in the microbiology laboratory is the preferred option, or alternatively near patient ICU placement. It is also important to engage the clinical pharmacy, and specifically the Infectious Disease Pharmacist, in the sales process as an additional key stakeholder and decision maker.

OpGen expects that the entire sales process, from the introductory visit to the point in time when the hospital begins routinely purchasing Application Cartridges or Acuitas consumables, known as the push-pull triangle model, which includes the lab, the clinicians and the finance entity, will take around nine to twelve months, based on the experience of competitors and peer companies, in the United States and about the same time from start to finish in the EU. Depending on the time of year and budget cycle, however, a contractual arrangement can take significantly longer. An integral part of the sales process is the placement of demo systems without payment for demo evaluation purpose.

OpGen's marketing provides sales and sales support tools adapted to the specifics of each stakeholder and stimulates demand by setting up awareness campaigns for lab personnel, clinicians and general hospital stakeholders. In the more developed markets of the EU and the RoW, additional customer segmentation reflects the business opportunity per customer or institution and is linked to size of the hospital reflected in the number of beds available at the institution. Therefore, the sales strategy is based on a key account management approach, initially only targeting large hospitals with clear focus on departments like pulmonology/pneumology, large ICUs or orthopedics wards depending on the particular Application Cartridge being promoted.

The focus is on high-volume consumable orders (Application Cartridges and other consumables) instead of driving revenues and profits through hardware placements (Unyvero System installations). Consequently, OpGen and its distribution partners aim to optimize the utilization of each placed hardware unit rather than solely maximizing the installed base of instruments. Therefore, OpGen, with its tests primarily targeting in-patients (hospitalized) with severe infections, is focusing its sales and commercialization efforts on laboratories in hospitals and independent laboratories serving larger hospitals.

OpGen and its distribution partners will also face certain market entry barriers mostly related to upfront investments for the implementation of its new technology, as most laboratories and microbiology centers are cost centers, which do not directly benefit from the current DRG reimbursement scheme. Additionally, the Unyvero and Acuitas platforms will be an add-on test not replacing traditional testing – in this case cultures, which are perceived as comparatively cheap. Therefore, OpGen pursues a sales strategy whereby it offers customers a number of different financial options for its products and services, including rental agreements (pursuant to which OpGen would provide the instruments on the basis that the customer commits to buying a certain number of Application Cartridges or other consumables from OpGen over a set period of time, with the cost of such Application Cartridges or Acuitas consumables incorporating a reagent rental charge for the use of the instrumentation), or a straight cash purchase of the Unyvero or Acuitas platforms, as applicable. Similar concepts are employed by OpGen's distribution partners at their discretion.

As OpGen is marketing its innovative Unyvero and Acuitas Platforms to a diverse and demanding customer base implementing solutions that offers the potential to improve upon the current standard of care, the Company's management believes it will need to continue making additional investments in clinical validation, scientific publications, brand awareness and market education worldwide, but with a focus in the EU and United States. Some of the Company's tests will require market access activities to prove their value and to obtain sufficient reimbursement by relevant payers for certain countries.

OpGen has developed a full suite of marketing communications tools using print and online channels. OpGen also supplies supporting evidence for the various individual stakeholders, for instance approaching microbiologists and clinicians with first-in-class scientific marketing. This not only includes the classical marketing mix (i.e. a set of marketing tools regarding product, price, place and promotion), but also compiles information on health economics and clinical outcomes research.

In addition, OpGen's marketing focuses on medical education of physicians through its scientific affairs team of clinical application specialists, participation in scientific conferences, organizing scientific sessions and symposia, and by publications in peer-reviewed journals.

In order to receive valuable input during research and development, stimulate market awareness and the demand for its products, OpGen has made a significant investment in establishing clinical and scientific advisory boards in Europe and the United States, comprised of key opinion leaders. In addition, follow-on research and clinical studies are conducted at key opinion leader, or KOL, sites, which assist in increasing market awareness. The KOL selection by OpGen is based on the following criteria:

- The KOL has a strong reputation in the area of infectious diseases and/or in molecular diagnostics;
- The KOL is a key opinion leader in the clinical and/or laboratory space with strong influence on peers; and
- The KOL is an 'early innovator', a member of clinical society, an editor of scientific journals or a member of a guideline-setting agency and could therefore act as a promoter of the product.

Distribution Channels

To distribute the Unyvero System and the Application Cartridges, OpGen has adopted a dual approach combining direct sales in the United States with indirect sales through specialized distributors in European countries such as Germany, Austria, Switzerland, UK, France, Belgium, Netherlands, Luxemburg, Spain, Italy, Russia, Bulgaria, Romania, Greece, Israel, the Middle East, including Qatar, Kuwait and the UAE and Asian countries such as Vietnam, Indonesia, Malaysia, Singapore, Thailand, China, Taiwan and Hong Kong and other markets such as Central and Latin American markets.

The choice between direct sales and indirect sales distribution is based on available funding for OpGen's commercial operations, the attractiveness of the market in terms of size, pricing, and reimbursement, the ease of market access in terms of regulations, structure and complexity of the healthcare system, and payer situation. Markets are also selected based on the availability of suitable distributors with appropriate size, portfolio, sales channels, experience, networks, and reputation to introduce an innovative product like Unyvero in their respective market. It is also not uncommon for MDx companies to start with a distributor model before going direct once economics permit establishing a direct sales infrastructure.

OpGen going forward will regularly evaluate on a case-by-case basis whether the chosen distribution channel is adequate to also cater for the new target disease segments, or whether a new structure should be put in place.

Direct Sales U.S. Market

OpGen markets and sells the Unyvero and Acuitas platforms and will market any future cleared Application Cartridges and other consumables directly in the United States through its own U.S.-based commercial organization including sales, marketing and after-sales support.

As of December 31, 2020, OpGen had an installed base of 23 Unyvero Analyzers across the United States and in different types of hospitals and labs.

Indirect Sales Markets

OpGen enters into a standard distribution agreement template for most of its Unyvero distributors, which specifies the particular Unyvero product and the respective distribution territory. The distribution agreements typically contain provisions for exclusive distribution within a particular territory and for specified term, typically from three to five-years. During that period, the distributor has exclusive rights to market, sell and distribute all Unyvero products. In return, each distributor needs to commit to annual minimum purchases of Unyvero Systems as well as Application Cartridges. Transfer prices for the Unyvero Systems and Application Cartridges are defined and reflect typical MDx industry distributor margins on consumable sales. If a distributor fails to meet its annual minimum commitments

fixed in the contract, the Company has the right to either terminate such agreement in its entirety, or to terminate such distributor's territory exclusivity in such country. Each of these agreements can be extended by mutual agreement between the parties. Furthermore, the agreements also contain typical change of control provisions, which comprise a merger of the company, the sale of all assets or the liquidation of the company. None of these change of control provisions are expected to have any impact whatsoever post business combination with OpGen as these contracts are expected to continue unchanged.

OpGen, through its subsidiary Curetis, has entered into distribution agreements with over 20 distributors covering more than 40 countries. Distribution agreements usually feature minimal sales commitments and purchase commitments of the Unyvero Systems and Application Cartridges commensurate with the size and structure of the respective market. The Company has several distribution agreements in place for the following European countries:

- Belgium, France, Germany, Greece, Italy, Luxemburg, Netherlands, Portugal, Spain, Switzerland, United Kingdom: A. Menarini Diagnostics;
- Austria, Czech Republic, Slovakia, Slovenia and Croatia: Axon Lab;
- Romania: Synttergy Consult LTD;
- Bulgaria: SGP Bio Dynamics Ltd;
- Ireland: Cruinn Diagnostics;
- Russia, Ukraine, Kazakhstan: BioLine LLC;
- Belarus: BioLine BS LLC; and
- Bosnia and Hercegovina, Montenegro, Serbia, North Macedonia: Ako Med d.o.o.,

In connection with these distribution agreements, distributors are contractually obligated to:

- cater for local product registrations as required;
- perform local clinical studies as required;
- take responsibility for local marketing based on guidelines and materials provided by Curetis' global marketing team;
- maintain a regulatory system as required;
- maintain a local inventory; and
- install the Unyvero System, train customers, and provide first-level service.

Outside of the EU, OpGen currently plans to commercialize Unyvero through distributors. Currently further distribution agreements are in place for the following countries:

- Qatar & UAE: Al Zahrawi Medical LLC;
- Kuwait: ATC;
- Singapore, Malaysia, Indonesia and Thailand: Acumen Research Laboratories;
- China, Taiwan and Hong Kong: Beijing Clear Biotech/ Technomed (Hong Kong) Ltd;
- Vietnam: Quaphaco;
- Israel: Rhenium Ltd (terminated in 2021);
- Egypt: Future Horizons Scientific;
- Mexico: Quimica Valaner;
- Colombia: Annar; and
- Uruguay: Biko S.A. (terminated in 2021)

The total contractual minimum purchase requirements of all current distributors is 409 Unyvero Systems of which about 360 are part of BCB's commitment, which applies over an eight year period following NMPA approval, plus approximately 1.5 million Application Cartridges which are also part of BCB's commitment during the same period). Failure of distributors to reach minimum purchase quantities has not led to any "forced" purchase of the minimum quantities in the past but can lead to a termination of the distribution agreements or termination of exclusivity in territories for such distributor at the sole discretion of OpGen and its Curetis subsidiary. The above minimum purchase requirements do not guarantee any certain minimum future levels of revenues.

With respect to after-sales support and maintenance, OpGen has established a concept of system replacement instead of onsite repair. In the event of system failure or required maintenance, systems are rapidly replaced (within one or a few days), minimizing downtime for the customer as well as reducing the need for a costly service organization. In certain instances, OpGen uses its own small field service engineering team to provide ad hoc on-site repair and service. In the future OpGen expects to establish a service maintenance arrangement where customers pay for support and repair based on what service package they have purchased.

Manufacturing

During 2020, we manufactured all our Unyvero products in Germany (Unyvero systems are manufactured by Zollner Elektronik AG and Unyvero cartridges and consumables at our own manufacturing facility in Bodelshausen, Germany), and all our FDA-cleared and CE-IVD-marked QuickFISH and PNA FISH products in our Gaithersburg, Maryland facility.

Manufacturing of our CE-IVD-marked and FDA-cleared products is performed under the respective applicable relevant current standards – Quality System Regulation as required by the FDA or other relevant regulatory bodies for the manufacture of IVD labeled products. These regulations carefully control the manufacture, testing and release of IVD products as well as raw material receipt and control. We also have ongoing Post Market surveillance and vigilance responsibilities under applicable European and FDA regulations, and are subject to periodic inspections by the FDA or other relevant regulatory bodies to determine compliance with the FDA's or other applicable requirements, including primarily the quality system regulations and medical device reporting regulations. The results of these inspections can include inspectional observations on FDA's Form 483, warning letters, or other forms of enforcement.

For instrument manufacturing, OpGen's subsidiary Curetis has decided to co-develop and subsequently outsource all of its Unyvero A50 instrument manufacturing to Zollner. With regard to Application Cartridges, they are developed and manufactured entirely in-house, using equipment provided by Contexo and certain components provided by Scholz. Curetis has established a sophisticated manufacturing site for its cartridges where it has full control over the entire production process ensuring that Application Cartridges meet stringent quality requirements.

Curetis' EMS (Electronic Manufacturing Services) provider Zollner is an established and experienced medical device manufacturer for large global companies and has flexible production processes ensuring it can meet demands with different volume requests. Zollner has established a Unyvero dedicated manufacturing island and Unyvero team where in a single eight-hour shift for five days a week, up to four systems (Unyvero L4 Lysator, Unyvero C8 Cockpit and Unyvero A50 Analyzer) can be assembled and tested per week. Zollner has an established 24/7 manufacturing operation, providing significant capacities and capabilities for major scale-up of Unyvero manufacturing operations. The Company's management believes that manufacturing capacity will not become a bottleneck in the foreseeable future. Zollner also has all required certifications under all applicable ISO standards for IVD instrument manufacture and is an FDA registered establishment for the manufacturing of the Unyvero A50 instruments. So far, no decision has been made on the selection of the OEM provider for the series production of the Unyvero A30 *RQ* systems.

As part of its operational strategy, OpGen's subsidiary Curetis decided to build and operate its own manufacturing facility inside premises leased to it for the manufacturing of the Application Cartridges. The Application Cartridge manufacturing facility based in Bodelshausen, Germany, has been operational since 2011. Curetis is able to manufacture sufficient product to meet current and forecasted demand. OpGen expects future Application Cartridges to be used with the Unyvero A30 *RQ* Analyzer for own R&D purposes, potential own MDx products of OpGen such as the Acuitas IVD products and/or potential products by Unyvero A30 *RQ* licensees could also be manufactured in Bodelshausen, in a dedicated manufacturing line module to be developed and built and using plastic parts manufactured by Scholz.

The Curetis facilities at Holzgerlingen, Germany, as well as manufacturing facility in Bodelshausen, Germany were subject to an FDA inspection in February 2019, which was successfully completed with no FDA Form 483 observations.

Zollner

On May 27, 2009, OpGen's subsidiary Curetis and Zollner Elektronik AG, Zandt, Germany, or Zollner, entered into a framework agreement, pursuant to which Zollner performs certain development and manufacturing services for the Unyvero System. Under the terms of the agreement, each party retains rights to its respective intellectual property. The agreement specifies that manufacturing intellectual property created jointly or solely by Zollner while performing work and services for Curetis shall be solely with Zollner. For any manufacturing intellectual property owned by Zollner, Curetis receives a non-exclusive, non-transferable, world-wide, royalty free, irrevocable perpetual license (without a right to sublicense) to use, provided that such manufacturing intellectual property is

embodied in a product provided to Curetis. As of today, there is no such manufacturing intellectual property. The agreement is for an indefinite period of term and may be terminated with 12 months' prior written notice.

The framework agreement has been expanded by a development agreement in 2010 and related project agreements for various development projects as well as by a strategic supply agreement signed in June 2013 under which Zollner became the OEM contract manufacturer for all Unyvero instrument systems for Curetis.

Scholz

On February 1, 2013, Curetis and Scholz entered into a framework agreement, pursuant to which Scholz is requested to perform certain services in the area of tool development and tool making (injection molding tools to make plastic parts) and manufacturing product components (i.e., all plastic parts for the Application Cartridges) for Curetis. The parts for the Unyvero A50 products include among other things, the base plates, valve plate, PCR chamber parts, spin column holder, waste chamber, reagent container, plungers and housing body parts. All rights, title, interest and ownership in the injection molding tools and plastic products specified in this agreement, including the respective intellectual property rights shall be transferred and assigned to and solely belong to Curetis. Under this agreement, Scholz guarantees that all such rights solely belong to Curetis. The framework agreement constitutes the legal basis for all legal relations between the parties after February 2013, in particular for the supply agreement.

In addition to volume production with these pre-existing molds, Curetis subsequently commissioned a series of multi-cavity injection molds (owned by Curetis yet stored and used on site at Scholz) under a strategic lease agreement with Scholz for all injection molded plastics parts entered into on July 28, 2015. The agreement is for an indefinite period of term and may be terminated with 12 months' prior written notice or may be terminated earlier by Curetis once the last order for related plastic parts has been fulfilled.

Under the framework agreement with Scholz, Curetis in 2018 also commissioned several single- and multi-cavity injection models for parts of the Unyvero A30 *RQ* cartridge, namely molds for 'Frame bottom', 'Frame top', 'PCR Disc', 'Drive Ring', 'Switching Wheel bottom', 'Switching Wheel top', 'Sealing Ring switching wheel' und 'Sealing Ring PCR disc'. These injection molds were developed, manufactured and put into service by Scholz over the course of 2018 and 2019 under the same terms as described above for the injection molds for the Unyvero A50 cartridges.

Supply Agreements

Beginning in October 2017, Curetis entered into a supply agreement, dated January 1, 2010, with a large single-source supplier, which updated a prior supply agreement between them, for purchase of PCR Master Mix reagent and other product components, which are used as integral parts of Curetis' Application Cartridges. Pursuant to the agreement, Curetis has the right to resell such product components supplied under the agreement, except for the PCR Master Mix, in conjunction and jointly repackaged with Curetis' products worldwide. Further, the agreement provides that Curetis has the right to resell the PCR Master Mix repackaged and refilled for use only in conjunction with Curetis' products worldwide. Pursuant to the PCR Master Mix supply agreement, Curetis' distribution right is limited to the sale to end-users and Curetis' distributors and does not include sales to users who re-sell Curetis products in modified form (e.g. using their own brand) or sales, which would violate any sanctions, embargos or foreign trade restrictions issued by the EU or the United States Further, Curetis, or any of its affiliates or distributors, are not permitted to resell any of the product components, including the PCR Master Mix, to third parties as stand-alone items for use other than in conjunction with Curetis' products. Under the agreement, Curetis is subject to certain minimum annual purchase requirements.

Raw Materials and Suppliers for Acuitas

OpGen procures PCR amplification reagents and the QuantStudio 5 Real-Time PCR System from Thermo Fisher Scientific. DNA purification reagents and the EZ1 DNA Purification System are procured from QIAGEN, NV. We purchase the PNA probes, glass slides and specialty consumables for our QuickFISH products from third party manufacturers who have long lead times and who manufacture several of these products for us on a sole source basis. We also purchase our collection kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors. While we have developed alternative sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective or whether alternative sources will be available when we need them. If these suppliers can no longer provide us with the materials we need to manufacture our Acuitas AMR Gene Panel products or our QuickFISH products, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, our business would be negatively affected.

Seasonality of Business

We do not believe our business is subject to seasonality. However, our business can be subject to and affected by the business practices of our business partners. To the extent that the availability of inventory or materials from or development practices of our partners is seasonal, our sales may be subject to fluctuations quarter to quarter or year over year.

Quality Assurance

Our global quality and regulatory affairs function oversees the quality of our R&D operations, laboratories and our FDA-cleared and CE-IVD-marked diagnostic products as well as the quality systems used in research and development, manufacturing and commercialization such as client services, billing operations and sales and marketing. We have established a quality assurance system across our entire business, including implementation and maintenance, document control, supplier qualification, corrective or preventive actions, oversight, and employee training processes. We monitor and seek to improve our quality over time in compliance with all applicable regulations.

Payments and Reimbursements

Our Unyvero tests, SARS-CoV-2 tests, Acuitas AMR Gene Panel (RUO) tests are, and our PNA FISH and QuickFISH were, and other future products and services will be, sold to hospitals, laboratories, and public health organizations as products and on a fee-for-service basis. When hospital and health system clients purchase our products, we bill them directly for the purchase of test kits and consumables. We believe that hospitals will recoup costs of our products and services by obtaining reimbursement from the government or private insurance companies for in-bed occupancies, which traditionally includes all testing required for admitted patients. When our tests are used prior to hospital admission, hospitals, clinical laboratories, and other healthcare provider customers that purchase our products may bill various third-party payers to cover all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our products.

In the IVD market, sales volumes and prices of innovative products will depend in large part on the availability of coverage and reimbursement from third-party payers, which includes depending on public funding through governmental programs, private insurance plans and workers' compensation plans. In most healthcare settings, reimbursement schemes are complex, processes to achieve reimbursement for new technologies is tedious and time consuming and payers may deny coverage or reimbursement. As a result, even though a new product may have been cleared for commercial distribution, it may find limited demand for the product until reimbursement approval has been obtained from governmental and private third-party payers. However, specific reimbursement codes for laboratory tests are in most countries only applicable for out-patient's healthcare. In addition, some public funding is already available in most countries for certain established tests and is often technology specific, thus code stacking or cross-walking and using corresponding codes is quite usual to overcome challenging reimbursement situations.

OpGen has analyzed existing reimbursement schemes in Germany, Austria and Switzerland, as well as other European countries and the United States, where hospitalized in-patients with severe infections are typically covered under the DRG system. With DRG, hospitals receive a lump-sum payment, e.g., up to €22,000 in Germany for a life-threatening case of VAP treated in intensive care. Therefore, OpGen has taken the strategic direction to target hospitalized patients first as in most countries DRG systems as hospitals' general financing are in place covering diagnostics as part of a lump sum payment per patient without specific reimbursement codes for a laboratory test required.

In addition, the current list prices and future anticipated prices for Unyvero Application Cartridges and Acuitas AMR Gene Panel consumables, amount to a small fraction of this overall DRG payment. It is also favorable in some countries, such as the United States, that pathogen identification by a lab test may even warrant coding to higher DRG rates. For example, OpGen's marketing team has been working with outside consultants to correctly position the LRT Application Cartridge in the context of relevant DRG codes so that, based on the pathogens identified by the LRT Application Cartridge, it can offer hospitals more favorable DRG coding and higher reimbursement on a per patient case overall.

OpGen's management believes that existing DRG reimbursement scheme codes and optimization potential based on a Unyvero or Acuitas diagnostic within those applicable DRGs and their national equivalents can be used in most major markets and therefore an adoption of the Unyvero and Acuitas technology seems feasible.

Intellectual Property

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. To that end, in order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We therefore rely on a combination of patents, copyrights and trademarks, as well as contracts, such as confidentiality, invention assignment and licensing agreements. We also rely upon trade secret laws to protect unpatented know-how and continuing technological innovation. In addition, we have what we consider to be reasonable security measures in place to maintain confidentiality. Our intellectual property strategy is intended to develop and maintain our competitive position.

As of December 31, 2020, OpGen had a patent portfolio of 49 granted patents and 19 patent applications excluding the FISH and Argus intellectual property as mentioned below. 37 of the granted patents and 4 of the pending patent applications are from Curetis and 10 of the granted patents and 15 of the pending patent applications are from Ares Genetics.

As part of the aforementioned portfolio, we have one issued US patent, one allowed US patent and one pending US patent application related to our Acuitas products. In November 2019, the U.S. Patent and Trademark Office issued an OpGen patent covering the Lighthouse Profiling technology used in the Company's software for tracking antimicrobial resistant pathogens. The patent covers the use of the Company's Acuitas Lighthouse® Software for real-time monitoring of superbug infections and other multi--drug resistant infections. On December 29th 2020, the U.S. Patent and Trademark Office issued an OpGen patent covering detection of multi-drug resistant organisms used in the Company's Acuitas product. The patent covers the use of Acuitas for identification and characterization of genes and gene families associated with multi-gene resistance in biological samples in the screening, diagnosis, therapy, epidemiological surveillance, and monitoring of multi-gene resistant colonization and infection.

As part of the aforementioned portfolio, there are two pending U.S. non-provisional patent applications and 8 issued U.S. patents related to our FISH products. These issued patents begin to expire in November 2024 and will be fully expired by October 2033. We are currently in the process of sunsetting our FISH intellectual property. A majority of our issued and exclusively licensed FISH patents from Dako Denmark A/S expired over the last six years. The remaining nine exclusively licensed U.S. FISH patents expire between 2021 and 2024.

We have ownership rights to 8 issued U.S. patents related to our Argus products. These issued patents begin to expire in November 2026 and will be fully expired by July 2031. We are currently in the process of sunsetting our Argus intellectual property.

We intend to file additional patent applications in the United States and abroad to strengthen our intellectual property rights; however, our patent applications (including the patent applications listed above) may not result in issued patents in a timely fashion or at all, and we cannot assure investors that any patents that have issued or might issue will protect our technology.

We require all employees and technical consultants working for us to execute confidentiality agreements, which provide that all confidential information received by them during the course of the employment, consulting or business relationship be kept confidential, except in specified circumstances. Our agreements with our research employees provide that all inventions, discoveries and other types of intellectual property, whether or not patentable or copyrightable, conceived by the individual while he or she is employed by us are assigned to us. We cannot provide any assurance, however, that employees and consultants will abide by the confidentiality or assignment terms of these agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our technology or obtain and use information that we regard as proprietary.

Regulation

The following is a summary of the regulations materially affecting our business and operations.

Federal Oversight of Research-Use-Only Products

We currently offer for sale and sell some of our Unyvero and Acuitas AMR Gene Panel (RUO) tests to CROs, pharmaceutical companies, reference laboratories, hospitals and other health care facilities for research use only. RUO and investigational use only, or IUO, products are not intended for human clinical use and must be properly labeled in accordance with FDA guidance. Claims for RUOs and IUOs related to safety, effectiveness, or clinical utility or that are intended for human diagnostic or prognostic use are prohibited. In November 2013, the FDA issued guidance titled "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only – Guidance for Industry and Food and Drug Administration Staff." This guidance sets forth the requirements to utilize such designations, labeling requirements and acceptable distribution practices, among other requirements.

Mere placement of an RUO or IUO label on an IVD product does not render the device exempt from otherwise applicable clearance, approval or other requirements. The FDA may determine that the device is intended for use in clinical diagnosis based on other evidence, including how the device is marketed.

Our Acuitas AMR Gene Panel test was launched for RUO purposes in early 2018 and the Unyvero UTI assay was launched for RUO purposes in Q2-2020. We cannot predict the potential effect the FDA's current and forthcoming guidance IUOs/RUOs will have on our product offerings or materials used to perform our diagnostic services. We cannot be certain that the FDA might not promulgate rules or issue guidance documents that could affect our ability to purchase materials necessary for the performance of our diagnostic services. Should any of the reagents obtained by us from vendors and used in conducting our diagnostic services be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of service or delaying, limiting or prohibiting the purchase of reagents necessary to perform the service.

We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our surveillance and diagnostic services, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. We expect that new legislative proposals will be introduced from time to time. It is

possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA, which may result in new or increased regulatory requirements for us to continue to offer our diagnostic services or to develop and introduce new services.

FDA's Premarket Clearance and Approval Requirements

The FDA also has broad authority over the regulation of medical devices marketed for sale in the United States. The FDA regulates the research, clinical testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, promotion, distribution and production of medical devices. The FDA also regulates the export of medical devices manufactured in the United States to international markets.

Under the Food, Drug, and Cosmetic Act, or FDC Act, the FDA classifies medical devices into one of three classes: Class I, Class II or Class III. Devices deemed to pose lower risk are placed into either Class I or Class II.

Class I devices are deemed to pose the lowest risk to the patient. Accordingly, Class 1 devices are subject to the lowest degree of regulatory scrutiny and need only comply with the FDA's General Controls. The General Controls include compliance with the registration, listing, adverse event reporting requirements, and applicable portions of the Quality System Regulation, or QSR as well as the general misbranding and adulteration prohibitions. Unless specifically exempted in the regulations, general controls require a company that intends to market a Class I device, like us, to gain clearance for marketing through the 510(k) process. Many Class I devices, however, are exempt from 510(k) clearance because the level of risk is low.

Class II devices are considered higher risk devices than Class I devices. Class II devices are subject to General Controls as well as additional special controls. Special controls may include labeling requirements, mandatory performance standards, and post market surveillance. Generally, companies that intend to market Class II devices, like us, must comply with applicable regulations and submit a 510(k) premarket submission for review to receive clearance to list and market their devices. The 510(k) must establish substantial equivalence to a predicate device. Some Class II devices are exempt from filing a 510(k) but in some instances, Class II devices may be required to file a Premarket Approval, or PMA, application, for example, when changes in their technology or intended use present novel risks that warrant separate review as a Class III medical device.

Class III devices are deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices for which no substantially equivalent previously cleared device exists and require a PMA before commercialization.

All medical device manufacturers must register their establishments and list their devices with the FDA. Establishment registration requires the payment of user fees. In addition, both 510(k) premarket submissions and PMA applications are subject to the payment of user fees, paid at the time of submission for FDA review.

510(k) Clearance Pathway

We are currently working to submit our Unyvero tests and Acuitas AMR Gene Panel test for isolates for clearance under Section 510(k) of the FDC Act. Such tests are classified as medical devices, and we have to submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of premarket approval applications. FDA's 510(k) clearance pathway usually takes from three to twelve months; by statute, the FDA has 90 days to review the pre-market notification. On average the review time is approximately six months, but it can take significantly longer than twelve months in some instances (e.g. in the case of the Acuitas AMR Gene Panel (isolates) as well as original Unyvero LRT products a total of over 18 months), as the FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, require a PMA. The FDA requires each manufacturer to determine whether the proposed change requires submission of a new 510(k) notice, or a premarket approval, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. If the FDA requires us to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties. We have

made, and plan to continue to make, additional product enhancements to products that we believe do not require new 510(k) clearances, but we cannot guarantee that the future enhancements, should they occur, will be exempt from new 510(k) clearances.

De Novo Classification Request

The Food and Drug Administration Modernization Act of 1997, or FDAMA, added the De Novo classification option as an alternate pathway to classify low to moderate risk novel medical devices that had automatically been placed in Class III after receiving a not substantially equivalent determination in response to a premarket notification 510(k) submission. FDAMA also permits a sponsor to submit a De Novo classification request to the FDA for a product otherwise requiring a PMA application without first being required to submit a 510(k) application. The De Novo classification process is generally more costly and time consuming than the 510(k) process. Both, the Unyvero application cartridge products as well as Acuitas AMR Gene Panel for isolates have been subject to the De Novo process and we expect the Unyvero UTI and IJI to also fall under the De Novo process.

Premarket Approval Pathway

A PMA application must be submitted if a device cannot be cleared through the 510(k) process. The PMA application process is generally more costly and time consuming than the 510(k) process. A PMA application must be supported by extensive data including, but not limited to, analytical, preclinical, clinical trials, manufacturing, statutory preapproval inspections, and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use.

After a PMA application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application can take between one and three years, but it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The preapproval inspections conducted by the FDA include an evaluation of the manufacturing facility to ensure compliance with the QSR, as well as inspections of the clinical trial sites by the Bioresearch Monitoring group to evaluate compliance with good clinical practice and human subject protections. New premarket approval applications or premarket approval application supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. Significant changes to an approved PMA require a 180-day supplement, whereas less substantive changes may utilize a 30-day notice, or the 135-day supplement. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application and may not require as extensive clinical data or the convening of an advisory panel. None of our products are currently approved under a premarket approval.

Clinical Trials

Clinical trials are almost always required to support a De Novo or PMA application and are usually required to support non-exempt Class I and Class II 510(k) premarket submissions. Clinical trials may also be required to support certain marketing claims. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to file an investigational device exemption, or IDE application with the FDA and obtain IDE approval prior to conducting the human clinical trials. The IDE application must be supported by appropriate data, such as analytical, animal and laboratory testing results, manufacturing information, and an Investigational Review Board, or IRB approved protocol showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA prior to initiation of enrollment of human subjects. Clinical trials for a significant risk device may begin once the investigational device exemption application is approved by the FDA. If the clinical trial design is deemed to be "non-significant risk," the clinical trial may eligible for the "abbreviated" IDE requirements; in some instances IVD clinical trials may be exempt from the more burdensome IDE requirements if the test uses a noninvasive sampling method, does not introduce energy into the subject, and is not used in a diagnostic procedure without confirmation of the diagnosis by another established medically diagnostic procedure or product. All clinical trials conducted to support a premarket submission must be conducted in accordance with FDA regulations and Federal and state regulations concerning human subject protection, including informed consent, oversight by an IRB and healthcare privacy requirements. A clinical trial may be suspended by the FDA or the IRB review board at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the study. Even if a study is completed, the results of our clinical testing may not demonstrate the safety and efficacy of the device or may be equivocal or otherwise not be sufficient to obtain approval of our product. Similarly, in Europe the clinical study must be approved by the local ethics committee and in some cases, including studies of high-risk devices, by the Ministry of Health in the applicable country.

Pervasive and Continuing FDA Regulation

Numerous regulatory requirements apply to products classified as devices, such as ours, and would continue to apply. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the development and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product design modifications that affect the safety or effectiveness of one of our cleared devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

OpGen's Gaithersburg, Maryland facility is currently registered as a manufacturer with the FDA to manufacture our FISH products, whereas the Curetis Bodelshausen, Germany facility is registered with the FDA for all Unyvero cartridge and consumable manufacturing. We and any third-party manufacturers are subject to announced and unannounced inspections by the FDA to determine our compliance with quality system regulation and other regulations.

Failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, which might include any of the following sanctions: (1) untitled letters, Form 483 observations, warning letters, fines, injunctions, consent decrees and civil penalties; (2) unanticipated expenditures to address or defend such actions; (3) customer notifications for repair, replacement and refunds; (4) recall, detention or seizure of our products; (5) operating restrictions or partial suspension or total shutdown of production; (6) refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products; (7) operating restrictions; (8) withdrawing 510(k) clearances or PMA approvals that have already been granted; (9) refusal to grant export approval for our products; or (10) criminal prosecution.

After a medical device is placed on the market, numerous regulatory requirements apply. These include: all of the relevant elements of the QSR, labeling regulations, restrictions on promotion and advertising, the medical device reporting (which requires the manufacturer to report to the FDA if its device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), the Reports of Corrections and Removals regulations (which requires manufacturers to report certain recalls and field actions to the FDA), and other post-market requirements.

Health Insurance Portability and Accountability Act

Under HIPAA, the Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of protected health information used or disclosed by healthcare providers, such as us, and by certain vendors of ours, also known as our business associates. The regulations include limitations on the use and disclosure of protected health information and impose notification requirements in the event of a breach of protected health information. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties.

We have developed and implemented policies and procedures designed to comply with these regulations. The requirements under these regulations may change periodically and could have an effect on our business operations if compliance becomes substantially more costly than under current requirements.

In addition to Federal privacy regulations, there are a number of state laws governing confidentiality of health information that are applicable to our business. If our business expands internationally, we would be subject to compliance with other laws regarding confidentiality of health information and privacy.

New laws governing privacy may be adopted in the future as well. We have taken steps to comply with health information privacy requirements to which we are aware that we are subject. However, we cannot assure you that we are or will remain in compliance with diverse privacy requirements in all of the jurisdictions in which we do business. Failure to comply with privacy requirements could result in civil or criminal penalties, which could have a materially adverse effect on our business.

Federal and State Physician Self-referral Prohibitions

As a manufacturer and seller of diagnostic tests, we are subject to the Federal physician self-referral prohibitions, commonly known as the Stark Law, and to similar restrictions under the Maryland Physician Self-Referral Law. Together, these restrictions generally prohibit us from billing a patient or any governmental or private payor for any clinical laboratory services when the physician ordering the service, or any member of such physician's immediate family, has an investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

Both the Stark Law and the Maryland Physician Self-Referral Law contain an exception for compensation paid to a physician for personal services rendered by the physician. We have compensation arrangements with a number of physicians for personal services, such as clinical advisory board services, speaking engagements and other consulting activities. We have structured these arrangements with terms intended to comply with the requirements of the personal services exception to the Stark Law and the Maryland Physician Self-Referral Law.

However, we cannot be certain that regulators would find these arrangements to be in compliance with the Stark Law, the Maryland Physician Self-Referral Law, or similar state laws. We would be required to refund any payments we receive pursuant to a referral prohibited by these laws to the patient, the payor or the Medicare program, as applicable.

Sanctions for a violation of the Stark Law include the following:

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- a civil penalty of up to $15,000 for each service arising out of the prohibited referral
- possible exclusion from Federal healthcare programs, including Medicare and Medicaid; and
- a civil penalty of up to $100,000 against parties that enter into a scheme to circumvent the Stark Law's prohibition.
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These prohibitions apply regardless of the reasons for the financial relationship and the referral. No finding of intent to violate the Stark Law is required for a violation. In addition, knowing violations of the Stark Law may also serve as the basis for liability under the Federal False Claims Act, which prohibits knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to the U.S. Government.

Further, if we submit claims in violation of the Maryland Physician Self-Referral Law, we can be held liable to the payer for any reimbursement received for the services by us. Finally, other states have self-referral restrictions with which we have to comply that differ from those imposed by Federal and Maryland law. While we have attempted to comply with the Stark Law and the Maryland Physician Self-Referral Law, it is possible that some of our financial arrangements with physicians could be subject to regulatory scrutiny at some point in the future, and we cannot provide assurance that we will be found to be in compliance with these laws following any such regulatory review.

Federal and State Anti-Kickback Laws

The Federal healthcare program Anti-Kickback Law makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under any Federal healthcare program. A violation of the Anti-Kickback Law may result in imprisonment for up to five years and fines of up to $250,000 in the case of individuals and $500,000 in the case of organizations. Convictions under the Anti-Kickback Law result in mandatory exclusion from Federal healthcare programs for a minimum of five years. In addition, HHS has the authority to impose civil assessments and fines and to exclude healthcare providers and others engaged in prohibited activities from Medicare, Medicaid and other Federal healthcare programs. Actions which violate the Anti-Kickback Law also incur liability under the Federal False Claims Act.

Although the Anti-Kickback Law applies only to Federal healthcare programs, a number of states, including Maryland, have passed statutes substantially similar to the Anti-Kickback Law pursuant to which similar types of prohibitions are made applicable to all other health plans and third-party payers. Violations of Maryland's anti-kickback law are punishable by tiered criminal penalties based on the crime with a maximum penalty of life imprisonment and fines of up to $200,000, or both. Civil penalties include three times the amount of any overpayment made in violation of the statute.

Federal and state law enforcement authorities scrutinize arrangements between healthcare providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals or induce the purchase or prescribing of particular products or services. The law enforcement authorities, the courts and Congress have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of payments between healthcare providers and actual or potential referral sources. Generally, courts have taken a broad interpretation of the scope of the Anti-Kickback Law, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases.

In addition to statutory exceptions to the Anti-Kickback Law, regulations provide for a number of safe harbors. If an arrangement meets the provisions of a safe harbor, it is deemed not to violate the Anti-Kickback Law. An arrangement must fully comply with each element of an applicable safe harbor in order to qualify for protection. There are no regulatory safe harbors to the Maryland anti-kickback law.

Among the safe harbors that may be relevant to us is the discount safe harbor. The discount safe harbor potentially applies to discounts provided by providers and suppliers, including laboratories, to physicians or institutions. If the terms of the discount safe harbor are met, the discounts will not be considered prohibited remuneration under the Anti-Kickback Law. Maryland does not have a discount safe harbor.

The personal services safe harbor to the Anti-Kickback Law provides that remuneration paid to a referral source for personal services will not violate the Anti-Kickback Law provided all of the elements of that safe harbor are met. One element is that if the agreement is intended to provide for the services of the physician on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement must specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

Our personal services arrangements with some physicians may not meet the specific requirement of this safe harbor that the agreement specify exactly the schedule of the intervals of time to be spent on the services because the nature of the services, such as speaking engagements, does not lend itself to exact scheduling and therefore meeting this element of the personal services safe harbor is impractical. Failure to meet the terms of the safe harbor does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances.

While we believe that we are in compliance with the Anti-Kickback Law and the Maryland anti-kickback law, there can be no assurance that our relationships with physicians, academic institutions and other customers will not be subject to investigation or challenge under such laws. If imposed for any reason, sanctions under the Anti-Kickback Law and the Maryland anti-kickback law could have a negative effect on our business.

Other Federal and State Fraud and Abuse Laws

In addition to the requirements discussed above, several other healthcare fraud and abuse laws could have an effect on our business. For example, provisions of the Social Security Act permit Medicare and Medicaid to exclude an entity that charges the Federal healthcare programs substantially in excess of its usual charges for its services. The terms “usual charge” and “substantially in excess” are ambiguous and subject to varying interpretations.

Further, the Federal False Claims Act prohibits a person from knowingly submitting a claim, making a false record or statement in order to secure payment or retaining an overpayment by the Federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the Federal government by a private party having knowledge of the alleged fraud, also known as qui tam lawsuits. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government’s involvement, then the plaintiff will receive a percentage of the recovery. It is not uncommon for qui tam lawsuits to be filed by employees, competitors or consultants.

Finally, the Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. Violation of these provisions may result in fines, imprisonment or both, and possible exclusion from Medicare or Medicaid programs. Maryland has an analogous state false claims act applicable to state health plans and programs, as do many other states.

International Regulation

Sales of diagnostic tests like our Unyvero tests, SARS CoV-2 test kits, QuickFISH and PNA FISH products outside the United States would be subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we would need to obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. OpGen currently distributes its QuickFISH and PNA FISH products in the European Union through its wholly owned Curetis GmbH subsidiary who also distribute all Unyvero products ex U.S. via a network of distribution partners. The time required to obtain

approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ significantly. If we elect to, or are required to, seek clearance of or approval for any of our products from the FDA, we may be able to commercialize such products with shorter lead time in international markets, but would need to establish international operations in order to do so.

Environmental Matters

Our operations require the use of hazardous materials (including biological materials) which subject us to a variety of Federal, state and local environmental and safety laws and regulations. Some of these regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or new regulations will affect our business, operations or the cost of compliance.

Human Capital Resources

As of December 31, 2020, we had 110 employees worldwide, with 41 employed in the United States, 55 employed in Germany at Curetis GmbH, and 14 employed in Austria at Ares Genetics GmbH. Of our 110 worldwide employees, 94 are full-time employees. Except for the managing director of Ares Genetics our Austrian employees are subject to the collective bargaining agreement 2021 for employees of companies in the automated data processing and IT services industry. Other than that, none of our employees worldwide are subject to a collective bargaining arrangement. The 41 employees in the United States primarily work in our Gaithersburg, Maryland location or are field based marketing, sales, and service employees.

We compete in the highly competitive healthcare and life sciences industry. Our ability to operate and compete effectively and execute our strategy requires us to attract, develop and retain talented personnel for positions in research, quality assurance, clinical, commercial and other positions. Recruiting and retaining our personnel depends on factors, such as compensation and benefits, development and career opportunities, and work culture and environment. We accordingly invest in our employees in a number of different ways.

Culture

Our goal is to create and foster a culture of high performance and accountability through the attraction, retention and development of expert talent. We compete for top talent with effective recruitment strategies, well defined roles and attractive total compensation packages. We keep talent engaged through appreciation, communication and creation of a great work environment. We support employee growth professionally and personally through formal and informal opportunities and leadership support.

We also believe it is critical that our employees are informed and engaged. We communicate frequently and transparently with our employees through a variety of communication methods. We believe these engagement efforts keep employees informed about our strategy, culture and purpose and motivated to do their best work.

Compensation

In addition to competitive base salaries, we offer incentive-based compensation programs tied to the performance of key objectives. We also provide compensation in the form of restricted stock unit grants and stock options.

Health & Wellness

The physical health and wellbeing, life balance and mental health of our employees is vital to our success. Throughout 2020, health and wellness was a key focus of the Company, especially in light of the pandemic. Many of our employee communications focused on the physical and mental health of our employees. We remain committed to providing our workforce with flexible remote working schedules to suit their personal needs through this challenging time. We also continue to benchmark all of our health insurance offerings to ensure plan competitiveness.

Throughout the COVID-19 pandemic, employee safety is of top priority. Most of our employees globally have been working from home since the beginning of the pandemic, except for those with a business need to engage in work onsite. Ongoing safety measures were put into place at each of our locations including implementing pre-screening and social distancing requirements in addition to providing PPE.

Glossary

The following scientific, healthcare, regulatory and OpGen-specific terms are used throughout this Annual Report:

"Acuitas AMR Gene Panel (Isolates)" is a qualitative nucleic acid-based in vitro diagnostic test that is capable of simultaneous detection and identification of multiple bacterial nucleic acids and select genetic determinants of antimicrobial resistance from bacterial colonies isolated from any specimen.

"Acuitas Lighthouse" is our informatics platform, developed internally to provide real-time information on the MDRO status for patients and hospitals. We combine our molecular test information and microbiology test results to create Acuitas Lighthouse profiles for hospitals, health systems and communities, which we call our Acuitas Lighthouse informatics. Acuitas Lighthouse profiling facilitates MDRO tracking and results can be aggregated with hospital data to provide customized reports including alerts, prevalence, trend analysis and transmission information.

"AI" means Artificial Intelligence.

"AMR" means antimicrobial resistance.

"antibiotic stewardship" has been defined by the CDC to mean hospital-based programs dedicated to improving use of antibiotic therapy with the goal of optimizing the treatment of infections and reducing the adverse events associated with antibiotic use.

"ARESdb" means ARES reference database on antimicrobial resistance.

"ARESupa" means ARES universal pathogenome assay.

"ares-genetics.cloud" means ARES web application available under ares-genetics.cloud.

"AST" means Antimicrobial Susceptibility Testing.

"BCU" means blood culture.

"CAP"-Community-Acquired Pneumonia.

"CDC" means the U.S. Centers for Disease Control and Prevention.

"CMS" means the Centers for Medicare and Medicaid Services.

"CRE" means carbapenem-resistant Enterobacteriaceae, an MDRO.

"DNA sequencing" is the process of determining the precise order of nucleotides within a DNA molecule.

"DRG" means Diagnosis Related Group.

"ESBL" means extended spectrum beta lactamase bacteria.

"FDA" means the U.S. Food and Drug Administration.

"HAIs" means healthcare-associated infections. Such infections could arise first in the hospital or other healthcare setting, or could result from a patient, colonized with an organism, developing an active infection once admitted to the hospital or other healthcare setting.

"HAP" means Hospital-Acquired Pneumonia.

"HIPAA" means the Federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act. HIPAA and HITECH Act are Federal laws mandating security and privacy of protected personal health information of patients.

"HPN" means hospitalized pneumonia.

"IAI" means intra-abdominal infection.

"IJI" means implant & joint infections.

"informatics" refers to methods, algorithms and processes for the collection, classification, storage and analysis of biochemical and biological data and information using computers, especially as applied in molecular genetics and genomics. Our focus is on acquiring such data and information related to MDROs to assist in diagnosis and screening of patients and antibiotic stewardship initiatives by acute care hospitals. When we use the term "advanced informatics," we mean informatics combined with higher levels of complexity, sophistication and subject matter expertise related to MDROs, diagnostics, antibiotic stewardship, and the development of associated analysis tools, or the novel application of existing informatics in future products or services. In this Annual Report, we also sometimes use the phrase "informatics products and services," often interchangeably with "informatics platform," to describe the Company's focus on the use of informatics and advanced informatics in its current and future product and service offerings.

"informatics platform" means a combination of software tools and analytical processes that streamline the production and analysis of informatics data. When we use the term informatics platform, we are primarily referring to Acuitas Lighthouse.

"ITI" means implant & tissue infection.

"IVD" means in vitro diagnostic.

"KPC" means Klebsiella pneumoniae Carbapenemase, an MDRO.

"LRT" means lower respiratory tract infection.

"LRT BAL" means lower respiratory tract infection including for bronchoalveolar lavage (BAL and mini-BAL) samples.

"MDRO" means a multidrug-resistant organism.

"ML" means machine learning.

"NGS" means Next Generation Sequencing.

"PCR" means polymerase chain reaction.

"PNA" means peptide nucleic acid.

"QSR" means Quality System Regulation.

"SEC" means the U.S. Securities and Exchange Commission.

"Securities Act" means the Securities Act of 1933, as amended.

"VAP" means Ventilator-associated Pneumonia.

"UTI" means urinary tract infection.

Corporate Information

OpGen, Inc. was incorporated in Delaware in 2001. The Company's headquarters and principal operations are in Gaithersburg, Maryland. The Company also has operations in Germany, and Austria.

Available Information

The Company maintains a website at www.opgen.com. Our Code of Business Conduct and Ethics is available on our website. We are not incorporating our website into this Annual Report. Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are available free of charge on our website as soon as practicable after electronic filing of such material with, or furnishing it to, the SEC. This information may be read at the SEC website at http://www.sec.gov.

Item 1A. Risk Factors

The following are significant factors known to us that could materially harm our business, financial condition or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this Annual Report. The risks described are not the only risks we are facing. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, also may adversely affect our business, financial condition and operating results. If any of these risks actually occur, our business, financial condition, and operating results could suffer significantly.

Risks Related to Our Business

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, 2020 and 2019 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, 2020 and 2019, we had net losses of $26.2 million and $12.4 million, respectively. From our inception through December 31, 2020, we had an accumulated deficit of $200.7 million. The reports of our independent registered public accounting firm on our financial statements for the years ended December 31, 2020 and 2019 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, including the March 2019 Public Offering, the October 2019 Public Offering, an at-the-market, or ATM, public offering which commenced in September 2016 and terminated in October 2019, an ATM public offering which commenced in February 2020 (the "2020 ATM Offering") and the November 2020 Private/Public Offering. The net proceeds from such financings were approximately $46.9 million. We cannot assure you that we can continue to raise the capital necessary to fund our business.

Even if we achieve significant revenues, we may not become profitable, and even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain consistently profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business or continue to pursue our growth strategy. We have no committed sources of capital and may find it difficult to raise money on terms favorable to us or at all. The failure to obtain sufficient capital to support our operations would have an adverse effect on our business, financial condition and results of operations.

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 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.

For example in 2016, our subsidiary Curetis entered into a contract for an up to €25 million senior, unsecured loan financing facility from the European Investment Bank ("EIB"), which we assumed in connection with our acquisition of Curetis. As of December 31, 2020, $25.9 million plus deferred interest in the amount of approximately $3.8 million was outstanding under the contract.

We believe that additional equity financings are the most likely source of capital going forward. 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 including the 2021 Offering and 2021 Warrant Exercise will be sufficient to fund operations into the second quarter of 2022. In the event we are unable to successfully raise additional capital during or before the second quarter of 2022, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to immediately reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until we are able to obtain sufficient financing. If such sufficient financing is not received 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.

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, realize the anticipated benefits from our distribution, collaboration and other commercial partners. If we are not able to grow the combined business of OpGen as a commercial enterprise, our financial condition will be negatively impacted.

The process to obtain and maintain FDA clearances or approvals for our products is complex and time and resource consuming. If we fail to obtain such clearances or approvals, our business and results of operations will be materially adversely impacted.

The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In May 2019, we filed a 510(k) submission with the FDA seeking clearance of our Acuitas AMR Gene Panel (Isolates) diagnostic test. In July 2019, we received correspondence from the FDA requesting additional information related to this filing. On January 6, 2020, OpGen filed a formal response to the FDA's July 2019 AI Request. Subsequently, the FDA issued a second AI Request on January 17, 2020 to formalize additional questions and remaining requests for information from the earlier July 2019 AI Request. On October 13, 2020 we submitted what we believe to be the final comprehensive formal response which addresses all of the FDA's questions and feedbacks received to date and we anticipate a near term clearance decision, as the FDA resumed its review activity in January 2021 following the FDA's announcement of an anticipated 90-day staffing surge to address COVID-19 related EUAs and suspending all review activity in early November 2020. If we cannot successfully address the questions posed by the FDA, our receipt of clearance for this product will be delayed. In addition, the time and expense needed to respond to the FDA's request for additional information may divert time and attention from our other regulatory submissions in process, which may adversely affect our strategy and ability to commercialize our diagnostic tests and bioinformatics products and services.

We expect our ability to utilize our net operating loss carryforwards will be limited as a result of an "ownership change," as defined in Section 382 of the Internal Revenue Code triggered by consummation of the transaction with Curetis.

As of December 31, 2020, we had approximately $196.5 million of net operating loss, or NOL, carryforwards for U.S. federal tax purposes. Under U.S. federal income tax law, we generally can use our NOL carryforwards (and certain tax credits) to offset ordinary taxable income, thereby reducing our U.S. federal income tax liability, for up to 20 years from the year in which the losses were generated, after which time they will expire. State NOL carryforwards (and certain tax credits) generally may be used to offset future state taxable income for 20 years from the year in which the losses are generated, depending on the state, after which time they will expire. The rate at which we can utilize our NOL carryforwards is limited (which could result in NOL carryforwards expiring prior to their use) each time we experience an "ownership change," as determined under Section 382 of the Internal Revenue Code. A Section 382 ownership change generally occurs if a shareholder or a group of shareholders who are deemed to own at least 5% of our common stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. If an ownership change occurs, Section 382 generally would impose an annual limit on the amount of post-ownership change taxable income that may be offset with pre-ownership change NOL carryforwards equal to the product of the total value of our outstanding equity immediately prior to the ownership change (reduced by certain items specified in Section 382) and the U.S. federal long-term tax-exempt interest rate in effect at the time of the ownership change. A number of special and complex rules apply in calculating this Section 382 limitation. While the complexity of Section 382 makes it difficult to determine whether and when an ownership change has occurred, and if a portion of our NOLs is subject to an annual limitation under Section 382, we believe that an additional ownership change may occur upon the consummation of the transaction with Curetis. In addition, our ability to use our NOL carryforwards will be limited to the extent we fail to generate enough taxable income in the future before they expire. Existing and future Section 382 limitations and our inability to generate enough taxable income in the future could result in a substantial portion of our NOL carryforwards expiring before they are used. In addition, under the 2017 Tax Cut and Jobs Act, effective for losses arising in taxable years beginning after December 31, 2017, the deduction for NOLs is limited to 80% of taxable income, NOLs can no longer be carried back, and NOLs can be carried forward indefinitely.

Our products and services may never achieve significant commercial market acceptance.

Our products and services may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or profits for us. Our ability to achieve commercial market acceptance for our products will depend on several factors, including:

- our ability to convince the medical community of the clinical utility of our products and services and their potential advantages over existing tests, including our surveillance services offering, despite the lack of reimbursement for such services;
- our ability to successfully develop automated rapid pathogen identification and antibiotic resistance testing products and services, including bioinformatics, and convince hospitals and other healthcare providers of the patient safety, improved patient outcomes and potential cost savings that could result;
- our ability to grow our microbial isolate and antibiotic resistance genes knowledgebases and bioinformatics offerings;

- our ability to convince the medical community of the accuracy and speed of our products and services, as contrasted with the current methods available; and
- the willingness of hospitals and physicians to use our products and services.

Our future success is dependent upon our ability to expand our customer base.

The current customers we are targeting for our Unyvero and Acuitas test products and services are hospital systems, acute care hospitals, particularly those with advanced care units, such as intensive care units, community-based hospitals and governmental units, such as public health facilities and other laboratories. We need to provide a compelling case for the savings, patient safety and recovery, reduced length of stay and reduced costs that come from adopting our MDRO diagnosis and antibiotic stewardship products and services. If we are not able to successfully increase our customer base, sales of our products and our margins may not meet expectations. The same holds true for customers and partners for our ARESdb based offerings and solutions. Attracting new customers and introducing new products and services requires substantial time and expense. Any failure to expand our existing customer base, or launch new products and services, would adversely affect our ability to improve our operating results.

We ***are developing diagnostic products for the more rapid identification of MDROs and antibiotic resistance genomic information. If we are unable to successfully develop, receive regulatory clearance or approval for or commercialize such products and services, our business will be materially, adversely affected.***

We are developing an under three hour as well as four to five hour antibiotic resistance diagnostic product that we believe could help address many of the current issues with the need for more rapid identification of infectious diseases and testing for antibiotic resistance. Development of such diagnostic products is difficult and we cannot assure you that we will be successful in such product development efforts, or, if successful, that we will receive the necessary regulatory clearances to commercialize such products. We have identified dozens of resistance genes to help guide clinicians with their antibiotic therapy decisions. Although we have demonstrated preliminary feasibility, and confirmed genotype/phenotype predictive algorithms, such product development efforts will require us to work collaboratively with other companies, academic and government laboratories, and healthcare providers to access sufficient numbers of microbial isolates, develop the diagnostic tests, successfully conduct the necessary clinical trials and apply for and receive regulatory clearances or approvals for the intended use of such diagnostic tests. In addition, we would need to successfully commercialize such products. Such product development, clearance or approval and commercialization activities are time-consuming, expensive and we are not assured that we will have sufficient funds to successfully complete such efforts. Any significant delays or failures in this process could have a material adverse effect on our business and financial condition.

We offer these products in development to the research use only market and for other non-clinical research uses prior to receiving clearance or approval to commercialize these products in development for use in the clinical setting. We need to comply with the applicable laws and regulations regarding such other uses. Failure to comply with such laws and regulations may have a significant impact on the Company.

We may enter into agreements with U.S. or other government agencies, which could be subject to uncertain future funding.

The presence of MDROs and the need for antibiotic stewardship activities have prompted state, federal and international government agencies to develop programs to combat the effects of MDROs. Since 2018, we have been party to a collaboration, called the New York State Infectious Disease Digital Health Initiative, with the New York State DOH and ILÚM (now IDC) to develop a research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions in New York State.

In the future, we may seek to enter into additional agreements with governmental funding sources or contract with government healthcare organizations to sell our products and services. Under such agreements, we would rely on the continued performance by these government agencies of their responsibilities under these agreements, including adequate continued funding of the agencies and their programs. We have no control over the resources and funding that government agencies may devote to these agreements, which may be subject to annual renewal.

Government agencies may fail to perform their responsibilities under these agreements, which may cause them to be terminated by the government agencies. In addition, we may fail to perform our responsibilities under these agreements. Any government agreements would be subject to audits, which may occur several years after the period to which the audit relates. If an audit identified significant unallowable costs, we could incur a material charge to our earnings or reduction in our cash position. As a result, we may be unsuccessful entering, or ineligible to enter, into future government agreements.

If the utility of our current products and products in development is not supported by studies published in peer-reviewed medical publications, the rate of adoption of our current and future products and services by clinicians and healthcare facilities may be negatively affected.

The results of our clinical and economic validation studies involving our products have been presented at major infectious disease and infection control society meetings. We need to maintain and grow a continued presence in peer-reviewed publications to promote clinician adoption of our products. We believe that peer-reviewed journal articles that provide evidence of the utility of our current and future products and services, and adoption by key opinion leaders in the infectious disease market are very important to our commercial success. Clinicians typically take a significant amount of time to adopt new products and testing practices, partly because of perceived liability risks and the uncertainty of a favorable cost/benefit analysis. It is critical to the success of our sales efforts that we educate a sufficient number of clinicians and administrators about our products and demonstrate their clinical benefits. Clinicians may not adopt our current and future products and services unless they determine, based on published peer- reviewed journal articles and the experience of other clinicians, that our products provide accurate, reliable, useful and cost-effective information that is useful in MDRO diagnosis, screening and outbreak prevention. If our current and future products and services or the technology underlying our products and services or our future product offerings do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption could be negatively affected. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing our products, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenue from any product that is the subject of a study.

Our sales cycle for our marketed products and services is lengthy and variable, which makes it difficult for us to forecast revenue and other operating results.

The sales cycles for our products are lengthy, which will make it difficult for us to accurately forecast revenues in a given period, and may cause revenue and operating results to vary significantly from period to period. Potential customers for our products typically need to commit significant time and resources to evaluate our products, and their decision to purchase our products may be further limited by budgetary constraints and numerous layers of internal review and approval, which are beyond our control. We spend substantial time and effort assisting potential customers in evaluating our products. Even after initial approval by appropriate decision makers, the negotiation and documentation processes for the actual adoption of our products on a facility-wide basis can be lengthy. As a result of these factors, based on our experience to date, our sales cycle, the time from initial contact with a prospective customer to routine commercial use of our products, has varied and could be 12 months or longer, which has made it difficult for us to accurately project revenues and operating results. In addition, the revenue generated from sales of our products may fluctuate from time to time due to changes in the testing volumes of our customers. As a result, our results may fluctuate on a quarterly basis, which may adversely affect the price of our common stock.

We are currently party to, and may enter into additional collaborations with third parties to develop product and services candidates. If these collaborations are not successful, our business could be adversely affected.

We are currently party to a few collaborations and anticipate that we will enter into additional collaborations related to our MDRO and informatics products and services. Such collaborations are and may be with pharmaceutical companies, platform companies or other participants in our industry. We have limited control over the amount and timing of resources that any such collaborators could dedicate to the development or commercialization of the subject matter of any such collaboration. Our ability to generate revenues from these arrangements would depend on our and our collaborator's abilities to successfully perform the functions assigned to each of us in these arrangements. Our relationships with collaborators may pose several risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- we may not achieve any milestones, or receive any milestone payments, under our collaborations, including milestones and/or payments that we expect to achieve or receive;
- the clinical trials, if any, conducted as part of these collaborations may not be successful;
- a collaborator might elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors, such as an acquisition, that diverts resources or creates competing priorities;
- we may not have access to, or may be restricted from disclosing, certain information regarding product or services candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product or services candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product or services candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product or services, which may cause collaborators to cease to devote resources to the commercialization of our product or services candidates;
- a collaborator with marketing and distribution rights to one or more of our product or services candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product or services candidates, may cause delays or termination of the research, development or commercialization of such product or services candidates, may lead to additional responsibilities for us with respect to such product or services candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to a collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product or services candidates.

If our collaborations do not result in the successful development and commercialization of products or services, we may not receive any future research funding or milestone or royalty payments under the collaborations. If we do not receive the funding we would expect under these agreements, our development of product and services candidates could be delayed, and we may need additional resources to develop our product candidates.

We may not be successful in finding strategic collaborators for continuing development of certain of our product or services candidates or successfully commercializing or competing in the market for certain indications.

We may seek to develop strategic partnerships for developing certain of our product or services candidates, due to capital costs required to develop the product or services candidates or manufacturing constraints. We may not be successful in our efforts to establish such a strategic partnership or other alternative arrangements for our product or services candidates because our research and development pipeline may be insufficient, our product or services candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product or services candidates as having the requisite potential to demonstrate commercial success.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product or service candidate, reduce or delay our development program, delay our potential commercialization, reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates and our business, financial condition, results of operations and prospects may be materially and adversely affected.

We are an early commercial stage company and may never be profitable.

We rely principally on the commercialization of our Unyvero, ARESdb based, and Acuitas products and services to generate future revenue growth. To date, our products have delivered only minimal revenue. We believe that our commercialization success is dependent upon our ability to significantly increase the number of hospitals, long-term care facilities and other inpatient healthcare settings that use our products. If demand for products does not increase as quickly as we have planned, we may be unable to increase our revenue levels as expected. We are currently not profitable. Even if we succeed in increasing adoption of our products by our target markets, maintaining and creating relationships with our existing and new customers and developing and commercializing additional molecular testing products, we may not be able to generate sufficient revenue to achieve or sustain profitability.

We have limited experience in marketing and selling our products, and if we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenue to achieve or sustain profitability.

We sell our products through our own direct sales force, which sells our products in the US and via distribution partners in all other territories. All of these products and services may be offered and sold to different potential customers or involve discussions with multiple personnel in in-patient facilities. Our future sales will depend in large part on our ability to increase our marketing efforts and adequately address our customers' needs. The inpatient healthcare industry is a large and diverse market. We will need to attract and develop sales and marketing personnel with industry expertise. Competition for such employees is intense. We may not be able to attract

and retain sufficient personnel to maintain an effective sales and marketing force. If we are unable to successfully market our products and adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenue to achieve or sustain profitability.

If our manufacturing facilities become inoperable, our products, and our business will be harmed.

We manufacture our Unyvero products and SARS-CoV-2 test kits in our facility in Bodelshausen, Germany and our Acuitas products in our facility in Gaithersburg, Maryland and plan to eventually move manufacturing of Acuitas products to the Bodelshausen facility. We do not have redundant facilities for these products. Our facilities and the equipment we use manufacture our products would be costly to replace and could require substantial lead time to repair or replace, if damaged or destroyed. The facilities may be harmed or rendered inoperable by natural or man-made disasters, including flooding and power outages, which may render it difficult or impossible for us manufacture our products for some period of time. The inability to manufacture our products may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we carry insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

In order to establish redundant facilities, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. Additionally, any new manufacturing facility opened by us would be subject to FDA inspection and certification. If we fail to maintain our FDA certification or if our FDA certification is suspended, limited or revoked, we would not be able manufacture our products.

If demand for these products increase beyond our current forecasts or, regulatory requirements arise, we may not be able to meet our obligations to manufacture these products, and backlog or reduced demand for such products could occur. If any of these issues occur, it could have a material adverse effect on our financial condition and results of operations.

We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our materials and may not be able to find replacements or immediately transition to alternative suppliers.

We rely on several sole suppliers and manufacturers, including Zollner, Contexo, Thermo Fisher Scientific and QIAGEN, for supplying instrument systems and certain reagents, raw materials, supplies and substances which we use to manufacture our products. An interruption in our operations could occur if we encounter delays or difficulties in securing these items or manufacturing our products, and if we cannot, then obtain an acceptable substitute. Any such interruption or damage to third party suppliers or manufacturers for any reason, such as fire or other events beyond our control, including as a result of natural disasters, terrorist attacks, or the occurrence of a contagious disease or illness, such as the COVID-19 pandemic, could significantly affect our business, financial condition, results of operations and reputation.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenue or achieve and sustain profitability.

Our competitors include rapid diagnostic testing and traditional microbiology companies, commercial laboratories, information technology companies, and hospital laboratories who may internally develop testing capabilities. Principal competitive factors in our target market include organizational size, scale, and breadth of product offerings; rapidity of test results; quality and strength of clinical and analytical validation data and confidence in diagnostic results; cost effectiveness; ease of use; and regulatory approval status.

Our principal competition comes from traditional methods used by healthcare providers to diagnose and screen for MDROs and from other molecular diagnostic companies creating screening and diagnostic products such as Bosch, Cepheid, Becton-Dickinson, bioMérieux, Accelerate Diagnostics, T2 Biosystems, GenMark, Qiagen and Luminex.

We also face competition from commercial laboratories, such as Bio-Reference Laboratories, Inc., Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, Pathnostics, and EuroFins, which have strong infrastructure to support the commercialization of diagnostic laboratory services.

Competitors may develop their own versions of competing products in countries where we do not have patents or where our intellectual property rights are not recognized.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical, research and development and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by hospitals, physicians and payers as functionally equivalent to our product and service offering or offer products at prices designed to promote market penetration, which could force us to lower the list prices of our product and service offerings and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully against current

and future competitors, we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

Our products and services are not covered by reimbursement by Medicare, Medicaid and other governmental and third-party payors. If we cannot convince our customers that the savings from use of our products and services will increase their overall reimbursement, our business could suffer.

Our products and services do not currently receive reimbursement from Medicare, Medicaid, other governmental payors or commercial third-party payors. Policy and rule changes in reimbursement announced by CMS, including potential financial incentives for reductions in hospital acquired infection, and penalties and decreased Medicare reimbursement for patients with HAIs provide us with an opportunity to establish a business case for the purchase and use of our screening and diagnostic products and services. If we cannot convince our customers that the savings from use of our products and services will increase or stabilize their overall profitability and improve clinical outcomes, our business will suffer.

Failure in our information technology, storage systems or our ares.cloud and Acuitas Lighthouse Software could significantly disrupt our operations and our research and development efforts, which could adversely impact our revenues, as well as our research, development and commercialization efforts.

Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology systems, which support our operations and our research and development efforts, as well as our storage systems and our analyzers. Due to the sophisticated nature of the technology, we use in our products and service offerings, including our ARESdb and Acuitas Lighthouse Software services, we are substantially dependent on our information technology systems. Information technology systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, and in particular to operate our ARESdb and Acuitas Lighthouse Software, could adversely affect our ability to operate our business. Any interruption in the operation of our ARESdb and Acuitas Lighthouse Software, due to information technology system failures, part failures or potential disruptions in the event we are required to relocate our instruments within our facility or to another facility, could have an adverse effect on our operations.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including legally protected health information and personally identifiable information about our customers and their patients. We also store sensitive intellectual property and other proprietary business information, including that of our customers. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data center systems. These applications and data encompass a wide variety of business critical information, including research and development information, commercial information and business and financial information.

We face four primary risks relative to protecting this critical information: loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of our being unable to identify and audit our controls over the first three risks.

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store this critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions.

A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Any such breach or interruption could compromise our networks, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the federal HIPAA and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill facilities or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare Company financial information, provide information about our current and future solutions and other patient and clinician education and outreach efforts through our website, and manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the U.S. and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

Data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

The collection, use, storage, transfer, and other processing of personal data, including personal health data, regarding individuals in the European Economic Area is governed, as of May 2018, by the General Data Protection Regulation, or GDPR. The GDPR imposes several requirements on companies that process personal data, including requirements relating to the processing of health and other sensitive data, the consent of the individuals to whom the personal data relates, the information provided to the individuals regarding data processing activities, the notification of data processing obligations to the competent national data protection authorities and certain measures to be taken when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data out of the European Economic Area, including to the U.S. Failure to comply with the requirements of the GDPR, and the related national data protection laws of the European Union Member States, may result in fines and other administrative penalties. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules, including as implemented by individual countries. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any future European activities.

California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions against violators on July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA, and clinical trial regulations, as currently written, the CCPA may impact our business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business activities if they are adopted. The uncertainty surrounding the implementation of the CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

We cannot provide assurance that future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information, either of which may prevent us from undertaking or publishing essential research. These burdens or risks may prove too great for us to reasonably bear and may adversely affect our ability to achieve profitability or maintain profitably in the future.

If we are unable to develop products to keep pace with rapid technological, medical and scientific change, our operating results and competitive position could be harmed. New test development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize our diagnostic and screening products and services. The further development and commercialization of additional diagnostic and screening product and service offering are key to our growth strategy.

A key element of our strategy is to discover, develop, validate and commercialize a portfolio of additional diagnostic products and services to rapidly diagnose and effectively treat MDRO infections and reduce the associated costs to patients, inpatient facilities and the healthcare industry. We cannot assure you that we will be able to successfully complete development of or commercialize any of

our planned future products and services, or that they will be clinically usable. The product development process involves a high degree of risk and may take up to several years or more. Our new product development efforts may fail for many reasons, including:

- failure of the tests at the research or development stage;
- lack of clinical validation data to support the effectiveness of the tests;
- delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner;
- failure to obtain or maintain necessary certifications, licenses, clearances or approvals to market or perform the test; or
- lack of commercial acceptance by in-patient healthcare facilities and commercial partners.

Few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of new products, or we may be required to expend considerable resources repeating clinical studies or trials, which would adversely impact the timing for generating potential revenues from those new products. In addition, as we develop new products, we will have to make additional investments in our sales and marketing operations, which may be prematurely or unnecessarily incurred if the commercial launch of a product is abandoned or delayed.

If we use hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the use of hazardous materials and the handling of patient samples. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We are, or may be in the future, subject to compliance with additional laws and regulations relating to the protection of the environment and human health and safety, and including those relating to the handling, transportation and disposal of medical specimens, infectious and hazardous waste and Occupational Safety and Health Administration, or OSHA, requirements as well as their international equivalents. The requirements of these laws and regulations are complex, change frequently and could become more stringent in the future. Failure to comply with current or future environmental laws and regulations could result in the imposition of substantial fines, suspension of production, alteration of our production processes, cessation of operations or other actions, which could severely harm our business.

If we are sued for product liability or errors and omissions liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our products could lead to product liability claims if someone were to allege that a product failed to perform as it was designed. We may also be subject to liability for errors in the results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. For example, if we diagnosed a patient as having an MDRO but such result was a false positive, the patient could be unnecessarily isolated in an in-patient setting or receive inappropriate treatment. We may also be subject to similar types of claims related to products we may develop in the future. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain product liability and errors and omissions insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or errors and omissions liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation or cause us to suspend sales of our products and services. The occurrence of any of these events could have an adverse effect on our business and results of operations.

Risks Related to Our Securities and Public Company Status

If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated.

When we are no longer an emerging growth company and a smaller reporting company, our independent registered public accounting firm will be required to issue an attestation report on the effectiveness of our internal control over financial reporting. Even if our

management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

When we are no longer an emerging growth company and a smaller reporting company, if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Internal control deficiencies could also result in a restatement of our financial results in the future.

The market price of our common stock has been, and may continue to be, highly volatile, and such volatility could cause the market price of our common stock to decrease and could cause you to lose some or all of your investment in our common stock.

During the period from our initial public offering in May 2015 through December 31, 2020, the market price of our common stock fluctuated from a high of $2,720.00 per share to a low of $0.92 per share, and our stock price continues to fluctuate. The market price of our common stock may continue to fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- our ability to grow our revenue and customer base;
- the announcement of new products or product enhancements by us or our competitors;
- developments concerning regulatory oversight and approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- successes or challenges in our collaborative arrangements or alternative funding sources;
- developments in the health care and life science industries;
- the results of product liability or intellectual property lawsuits;
- future issuances of common stock or other securities;
- the addition or departure of key personnel;
- announcements by us or our competitors of acquisitions, investments or strategic alliances; and
- general market conditions and other factors, including factors unrelated to our operating performance.

Further, the stock market in general, and the market for health care and life science companies in particular, has recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock and the loss of some or all of your investment.

The exercise of outstanding common stock purchase warrants and stock options will have a dilutive effect on the percentage ownership of our capital stock by existing stockholders.

As of December 31, 2020, we had outstanding warrants to acquire 5,848,131 shares of our common stock, and stock options to purchase 1,664,522 shares of our common stock. The expiration of the term of such options and warrants range from May 2021 to May 2026. A significant number of such warrants are out of the money, but the holders have the right to affect a cashless exercise of such warrants. If a significant number of such warrants and stock options are exercised by the holders, the percentage of our common stock owned by our existing stockholders will be diluted.

Risks Related to Regulation of Our Business

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our products, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

We have submitted one 510(k) submission with the FDA for our Acuitas AMR Gene Panel (Isolates) test and have plans to submit additional *De Novo* classification requests for our Unyvero UTI test and, Unyvero IJI test in the future. Such process is complex, time consuming and expensive. For any filed 510(k) or *De Novo* submission, the FDA may not clear or grant these products for the indications that are necessary or desirable for successful commercialization. Failure to receive, or a significant delay in receiving, a required clearance or granted request for our products would have a material adverse effect on our ability to expand our business.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses.

We are currently offering for sale some products RUO to CROs, pharmaceutical companies, hospitals and other healthcare facilities. We believe that our promotional activities for these products falls within the scope of the FDA's enforcement discretion and applicable premarket exemptions. However, the FDA could disagree and require us to stop promoting our products for unapproved or "off-label" uses unless and until we obtain FDA clearance or approval for those uses. We could be subject to regulatory or enforcement actions for any violations, including, but not limited to, the issuance of an untitled letter, a Form 483 letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products would be impaired.

A number of the rapid diagnostic products are regulated by the FDA and non-U.S. regulatory authorities. If we or our suppliers fail to comply with ongoing FDA, or other foreign regulatory authority, requirements, or if we experience unanticipated problems with the products, these products could be subject to restrictions or withdrawal from the market.

We do not have significant experience in complying with the rules and regulations of the FDA and foreign regulatory authorities. The rapid diagnostic products regulated as medical devices, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such products, are subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA's QSR regulations for the manufacture, labeling, distribution and promotion of products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval, and with ISO regulations. The FDA enforces the QSR and similarly, other regulatory bodies with similar regulations enforce those regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions against us: (1) untitled letters, Form 483 observation letters, warning letters, fines, injunctions, consent decrees and civil penalties; (2) unanticipated expenditures to address or defend such actions; (3) customer notifications for repair, replacement and refunds; (4) recall, detention or seizure of our products; (5) operating restrictions or partial suspension or total shutdown of production; (6) refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products; (7) operating restrictions; (8) withdrawing 510(k) clearances or PMA approvals that have already been granted; (9) refusal to grant export approval for our products; or (10) criminal prosecution.

If any of these actions were to occur, it could harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, if any of our key component suppliers are not in compliance with all applicable regulatory requirements, we may be unable to produce our products on a timely basis and in the required quantities, if at all.

We and our suppliers are also subject to periodic inspections by the FDA to determine compliance with the FDA's requirements, including primarily the QSR and medical device reporting regulations. The results of these inspections can include inspectional observations on FDA's Form 483, untitled letters, warning letters, or other forms of enforcement. Since 2009, the FDA has significantly increased its oversight of companies subject to its regulations, by hiring new investigators and stepping up inspections of manufacturing facilities. The FDA has recently also significantly increased the number of warning letters issued to companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our FDA-cleared products are ineffective or pose an unreasonable health risk, the FDA could take a number of regulatory actions, including but not limited to, preventing us from manufacturing any or all of our devices or performing laboratory testing on human specimens, which could materially adversely affect our business.

Some of the clearances obtained are subject to limitations on the intended uses for which the product may be marketed, which can reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or

distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

If we were to lose, or have restrictions imposed on, FDA clearances received to date, or clearances we may receive in the future, our business, operations, financial condition and results of operations would likely be significantly adversely affected.

Modifications to our marketed products may require new 510(k) clearances or PMA approvals or, in the future, new CE-IVD markings, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

If we modify any of our CE-IVD marked or FDA-cleared products, such modifications may require additional future approvals and filings, e.g., notified body authorization or FDA clearance. Modifications to a CE-IVD marked or 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, may require additional approvals or filings or a new or revised 510(k) submission, or possibly, a PMA.

The FDA and other regulatory authorities, including notified bodies, require every medical device manufacturer to make this determination, with the potential for the regulatory authorities to impose additional requirements. The applicable regulatory authority nevertheless maintains the right to disagree with a company's decisions regarding whether new clearances or approvals are necessary. If the FDA or any other relevant regulatory authority requires us to submit additional filings, such as a technical file review and CE-marking, 510(k) submission, or file a PMA, for any modification to a previously cleared product, we may be required to cease marketing and distributing, or to recall the modified product until we obtain such clearance or approval, and we may be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to recall if the FDA or any other relevant regulatory authority determines, for any reason, that our products are not safe or effective. A mandate for a recall or correction, or where new or revised regulatory submissions are required, could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA or other relevant regulatory agencies in other territories.

New or revised regulatory requirements may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

In 2017, the EU Regulation on In Vitro Diagnostic Medical Devices (Regulation (EU) 2017/746) ("IVDR") was adopted. The IVDR will apply commencing on May 26, 2022 and is, among other things, intended to establish a uniform, transparent, predictable and sustainable regulatory framework across European Economic Area. Once applicable, the IVDR will introduce new classification rules for in vitro diagnostic medical devices and new regulatory requirements. Moreover, the scrutiny imposed by notified bodies for the technical documentation related these devices will increase considerably. Complying with the requirements of this regulation may result in the reclassification of existing CE-IVD marked product and require additional filings with the notified body or competent authority. Additional filings and or modifications to products to comply with the IVDR, could result in significant delays, increased costs associated with modification of a product, loss of revenue and other significant expenditures.

Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of regulated products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture.

Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA and international medical device reporting regulations, medical device manufacturers are required to report to the applicable regulatory authority information that a device has, or may have, caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events within the required timeframes, or at all, the regulatory authorities could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

We may generate a larger portion of our future revenue internationally and would then be subject to increased risks relating to international activities which could adversely affect our operating results.

A significant portion of our current revenue and anticipated future revenue growth will come from international sources as we implement and expand overseas operations. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign health care and other regulatory requirements and laws, such as those relating to patient privacy;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act, or FCPA, and U.K. Bribery Act, data privacy requirements, labor laws and anti- competition regulations;
- export or import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- foreign exchange controls;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties protecting or procuring intellectual property rights.

As we expand internationally, our results of operations and cash flows would become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our expenses are generally denominated in the currencies in which our operations are located, which is in the United States, Germany, and Austria. If the value of the U.S. dollar increases relative to foreign currencies in the future, in the absence of a corresponding change in local currency prices, our future revenue could be adversely affected as we convert future revenue from local currencies to U.S. dollars. Conversely, a weakening of the value of the U.S dollar relative to foreign currencies would make our operations in Germany and Austria which operate in Euros relatively more expensive. If we dedicate resources to our international operations and are unable to manage these risks effectively, our business, operating results and prospects will suffer.

We face the risk of potential liability under the FCPA for past international distributions of products and to the extent we distribute products or otherwise operate internationally in the future.

In the past, we have distributed certain of our products internationally, and in the future, we may distribute our products internationally and possibly engage in additional international operations. The FCPA prohibits companies such as us from engaging, directly or indirectly, in making payments to foreign government and political officials for the purpose of obtaining or retaining business or securing any other improper advantage, including, among other things, the distribution of products and other international business operations. Like other U.S. companies operating abroad, we may face liability under the FCPA if we, or third parties we have used to distribute our products or otherwise advance our international business, have violated the FCPA or any of the relevant international equivalents. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures.

Risks Related to Compliance with Healthcare and Regulations

Changes in healthcare policy, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and operations.

In March 2010, both the Patient Protection and Affordable Care Act, or Affordable Care Act, and the reconciliation law known as Health Care and Education Reconciliation Act, with the Affordable Care Act, the 2010 Health Care Reform Legislation, were enacted. The constitutionality of the 2010 Health Care Reform Legislation was confirmed twice by the Supreme Court of the United States. The 2010 Health Care Reform Legislation has changed the existing state of the health care system by expanding coverage through voluntary state Medicaid expansion, attracting previously uninsured persons through the health care insurance exchanges and by modifying the methodology for reimbursing medical services, drugs and devices. The U.S. Congress is seeking to replace the 2010 Health Care Reform Legislation. At this time the Company is not certain as to the impact of federal health care legislation on its business.

The 2010 Health Care Reform Legislation includes the Open Payments Act (formerly referred to as the Physician Payments Sunshine Act), which, in conjunction with its implementing regulations, requires manufacturers of certain drugs, biologics, and devices that are reimbursed by Medicare, Medicaid and the Children's Health Insurance Program to report annually certain payments or "transfers of value" provided to physicians and teaching hospitals and to report annually ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. Recent amendments to the Open Payments Act expand the categories of health care providers for which reporting is required. The failure to report appropriate data accurately, timely, and completely could subject us to significant financial penalties. Other countries and several states currently have similar laws and more may enact similar legislation.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. Any changes in government regulation of the United States healthcare industry may result in decreased profits to us, which may adversely affect our business, financial condition and results of operations.

We are subject to potential enforcement actions involving false claims, kickbacks, physician self-referral or other federal or state fraud and abuse laws, and we could incur significant civil and criminal sanctions, which would hurt our business.

The government has made enforcement of the false claims, anti-kickback, physician self-referral and various other fraud and abuse laws a major priority. In many instances, private whistleblowers also are authorized to enforce these laws even if government authorities choose not to do so. In most of these cases, private whistleblowers brought the allegations to the attention of federal enforcement agencies. The risk of our being found in violation of these laws and regulations is increased by the fact that some of the laws and regulations have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. We could be subject to enforcement actions under the following laws:

- the federal Anti-Kickback Statute, which constrains certain marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent;
- federal physician self-referral laws, such as the Stark Law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third party payor, including commercial insurers, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If we or our operations, are found to be in violation of any of these laws and regulations, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. We will monitor changes in government enforcement as we grow and expand our business. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and hurt our reputation. If we were excluded from participation in U.S. federal healthcare programs, we would not be able to receive, or to sell our tests to other parties who receive reimbursement from Medicare, Medicaid and other federal programs, and that could have a material adverse effect on our business.

Risks Related to Our Intellectual Property

If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future.

In the future, we may license third-party technology to develop or commercialize new products. In return for the use of a third party's technology, we may agree to pay the licensor royalties based on sales of our solutions. Royalties are a component of cost of services and affect the margins on our products. We may also need to negotiate licenses to patents and patent applications after introducing a commercial product. Our business may suffer if we are unable to enter into the necessary licenses on acceptable terms, or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable.

If we are unable to protect our intellectual property effectively, our business would be harmed.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We apply for patents covering our products and technologies and uses thereof, as we deem appropriate, however we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our current or future patented technologies. We may not be successful in defending any challenges made against our patents or patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation can be uncertain and any attempt by us to enforce our patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing DNA.

In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests, like ours, are particularly uncertain. Various courts, including the U.S. Supreme Court, have recently rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that patent claims that recite laws of nature (for example, the relationship between blood levels of certain metabolites and the likelihood that a dosage of a specific drug will be ineffective or cause harm) are not themselves patentable. What constitutes a law of nature is uncertain, and it is possible that certain aspects of genetic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned and licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, methods and technologies that are patentable.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. If we are required to assert our rights against such party, it could result in significant cost and distraction.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We may also be subject to claims that our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and face increased competition to our business. A loss of key research personnel work product could hamper or prevent our ability to commercialize potential products, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Further, competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of our products and technologies. If our intellectual property does not adequately protect us against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We have not yet registered certain of our trademarks in all of our potential markets. If we apply to register these trademarks, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate coverage of our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

We may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect our business, operating results or financial condition.

We may receive notices of claims of direct or indirect infringement or misappropriation or misuse of other parties' proprietary rights from time to time. Some of these claims may lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or other rights, or the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us.

We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings, or other post-grant proceedings declared by the United States Patent and Trademark Office that could result in substantial cost to us. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, recent changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

Litigation may be necessary for us to enforce our patent and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require on acceptable terms or at all. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and, in the future, have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets. Third parties may assert that we are employing their proprietary technology without authorization. In addition, our competitors and others may have patents or may in the future obtain patents and claim that making, having made, using, selling, offering to sell or importing our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses on acceptable terms, if at all. We could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our financial results. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our business and our ability to gain market acceptance for our products.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our customers, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

The COVID-19 pandemic has adversely impacted 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, 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 fiscal year 2020 and into 2021. As the pandemic continues, we expect to continue to experience weakened demand for these products as a result of the reduction in elective and nonessential procedures, lower utilization of routine testing and related specimen collection, reduced spending 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 and/or planned future 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 have had and may continue to 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. The FDA recently notified us that the

agency plans to continue prioritizing emergency use authorization requests for diagnostic products intended to address the COVID-19 pandemic into 2021, which despite the fact that the FDA informed the Company of their re-start of the review of our response submitted to the AI letters at the end of January 2021, will continue to impact the statutory review periods for submissions, including the potential clearance decision on our Acuitas AMR Gene Panel (isolates) submission since the FDA does not currently commit to any MDUFA timelines.

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 and its mutations becomes more widespread, each day manufacturing closures, travel restrictions or lockdowns 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 as well as virtual marketing, sales and customer service interactions not being as effective as in-person interactions. While several vaccines have been approved for use, and with vaccination programs underway in many countries, the limited availability of vaccine and potential failure to be effective for all known mutations of the SARS-CoV-2 virus still makes it hard to predict if and when the pandemic will subside.

Moreover, we have transitioned a significant subset of our office-based employee population to a remote work environment in an effort to mitigate the spread of COVID-19, which may exacerbate certain risks to our business, including cybersecurity attacks and risk of phishing due to an increase in the number of points of potential attack, such as laptops and mobile devices (both of which are now being used in increased numbers). Additionally, we may find that remote work arrangements are not as efficient as physical operations.

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.

Our wholly-owned subsidiary, Curetis USA, secured a loan under the CARES Act Paycheck Protection Program ("PPP") in the aggregate amount of approximately $259 thousand. 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 previously 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.

During November of 2020, we filed for forgiveness of the secured loan we received under the PPP. As part of the forgiveness process, we were 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 as well as many governments around the world 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 and distributors 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 COVID-19 global pandemic or the development of potential tests or treatments. No assurance can be given that our products will aid in the testing or the treatment of this virus.

We offer products for the testing for SARS-CoV-2, the causal pathogen of COVID-19. We may offer other products for testing or treatment of coronavirus in the future. There can be no assurance that test for which our products are used, or any such future tests will be broadly adopted for use. We are among many companies that are trying to develop and commercialize tests for COVID-19, 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 GmbH. As of December 31, 2020, we owed indebtedness of $25.9 million of principal (plus deferred interest of $3.8 million) under a loan provided by the European Investment Bank with maturities in 2022, 2023, and 2024. 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.

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

Following the consummation of the combination with Curetis, we continued as the operating entity and both the size and geographic scope of our business significantly increased. 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. We have and may face further challenges integrating such geographically diverse businesses and implementing a smooth transition of business focus and governance in a timely or efficient manner, especially in light of the global COVID-19 pandemic. 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 our combination with Curetis 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.

Recent changes to our management and our board of directors may have a material impact on our business.

Oliver Schacht, Ph.D., the prior chief executive officer of Curetis N.V., became our chief executive officer at the closing of our business combination with Curetis in April 2020. Additionally, pursuant to the business combination, four new members of our board of directors were appointed by Curetis N.V. in April 2020. These new members of management and directors 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. Further, the ability of our new directors to quickly expand their knowledge of our operations is 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.

Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employee benefits liability, property, umbrella, business interruption, workers' compensation, product liability, errors and omissions and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

The integration of the 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 our business 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 businesses of OpGen and Curetis. The proposed transaction was complex and we have devoted and will need to continue 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.

While we currently qualify as a smaller reporting company under SEC regulations, we cannot be certain if we take advantage of the reduced disclosure requirements applicable to these companies that we will not make our common stock less attractive to investors. Once we lose smaller reporting company status, the costs and demands placed upon our management are expected to increase.

The SEC's rules permit smaller reporting companies to take advantage of certain exemptions from various reporting requirements applicable to other public companies. As long as we qualify as a smaller reporting company, based on our public float, and report less than $100 million in annual revenues in a fiscal year we are permitted, and we intend to, omit the auditor's attestation on internal control over financial reporting that would otherwise be required by the Sarbanes-Oxley Act.

We lost our status as an emerging growth company as of December 31, 2020. While we expect to remain a smaller reporting company and non-accelerated filer, we now face increased disclosure requirements as a non-emerging growth company, such as stockholder advisory votes on executive compensation ("say-on-pay"). Until such time that we lose smaller reporting company status, it is unclear if investors will find our common stock less attractive because we may rely on certain disclosure exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and could cause our stock price to decline.

As a result of the loss of our emerging growth company status, we expect the costs and demands placed upon our management to increase, as we now have to comply with additional disclosure and accounting requirements. In addition, even if we remain a smaller reporting company, if our public float exceeds $75 million and we report $100 million or more in annual revenues in a fiscal year, we will become subject to the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring an independent registered public accounting firm to provide an attestation report on the effectiveness of our internal control over financial reporting, making the public reporting process more costly.

General Risk Factors

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Act of 2010, as well as rules implemented by the SEC and the Nasdaq Stock Market, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, compliance with these rules and regulations has increased our legal, accounting and financial compliance costs and has made some activities more time-consuming and costly. It is also more expensive for us to obtain director and officer liability insurance.

We may be adversely affected by the current economic environment and future adverse economic environments.

Our ability to attract and retain customers, invest in and grow our business and meet our financial obligations depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States and inflationary pressures. We cannot anticipate all the ways in which the current economic climate and financial market conditions, and those in the future, could adversely impact our business.

We are exposed to risks associated with reduced profitability and the potential financial instability of our customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and diagnostic testing. If fewer patients are seeking medical care because they do not have insurance coverage, we may experience reductions in revenues, profitability and/or cash flow. In addition, if economic challenges in the United States result in widespread and prolonged unemployment, either regionally or on a national basis, a substantial number of people may become uninsured or underinsured. To the extent such economic challenges result in less demand for our proprietary tests, our business, results of operations, financial condition and cash flows could be adversely affected.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

The Company subleases 10,719 square feet of office and laboratory space at our headquarters in Gaithersburg, Maryland. The Company has signed a ten year lease for a new 10,100 square foot corporate headquarters in Rockville, Maryland that is currently under construction. The Company expects to take occupancy of the new office space in April 2021 and laboratory space in May 2021. The Company also leases 12,770 square feet of space at its facility in Woburn, Massachusetts under an operating lease that expires in January 2022. The Company entered into a sublease agreement for this space in February 2021 that expires in January 2022.

Curetis leases approximately 17,000 square feet of manufacturing and logistics space for its FDA registered manufacturing plant in Bodelshausen, Germany, which include tailored cleanrooms, automated Application Cartridge manufacturing equipment and laboratory facilities. The lease term expires in June 2025. Furthermore, Curetis leases approximately 17,000 square feet of office and lab space at its FDA registered headquarters located in Holzgerlingen, Germany, which are used for R&D, operations, and G&A purposes. The lease term has recently been extended until August 31, 2025, with a subsequent option to extend the term by another four years. Curetis' US subsidiary leases 5,003 square feet of office space in San Diego, California under and operating lease that expires in May 2022.

Ares Genetics leases 1,299 square feet of office space in Vienna, Austria under an operating lease that expires in February 2022. Additionally, Ares subleases 1,046 square feet of laboratory space in Vienna, Austria under an operating lease that expires in December 2022.

Rent expenses under the Company's facility operating leases for the years ended December 31, 2020 and 2019 were $1,154,927 and $862,143, respectively.

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock has traded on The Nasdaq Capital Market under the symbol "OPGN", since May 5, 2015. Prior to such time, there was no public market for our common stock.

Stockholder Information

As of December 31, 2020, there were approximately 38 stockholders of record of our common stock, which does not include stockholders that beneficially own shares held in a "nominee" or in "street" name.

Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data

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

Item 7. 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 our audited consolidated financial statements and the accompanying notes thereto included elsewhere in this Annual Report. 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 in the section titled "Risk Factors" included under Part I, Item 1A of this Annual Report.

Overview

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

On April 1, 2020, the Company completed a business combination transaction (the "Transaction") with Curetis N.V., a public company with limited liability under the laws of the Netherlands (the "Seller" or "Curetis N.V."), as contemplated by the Implementation Agreement, dated as of September 4, 2019 (the "Implementation Agreement"), by and among the Company, the Seller, and Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and wholly-owned subsidiary of the Company ("Purchaser"). Pursuant to the Implementation Agreement, the Purchaser acquired all of the shares of Curetis GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany ("Curetis GmbH"), and certain other assets and liabilities of the Seller (together, "Curetis"). Curetis is an early commercial-stage molecular diagnostics (MDx) company focused on rapid infectious disease testing for hospitalized patients with the aim to improve the treatment of hospitalized, critically ill patients with suspected microbial infection and has developed the innovative Unyvero molecular diagnostic solution for comprehensive infectious disease testing. The Transaction was designed principally to leverage each company's existing research and development and relationships with hospitals and clinical laboratories to accelerate the sales of both companies' products and services.

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

- The Unyvero Lower Respiratory Tract, or LRT, test is the first FDA cleared test that can be used for the detection of more than 90% of common causative agents of hospitalized pneumonia. According to the National Center for Health Statistics (2018), pneumonia is a leading cause of admissions to the hospital and is associated with substantial morbidity and mortality. The Unyvero LRT automated test detects 19 pathogens within less than five hours, with approximately two minutes of hands-on time and provides clinicians with a comprehensive overview of 10 genetic antibiotic resistance markers. We are also commercializing the Unyvero LRT BAL test for testing bronchoalveolar lavage, or BAL, specimens from patients with lower respiratory tract infections following FDA clearance received by Curetis in December 2019. The Unyvero LRT BAL automated test simultaneously detects 20 pathogens and 10 antibiotic resistance markers, and it is the first and only FDA-cleared panel that now also includes *Pneumocystis jirovecii*, a key fungal pathogen often found in immunocompromised patients that can be difficult to diagnose as the 20th pathogen on the panel. We believe the Unyvero LRT and LRT BAL tests have the ability to help address a significant, previously unmet medical need that causes over $10 billion in annual costs for the U.S. healthcare system, according to the Centers for Disease Control, or CDC.

- The Unyvero Urinary Tract Infection, or UTI, test which is CE-IVD marked in Europe is currently being made available to laboratories in the U.S. as a research use only or RUO kit. The test detects a broad range of pathogens as well as antimicrobial resistance markers directly from native urine specimens. As part of our portfolio strategy update on October 13, 2020, we have decided to proceed with the analytical and clinical performance evaluation including clinical trials required for a subsequent U.S. FDA submission.

- The Unyvero Invasive Joint Infection, or IJI, test, which is a variant developed for the U.S. market based on the CE-IVD-marked European Unyvero ITI test, has also been selected for analytical and clinical performance evaluation including clinical trials towards a future U.S. FDA submission. Microbial diagnosis of IJI is difficult because of challenges in sample collection, usually at surgery, and patients being on prior antibiotic therapy which minimizes the chances of recovering viable bacteria. We believe that Unyvero IJI could be useful in identifying pathogens as well as their AMR markers to help guide optimal antibiotic treatment for these patients.

- The Acuitas AMR Gene Panel (Isolates) is currently pending final FDA review and a potential clearance decision. The FDA recently notified us that the agency plans to continue prioritizing emergency use authorization requests for diagnostic products intended to address the COVID-19 pandemic for at least the remainder of the year, which will impact the statutory review periods for submissions, including the potential clearance decision on our Acuitas AMR Gene Panel (Isolates) submission. Despite the FDA having informed us of their resumed review at the end of January 2021 of the responses filed by OpGen to the AI letters, the FDA still does not commit to any MDUFA timelines. Once FDA cleared, we expect to commercialize the Acuitas AMR Gene Panel for isolates more broadly to customers in the U.S. The Acuitas AMR Gene Panel (Urine) test has been discontinued as part of the October 13, 2020 portfolio and pipeline strategy review.

- We are also developing novel bioinformatics tools and solutions to accompany or augment our current and potential future IVD products and may seek regulatory clearance for such bioinformatics tools and solutions to the extent they would be required either as part of our portfolio of IVD products or even as a standalone bioinformatics product.

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

OpGen's combined AMR bioinformatics offerings, once such products are cleared for marketing, if ever, will offer important new tools to clinicians treating patients with AMR infections. We have collaborated with Merck, Inc. to establish the Acuitas Lighthouse Knowledgebase, which is currently commercially available in the United States for RUO. The Acuitas Lighthouse Knowledgebase includes approximately 15,000 bacterial isolates from the Merck SMART surveillance network of 192 hospitals in 52 countries and other sources. Ares Genetics' ARESdb is a comprehensive database of genetic and phenotypic information. ARESdb was originally designed based on the SIEMENS microbiology strain collection covering resistant pathogens and its development has significantly expanded, also by transferring data from the Acuitas Lighthouse® into ARESdb to now cover approximately 55,000 bacterial isolates that have been sequenced using NGS technology and tested for susceptibility with applicable antibiotics from a range of over 100 antimicrobial drugs. In September 2019, Ares Genetics signed a technology evaluation agreement with an undisclosed global IVD corporation. In the collaboration, Ares Genetics further enriched ARESdb with a focus on certain pathogens relevant in a first, undisclosed infectious disease indication. Following the successful completion of this collaborative R&D project, the IVD partner exercised their option for a 90-day period of exclusive negotiations with Ares Genetics for a potential exclusive license to ARESdb in the field of human clinical diagnostics. Following the lapse of such 90-day period without any commercial deal being signed, Ares Genetics is now in multiple, nonexclusive parallel discussions with several interested parties and such discussions are ongoing.

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

The Unyvero A50 tests for up to 130 diagnostic targets (pathogens and resistance genes) in under five hours with approximately two minutes of hands-on time. The system was first CE-IVD-marked in 2012 and was FDA cleared in 2018 along with the LRT test through a *De Novo* request. As of December 31, 2020, there is an installed base of about 179 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 *RQ* has a small laboratory footprint and has an attractive cost of goods profile. Curetis has been following a partnering strategy for the Unyvero A30 *RQ*.

The Company has extensive partner and distribution relationships to help accelerate the establishment of a global infectious disease diagnostic testing and informatics business. Partners include A. Menarini Diagnostics for pan-European distribution to currently 11 countries and Beijing Clear Biotech Co. Ltd. for Unyvero A50 product distribution in China. We have a network currently consisting of over 20 distributors covering more than 40 countries. With the discontinuation of our FISH products business in Europe we expect that network of distributors to be reduced to only those distributors actively commercializing our Unyvero line of products and / or CE-IVD-marked SARS CoV-2 test kits.

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

Our headquarters are in Gaithersburg, Maryland, and our principal operations are in Gaithersburg, Maryland and Holzgerlingen and Bodelshausen, both in Germany. We also have operations in Vienna, Austria. The Company will move its headquarters in April 2021 and US operations in May 2021 from Gaithersburg, Maryland to Rockville, Maryland. We operate in one business segment.

Financing Transactions

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. The following financing transactions took place during 2019 and 2020:

- 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, 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 December 31, 2019, all 2,109,830 pre-funded warrants issued in the October 2019 Public Offering have been exercised.
- On February 11, 2020, the Company entered into an ATM Agreement with Wainwright, which was subsequently amended and restated on November 13, 2020, to add BTIG as a sales agent, pursuant to which the Company may offer and sell from time to time in an "at the market offering," at its option, up to an aggregate of $22.1 million of shares of its common stock through the sales agents. During the year ended December 31, 2020, the Company sold 7,521,610 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds of approximately $15.8 million, and gross proceeds of $16.7 million.
- On November 25, 2020, the Company closed a private placement with one healthcare-focused U.S. institutional investor of (i) 2,245,400 shares of common stock together with 2,245,400 warrants (the "Common Warrants") to purchase up to 2,245,400 shares of common stock and (ii) 2,597,215 pre-funded warrants (the "Pre-Funded Warrants"), with each Pre-Funded Warrant exercisable for one share of common stock, together with 2,597,215 Common Warrants to purchase up to 2,597,215 shares of common stock. Each share of common stock and accompanying Common Warrant were sold together at a combined offering price of $2.065, and each Pre-funded Warrant and accompanying Common Warrant were sold together at a combined offering price of $2.055. The Common Warrants have an exercise price of $1.94 per share and are exercisable commencing on the six month anniversary of the date of issuance, and will expire five and one half (5.5) years from the date of issuance (collectively, the "2020 PIPE"). The 2020 PIPE raised aggregate net proceeds of $9.3 million, and gross proceeds of $10.0 million.
- During the year ended December 31, 2020, approximately 4.3 million common warrants issued in our October 2019 Public Offering were exercised raising net proceeds of approximately $8.7 million.

In addition to the foregoing, the Company also completed the following financing transactions during 2021:

- On February 11, 2021, the Company closed a registered direct offering (the "February 2021 Offering") with a single U.S.-based, healthcare-focused institutional investor for the purchase of (i) 2,784,184 shares of common stock and (ii) 5,549,149 pre-funded warrants (the "Pre-Funded Warrants"), with each Pre-Funded Warrant exercisable for one share of common stock. The Company also issued to the investor, in a concurrent private placement, unregistered common share purchase warrants (the "Common Warrants") to purchase 4,166,666 shares of the Company's common stock. Each share of common stock and accompanying Common Warrant were sold together at a combined offering price of $3.00, and each Pre-Funded Warrant and accompanying Common Warrant were sold together at a combined offering price of $2.99. The Pre-Funded Warrants are immediately exercisable, at an exercise price of $0.01, and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The Common Warrants have an exercise price of $3.55 per share, are exercisable commencing on the six-month anniversary of the date of issuance, and expire five and one half (5.5) years from the date of issuance. The February 2021 Offering raised aggregate net proceeds of $23.4 million, and gross proceeds of $25.0 million.
- As noted above on November 23, 2020, the Company entered into a securities purchase agreement with an institutional investor (the "Holder"), pursuant to which the Company issued to the Investor, securities of the Company, including warrants (the "Existing Warrants") to purchase up to 4,842,615 shares of common stock of the Company (the "Warrant Shares"). The Existing Warrants were exercisable six months after their issuance at an exercise price of $1.94 per share and expire on the fifth and a half year anniversary of the date of issuance. On March 9, 2021, the Company entered into a Warrant Exercise Agreement (the "Exercise Agreement") with the Holder. Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of the remaining 4,842,615 outstanding Existing Warrants for cash, pursuant to the terms of and subject to beneficial

ownership limitations contained in the Existing Warrants, the Company agreed to issue to the Holder, new warrants (the "New Warrants") to purchase 0.65 shares of Common Stock for each share of Common Stock issued upon such exercise of the remaining 4,842,615 outstanding Existing Warrants pursuant to the Exercise Agreement or an aggregate of 3,147,700 New Warrants. The terms of the New Warrants are substantially similar to those of the Existing Warrants, except that the New Warrants will have an exercise price of $3.56. The New Warrants are immediately exercisable and expire five years from the date of the Exercise Agreement. On March 12, 2021, the Company and the Holder amended the Exercise Agreement to provide that the Holder would pay the Company $0.08125 for each New Warrant issued to the Holder. The Holder paid an aggregate of $255,751 to the Company for the purchase of the New Warrants. The Company received aggregate gross proceeds before expenses of approximately $9.65 million from the exercise of all of the remaining 4,842,615 outstanding Existing Warrants held by the Holder and the payment of the purchase price for the New Warrants.

Results of Operations for the Years Ended December 31, 2020 and 2019

Revenues

	Years Ended December 31,	
	2020	**2019**
Revenue		
Product sales	$ 2,704,364	$ 2,168,179
Laboratory services	167,736	5,435
Collaboration revenue	1,342,341	1,325,000
Total revenue	$ 4,214,441	$ 3,498,614

The Company's total revenue for the year ended December 31, 2020 increased 20%, to $4.2 million from $3.5 million, when compared to the same period in 2019. This increase is primarily attributable to:

- Product Sales: the increase in revenue of 25% in the 2020 period compared to the 2019 period is primarily attributable to the inclusion of Curetis' products sales subsequent to the Transaction, offset in part by a reduction in the sale of the Company's FISH rapid pathogen ID testing products due to the loss of large customers and COVID-19;
- Laboratory Services: the increase in revenue in the 2020 period compared to the 2019 period is primarily attributable to the inclusion of Ares Genetics' laboratory services subsequent to the Transaction; and
- Collaboration Revenue: the decrease in collaboration revenue of 1% in the 2020 period compared to the 2019 period is primarily the result of by lower revenue from our contract with the New York State DOH offset by the inclusion of Ares Genetics' Collaboration revenue subsequent to the Transaction.

Operating expenses

	Years Ended December 31,	
	2020	**2019**
Cost of products sold	$ 3,360,280	$ 911,565
Cost of services	488,211	720,156
Research and development	9,964,720	5,121,168
General and administrative	8,801,661	6,252,442
Sales and marketing	3,094,092	1,464,721
Transaction costs	471,522	779,048
Impairment of right-of-use asset	101,838	520,759
Impairment of intangible assets	750,596	—
Gain on sale of equipment	(100,000)	—
Total operating expenses	$ 26,932,920	$ 15,769,859

The Company's total operating expenses for the year ended December 31, 2020 increased 71%, to $26.9 million from $15.8 million, when compared to the same period in 2019. This increase is primarily attributable to:

- Costs of products sold: expenses for the year ended December 31, 2020 increased approximately 269% when compared to the same period in 2019. The change in costs of products sold is primarily attributable to the inclusion of Curetis' cost of products

sold subsequent ‘to the Transaction as well as increased regulatory costs and an increase in the Company’s write off of its FISH inventory;

- Costs of services: expenses for the year ended December 31, 2020 decreased approximately 32% when compared to the same period in 2019. The change in cost of service was primarily attributable to lower costs associated with our New York State DOH contract partially offset by the inclusion of Curetis’ and Ares Genetics’ cost of services subsequent to the Transaction;
- Research and development: expenses for the year ended December 31, 2020 increased approximately 95% when compared to the same period in 2019. The change in research and development is primarily attributable to the inclusion of Curetis’ and Ares’ research and development expenses subsequent to the Transaction;
- General and administrative: expenses for the year ended December 31, 2020 increased approximately 41% when compared to the same period in 2019, primarily due to the inclusion of Curetis’ expenses subsequent to the Transaction;
- Sales and marketing: expenses for the year ended December 31, 2020 increased approximately 111% when compared to the same period in 2019, primarily due to the inclusion of Curetis’ sales and marketing expenses subsequent to the Transaction, partially offset by lower travel costs;
- Transaction costs: transaction costs for the year ended December 31, 2020 decreased approximately 39% when compared to the same period in 2019, primarily due to the timing of the Transaction announcement in 2019;
- Impairment of intangible assets: impairment of intangible assets for the year ended December 31, 2020 represents the write down of intangible assets acquired from AdvanDx in 2015;
- Impairment of right-of-use asset: impairment of right-of-use asset for the year ended December 31, 2020 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 and the additional impairment expense in 2020; and
- Gain on sale of equipment: gain on sale of equipment for the year ended December 31, 2020 represents the sale of laboratory equipment to one of our vendors.

Other expense

	Years Ended December 31,	
	2020	2019
Gain on extinguishment of debt	$ 884,970	$ —
Interest expense	(3,399,384)	(187,549)
Foreign currency transaction (losses) gains	(1,468,855)	2,410
Change in fair value of derivative financial instruments	517,680	67
Interest and other income	105,627	9,859
Total other expense	$ (3,359,962)	$ (175,213)

Other expense for the year ended December 31, 2020 increased to a net expense of $3,359,962 from a net expense of $175,213 in the same period of 2019. The increase was primarily a result of an increase in interest expense associated with the debt assumed as part of the Transaction with Curetis offset by a gain on extinguishment of debt related to the Company’s PPP loan.

Liquidity and Capital Resources

At December 31, 2020, the Company had cash and cash equivalents of $13.4 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 significant funds in 2020 and 2019, including:

On November 25, 2020, the Company closed the 2020 PIPE of 2,245,400 shares of common stock together with 2,597,215 pre-funded warrants. The 2020 PIPE raised aggregate net proceeds of $9.3 million, and gross proceeds of $10.0 million.

On February 11, 2020, we entered into the 2020 ATM Agreement, pursuant to which we may offer and sell from time to time at our option, up to an aggregate of $22.1 million of shares of our common stock through the sales agents. During the year ended December 31, 2020, the Company sold 7,521,610 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds of approximately $15.8 million, and gross proceeds of $16.7 million.

During the year ended December 31, 2020, approximately 4.3 million common warrants issued in the Company’s October 2019 Public Offering were exercised raising net proceeds of approximately $8.7 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.

Sources and uses of cash

The following table summarizes the net cash provided by (used in) operating activities, investing activities and financing activities for the periods indicated:

	Years Ended December 31,	
	2020	2019
Net cash used in operating activities	$ (23,396,532)	$ (11,505,439)
Net cash used in investing activities	(1,063,505)	(2,502,576)
Net cash provided by financing activities	34,087,148	12,168,146

Net cash used in operating activities

Net cash used in operating activities in 2020 consisted primarily of our net loss of $26.2 million, reduced by certain non-cash items, including depreciation and amortization expense of $2.3 million, non-cash interest of $2.6 million, share-based compensation of $0.3 million, partially offset by gains on debt forgiveness of $0.9 million, changes in warrant liabilities of $0.5 million, and the net change in operating assets and liabilities of $2.3 million. Net cash used in operating activities in 2019 consisted primarily of our net loss of $12.4 million, reduced by certain non-cash items, including depreciation and amortization expense of $0.9 million, share-based compensation of $0.4 million, partially offset by the net change in operating assets and liabilities of $0.9 million.

Net cash used in investing activities

Net cash used in investing activities in 2020 consisted primarily of funds provided to Curetis GmbH as part of the Interim Facility offset by the acquisition of Curetis net of cash acquired of $1.3 million. Net cash provided by investing activities for the year ended December 31, 2019 consisted of funds provided to Curetis GmbH as part of the Interim Facility and purchases of property and equipment offset by proceeds from the sale of equipment.

Net cash provided by financing activities

Net cash provided by financing activities in 2020 of $34.1 million consisted primarily of net proceeds from the 2020 PIPE, 2020 ATM Offering and exercises of common stock warrants and issuance of debt. Net cash provided by financing activities in 2019 of $12.2 million consisted primarily of net proceeds from the October 2019 Public Offering and March 2019 Public Offering.

Funding requirements

Our primary use of cash is to fund operating expenses, including our research and development expenditures. Our future funding requirements will depend on many factors, including the following:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our products;
- the clinical development plans we establish for these products;
- the number and characteristics of products that we develop;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA and other comparable foreign regulatory authorities;
- the terms of our existing and any future license or collaboration agreements we may choose to enter into, including the amount of upfront, milestone and royalty obligations;
- the other costs associated with in-licensing new technologies, such as any increased costs of research and development and personnel;

- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the degree of commercial success achieved following the successful completion of development and regulatory approval activities for our products.
- the cost to establish and maintain collaborations on favorable terms, if at all; and
- the cost to comply with our obligations as a public company.

Critical Accounting Policies and Use of Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our audited 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 to the accompanying audited 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.

Business Combinations

We allocate the fair value of purchase consideration to the tangible assets acquired, liabilities assumed, and intangible assets acquired based on their estimated acquisition date fair values. The excess of the fair value of the purchase consideration over the fair values of the identifiable assets acquired and liabilities assumed is recorded as goodwill. When determining the fair values of assets acquired and liabilities assumed, we make significant estimates and assumptions, especially with respect to intangible assets and debt instruments.

Critical estimates in valuing certain intangible assets include but are not limited to future expected cash flows from customer/distributions relationships, developed technology, and in-process research & development discount rates, and terminal values. Our estimate of fair value is based upon assumptions believed to be reasonable, but actual results may differ from estimates.

We determine the fair value of assumed debt using a discounted cash flow analysis using interest rates for debt with similar terms and maturities. Differences between the fair value and the stated value is recorded as a discount or premium and amortized over the remaining term using the effective interest method. We utilize a Monte Carlo simulation method to determine the fair value of conversion notes, which utilizes inputs including the common stock price, volatility of common stock, the risk-free interest rate and the probability of conversion to common shares at the conversion rate.

Other estimates associated with the accounting for the acquisition may change as additional information becomes available regarding the assets acquired and liabilities assumed, as more fully discussed in Note 4 – Business Combination of the notes to the consolidated financial statements (Part II, Item 8 of this Form 10-K).

Revenue Recognition

The Company derives revenues from (i) the sale of QuickFISH and PNA FISH diagnostic test products, Unyvero Application cartridges, Unyvero Systems, SARS CoV-2 tests, 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.

Impairment of Long-Lived Assets

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

Definite-lived intangible assets include trademarks, developed technology, software and customer relationships. 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.

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

Goodwill represents the excess of the purchase price paid when the Company acquired AdvanDx, Inc. in July 2015 and Curetis in April 2020, over the fair values of the acquired tangible or intangible assets and assumed liabilities. The Company will conduct an impairment test of goodwill on an annual basis as of December 31 of each year 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.

Share-Based Compensation

Share-based payments to employees, directors and consultants are recognized at fair value. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option. The estimated fair value of equity instruments issued to nonemployees is recorded at fair value on the earlier of the performance commitment date or the date the services required are completed.

For all time-vesting awards granted, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. Share-based compensation expense recognized is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period. The fair value of share-based payments is estimated, on the date of grant, using the Black-Scholes model. Option valuation models, including the Black-Scholes model, require the input of highly subjective estimates and assumptions, and changes in those estimates and assumptions can materially affect the grant-date fair value of an award. These assumptions include the fair value of the underlying and the expected life of the award.

See additional discussion of the use of estimates relating to share-based compensation, and a discussion of management's methodology for developing each of the assumptions used in such estimates, in Note 3 to the accompanying consolidated financial statements.

Recent Accounting Pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 3 to our consolidated financial statements appearing elsewhere in this filing, such standards will not have a material impact on our consolidated financial statements or do not otherwise apply to our operations.

Off-Balance Sheet Arrangements

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

JOBS Act

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Item 8. Financial Statements

The Company's consolidated financial statements and the report of our independent registered public accounting firm are included in this Annual Report as indicated in Part IV, Item 15.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company's management evaluated, with the participation of the Company's principal executive and principal financial officers, the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2020. We maintain disclosure controls and 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, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding disclosure. Based on their evaluation, management has concluded that the Company's disclosure controls and procedures were effective as of December 31, 2020.

Our evaluation excluded Curetis and its subsidiaries which were acquired in April 2020. As of and for the year ended December 31, 2020 Curetis and its subsidiaries represented approximately 67% of total assets and 54% of revenue of the Company. In accordance with guidance issued by the SEC, companies are allowed to exclude acquisitions from their assessment of internal controls over financial reporting during the first year subsequent to the acquisition while integrating with acquired operations.

Changes in Internal Control over Financial Reporting

On April 1, 2020, OpGen completed its business combination transaction of Curetis. The Company has not yet completed an assessment of the design and/or operating effectiveness of Curetis' internal control over financial reporting. There were no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). The Company's internal control system was designed to provide reasonable assurance regarding the preparation and fair presentation of published financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of management, including the Company's Chief Executive Officer and Chief Financial Officer, the Company assessed the effectiveness of internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in its statement "Internal Control-Integrated Framework (2013)."

Based on this assessment, management has concluded that, as of December 31, 2020, internal control over financial reporting is effective based on these criteria.

This Annual Report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to the rules of the SEC that permit the Company to provide only management's report in this Annual Report.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this item is incorporated herein by reference to the similarly named section of our Definitive Proxy Statement for our 2021 Annual Meeting of Stockholders.

Item 11. Executive Compensation

Information required by this item is incorporated herein by reference to the similarly named section of our Definitive Proxy Statement for our 2021 Annual Meeting of Stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information required by this item is incorporated herein by reference to the similarly named section of our Definitive Proxy Statement for our 2021 Annual Meeting of Stockholders.

Item 13. Certain Relationships and Related Person Transactions, and Director Independence

Information required by this item is incorporated herein by reference to the similarly named section of our Definitive Proxy Statement for our 2021 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services

Information required by this item is incorporated herein by reference to the similarly named section of our Definitive Proxy Statement for our 2021 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements.

The consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the years then ended, the related notes to the consolidated financial statements and the report of CohnReznick LLP, independent registered public accounting firm, are filed herewith following the signature page.

(a)(2) Financial Statement Schedules.

Not applicable.

(a)(3) Exhibits: See below

(b) Exhibits

EXHIBIT INDEX

Exhibit Number	Description
3.1.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of Current Report on Form 8-K, File No. 001-37367, filed on May 13, 2015)
3.1.2	Certificate of Correction to Amended and Restated Certificate of Incorporation of the Registrant, dated June 6, 2016 (incorporated by reference to Exhibit 3.1 of Current Report on Form 8-K, filed on June 6, 2016)
3.1.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant dated and filed with the Delaware Secretary of State on January 17, 2018 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on January 17, 2018)

Exhibit Number	Description
3.1.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of OpGen, Inc., filed with the Secretary of the State of Delaware on August 28, 2019 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on August 28, 2019)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Form S-1, File No. 333-202478, filed on March 3, 2015)
3.3	Amendment to the Amended and Restated Bylaws of OpGen, Inc., dated August 5, 2020 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on August 11, 2020)
4.1	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrants Annual Report on Form 10-K, filed on March 24, 2020)
4.2	Form of 2015 Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.6 of Form S-1/A, File No. 333-202478, filed on March 20, 2015)
4.3	Form of Underwriters' Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.2 of Current Report on Form 8-K, File No. 001-37367, filed on May 13, 2015)
4.4	Form of Warrant to Purchase Common Stock (issued to jVen Capital, LLC and Merck Global Health Innovation Fund) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K Amendment No. 2, filed on July 10, 2017)
4.5	Form of Offered Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.8 of Form S-1/A, File No. 333-202478, filed on April 23, 2015)
4.6	Form of 2016 Warrant to Purchase Common Stock of the Registrant (incorporated by reference to Exhibit 4.1 of Current Report on Form 8-K, filed on May 17, 2016)
4.7	Form of Common Stock Purchase Warrant for July 2017 Public Offering (incorporated by reference to Exhibit 4.4 to the Registrants Form S-1, Amendment No. 2, File No. 333-218392, filed on July 11, 2017)
4.8	Form of Placement Agent Warrant for July 2017 Public Offering (incorporated by reference to Exhibit 4.5 to the Registrants Form S-1, File No. 333-218392, filed on July 11, 2017)
4.9	Form of Common Stock Purchase Warrant for February 2018 Public Offering (incorporated by reference to Exhibit 4.3 to the Registrants Form S-1/A, File No. 333-222140, filed on January 31, 2018)
4.10	Form of Placement Agent Warrant for February 2018 Public Offering (incorporated by reference to Exhibit 4.5 to the Registrants Form S-1/A, File No. 333-222140, filed on January 31, 2018)
4.11	Form of Underwriter's Warrant for October 2019 Public Offering (incorporated by reference to Exhibit 4.10 to the Registrants Form S-1/A, File No. 333-233775, filed on October 11, 2019)
4.12	Form of Common Stock Purchase Warrant for October 2019 Public Offering (incorporated by reference to Exhibit 4.11 to the Registrants Form S-1/A, File No. 333-233775, filed on October 11, 2019)
4.13*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
4.14	Form of Common Stock Purchase Warrant for 2020 PIPE (incorporated by reference to Exhibit 4.1 to the Registrants, Current Report on Form 8-K, filed on November 24, 2020)
4.15	Form of Pre-Funded Common Stock Purchase Warrant for 2020 PIPE (incorporated by reference to Exhibit 4.2 to the Registrants, Current Report on Form 8-K, filed on November 24, 2020)

Exhibit Number	Description
10.1	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.2 of Form S-1, File No. 333-202478, filed on March 3, 2015)
10.2	2015 Equity Incentive Plan, as amended and restated on March 29, 2018 (incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 29, 2018)
10.3 !	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.16 to the Registrant's Form S-1, Amendment No. 2, File No. 333-202478, filed on April 6, 2015)
10.4	Warrant Agreement, dated as of May 8, 2015, between the Registrant and Philadelphia Stock Transfer, Inc., as warrant agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 13, 2015)
10.5.1 !	Form of Stock Option Agreement under the 2015 Equity Incentive Plan for employees and consultants (incorporated by reference to Exhibit 10.9.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 24, 2017)
10.5.2 !	Form of Stock Option Agreement under the 2015 Equity Incentive Plan for non-employee directors (initial grant) (incorporated by reference to Exhibit 10.9.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 24, 2017)
10.5.3 !	Form of Stock Option Agreement under the 2015 Equity Incentive Plan for non-employee directors (annual grant) (incorporated by reference to Exhibit 10.9.3 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 24, 2017)
10.6 !	Form of Restricted Stock Unit Award Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed March 24, 2017)
10.7 !	Stock Option Award Agreement, dated April 28, 2016, by and between the Registrant and Evan Jones (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed on August 11, 2016)
10.8 !	Executive Change In Control and Severance Benefits Agreement, dated September 24, 2018 between OpGen, Inc. and Timothy C. Dec (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed on September 25, 2018)
10.9 !	Executive Change In Control and Severance Benefits Agreement, dated September 24, 2018 between OpGen, Inc. and Vadim Sapiro (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed on September 25, 2018).
10.10 !	OpGen, Inc. Retention Plan for Executives (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 25, 2018)
10.11	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)
10.12	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)
10.13	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).
10.14 !	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).
10.15	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).
10.16 !	Transition Agreement between OpGen, Inc. and Evan Jones (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on April 2, 2020)
10.17	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).

Exhibit Number	Description
10.18	Term Note between Curetis USA Inc. and Silicon Valley Bank, dated April 22, 2020 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on April 28, 2020).
10.19 !	Managing Director's Employment Contract by and between Curetis GmbH and Oliver Schacht, Ph.D dated August 6, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 11, 2020).
10.20 !	Managing Director's Employment Contract by and between Curetis GmbH and Johannes Bacher, dated August 6, 2020 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on August 11, 2020).
10.21	Exclusive International Distributor Agreement, dated as of September 25, 2015, between Curetis AG and Beijing Clear Biotech Co. Ltd (incorporated by reference to Exhibit 10.32.1 to the Registrant's Form S-4/A filed on December 20, 2019).
10.22	Amendment 1 to the Exclusive International Distributor Agreement, dated as of October 11, 2018, between Curetis GmbH and Beijing Clear Biotech (incorporated by reference to Exhibit 10.32.2 to the Registrant's Form S-4/A filed on December 20, 2019).
10.23	Assumption of contract, dated as of May 30, 2016, by and between Curetis GmbH, Beijing Clear Bio-tech Co. Ltd and Technomed (Hong Kong) Ltd. (incorporated by reference to Exhibit 10.32.3 to the Registrant's Form S-4/A filed on December 20, 2019).
10.24	Non-Exclusive Patent License and Research Collaboration Agreement, dated as of October 5, 2015, between Acumen Research Laboratories Pte Ltd and Curetis AG (incorporated by reference to Exhibit 10.33 to the Registrant's Form S-4/A filed on December 20, 2019).
10.25	Exclusive International Distributor Agreement, dated as of October 5, 2015, between Curetis AG and Acumen Research Laboratories Pte Ltd (incorporated by reference to Exhibit 10.34.1 to the Registrant's Form S-4/A filed on December 20, 2019).
10.26	Amendment 1 to the Exclusive International Distributor Agreement, dated as of October 5, 2015, between Curetis GmbH and Acumen Research Laboratories Pte Ltd (incorporated by reference to Exhibit 10.34.2 to the Registrant's Form S-4/A filed on December 20, 2019).
10.27	Technology Transfer, Technical Cooperation and License Agreement, dated as of September 7, 2016, by and between Curetis GmbH and Siemens Technology Accelerator GmbH (incorporated by reference to Exhibit 10.35.1 to the Registrant's Form S-4/A filed on December 20, 2019).
10.28	First Amendment Agreement to the Technology Transfer, Technical Cooperation and License Agreement, dated as of May 17, 2018, by and between Ares Genetics GmbH and Siemens Technology Accelerator GmbH (incorporated by reference to Exhibit 10.35.2 to the Registrant's Form S-4/A filed on December 20, 2019).
10.29	Memorandum of Understanding, dated as of September 12, 2017, between Curetis GmbH, Ares Genetics GmbH and MGI Tech Co., Ltd. (incorporated by reference to Exhibit 10.36 to the Registrant's Form S-4/A filed on December 20, 2019).
10.30	Authorization and Supply Agreement, dated as of January 10, 2018, between MGI Tech Co., Ltd. And Curetis GmbH (incorporated by reference to Exhibit 10.37 to the Registrant's Form S-4/A filed on December 20, 2019).
10.31	Technology Purchase Agreement, dated as of December 13, 2016, between Systec Elektronik und Software GmbH, Carpegen GmbH and Curetis GmbH (incorporated by reference to Exhibit 10.38 to the Registrant's Form S-4/A filed on December 20, 2019).
10.32	Services Frame Agreement, dated as of December 14, 2018, between Ares Genetics GmbH and Sandoz International GmbH (incorporated by reference to Exhibit 10.39.1 to the Registrant's Form S-4/A filed on December 20, 2019).
10.33	Work Order Agreement, dated as of December 14, 2018, between Ares Genetics GmbH and Sandoz International GmbH (incorporated by reference to Exhibit 10.39.2 to the Registrant's Form S-4/A filed on December 20, 2019).
10.34	License Agreement, dated as of February 18, 2019, between Ares Genetics GmbH and QIAGEN GmbH and the QIAGEN Affiliates (incorporated by reference to Exhibit 10.40.1 to the Registrant's Form S-4/A filed on December 20, 2019).
10.35	First Amendment to License Agreement, dated as of September 18, 2019, between Ares Genetics GmbH and QIAGEN GmbH (incorporated by reference to Exhibit 10.40.2 to the Registrant's Form S-4/A filed on December 20, 2019).
10.36	Technology Evaluation Agreement, dated as of September 13, 2019, between Ares Genetics and [***](incorporated by reference to Exhibit 10.41 to the Registrant's Form S-4/A filed on December 20, 2019).

Exhibit Number	Description
10.37	Amendment and Restatement Agreement in relation to the Finance Contract, dated December 12, 2016, dated as of May 20, 2019, between Curetis GmbH, Curetis N.V., Curetis USA INC., Ares Genetics GmbH and European Investment Bank (incorporated by reference to Exhibit 10.42 to the Registrant's Form S-4/A filed on December 20, 2019).
10.38 !	Executive Employment Agreement by and between the Company and Oliver Schacht, dated as of October 29, 2020. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on November 2, 2020).
10.39 !	2020 Stock Options Plan, dated September 30, 2020 (incorporated by reference to Exhibit 10.3 to the Registrants Quarterly Report on Form 10-Q filed on November 16, 2020)
10.40 !	Form of Director Grant to the 2020 Stock Options Plan (incorporated by reference to Exhibit 10.4 to the Registrants Quarterly Report on Form 10-Q filed on November 16, 2020)
10.41 !	Form of Employee Grant to the 2020 Stock Options Plan (incorporated by reference to Exhibit 10.5 to the Registrants Quarterly Report on Form 10-Q filed on November 16, 2020)
10.42	Lease Agreement, dated as of November 11, 2020, between the Registrant and Key West MD Owner, LLC (the "Landlord") (incorporated by reference to Exhibit 10.6 to the Registrants Quarterly Report on Form 10-Q filed on November 16, 2020)
10.43	Form of Securities Purchase Agreement, dated November 23, 2020, by and between OpGen, Inc. and the purchaser party thereto. for 2020 PIPE (incorporated by reference to Exhibit 10.1 to the Registrants Current Report on Form 8-K, filed on November 24, 2020)
10.44	Placement Agent Agreement, dated November 23, 2020, by and between OpGen, Inc. and Alliance Global Partners (incorporated by reference to Exhibit 10.2 to the Registrants Current Report on Form 8-K, filed on November 24, 2020)
21.1 *	Subsidiaries of the Registrant
23.1 *	Consent of CohnReznick LLP
31.1 *	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2 *	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/ 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1 *	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101 *	Interactive data files pursuant to Rule 405 of Regulation S-T; (i) the Balance Sheets, (ii) the Statements of Operations and Comprehensive Loss, (iii) the Statements of Stockholders' Equity, (iv) Statements of Cash Flows and (v) the Notes to the Financial Statements

* Filed herewith
! Denotes management compensation plan or contract

(c) Not applicable.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

OPGEN, INC.

By: /s/ Oliver Schacht
Oliver Schacht, Ph.D.
Chief Executive Officer

Date: March 29, 2021

By: /s/ Timothy C. Dec
Timothy C. Dec
Chief Financial Officer

Date: March 29, 2021

POWER OF ATTORNEY

We, the undersigned officers and directors of OpGen, Inc., hereby severally constitute and appoint Oliver Schacht and Timothy C. Dec, our true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution in her or him for her or him and in her or his name, place and stead, and in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as she or he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or her or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Oliver Schacht, Ph.D. Oliver Schacht, Ph.D.	Chief Executive Officer and Director (principal executive officer)	March 29, 2021
/s/ Timothy C. Dec Timothy C. Dec	Chief Financial Officer (principal financial officer and principal accounting officer)	March 29, 2021
/s/ Mario Crovetto Mario Crovetto	Director	March 29, 2021
/s/ R. Donald Elsey R. Donald Elsey	Director	March 29, 2021
/s/ Prabha Fernandes Prabha Fernandes	Director	March 29, 2021
/s/ Evan Jones Evan Jones	Director	March 29, 2021
/s/ William Rhodes William Rhodes	Director	March 29, 2021

OPGEN, INC.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
OpGen, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of OpGen, Inc. and subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the years then ended and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred losses from operations since inception and will need additional capital to fund future operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as the Company's auditor since 2014.

Tysons, Virginia
March 29, 2021

OpGen, Inc.
Consolidated Balance Sheets
As of December 31,

	2020	2019
Assets		
Current assets		
Cash and cash equivalents	$ 13,360,463	$ 2,708,223
Accounts receivable, net	653,104	567,811
Inventory, net	1,485,986	473,030
Note receivable	—	2,521,479
Prepaid expenses and other current assets	1,388,090	396,760
Total current assets	**16,887,643**	**6,667,303**
Property and equipment, net	3,259,487	130,759
Finance lease right-of-use assets, net	449,628	958,590
Operating lease right-of-use assets	2,082,300	1,043,537
Goodwill	8,024,729	600,814
Intangible assets, net	16,580,963	817,550
Strategic inventory	1,686,342	—
Other noncurrent assets	779,953	203,271
Total assets	**$ 49,751,045**	**$ 10,421,824**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,868,666	$ 1,056,035
Accrued compensation and benefits	2,126,511	855,994
Accrued liabilities	1,437,141	1,046,661
Deferred revenue	9,808	9,808
Short-term notes payable	699,000	373,599
Short-term finance lease liabilities	266,470	579,030
Short-term operating lease liabilities	964,434	1,017,414
Total current liabilities	**7,372,030**	**4,938,541**
Note payable	19,378,935	329,456
Derivative liabilities	112,852	—
Long-term finance lease liabilities	46,794	313,263
Long-term operating lease liabilities	1,492,544	547,225
Other long-term liabilities	156,635	—
Total liabilities	**28,559,790**	**6,128,485**
Commitments and Contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; none issued and outstanding at December 31, 2020 and 2019, respectively	—	—
Common stock, $0.01 par value; 50,000,000 shares authorized; 25,085,534 and 5,582,280 shares issued and outstanding at December 31, 2020 and 2019, respectively	250,855	55,823
Additional paid-in capital	219,129,045	178,779,814
Accumulated deficit	(200,735,827)	(174,524,983)
Accumulated other comprehensive income (loss)	2,547,182	(17,315)
Total stockholders' equity	**21,191,255**	**4,293,339**
Total liabilities and stockholders' equity	**$ 49,751,045**	**$ 10,421,824**

See accompanying notes to consolidated financial statements.

OpGen, Inc.
Consolidated Statements of Operations and Comprehensive Loss
For The Years Ended December 31,

	2020	2019
Revenue		
Product sales	$ 2,704,364	$ 2,168,179
Laboratory services	167,736	5,435
Collaboration revenue	1,342,341	1,325,000
Total revenue	**4,214,441**	**3,498,614**
Operating expenses		
Cost of products sold	3,360,280	911,565
Cost of services	488,211	720,156
Research and development, net	9,964,720	5,121,168
General and administrative	8,801,661	6,252,442
Sales and marketing	3,094,092	1,464,721
Transaction costs	471,522	779,048
Impairment of right-of-use asset	101,838	520,759
Impairment of intangible assets	750,596	—
Gain on sale of equipment	(100,000)	—
Total operating expenses	**26,932,920**	**15,769,859**
Operating loss	**(22,718,479)**	**(12,271,245)**
Other (expense) income		
Gain on extinguishment of debt	884,970	—
Interest and other income, net	105,627	9,859
Interest expense	(3,399,384)	(187,549)
Foreign currency transaction (losses)/gains	(1,468,855)	2,410
Change in fair value of derivative financial instruments	517,680	67
Total other expense	**(3,359,962)**	**(175,213)**
Loss before income taxes	**(26,078,441)**	**(12,446,458)**
Provision for income taxes	132,403	—
Net loss	**$ (26,210,844)**	**$ (12,446,458)**
Net loss per common share - basic and diluted	**$ (1.66)**	**$ (7.70)**
Weighted average shares outstanding - basic and diluted	15,800,781	1,616,939
Net loss	$ (26,210,844)	$ (12,446,458)
Other comprehensive income (loss) - foreign currency translation	2,564,497	(4,222)
Comprehensive loss	**$ (23,646,347)**	**$ (12,450,680)**

See accompanying notes to consolidated financial statements.

OpGen, Inc.
Consolidated Statements of Stockholders' Equity
For the Years Ended December 31,

	Common Stock		Preferred Stock		Additional	Accumulated Other		
	Number of Shares	Amount	Number of Shares	Amount	Paid-in Capital	Comprehensive Income (Loss)	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	5,150,000	51,500	—	—	13,010,908	—	—	13,062,408
Issuance of RSUs	12	—	—	—	—	—	—	—
Stock compensation expense	—	—	—	—	372,870	—	—	372,870
Stock cancellation	(18)	—	—	—	—	—	—	—
Foreign currency translation	—	—	—	—	—	(4,222)	—	(4,222)
Net loss	—	—	—	—	—	—	(12,446,458)	(12,446,458)
Balances at December 31, 2019	**5,582,280**	**55,823**	**—**	**—**	**178,779,814**	**(17,315)**	**(174,524,983)**	**4,293,339**
Offering of common stock and warrants, net of issuance costs	4,842,615	48,426	—	—	9,240,703	—	—	9,289,129
At the market offering, net of offering costs	7,521,610	75,216	—	—	15,746,706	—	—	15,821,922
Warrant exercises	4,341,000	43,410	—	—	8,638,590	—	—	8,682,000
Issuance of RSUs	5,916	59	—	—	(59)	—	—	—
Stock compensation expense	—	—	—	—	316,086	—	—	316,086
Shares issued to settle convertible notes	763,905	7,639	—	—	1,443,158	—	—	1,450,797
Shares issued in business combination	2,028,208	20,282	—	—	4,827,135	—	—	4,847,417
Value of equity awards assumed in business combination	—	—	—	—	136,912	—	—	136,912
Foreign currency translation	—	—	—	—	—	2,564,497	—	2,564,497
Net loss	—	—	—	—	—	—	(26,210,844)	(26,210,844)
Balances at December 31, 2020	**25,085,534**	**$ 250,855**	**—**	**—**	**$ 219,129,045**	**$ 2,547,182**	**$ (200,735,827)**	**$ 21,191,255**

See accompanying notes to consolidated financial statements.

OpGen, Inc.
Consolidated Statements of Cash Flows
For the Years Ended December 31,

	2020	2019
Cash flows from operating activities		
Net loss	$ (26,210,844)	$ (12,446,458)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	2,334,739	921,379
Noncash interest expense	2,632,241	13,158
Noncash interest income	(87,233)	(21,479)
Stock compensation expense	316,086	372,870
(Gain) loss on sale of equipment	(100,000)	9,904
Gain on extinguishment of debt	(884,970)	—
Change in fair value of warrant liability	(517,680)	(67)
Impairment of right-of-use asset	101,838	520,759
Impairment of intangible assets	750,596	—
Changes in operating assets and liabilities, net of acquisition		
Accounts receivable	438,284	(195,019)
Inventory	(410,341)	70,286
Other assets	1,152,200	577,193
Accounts payable	(481,453)	(503,516)
Accrued compensation and other liabilities	(1,559,881)	(818,433)
Deferred revenue	(870,114)	(6,016)
Net cash used in operating activities	**(23,396,532)**	**(11,505,439)**
Cash flows from investing activities		
Acquisition of business net of cash acquired	1,266,849	—
Note receivable	(2,200,000)	(2,500,000)
Purchases of property and equipment	(130,354)	(31,826)
Proceeds from sale of equipment	—	29,250
Net cash used in investing activities	**(1,063,505)**	**(2,502,576)**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	15,821,922	4,782,509
Proceeds from issuance of units and exercises of pre-funded warrants, net of selling costs	—	8,279,899
Proceeds from issuance of common stock and pre-funded warrants in private placement, net of selling costs	9,289,129	—
Proceeds from the exercise of common warrants	8,682,000	—
Proceeds from debt, net of issuance costs	1,871,308	470,519
Payments on debt	(998,182)	(828,850)
Payments on finance lease obligations	(579,029)	(535,931)
Net cash provided by financing activities	**34,087,148**	**12,168,146**
Effects of exchange rates on cash	1,586,541	(3,735)
Net increase (decrease) in cash, cash equivalents and restricted cash	11,213,652	(1,843,604)
Cash, cash equivalents and restricted cash at beginning of year	2,893,603	4,737,207
Cash, cash equivalents and restricted cash at end of year	**$ 14,107,255**	**$ 2,893,603**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 952,050	$ 187,359
Supplemental disclosures of noncash investing and financing activities		
Right-of-use assets acquired through operating leases	$ 1,008,039	$ —
Right-of-use assets acquired through finance leases	$ —	$ 528,413
Conversion of accounts payable to finance lease	$ —	$ 63,600
Shares issued in business combination	$ 4,847,417	$ —
Shares issued to settle convertible notes	$ 1,450,797	$ —
Note receivable from sale of equipment included in other assets	$ 100,000	$ —

See accompanying notes to consolidated financial statements.

Note 1 - Organization

OpGen, Inc. ("OpGen" or the "Company") was incorporated in Delaware in 2001. On April 1, 2020, OpGen completed its business combination transaction (the "Transaction") with Curetis N.V., a public company with limited liability under the laws of the Netherlands (the "Seller" or "Curetis N.V."), as contemplated by the Implementation Agreement, dated as of September 4, 2019 (the "Implementation Agreement"), by and among the Company, the Seller, and Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and wholly-owned subsidiary of the Company ("Purchaser"). Pursuant to the Implementation Agreement, the Purchaser acquired all of the shares of Curetis GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany ("Curetis GmbH"), and certain other assets and liabilities of the Seller (together, "Curetis") (see Note 4). References in this report to the "Company" include OpGen and its wholly-owned subsidiaries. The Company's headquarters are in Gaithersburg, Maryland, and its principal operations are in Gaithersburg, Maryland; Holzgerlingen and Bodelshausen, Germany; and Vienna, Austria. The Company operates in one business segment.

OpGen Overview

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

On October 13, 2020, the Company announced its decision to discontinue the QuickFISH and PNA FISH product portfolio in its entirety by June 30, 2021 and certain licensing agreements with Life Technologies, a subsidiary of ThermoFisher, have therefore been terminated accordingly as of such date (see note 10). The Company's FISH customers and distribution partners have been informed accordingly and last orders have been received and processed during the last few months. The discontinuance of these product lines did not qualify for discontinued operations reporting.

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

Note 2 - Going Concern and Management's Plans

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

- On November 23, 2020, the Company entered into a Purchase Agreement with an institutional investor (the "Holder"), pursuant to which the Company issued to the Investor, securities of the Company, including warrants (the "Existing Warrants") to purchase up to 4,842,615 shares of Common Stock, of the Company (the "Warrant Shares"). The Existing Warrants were exercisable six months after their issuance at an exercise price of $1.94 per share and expire on the fifth and a half year anniversary of the date of issuance. On March 9, 2021, the Company entered into a Warrant Exercise Agreement (the "Exercise Agreement") with the Holder. Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of the remaining 4,842,615 outstanding Existing Warrants for cash, pursuant to the terms of and subject to beneficial ownership limitations contained in the Existing Warrants, the Company agreed to issue to the Holder, new warrants (the "New Warrants") to purchase 0.65 shares of Common Stock for each share of Common Stock issued upon such exercise of the remaining 4,842,615 outstanding Existing Warrants pursuant to the Exercise Agreement or an aggregate of 3,147,700 New Warrants. The terms of the New Warrants will be substantially similar to those of the Existing Warrants, except that the New Warrants will have an exercise price of $3.56. The New Warrants will be immediately exercisable and will expire five years from the date of the Exercise Agreement. The Holder will pay an aggregate of $255,751 to the Company for the purchase of the New Warrants. The Company received aggregate gross proceeds before expenses of approximately $9.65 million from the exercise of all of the remaining 4,842,615 outstanding Existing Warrants held by the Holder and the payment of the purchase price for the New Warrants (together, the "2021 Warrant Exercise".

- On February 11, 2021, the Company closed a private placement (the "February 2021 Offering") with a single U.S.-based, healthcare-focused institutional investor for the purchase of (i) 2,784,184 shares of common stock and (ii) 5,549,149 pre-funded

warrants, with each pre-funded warrant exercisable for one share of common stock. The Company also issued to the investor, in a concurrent private placement, unregistered common share purchase warrants to purchase 4,166,666 shares of the Company's common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of $3.00, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of $2.99. The pre-funded warrants are immediately exercisable, at an exercise price of $0.01, and may be exercised at any time until all of the pre-funded warrants are exercised in full. The common warrants will have an exercise price of $3.55 per share, will be exercisable commencing on the six-month anniversary of the date of issuance, and will expire five and one half (5.5) years from the date of issuance. The February 2021 Offering raised aggregate net proceeds of $23.4 million, and gross proceeds of $25.0 million.

- On November 25, 2020, the Company closed a private placement (the "2020 PIPE") with one healthcare-focused U.S. institutional investor for the purchase of (i) 2,245,400 shares of common stock (ii) 4,842,615 warrants to purchase shares of common stock and (iii) 2,597,215 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of $2.065, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of $2.055. The common warrants have an exercise price of $1.94 per share, and are exercisable commencing on the six month anniversary of the date of issuance, and will expire five and one half (5.5) years from the date of issuance. The 2020 PIPE raised aggregate net proceeds of $9.3 million, and gross proceeds of $10.0 million. As of December 31, 2020, all 2,597,215 pre-funded warrants issued in the 2020 PIPE have been exercised.

- On February 11, 2020, the Company entered into an At the Market Common Offering (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), which we amended and restated on November 13, 2020 to add BTIG, LLC ("BTIG"), pursuant to which the Company may offer and sell from time to time in an "at the market offering", at its option, up to an aggregate of $22.1 million of shares of the Company's common stock through the sales agents, (the "2020 ATM Offering"). During the year ended December 31, 2020, the Company sold 7,521,610 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately $15.8 million, and gross proceeds of $16.7 million.
- 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 December 31, 2019, all 2,109,830 pre-funded warrants issued in the October 2019 Public Offering had been exercised. During the year ended December 31, 2020, 4,341,000 common warrants issued in the October 2019 Public Offering were exercised for net proceeds of approximately $8.7 million. As of December 31, 2020, 359,000 common warrants issued in the October 2019 Public Offering remain outstanding.
- 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. There can be no assurance that the Company will be able to complete any such transaction on acceptable terms or otherwise. The Company believes that current cash including the net proceeds from the February 2021 Offering and 2021 Warrant Exercise will be sufficient to fund operations into the second quarter of 2022. 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 second quarter of 2022, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances, the Company would be compelled to immediately reduce general and administrative expenses and delay research and development projects, pause or abort clinical trials including the purchase of scientific equipment and supplies, until it is able to obtain sufficient financing. If such sufficient financing is not received on a timely basis, the Company would then need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

Note 3 - Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The consolidated financial statements consolidate the operations of all controlled subsidiaries; all intercompany activity is eliminated.

Foreign Currency

The Company has subsidiaries located in Holzgerlingen, Germany; Vienna, Austria; and Copenhagen, Denmark, each of which use currencies other than the U.S. dollar as their functional currency. As a result, all assets and liabilities are translated into U.S. dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at the average exchange rates prevailing during the reporting period. Translation adjustments are reported in accumulated other comprehensive income loss), a component of stockholders' equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive income (loss) at December 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 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, determining the fair value of assets acquired and liabilities assumed in business combinations, the estimated useful lives of long-lived assets, and the recoverability of long-lived assets. Actual results could differ from those estimates.

Fair value of financial instruments

Financial instruments classified as current assets and liabilities (including cash and cash 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.

For additional fair value disclosures, see Note 6.

Cash and cash equivalents and restricted cash

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. The Company has cash and cash equivalents deposited in financial institutions in which the balances occasionally exceed the Federal Deposit Insurance Corporation ("FDIC") insured limit of $250,000. The Company has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk.

At December 31, 2020 and 2019, the Company had funds totaling $746,792 and $185,380, respectively, which are required as collateral for letters of credit benefiting its landlords and for credit card processors. These funds are reflected in other noncurrent assets on the accompanying 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 consolidated statements of cash flows:

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 13,360,463	$ 2,708,223
Restricted cash	746,792	185,380
Total cash, cash equivalents and restricted cash in the consolidated statements of cash flows	$ 14,107,255	$ 2,893,603

Accounts receivable

The Company's accounts receivable result from revenues earned but not 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 December 31, 2020 and 2019, respectively.

At December 31, 2020, the Company had accounts receivable from one customer which individually represented 20% of total accounts receivable. At December 31, 2019, the Company had accounts receivable from one customer which individually represented 44% of total accounts receivable. For the year ended December 31, 2020, revenue earned from one customer represented 21% of total revenues. For the year ended December 31, 2019, revenue earned from one customer represented 38% 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:

	December 31,	
	2020	2019
Raw materials and supplies	$ 773,021	$ 315,542
Work-in-process	87,159	35,080
Finished goods	2,312,148	122,408
Total	$ 3,172,328	$ 473,030

Inventory includes Unyvero instrument systems, Unyvero cartridges, reagents and components for Unyvero, Acuitas, QuickFISH and PNA FISH products, Curetis SARS CoV-2 test kits, and reagents and supplies used for the Company's laboratory services. Inventory reserves for obsolescence and expirations were $288,378 and $92,454 at December 31, 2020 and 2019, respectively.

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

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

Long-lived assets

Property and equipment

Property and equipment is stated at cost and depreciated on a straight-line basis over the estimated useful lives of the related assets. The estimated service lives range from three to ten years. Depreciation expense was $1,152,954 and $186,244 for the years ended December 31, 2020 and 2019, respectively. Property and equipment consisted of the following at December 31, 2020 and 2019:

	December 31,	
	2020	2019
Laboratory and manufacturing equipment	$ 6,317,340	$ 3,310,290
Office furniture and equipment	1,259,838	631,774
Computers and network equipment	1,692,154	1,469,534
Leasehold improvements	752,493	745,800
	10,021,825	6,157,398
Less accumulated depreciation	(6,762,338)	(6,026,639)
Property and equipment, net	$ 3,259,487	$ 130,759

Property and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which we can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. During the years ended December 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 effective interest method of recognition. The Company has made certain accounting policy elections whereby the Company (i) does not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12 months or less) and (ii) combines lease and non-lease elements of our operating leases.

ROU Assets

ROU assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which the Company can identify assets. If such assets are considered to be impaired, impairment is recognized as the amount by which the carrying amount of assets exceeds the fair value of the assets. 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 year ended December 31, 2019. The Company also recorded an additional impairment charge of $101,838 during the year ended December 31, 2020 related to its ROU asset associated with its Woburn, Massachusetts office lease.

Intangible assets and goodwill

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

Finite-lived and indefinite-lived intangible assets

Intangible assets include trademarks, developed technology, In-Process Research & Development, software and customer relationships and consisted of the following as of December 31, 2020 and 2019:

			December 31, 2020				December 31, 2019	
	Subsidiary	Cost	Accumulated Amortization	Impairment	Effect of foreign exchange rates	Net Balance	Accumulated Amortization	Net Balance
Trademarks and tradenames	AdvanDx	$ 461,000	$ (217,413)	$ (243,587)	$ —	$ —	$ (205,887)	$ 255,113
Developed technology	AdvanDx	458,000	(308,526)	(149,474)	—	—	(292,170)	165,830
Customer relationships	AdvanDx	1,094,000	(736,465)	(357,535)	—	—	(697,393)	396,607
Trademarks and tradenames	Curetis	1,768,000	(147,161)	—	194,119	1,814,958	—	—
Distributor relationships	Curetis	2,362,000	(131,070)	—	259,336	2,490,266	—	—
A50 - Developed technology	Curetis	349,000	(41,504)	—	38,319	345,815	—	—
Ares - Developed technology	Curetis	5,333,000	(317,060)	—	585,536	5,601,476	—	—
A30 - In-Process Research & Development	Curetis	5,706,000	—	—	622,448	6,328,448	—	—
		$ 17,531,000	$ (1,899,199)	$ (750,596)	$ 1,699,758	$ 16,580,963	$ (1,195,450)	$ 817,550

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

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

Acquired IPR&D represents the fair value assigned to those research and development projects that were acquired in a business combination for which the related products have not received regulatory approval and have no alternative future use. IPR&D is capitalized at its fair value as an indefinite-lived intangible asset, and any development costs incurred after the acquisition are expensed as incurred. Upon achieving regulatory approval or commercial viability for the related product, the indefinite-lived intangible asset is accounted for as a finite-lived asset and is amortized on a straight-line basis over the estimated useful life. If the project is not completed or is terminated or abandoned, the Company may have an impairment related to the IPR&D which is charged to expense. Indefinite-

lived intangible assets are tested for impairment annually and whenever events or changes in circumstances indicate that the carrying amount may be impaired. Impairment is calculated as the excess of the asset's carrying value over its fair value.

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 $672,823 and $267,816 for the years ended December 31, 2020 and 2019, respectively. Expected future amortization of intangible assets is as follows:

Year Ending December 31,		
2021	$	849,055
2022		849,055
2023		849,055
2024		849,055
2025		849,055
Thereafter		6,007,240
Total	$	10,252,515

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 year ended December 31, 2020, events and circumstances indicated the Company's FISH intangible assets might be impaired. These circumstances included decreased product sales related to the COVID-19 pandemic and the loss of significant customers. Management's updated estimate of undiscounted cash flows indicated that such carrying amounts were no longer expected to be recovered and that the FISH intangible assets were impaired. The Company's analysis determined that the fair value of the assets was $0 and the Company recorded an impairment loss of $750,596.

Goodwill

Goodwill represents the excess of the purchase price paid when the Company acquired AdvanDx, Inc. in July 2015 and Curetis in April 2020, over the fair values of the acquired tangible or intangible assets and assumed liabilities. Goodwill is not tax deductible in any relevant jurisdictions. The Company's goodwill balance as of December 31, 2020 and 2019 was $8,024,729 and $600,814, respectively.

The changes in the carrying amount of goodwill as of December 31, 2020, and since December 31, 2019, were as follows:

Balance as of December 31, 2019	$	600,814
Acquisition of Curetis		6,688,652
Effect of foreign exchange rates		735,263
Balance as of December 31, 2020	$	8,024,729

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 years ended December 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, Unyvero Application cartridges, Unyvero Systems, SARS CoV-2 tests, 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.

Government grant agreements and research incentives

From time to time, the Company may enter into arrangements with governmental entities for the purposes of obtaining funding for research and development activities. The Company recognizes funding from grants and research incentives received from Austrian government agencies in the consolidated statements of operations and comprehensive loss in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants or incentives were provided have been met. For grants under funding agreements and for proceeds under research incentive programs, the Company recognizes grant and incentive income in an amount equal to the estimated qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage. The Company classifies government grants received under these arrangements as a reduction to the related research and development expense incurred. The Company analyzes each arrangement on a case-by-case basis. For the year ended December 31, 2020, the Company recognized $495,153 as a reduction of research and development expense related to government grant arrangements. There were no grant proceeds recognized for the year ended December 31, 2019. As of December 31, 2020, the Company had earned but not yet received $413,530 related to these agreements and incentives included in prepaid expenses and other current assets.

Research and development costs, net

Research and development costs are expensed as incurred. Research and development costs primarily consist of salaries and related expenses for personnel, other resources, laboratory supplies, 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. A discussion of management's methodology for developing each of the assumptions used in the Black-Scholes model is as follows:

Fair value of common stock

For periods prior to the Company's IPO in May 2015, given the lack of an active public market for the common stock, the Company's board of directors determined the fair value of the common stock. In the absence of a public market, and as an emerging company with no significant revenues, the Company believed that it was appropriate to consider a range of factors to determine the fair market value of the common stock at each grant date. The factors included: (1) the achievement of clinical and operational milestones by the Company; (2) the status of strategic relationships with collaborators; (3) the significant risks associated with the Company's stage of development; (4) capital market conditions for life science and medical diagnostic companies, particularly similarly situated, privately held, early stage companies; (5) the Company's available cash, financial condition and results of operations; (6) the most recent sales of the Company's preferred stock; and (7) the preferential rights of the outstanding preferred stock. Since the IPO, the Company uses the quoted market price of its common stock as its fair value.

Expected volatility

Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. Until a significant trading history for its common stock develops, the Company has identified several public entities of similar size, complexity and stage of development; accordingly, historical volatility has been calculated using the volatility of this peer group.

Expected dividend yield

The Company has never declared or paid dividends on its common stock and has no plans to do so in the foreseeable future.

Risk-free interest rate

This is the U.S. Treasury rate for the day of each option grant during the year, having a term that most closely resembles the expected term of the option.

Expected term

This is the period of time that the options granted are expected to remain unexercised. Options granted have a maximum term of 10 years. The Company estimates the expected term of the option to be 6.25 years for options with a standard four-year vesting period, using the simplified method. Over time, management will track actual terms of the options and adjust their estimate accordingly so that estimates will approximate actual behavior for similar options.

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

The Company also has foreign NOL carryforwards of $160,540,528 at December 31, 2020 from their foreign subsidiaries. $138,576,755 of those foreign NOL carryforwards are from the Company's operations in Germany. Despite the NOL carryforwards, the Company may have a current and future tax liability due to the nuances of German tax law around the use of NOL's within a consolidated group. There is no assurance that 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 7.5 million shares and 5.1 million shares as of December 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 ROU 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 consolidated financial statements.

Recently issued accounting standards

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes,* which removes certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period, the recognition of deferred tax liabilities for outside basis differences and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The Company will adopt ASU 2019-12 during the year beginning January 1, 2021 and is currently evaluating the impact of the new guidance on its consolidated financial statements.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference* Rate *Reform on Financial Reporting*. The new guidance under ASU 2020-04 provides optional expedients and exceptions for applying U.S. GAAP to contracts, hedging relationships and other transactions affected by reference rate reform if certain criteria are met. The amendments apply only to contracts and hedging relationships that reference LIBOR or another reference rate expected to be discontinued due to reference rate reform. These amendments are effective immediately and may be applied prospectively to contract modifications made and hedging relationships entered into or evaluated on or before December 31, 2022. The Company is in the process of assessing the impact, if any, that ASU No. 2020-04 is expected to have on the Company's results of operations, financial condition and/or financial statement disclosures.

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

Note 4 – Business Combination

On April 1, 2020, the Company completed its business combination transaction with Curetis N.V., a public company with limited liability under the laws of the Netherlands, as contemplated by the Implementation Agreement, dated as of September 4, 2019, by and among the Company, the Seller, and Crystal GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany and wholly-owned subsidiary of the Company. Pursuant to the Implementation Agreement, the Purchaser acquired all of the shares of Curetis GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany, and certain other assets and liabilities of the Seller, as further described below, and paid, as the sole consideration, 2,028,208 shares of the Company's common stock, to the Seller, and reserved for future issuance (a) 134,356 shares of common stock, in connection with its

assumption of the Seller's 2016 Stock Option Plan, as amended (the "Seller Stock Option Plan"), and the outstanding awards thereunder, and (b) 500,000 shares of common stock to be issued upon the conversion, if any, of certain convertible notes issued by the Seller.

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

Curetis' assets and liabilities were measured and recognized at their fair values as of the transaction date and combined with the assets, liabilities and results of operations of OpGen after the consummation of the business combination. The allocation of the purchase price to acquired assets and assumed liabilities based on their underlying fair values requires the extensive use of significant estimates and management's judgment. The allocation of the purchase price is preliminary at this time, and will remain as such until management completes valuations and other studies in order to finalize the valuation of the net assets acquired. These provisional estimates will be adjusted upon the availability of further information regarding events or circumstances which exist at the acquisition date and such adjustments may be significant.

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

Purchase Price

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

(i) The price per share of OpGen's common stock was based on the closing price as reported on the Nasdaq Capital Market on April 1, 2020.
(ii) The fair value of the stock options assumed was determined using the Black-Scholes option pricing model.
(iii) To derive the fair value of the convertible notes, the Company estimated the fair value of the convertible notes with and without the derivative liability using a scenario analysis and Monte Carlo simulation.
(iv) The fair value of the EIB debt is determined using a discounted cash flow analysis with current applicable rates for similar instruments.

Net Assets Acquired

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

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

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

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

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

The following unaudited pro forma financial information summarizes the results of operations for the periods indicated as if the Transaction had been completed as of January 1, 2019. Pro forma information primarily reflects adjustments relating to the amortization of intangibles acquired and elimination of interest expense due under the interim facility. The pro forma amounts do not purport to be indicative of the results that would have actually been obtained if the acquisition occurred as of January 1, 2019 or that may be obtained in the future.

Unaudited pro forma results	**Years ended December 31,**	
	2020	**2019**
Revenues	$ 5,239,192	$ 6,053,766
Net loss	(29,319,303)	(38,435,605)
Net loss per share	(1.86)	(23.77)

Note 5 - Revenue from Contracts with Customers

Disaggregated Revenue

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

	Years Ended December,	
	2020	2019
Product sales	$ 2,704,364	$ 2,168,179
Laboratory services	167,736	5,435
Collaboration revenue	1,342,341	1,325,000
Total revenue	$ 4,214,441	$ 3,498,614

Revenues by geography are as follows:

	Years Ended December,	
	2020	2019
Domestic	$ 1,917,367	$ 3,322,615
International	2,297,074	175,999
Total revenue	$ 4,214,441	$ 3,498,614

Deferred revenue

Changes in deferred revenue for the period were as follows:

Balance at December 31, 2019	$ 9,808
Acquired deferrals from Curetis	829,275
Revenue recognized in the current period from the amounts in the beginning balance	—
Revenue recognized in the current period from the amounts acquired from Curetis	(870,114)
Effect of foreign exchange rates	40,839
Balance at December 31, 2020	$ 9,808

Contract assets

The Company had approximately $18,000 of contract assets as of December 31, 2020, which are generated when contractual billing schedules differ from revenue recognition timing. The Company had no contract assets as of December 31, 2019. 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 December 31, 2020 and 2019.

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 year ended December 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.

In June 2019, Curetis drew down a third tranche of EUR 5.0 million from the European Investment Bank ("EIB"). In return for EIB waiving the condition precedent of a minimum cumulative equity capital raised of EUR 15 million to disburse this EUR 5.0 million tranche, the parties agreed on a 2.1% participation percentage interest ("PPI"). Upon maturity of the tranche, EIB would be entitled to an additional payment that is equity-linked and equivalent to 2.1% of the then total valuation of Curetis N.V. On July 9, 2020, the Company negotiated an amendment to the EIB debt financing facility. As part of the amendment, the parties adjusted the PPI percentage applicable to the previous EIB tranche of EUR 5.0 million which was funded in June 2019 from its original 2.1% PPI in Curetis N.V.'s equity value upon maturity to a new 0.3% PPI in OpGen's equity value upon maturity between mid-2024 and mid-2025. This right constitutes an embedded derivative, which is separated and measured at fair value with changes being accounted for through profit or loss. The Company determines the fair value of the derivative using a Monte Carlo simulation model. Using this model, level 3 unobservable inputs include estimated discount rates and estimated risk-free interest rates.

The Company's convertible debt with YA II PN, LTD (see Note 7) included a conversion feature which constitutes an embedded derivative, which is separated and measured at fair value with subsequent changes being accounted for through profit or loss. The Company determines the fair value of the derivative using a Monte Carlo simulation model. Using this model, level 3 unobservable inputs include estimated volatility rates and estimated risk-free interest rates.

The fair value of level 3 liabilities measured at fair value on a recurring basis for the year ended December 31, 2020 was as follows:

Description	Balance at December 31, 2019	Acquired from Curetis	Change in Fair Value	Effect of Foreign Exchange Rates	Balance at December 31, 2020
Participation percentage interest liability	$ —	$ 173,373	$ (75,222)	$ 14,701	$ 112,852
Embedded conversion option liability	—	442,458	(442,458)	—	—
Total revenue	$ —	$ 615,831	$ (517,680)	$ 14,701	$ 112,852

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

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

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

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

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

The Company measures its long-lived assets, including property and equipment and intangible assets (including goodwill), at fair value on a non-recurring basis when a triggering event requires such evaluation. During the year ended December 31, 2020, the Company recorded impairment expense of $750,596 related to its intangible assets and $101,838 related to its ROU assets (see Note 3).

Note 7 – Debt

The following table summarizes the Company's long-term debt and short-term borrowings as December 31, 2020 and 2019:

	December 31, 2020	2019
EIB	$ 25,936,928	$ —
PPP	259,353	—
MGHIF	331,904	662,789
Insurance financings	107,742	40,266
Total debt obligations	26,635,927	703,055
Unamortized debt discount	(6,557,992)	—
Carrying value of debt	20,077,935	703,055
Less current portion	(699,000)	(373,599)
Long-term debt	$ 19,378,935	$ 329,456

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 OpGen's assets excluding the assets of Curetis GmbH, Curetis USA, and Ares Genetics.

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

On June 11, 2018, the Company executed an Allonge to the MGHIF Note. The Allonge provided that accrued and unpaid interest of $285,512 due as of July 14, 2018, the original maturity date, be paid through the issuance of shares of OpGen's common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the MGHIF Note to six semi-annual payments of $166,667 plus accrued and unpaid interest beginning on January 2, 2019 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. Subsequent to December 31, 2020 the Company paid the final principal and accrued interest payment to MGHIF and the lien on the Company's IP was released.

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.

Yorkville Convertible Notes

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

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

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

EIB Loan Facility

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

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

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

In June 2019, Curetis drew down a third tranche of €5 million from the EIB. In line with all prior tranches, the majority of interest is also deferred into the bullet repayment structure upon maturity. In return for EIB waiving the condition precedent of a minimum cumulative equity capital raised of €15 million to disburse this €5 million tranche, the parties agreed on a 2.1% PPI. Upon maturity of the tranche, not before approximately mid-2024 (and no later than mid-2025) EIB would be entitled to an additional payment that is equity-linked and equivalent to 2.1% of the then total valuation of Curetis N.V. As part of the amendment between the Company and EIB on July 9, 2020, the parties adjusted the PPI percentage applicable to the previous EIB tranche of €5 million which was funded in June 2019 from its original 2.1% PPI in Curetis N.V.'s equity value upon maturity to a new 0.3% PPI in OpGen's equity value upon maturity. This right constitutes an embedded derivative, which is separated and measured at fair value with changes being accounted for through income or loss.

On July 9, 2020, the Company negotiated an amendment to the EIB debt financing facility for an additional €5 million tranche. This additional tranche is earmarked to co-fund R&D programs across several of the platforms and the entire product portfolio of OpGen subsidiaries Curetis and Ares Genetics as it relates to COVID-19.

This additional tranche, which can be drawn down, subject to certain conditions, at Curetis' option within nine months from the Effective Date of the amendment, will also have a five-year term to maturity from such draw-down date and will accrue interest at a rate of 10% per annum. All interest payments during that five-year term are compounded and become payable only upon maturity of the principal amount of this tranche. The EIB tranche disbursement will become available subject to typical conditions precedent including a pledge of certain Curetis IP rights as security to EIB. All other terms and conditions of the EIB financing contract with Curetis remain unchanged.

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

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

As of December 31, 2020, the outstanding borrowings under all tranches were €21,136,768 (approximately USD $25,936,000), including deferred interest payable at maturity of €3,136,768 (approximately USD $3,849,000).

PPP

On April 22, 2020, the Company entered into a Term Note (the "Company Note") with Silicon Valley Bank (the "Bank") pursuant to the Paycheck Protection Program (the "PPP") of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") administered by the U.S. Small Business Administration. The Company's wholly-owned subsidiary, Curetis USA Inc. ("Curetis USA" and collectively with the Company, the "Borrowers"), also entered into a Term Note with the Bank (the "Subsidiary Note," and collectively

with the Company Note, the "Notes"). The Notes are dated April 22, 2020. The principal amount of the Company Note 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 amounts due under the Notes, in an amount equal to the sum of qualified expenses under the PPP, which include payroll costs, rent obligations, and covered utility payments incurred during the twenty-four weeks following disbursement under the Notes. The entire proceeds were used under the Notes for such qualifying expenses. OpGen filed for forgiveness of the Subsidiary note during November 2020. The Company Note was forgiven in November of 2020.

Subject to any forgiveness under the PPP, the Subsidiary Note matures two years following the date of issuance and includes a period for the first ten months during which time required payments of interest and principal are deferred. Beginning on the eleventh month following the date of issuance, the Company is required to make 14 monthly payments of principal and interest. The Subsidiary Note may be prepaid at any time prior to maturity with no prepayment penalties. The Subsidiary Note provides for customary events of default, including, among others, those relating to breaches of their obligations under the Subsidiary Note, including a failure to make payments, any bankruptcy or similar proceedings involving the Borrower, and certain material effects on the Borrowers' ability to repay the Subsidiary Note. The Borrower did not provide any collateral or guarantees for the Subsidiary Note.

Total interest expense (including accretion of fair value to face value and amortization of debt discounts and financing fees) on all debt instruments was $3,399,984 and $187,549 for the years ended December 31, 2020 and 2019, respectively.

Note 8 - Stockholders' Equity

As of December 31, 2020, the Company has 50,000,000 shares of authorized common shares and 25,085,534 shares issued and outstanding, and 10,000,000 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 December 31, 2020, the 2,109,830 pre-funded warrants issued in the October 2019 Public Offering have been exercised. Additionally, during the year ended December 31, 2020, 4,341,000 common warrants were exercised raising net proceeds of approximately $8.7 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, which we amended and restated on November 13, 2020 to add BTIG, LLC pursuant to which the Company may offer and sell from time to time in an "at the market offering," at its option, up to an aggregate of $22.1 million of shares of the Company's common stock through the sales agents. During the year ended December 31, 2020, the Company sold 7,521,610 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately $15.8 million, and gross proceeds of $16.7 million. As of December 31, 2020, remaining availability under the ATM Agreement is $5.4 million.

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

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

Stock options

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

In April 2015, the Board 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 IPO. Following the effectiveness of the 2015 Plan, no further grants have been made under the 2008 Plan. The 2015 Plan provides for the granting of incentive stock options within the meaning of Section 422 of the Code to employees and the granting of non-qualified stock options to employees, non-employee directors and consultants. The 2015 Plan also provides for the grants of restricted stock, restricted stock units, stock appreciation rights, dividend equivalents and stock payments to employees, non-employee directors and consultants.

Under the 2015 Plan, the aggregate number of shares of the common stock authorized for issuance may not exceed (1) 2,710 plus (2) the sum of the number of shares subject to outstanding awards under the 2008 Plan as of the 2015 Plan's effective date, that are subsequently forfeited or terminated for any reason before being exercised or settled, plus (3) the number of shares subject to vesting restrictions under the 2008 Plan as of the 2015 Plan's effective date that are subsequently forfeited. In addition, the number of shares that have been authorized for issuance under the 2015 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2016 and ending on (and including) January 1, 2025, in an amount equal to the lesser of (1) 4% of the outstanding shares of common stock on the last day of the immediately preceding fiscal year, or (2) another lesser amount determined by the Company's Board of Directors. 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 December 31, 2020, 6,025 shares remain available for issuance under the 2015 Plan.

On September 30, 2020, the Company held its 2020 Annual Meeting of Stockholders (the "2020 Annual Meeting"). At the 2020 Annual Meeting, stockholders of the Company voted to approve, among other things, a plan under which stock options to purchase an aggregate of 1.3 million shares of the Company's common stock would be made by the Board of Directors of the Company outside of the stockholder-approved equity incentive plan to its executive officers and non-employee directors (the "2020 Stock Options Plan"). The 2020 Stock Options Plan and the grant made thereunder were approved by the Board of Directors on August 6, 2020, subject to receipt of stockholder approval at the 2020 Annual Meeting. The aggregate number of shares of the Company's common stock authorized for issuance is 1,300,000 shares of common stock and all 1,300,000 million stock options were issued on September 30, 2020. Shares subject to awards granted under the 2020 Stock Options Plan that are forfeited or terminated before being exercised will not be available for re-issuance under the 2020 Stock Options Plan.

Replacement awards

In connection with the business combination with Curetis, the Company issued equity awards to Curetis employees ("2016 Plan"), consisting of stock options ("replacement awards") in exchange for their Curetis equity awards. The replacement awards consisted of 134,371 stock options with a weighted average grant date fair value of $1.68. The terms of these replacement awards are substantially similar to the original Curetis equity awards. The fair value of the replacement awards for services rendered through April 1, 2020, the acquisition date, was recognized as a component of the purchase consideration, with the remaining fair value of the replacement awards related to the post-combination services recorded as stock-based compensation over the remaining vesting period.

For the years ended December 31, 2020 and 2019, the Company recognized stock compensation expense as follows:

	Years Ended December 31,	
	2020	2019
Cost of services	$ 2,927	$ 2,781
Research and development	62,783	74,841
General and administrative	231,010	269,292
Sales and marketing	19,366	25,956
	$ 316,086	$ 372,870

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

As of December 31, 2020, the Company had unrecognized expense related to its stock options of $1.3 million, which will be recognized over a weighted average period of 3.1 years.

A summary of the status of options granted is presented below as of and for the years ended December 31, 2020 and 2019:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2019	10,578	$ 411.60	7.6	$ 522
Granted	—	$ —		
Exercised	—	$ —		
Forfeited	(302)	$ 222.17		
Expired	(622)	$ 269.87		
Outstanding at December 31, 2019	9,654	$ 418.10	8.0	$ —
Granted	1,525,000	$ 2.13		
Exercised	—	$ —		
Assumed in business combination	134,371	$ 48.40		
Forfeited	(3,631)	$ 21.11		
Expired	(872)	$ 473.92		
Outstanding at December 31, 2020	1,664,522	$ 7.99	9.4	$ —
Vested and expected to vest	1,664,522	$ 7.99	9.4	$ —
Exercisable at December 31, 2020	—	$ —	—	$ —

The total fair value of options vested in the years ended December 31, 2020 and 2019 was $549,341 and $375,789, respectively. The fair value of each option grant was estimated at the date of grant using the Black-Scholes option pricing model based on the assumptions below:

	Years Ended December 31,	
	2020	2019
Annual dividend	—	—
Expected life (in years)	5.25 - 6.25	—
Risk free interest rate	0.3%-0.5%	—
Expected volatility	40.9% - 46.6%	—

Restricted stock units

A summary of the status of restricted stock units granted is presented below as of and for the years ended December 31, 2020 and 2019:

	Number of Units	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2019	12	$ 623.20
Granted	17,150	$ 8.77
Vested	(12)	$ 623.20
Forfeited	(2,175)	$ 8.80
Unvested at December 31, 2019	14,975	$ 8.76
Granted	-	$ -
Vested	(5,924)	$ 8.51
Forfeited	(933)	$ 8.84
Unvested at December 31, 2020	8,118	$ 8.93

As of December 31, 2020, there was approximately $49,000 of unrecognized compensation cost related to restricted stock units, which is expected to be recognized over a weighted average period of 1.3 years.

Stock purchase warrants

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

Issuance	Exercise Price	Expiration	Outstanding at December 31, 2020 (1)	Outstanding at December 31, 2019 (1)
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
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	359,000	4,700,000
October 2019	$ 2.60	October 2024	235,000	235,000
November 2020	$ 1.94	May 2026	4,842,615	—
November 2020	$ 2.68	May 2026	242,130	—
			5,848,131	5,111,107

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

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

Note 9 - Income Taxes

The Company’s loss before income taxes was $26.1 million and $12.5 million for the years ended December 31, 2020 and 2019, respectively.
The Company’s provision for income taxes consists of the following for the years ended December 31, 2020 and 2019:

	December 31,	
	2020	2019
Current income tax provision		
Federal	$ —	$ —
State	—	—
Foreign	132,403	—
Total	132,403	$ —
Deferred income tax provision		
Federal	—	—
State	—	—
Foreign	—	—
Total	—	—
Total provision for income taxes	$ 132,403	—

At December 31, 2020 and 2019, the Company had net deferred tax assets of $103,185,302 and $54,359,488, respectively, primarily consisting of NOL carryforwards, research and development ("R&D") credits, and differences between depreciation and amortization recorded for financial statement and tax purposes. The Company's net deferred tax assets at December 31, 2020 and 2019 have been offset by a valuation allowance of $98,874,420 and $54,359,488, respectively. The valuation allowance has been recorded due to the uncertainty of realization of the deferred tax assets. The Company's deferred tax assets and liabilities as of December 31, 2020 and 2019 are as follows:

	December 31,	
	2020	2019
Deferred tax assets:		
NOL carryforward	$ 98,165,790	$ 51,247,762
R&E credit carryforward	2,559,479	2,559,479
Share-based compensation	319,397	325,571
Inventory reserve	—	23,213
Depreciation	100,157	1,754
Interest expense	1,233,203	95,077
ROU liabilities	475,645	—
Accruals and other	331,631	286,692
Total deferred tax assets	103,185,302	54,539,548
Valuation allowance	(98,874,420)	(54,359,488)
Deferred tax liabilities:		
Intangible assets	(3,885,485)	(180,060)
ROU assets	(425,397)	—
Net	$ —	$ —

The difference between the Company's expected income tax provision (benefit) from applying federal statutory tax rates to the pre-tax loss and actual income tax provision (benefit) relates to the effect of the following:

	2020	2019
Federal income tax benefit at statutory rates	21.0%	21.0%
Permanent adjustment	0.6%	(1.9)%
Provision to return adjustment	—	0.4%
State income tax benefit, net of federal benefit	3.5%	4.4%
Foreign rate differential	2.8%	—
Change in valuation allowance	(28.4)%	(23.9)%
	(0.5)%	0.0%

As of December 31, 2020 and 2019, management assessed the realizability of net deferred tax assets and evaluated the need for a valuation allowance against the net deferred tax assets. This evaluation utilizes the framework contained in ASC 740, *Income Taxes*, whereby management considers all available positive and negative evidence as of the balance sheet date to determine whether all or some portion of the Company's net deferred tax assets will be realized. Under this guidance, a valuation allowance must be

established for net deferred tax assets when it is more-likely-than-not (a probability level of more than 50%) that the asset will not be realized.

Management followed the guidance in ASC 740, which states that "a cumulative loss in recent years is a significant piece of negative evidence that is difficult to overcome" and concluded that the Company's net deferred tax assets were not realizable as of December 31, 2020 and 2019. Accordingly, a valuation allowance of $98.9 million and $54.4 million has been recorded to offset the net deferred tax assets.

The Company has federal NOL carryforwards of $196,511,928 and $188,282,298 at December 31, 2020 and 2019, respectively. The Company also has total Foreign NOL carryforwards at December 31, 2020 of $160,540,528 which is primarily driven by the Company's operations in Germany. The NOL carryforwards incurred prior to 2018 begin to expire in 2022. In December 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"), most of the provisions of which took effect starting in 2018. Under the Tax Act, the amount of post 2017 NOLs that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. In addition, the Tax Act generally eliminates the ability to carry back any NOL to prior taxable years, while allowing post 2017 unused NOLs to be carried forward indefinitely. Utilization of the NOL carryforward may be subject to an annual limitation as provided by Section 382 of the Internal Revenue Code. There can be no assurance that the NOL carryforward will ever be fully utilized. 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 Internal Revenue Code of 1986, as amended. The Company will continue to monitor this matter going forward. There can be no assurance that the NOL carryforwards will ever be fully utilized.

The Tax Act made broad and complex changes to the U.S. tax code, including, but not limited to: (i) reducing the U.S. federal corporate tax rate from 35 percent to 21 percent; (ii) eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; (iii) creating a new limitation on deductible interest expense; and (iv) changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017; and (v) changing the U.S. federal taxation of earnings of foreign subsidiaries. The U.S. change in federal taxation for foreign subsidiary earnings included a one-time toll charge on deemed repatriated earnings of foreign subsidiaries as of December 31, 2017. As a result of the accumulated losses in the Company's foreign subsidiary, the Company had no toll tax liability for the tax year ended December 31, 2017. For 2018, the Company considered in its estimated annual effective tax rate additional provisions of Tax Reform including changes to the deduction for interest expense pursuant to IRC Section 163(j) interest limitation.

On March 27, 2020, the Unites States enacted the Coronavirus Aid, Relief and Economic Security Act (CARES Act). The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions which are expected to impact the Company's financial statements include removal of certain limitations on utilization of net operating losses, increasing the loss carryback period for certain losses to five years, and increasing the ability to deduct interest expense, as well as amending certain provisions of the previously enacted Tax Cuts and Jobs Act. The Company doesn't believe that the CARES Act will have a material impact on its financial position, results of operations, or cash flows.

Note 10 - Commitments and Contingencies

Registration and other stockholder rights

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

Supply agreements

In June 2017, the Company entered into an agreement with Life Technologies Corporation, a subsidiary of Thermo Fisher Scientific ("LTC"), to supply the Company with Thermo Fisher Scientific's QuantStudio 5 Real-Time PCR Systems ("QuantStudio 5") to be used to run OpGen's Acuitas AMR Gene Panel tests. Under the terms of the agreement, the Company must notify LTC of the number of QuantStudio 5s that it commits to purchase in the following quarter. As of December 31, 2020, the Company had acquired twenty-four QuantStudio 5s including none during the year ended December 31, 2020. As of December 31, 2020, the Company has not committed to acquiring additional QuantStudio 5s in the next three months.

Curetis places frame-work orders for Unyvero-Systems and for raw materials for its cartridge manufacturing to ensure availability during commercial ramp-up-phase and also to gain volume-scale-effects with regards to purchase prices. Some of the electronic parts used for the production of Unyvero-Systems have lead times of many months, hence it is necessary to order such systems with long-term framework-orders to ensure the demands from the market are covered. The aggregate purchase commitments over the next twelve months are approximately $3.1 million.

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 a result, the Company has experienced a material impact on its business, financial condition and results of operations for the year ended December 31, 2020 and significant business disruptions as a result of the outbreak. For example, most of the Company's employees in the U.S. are currently working remotely from home, the Company has suspended virtually all business travel, and the Company is generally unable to physically meet with future and current customers to sell and market its products. In addition, the COVID-19 pandemic has interrupted many of the Company's clinical activities, which might delay its ability to complete clinical trials and obtain regulatory approval for new products including FDA clearance of its Acuitas AMR Gene Panel (Isolate) product.

The Company is monitoring the impacts of COVID-19 on the global economy and on its 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 the Company's operations and financial results. An extended period of global supply chain and economic disruption could materially affect the Company's business, results of operations, access to sources of liquidity and financial condition, as well as its ability to execute its business strategies and initiatives in their respective expected time frames. As a result, the Company is unable to estimate the potential impact on its business as of the date of this filing.

Note 11 – Leases

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

Lease Classification	December 31, 2020	December 31, 2019
ROU Assets:		
Operating	$ 2,082,300	$ 1,043,537
Financing	449,628	958,590
Total ROU assets	$ 2,531,928	$ 2,002,127
Liabilities		
Current:		
Operating	$ 964,434	$ 1,017,414
Finance	266,470	579,030
Noncurrent:		
Operating	1,492,544	547,225
Finance	46,794	313,263
Total lease liabilities	$ 2,770,242	$ 2,456,932

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

Maturity of Lease Liabilities	Operating	Finance	Total
2021	$ 1,005,811	$ 281,914	$ 1,287,725
2022	570,656	45,374	616,030
2023	424,495	3,364	427,859
2024	433,872	280	434,152
2025	409,055	—	409,055
Thereafter	2,782,432	—	2,782,432
Total lease payments	5,626,321	330,932	5,957,253
Less: Interest	(1,957,343)	(17,668)	(1,975,011)
Less: Tenant improvement allowance [(1)]	(1,212,000)	—	(1,212,000)
Present value of lease liabilities	$ 2,456,978	$ 313,264	$ 2,770,242

(1) In accordance with ASC 842, a tenant allowance should be included in the measurement of the consideration in the lease agreement at inception and reflected as a reduction to the right-of-use asset and a corresponding reduction to the right-use-liability if the lessee both controls the construction of the tenant improvements and the expects to fully earn all of the tenant allowance. OpGen has met both conditions at the inception of its Rockville, Maryland lease and has recorded the Tenant Improvement Allowance accordingly. As the cash for the Tenant Improvement Allowance is received from the lessor under the terms of the Rockville, Maryland lease, the corresponding right-of-use liability will increase and will be amortized as part of the right-of use asset and liability amortization over the term of the Rockville, Maryland Lease in accordance with ASC 842.

Consolidated statements of operations classification of lease costs as of the years ended December 31, 2020 and 2019 are as follows:

		Years ended December 31,	
Lease Cost	**Classification**	**2020**	**2019**
Operating	Operating expenses	$ 1,205,551	$ 869,968
Finance:			
Amortization	Operating expenses	508,962	467,319
Interest expense	Other expenses	57,247	75,018
Total lease costs		$ 1,771,760	$ 1,412,305

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

Other Information	**Total**
Weighted average remaining lease term (in years)	
Operating leases	8.7
Finance leases	1.1
Weighted average discount rate:	
Operating leases	7.0%
Finance leases	9.7%

Supplemental cash flow information for the years ended December 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	$ 1,205,551	$ 869,968
Finance leases	$ 57,247	$ 75,018
Cash used in financing activities		
Finance leases	$ 579,029	$ 535,931
ROU assets obtained in exchange for lease obligations:		
Operating leases	$ 1,008,039	$ —
Finance leases	$ —	$ 592,013

Note 12 - License Agreements, Research Collaborations and Development Agreements

NYSDOH

In 2018, the Company announced a collaboration with the New York State Department of Health ("DOH") and ILÚM Health Solutions, LLC ("ILÚM"), a wholly-owned subsidiary of Merck's Healthcare Services and Solutions division, to develop a state-of-the-art research program to detect, track, and manage antimicrobial-resistant infections at healthcare institutions statewide. 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. In April 2021, the Company began a second-year expansion phase to build on the successes and experience of the first year pilot phase while focusing on accomplishing the goal of the effort to improve patient outcomes and save healthcare dollars by integrating real-time epidemiologic surveillance with rapid delivery of antibiotic resistance results to care-givers via web-based and mobile platforms. The second year contract includes a quarterly retainer-based project fee as well as volume-dependent per test fees for a total contract value of up to $450,000 to OpGen. During the years ended December 31, 2020 and 2019, the Company recognized $388,000 and $1,325,000, respectively, of revenue related to the contract.

Sandoz

In December 2018, Ares Genetics entered into a service frame agreement with Sandoz International GmbH ("Sandoz"), to leverage Ares Genetics' database on the genetics of antibiotic resistance, ARESdb, and the ARES Technology Platform for Sandoz' anti-infective portfolio.

Under the terms of the frame agreement, which has an initial term of 36 months and is currently scheduled to terminate December 13, 2021, Ares Genetics and Sandoz intend to develop a digital anti-infectives platform, combining established microbiology laboratory methods with advanced bioinformatics and artificial intelligence methods to support drug development and life-cycle management. The

collaboration, in the short- to mid-term, aims to both rapidly and cost-effectively re-purpose existing antibiotics and design value-added medicines with the objective of expanding indication areas and to overcome antibiotic resistance, in particular with regards to infections with bacteria that has already developed resistance against multiple treatment options. In the longer-term, the platform is expected to inform the development of novel anti-infectives that are less prone to encounter resistance and thereby preserve antibiotics as an effective treatment option.

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

Qiagen

On February 18, 2019, Ares Genetics and Qiagen GmbH, or Qiagen, entered into a strategic licensing agreement for ARESdb and AREStools, in the area of antimicrobial resistance ("AMR") research. The agreement has a term of 20 years and may be terminated by Qiagen for convenience with 180 days written notice.

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

Under the terms of the agreement, Qiagen, in exchange for a moderate six figure up-front licensing payment, has received an exclusive RUO license to develop and commercialize general bioinformatics offerings and services for AMR research use only, based on Ares Genetics' database on the genetics of antimicrobial resistance, ARESdb, as well as on the ARES bioinformatics AMR toolbox, AREStools. Under the agreement, the parties agreed to a mid-single digit percentage royalty rate on Qiagen net sales, which is subject to a minimum royalty rate that steps up upon certain achieved milestones, which is payable to Ares Genetics. The parties also agreed to further modest six figure milestone payments upon certain product launches.

Global leading IVD corporation

On September 16, 2019, Ares Genetics entered into a multi-phase partnership with an undisclosed leading global in vitro diagnostics corporation, or the Partner, to jointly develop diagnostic solutions for infectious disease testing, based on next-generation sequencing, or NGS, technology. Ares Genetics and the Partner also entered into an R&D option agreement for the first phase of the partnership. Ares Genetics received an option fee of approximately $550,000. The initial 10-month term of the R&D collaboration, ended July 13, 2020, with payments excluding the option fee of approximately $1.2 million.

In the first phase of the collaboration, which lasted 10 months, the parties have further enriched ARESdb with a focus on certain pathogens relevant in a first, undisclosed infectious disease indication. Additional clinical isolates of such pathogens have been sequenced by Ares Genetics at its recently established NGS laboratory in Vienna, Austria. Based on this enlarged and enriched dataset, Ares Genetics has further developed the algorithms for predictive antibiotic resistance testing for drug/pathogen combinations particularly relevant in the targeted indication to enable NGS-based infectious disease diagnostics.

Under the initial agreement, the Partner funded Ares Genetics' R&D activities for the genotypic and phenotypic characterization of additional bacterial strains to augment ARESdb and the development of optimized algorithms for predicting antibiotic resistance. Furthermore, in return for the up-front option fee, the Partner obtained a three-month right for first negotiation for an exclusive human clinical diagnostic use license to ARESdb and the ARES Technology Platform.

The Company recognized approximately $870,000 of revenue related to the contract during the year ended December 31, 2020.

FISH License

The Company was party to one license agreement with Life Technologies to acquire certain patent rights and technologies related to its FISH product line. Royalties were incurred upon the sale of a product or service which utilizes the licensed technology. The Company terminated this license agreement in October 2020 effective as of June 30, 2020 in conjunction with its announced exit of the FISH business in June 2021. The Company paid a one-time settlement fee of $350,000 and will pay a 10% royalty on the sale of eligible products through June 2021 but is no longer subject to any minimum royalty obligations. The Company recognized net royalty expense of $(68,854) and $250,000 for the years ended December 31, 2020 and 2019, respectively.

Note 13 - Related Party Transactions

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

Note 14 – Subsequent Events

Subsequent to December 31, 2020, the Company paid the final principal and accrued interest payment to MGHIF and the lien on the Company's IP was released.

On February 11, 2021, the Company closed the February 2021 Offering with a single U.S.-based, healthcare-focused institutional investor for the purchase of (i) 2,784,184 shares of common stock and (ii) 5,549,149 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock. The Company also issued to the investor, in a concurrent private placement, unregistered common warrants to purchase 4,166,666 shares of the Company's common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of $3.00, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of $2.99. The pre-funded warrants are immediately exercisable, at an exercise price of $0.01, and may be exercised at any time until all of the pre-funded warrants are exercised in full. The common warrants will have an exercise price of $3.55 per share, will be exercisable commencing on the six-month anniversary of the date of issuance, and will expire five and one half (5.5) years from the date of issuance. The February 2021 Offering raised aggregate net proceeds of $23.4 million, and gross proceeds of $25.0 million. As of March 19, 2021, all pre-funded warrants issued in the February 2021 Offering have been exercised.

As previously reported, on November 23, 2020, the Company entered into a Purchase Agreement with the Holder pursuant to which the Company issued to the Investor, securities of the Company, including Existing Warrants to purchase up to 4,842,615 shares of common stock. The Existing Warrants were exercisable six months after their issuance at an exercise price of $1.94 per share and expire on the fifth and a half year anniversary of the date of issuance. On March 9, 2021, the Company entered into the Exercise Agreement with the Holder. Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of the remaining 4,842,615 outstanding Existing Warrants for cash, pursuant to the terms of and subject to beneficial ownership limitations contained in the Existing Warrants, the Company agreed to issue to the Holder, New Warrants to purchase 0.65 shares of common Stock for each share of common stock issued upon such exercise of the remaining 4,842,615 outstanding Existing Warrants pursuant to the Exercise Agreement or an aggregate of 3,147,700 New Warrants. The terms of the New Warrants will be substantially similar to those of the Existing Warrants, except that the New Warrants will have an exercise price of $3.56. The New Warrants will be immediately exercisable and will expire five years from the date of the Exercise Agreement. On March 12, 2021, the Company and the Holder amended the Exercise Agreement to provide that the Holder would pay the Company $0.08125 for each New Warrant issued to the Holder. The Holder will pay an aggregate of $255,751 to the Company for the purchase of the New Warrants. The Company received aggregate gross proceeds before expenses of approximately $9.65 million from the exercise of all of the remaining 4,842,615 outstanding Existing Warrants held by the Holder and the payment of the purchase price for the New Warrants.

In March 2021, the Company entered into a lease extension for its office and laboratory space in Holzgerlingen, Germany. The extension is for four years beginning in September of 2021 with an optional four year extension through September 2029. The total minimum payments due over the four year extension is approximately $810,000. The lease is subject to additional charges such as utilities and other costs.

Exhibit 4.13

DESCRIPTION OF THE REGISTRANT'S SECURITIES

REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description sets forth certain material terms and provisions of the securities of OpGen Inc. (the "Company," "we," "us" and "our") that are registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This description also summarizes relevant provisions of Delaware General Corporation Law (the "DGCL"). The following summary does not purport to be complete and is subject to, and is qualified in its entirety by reference to, the applicable provisions of the DGCL and our certificate of incorporation and our by-laws, copies of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.13 is a part. We encourage you to read our certificate of incorporation, our by-laws and the applicable provisions of the DGCL for additional information.

Our common stock, par value $0.01 per share, trading symbol OPGN is registered under Section 12(b) of the Exchange Act.

Authorized Capital Stock

As of December 31, 2020, our authorized capital stock consists of 50,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of preferred stock, par value $0.01 per share, of which 7,690,572 shares are available for future issuance. As of March 26, 2021, 38,266,482 shares of our common stock are issued and outstanding,

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. The Board of Directors are elected to a one year term; the Company does not have a staggered board. Holders of our common stock are entitled to receive ratably any dividends declared by the Board of Directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Registration Rights

Investors' Rights Agreement

Under the Third Amended and Restated Investors' Rights Agreement, dated as of December 18, 2013, among the Company and certain investors, or the investors' rights agreement, we granted registration rights to the holders of shares acquired prior to our initial public offering, or their permitted transferees. These rights are provided under the terms of the investors' rights agreement, and include demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered. The investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable shares in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them. The registration rights granted under the investors' rights agreement will terminate at the earlier of the closing of a deemed liquidation event and when all of the holders of registrable securities are eligible to be sold without restrictions under Rule 144 promulgated under the Securities Act within any 90-day period.

Bridge Financing Registration Rights

In connection with a bridge financing transaction, the Company entered into a registration rights agreement with jVen Capital and with Merck Global Health Innovation Fund ("MGHIF"), pursuant to which the investors were granted certain demand registration rights and piggyback registration rights in connection with subsequent registered offerings of the Company's common stock. The registrable securities include the shares of common stock underlying the warrants issued to jVen Capital and to MGHIF under the terms of bridge financing promissory notes issued and repaid in 2017.

Anti-Takeover Effects of Our Certificate of Incorporation, Bylaws and Delaware Law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only the Chair of the Board, the Chief Executive Officer or a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our certificate of incorporation must be approved by not less than 66 2/3% of the outstanding shares entitled to vote on the amendment, and not less than 66 2/3% of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least 66 2/3% of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue from time to time 7,690,572 shares of preferred stock in one or more series. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private

offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Exclusive Jurisdiction for Certain Actions

Our certificate of incorporation provides that, once our common stock is a "covered security," unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar exclusive forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could rule that this provision in our certificate of incorporation is inapplicable or unenforceable. In addition, this exclusive forum provision is intended to apply to claims arising under Delaware state law and would not apply to claims brought pursuant to the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent the provision could be construed to apply to such claims, there is uncertainty as to whether a court would enforce the provision in such respect, and our stockholders will not be deemed to have waived compliance with federal securities laws and the rules and regulations thereunder.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol "OPGN".

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Philadelphia Stock Transfer, Inc. The transfer agent's address is 2320 Haverford Rd., Suite 230, Ardmore, PA 19003.

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Exhibit 21.1

OPGEN, INC.

The following is a list of subsidiaries of OpGen, Inc. as of December 31, 2020:

Name	**Jurisdiction of Incorporation**
AdvanDx, Inc.	Delaware
OpGen A/S	Denmark
Crystal GmbH	Germany
Curetis GmbH	Germany
Curetis USA	Delaware
Ares Genetics GmbH	Austria

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statements No. 333-246354, No. 333-237513, No. 333-231511, No. 333-224035, No. 333-216932, No. 333-216929, No. 333-210489, and No. 333-205864 on Form S-8 and Registration Statements and Registration Statements No.333-250983, No. 333-239240, No. 333-236106, No. 333-213356 and No. 333-211996 on Form S-3 of OpGen, Inc. of our report, which includes an explanatory paragraph related to OpGen, Inc.'s ability to continue as a going concern, dated March 29, 2021, on our audits of the consolidated financial statements of OpGen, Inc. as of December 31, 2020 and 2019 and for the years then ended, included in this Annual Report on Form 10-K of OpGen, Inc. for the year ended December 31, 2020.

/s/ CohnReznick LLP

Tysons, Virginia
March 29, 2021

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 Annual Report on Form 10-K of OpGen, Inc.;

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

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

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

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, 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 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: March 29, 2021

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

Exhibit 31.2

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

I, Timothy C. Dec, certify that:

1. I have reviewed this Annual Report on Form 10-K of OpGen, Inc.;

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

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

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

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, 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 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: March 29, 2021

/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 Annual Report on Form 10-K of OpGen, Inc. (the "Company") for the year ended December 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: March 29, 2021
- /s/ Oliver Schacht
- Oliver Schacht, Ph.D.
- Chief Executive Officer
- (principal executive officer)

- Date: March 29, 2021
- /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.

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OpGen, Inc. Board of Directors

Oliver Schacht, Ph.D., *Chief Executive Officer and Director*

Mario Crovetto*(1)(2)*

Prabhavathi Fernandes, Ph.D. *(1)(2)(3)*

William E. Rhodes, III, *Chairman of the Board (2)*

R. Donald Elsey, *Chief Financial Officer, Lyra Therapeutics, Inc. (1)(3)*

Evan Jones *(3)*

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(1) Member of Audit Committee
(2) Member of Compensation Committee
(3) Member of Compliance Committee

OpGen, Inc. Executive Officers

Oliver Schacht, Ph.D., *Chief Executive Officer and Director*

Johannes Bacher, *Chief Operating Officer*

Timothy C. Dec, *Chief Financial Officer and Corporate Secretary*

Stock and Investor Information

Corporate Offices:
9717 Key West Avenue, Suite 100
Rockville, MD 20850
301.869.9683

Common Stock:
Common Stock is listed on the Nasdaq Capital Market under the symbol "OPGN"

Independent Auditors:
CohnReznick LLP
8000 Towers Crescent Dr
Suite1000
Tysons, VA 22182

Transfer Agent:
Philadelphia Stock Transfer, Inc.
2320 Haverford Road
Suite 230
Ardmore, PA 19003

At the written request of each record owner or beneficial owner of our securities we will provide, without charge, a copy of the OpGen, Inc. Annual Report on Form 10-K for the year ended December 31, 2020, or any exhibit thereto not included herein. Requests should be sent to the Corporate Secretary at the address above.

Except for the historical matters contained herein, statements made in this report are forward looking and are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995. Investors are cautioned that forward looking statements involve risks and uncertainties that may affect our business and prospects, including economic, competitive, governmental, technological, and other factors discussed in this report and in our filings with the Securities and Exchange Commission, including without limitation, the Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 29, 2021.

OpGen, Inc.
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Rockville, MD 20850
Telephone 301.869.9683
www.opgen.com