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, 2021

☐ **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.)**
9717 Key West Avenue Rockville, MD	**20850**
(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 June 30, 2021, was $86,778,295 (based upon the last reported sale price of $2.27 per share on June 30, 2021), on The Nasdaq Capital Market.

As of March 25, 2022, 46,557,750 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 2022 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, 2021.

OPGEN, INC.

ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2021

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K for the year ended December 31, 2021 (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:

- the continued impact of COVID-19 on our business and operations;
- our liquidity and working capital requirements, including our cash requirements over the next 12 months;
- our use of proceeds from capital financing transactions;
- the completion of our development efforts for our Unyvero UTI and IJI panels, Unyvero A30 *RQ* platform and ARESdb and the timing of regulatory submissions;
- our ability to establish a market for and sell our Acuitas AMR Gene Panel test for use with bacterial isolates;
- our ability to obtain regulatory clearance for and commercialize our product and services offerings;
- our ability to sustain or grow our customer base for our Unyvero IVD and Acuitas AMR Gene Panel products as well as our current research use only products;
- regulations and changes in laws or regulations applicable to our business, including regulation by the FDA, European Union, including pending IVDR requirements, and China's NMPA;
- our ability to further integrate the OpGen, Curetis, and Ares Genetics businesses;
- 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.

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. Along with our subsidiaries, Curetis GmbH and Ares Genetics GmbH, we are developing and commercializing molecular microbiology solutions helping to guide clinicians with more rapid and actionable information about life threatening infections to improve patient outcomes and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. Our current product portfolio includes Unyvero, Acuitas AMR Gene Panel, and the ARES Technology Platform including ARESdb, using NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction, as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit. The Company exited its FISH business in early 2021, and the Company's license agreement with Life Technologies, a subsidiary of Thermo Fisher, was terminated as of June 30, 2021.

On April 1, 2020, the Company completed a business combination transaction whereby the Company acquired Curetis GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany ("Curetis GmbH"). 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 business combination 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 (e.g. for bacterial pneumonias) is the first U.S. Food and Drug Administration, or FDA, cleared test that can be used for the detection of more than 90% of common causative agents of hospitalized pneumonia. According to the National Center for Health Statistics (2018), pneumonia is a leading cause of admissions to the hospital and is associated with substantial morbidity and mortality. The Unyvero LRT automated test detects 19 pathogens within less than five hours, with approximately two minutes of hands-on time and provides clinicians with a comprehensive overview of 10 genetic antibiotic resistance markers. We have commercialized the Unyvero LRT BAL test for testing bronchoalveolar lavage, or BAL, specimens from patients with lower respiratory tract infections following FDA clearance received by Curetis in December 2019. The Unyvero LRT BAL automated test simultaneously detects 20 pathogens and 10 antibiotic resistance markers, and it is the first and only FDA-cleared panel that also includes *Pneumocystis jirovecii*, a key fungal pathogen often found in immunocompromised patients (such as AIDS and transplant patients) that can be difficult to diagnose, as the 20th pathogen on the panel. We believe the Unyvero LRT and LRT BAL tests have the ability to help address a significant, previously unmet medical need that causes over $10 billion in annual costs for the U.S. healthcare system, according to the Centers for Disease Control, or CDC.

- Following registration of the Unyvero instrument system as an IVD for the Chinese market in early 2021, we are supporting our strategic partner Beijing Clear Biotech (BCB) in pursuing execution of a supplemental clinical trial with the Unyvero HPN test. As requested by the Chinese regulatory authority NMPA, this study is geared towards generating additional data in China that will complement a larger data set with data from abroad compiled from other clinical and analytical studies performed in the past.

- The Unyvero Urinary Tract Infection, or UTI, test, which is CE-IVD marked in Europe, is currently being made available to laboratories in the United States 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. We initiated a prospective multi-center clinical trial for the Unyvero UTI in the United States in the third quarter of 2021.

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

- On September 30, 2021, we received clearance from the FDA for our Acuitas AMR Gene Panel for bacterial isolates. The Acuitas AMR Gene Panel detects 28 genetic antimicrobial resistance, or AMR, markers in isolated bacterial colonies from 26 different pathogens. We believe the panel provides clinicians with a valuable diagnostic tool that informs about potential antimicrobial resistance patterns early and supports appropriate antibiotic treatment decisions in this indication. We expect to commercialize the Acuitas AMR Gene Panel for isolates more broadly to customers in the United States.

- 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 IVD 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).

OpGen's combined AMR bioinformatics offerings, when and if such products are cleared for marketing, will offer important new tools to clinicians treating patients with AMR infections. OpGen's subsidiary 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, as a result of transferring data from the discontinued Acuitas Lighthouse into ARESdb to now cover > 78,000 bacterial isolates that have been sequenced using NGS technology and tested for susceptibility with applicable antibiotics from a range of over 100 antimicrobial drugs. In the fourth quarter of 2021, Ares Genetics entered into a strategic database access deal with one of the world's leading microbiology and IVD corporations for their non-exclusive access to approximately 1.1% of Ares Genetics' total database asset at the time of signing. Ares Genetics continues to explore various discussions with several interested parties in potential future collaboration or licensing opportunities. Additional partnerships with a U.S. CLIA lab, a contract research organization ("CRO") and a major University Medical Center have been initiated and are ongoing and the collaboration master service agreement with Sandoz has recently been extended until January 2025.

In addition to potential future licensing and partnering, Ares Genetics intends to independently utilize the proprietary biomarker content in this database, as well as to build an independent business in NGS and AI based offerings for AMR research and diagnostics in collaboration with its current and potential future partners in the life science, pharmaceutical and diagnostics industries. Ares Genetics signed up Siemens Technology Accelerator and AGES (Austrian Agency for Health and Food Safety), as well as several other national institutions from various European countries as new customers.

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

The Company has extensive partner and distribution relationships to help accelerate the establishment of a global infectious disease diagnostic testing and informatics business. The Company's partners include A. Menarini Diagnostics S.r.l. for pan-European distribution to currently 12 countries and Beijing Clear Biotech Co. Ltd. for Unyvero A50 product distribution in China. We have a network of distributors covering countries in Europe, the Middle East and Africa, Asia Pacific and Latin America. With the discontinuation of our FISH products business in Europe, we have reduced our network of distributors to only those distributors actively commercializing our Unyvero line of products or CE-IVD-marked SARS-CoV-2 test kits.

OpGen will continue to develop and seek FDA and other regulatory clearances or approvals, as applicable, for our Unyvero UTI and IJI products. OpGen will continue to offer the FDA-cleared Unyvero LRT and LRT BAL Panels, and FDA-cleared Acuitas AMR Gene Panel tests, as well as the Unyvero UTI Panel as a RUO product to hospitals, public health departments, clinical laboratories, pharmaceutical companies and CROs. OpGen's subsidiary, Curetis, continues its preparations for achieving compliance with the upcoming European Union's In-Vitro-Diagnostic Device Regulation (IVDR), which officially will go into effect in May 2022. Given the lack of designated Notified Bodies at this time, and with the recently approved EU commission proposal to provide for generous multi-year grace periods for IVD products with current In-Vitro-Diagnostic Device Directive (IVDD) CE marking, it is now possible for Curetis to continue its portfolio of existing CE-IVD marked products until at least May 2025 and May 2026, respectively, as long as no material changes are being made to any of its products. Following May 2022, however, any new or changed CE marked products will be required to be IVDR compliant from the outset.

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

OpGen's Products and Products in Development

Through its subsidiary 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, manufactured and commercialized via the wholly owned Curetis GmbH subsidiary. On the bioinformatics side, OpGen has combined data from its now discontinued Acuitas Lighthouse 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. Colombia, Kuwait, Belarus, Singapore), 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, 2021, the distribution network comprises 14 distributors covering 31 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 Company has begun analytical and clinical performance evaluations, including clinical trials initiated in the third quarter of 2021, required for a subsequent U.S. FDA submission;
- 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.

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 30 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). The Unyvero A30 *RQ* Analyzer 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 A50 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, 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 integrates 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

The Unyvero L4 Lysator 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

The Unyvero C8 Cockpit 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 connectivity to hospital and laboratory information systems.

The Unyvero A50 Analyzer

The Unyvero A50 Analyzer instrument consists of mechanical, electronic, pneumatic and optical elements and enables a fully-automatic random-access processing of the A50 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

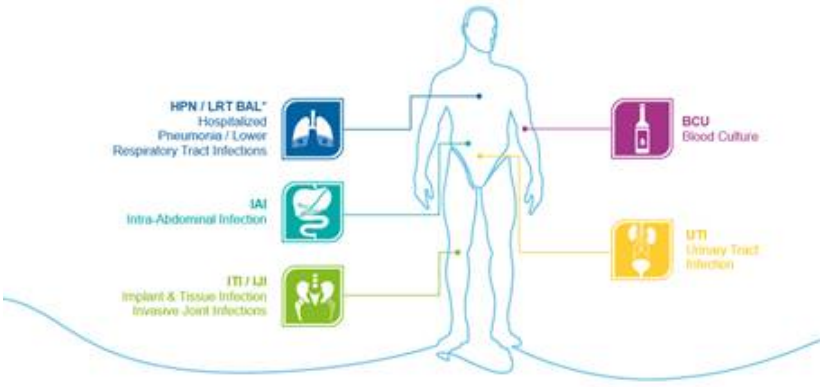

Figure 3: Currently available Application Cartridges

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. As part of our portfolio strategy update in the fourth quarter of 2020, we decided to proceed with the analytical and clinical performance evaluation including clinical trials required for a subsequent U.S. FDA submission for this Application Cartridge and initiated clinical trials in the third quarter of 2021.

Curetis' SARS-CoV-2 Kit

CE IVD marked in 2020, Curetis has developed and commercializes a PCR based rapid test kit for SARS-CoV-2 detection. It uses real-time reverse transcription polymerase chain reaction (RT-PCR) technology for qualitative detection of the SARS-CoV-2 virus isolated from oropharyngeal and nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider or for screening of asymptomatic individuals. This kit can be used with RNA isolated by performing standard RNA isolation processes, as well as with oropharyngeal or nasopharyngeal swabs collected in PCR compatible viral transport medium treated with PCR-Compatible Universal Lysis Buffer (PULB) provided in the kit.

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. Ares Genetics' 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 data from its now discontinued Acuitas Lighthouse 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 recently entered into a strategic data access deal with one of the world's leading microbiology and IVD corporations which obtained non-exclusive access to approximately 1.1% of Ares Genetics' then-current datasets.

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 research and development.

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 research and development. All services are based on NGS and Ares Genetics' proprietary, AI-powered antimicrobial resistance database ARESdb and the ARES Technology Platform for data interpretation. Ares Genetics expects to also begin offering its services in the United States.

In 2022, Ares Genetics launched AREScloud, a software as a service offering. The commercially available web application is intended for research use only and aims at professionals in clinical microbiology, public health, and microbial R&D. AREScloud intends to automate the accurate analysis and comprehensive interpretation of microbial genome data for surveillance and infection prevention and control applications. The web application leverages the contents of the proprietary ARESdb to enable the AI-assisted antibiogram prediction (referred to as predictive AST) directly from bacterial genome data.

OpGen's Acuitas AMR Gene Panel

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, which was 510(k)-cleared by the U.S. FDA on September 30, 2021 for testing bacterial isolates. This test had been made available in the United States as RUO before and had been used in such capacity in connection with The New York State Infectious Disease Digital Health Initiative for testing of bacterial isolates.

The Acuitas AMR Gene Panel is FDA cleared to detect a comprehensive panel of 28 genetic antimicrobial resistance (AMR) markers, covering select drugs in 9 classes of antibiotics, in isolated bacterial colonies from 26 different pathogens. An identified bacterial isolate is tested, and the antibiotic resistance gene markers associated with the selected bacterial species are reported as "Detected", "Not Detected" or "NA/NR".

Market Overview

Antibiotic Resistance – An Urgent Global Issue

Antimicrobial resistance (AMR) is one of the greatest global public health threats that has been recognized by many international bodies, including the World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention (CDC). A recent publication in The Lancet (January 19, 2022) confirms the rapid spread of AMR infections and highlights that an estimated 4.95 million deaths were associated with AMR in 2019, and between 2014 and 2019, the burden of fatalities directly attributable to bacterial AMR rose from 700K to 1.27M. The growing threat of AMR to public health is exacerbated by existing and newly developed antibiotics facing a wide range of drug resistance mechanisms in pathogens of concern. Recent Infectious Diseases Society of America (IDSA) treatment guidance for multidrug-resistant Gram-negative bacterial infections (Clin Infect Dis 2021 Apr 8;72(7):e169-e183) highlights how detection of AMR genes or a specific mechanism of resistance can help guide reporting practices for novel antimicrobial agents and tailor therapy for these difficult to treat infections. Furthermore, it can help with infection prevention and control initiatives such as patient isolation procedures when multiple isolates with the same AMR profile are detected as an early indication of transmission within a facility or for surveillance of serious or emerging AMR threats.

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.

Over the last decade, multidrug-resistant Gram-negative bacteria, frequently referred to as Superbugs, have been implicated in severe healthcare-associated infections (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.

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 14 distributors covering 31 countries.

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

Competition

We are developing a molecular diagnostics (MDx) business focused on leading a transformation in microbiology and infectious disease through precision medicine products and services that combine genomic data and bioinformatics. Our approach combines proprietary platforms and content, namely the FDA cleared and CE-IVD-marked Unyvero System and its DNA-based A50 Unyvero Panels, the FDA-cleared Acuitas AMR Gene Panel, and NGS applications based on leading AI-powered AMR knowledge-bases. 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 (a subsidiary of Danaher), Becton-Dickinson (BD), bioMérieux, Accelerate Diagnostics, T2 Biosystems, GenMark (a subsidiary of Roche), Qiagen, Luminex (acquired by DiaSorin), Thermo Fisher and Mobidiag (a subsidiary of Hologic). 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 bioinformatics offerings differentiate 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), GenMark (now a subsidiary of Roche) with its ePlex® platform, and 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 Nanosphere; now acquired by DiaSorin) (Verigene System® and Aries®), Becton-Dickinson (BD Max™), Binx Health (with io™ System), Roche (Cobas® Liat® and GeneWEAVE), Qiagen (QIAstat-Dx™), Biocartis N.V (Idylla™), Bosch (Vivalytic platform), SpeeDx (Plex/Resistance), 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 as well as 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 a large variety of antibiotic resistance markers in a single run.

Focusing on severe infectious diseases and having developed an 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 (e.g. on the Unyvero A30 platform) in the severe infectious disease area, Unyvero has a highly differentiated positioning in the market.

Although several direct competitors have in the past several 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 infectious diseases 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 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. 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 and pneumonia. According to publicly available sources, Accelerate Diagnostics has a CE-IVD pneumonia assay and it is believed to be planned for future U.S. FDA submission. Other companies, such as, Luminex (formerly Nanosphere; now DiaSorin), GenMark (now Roche), 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 and other companies developing rapid AST methods (Pattern Bioscience, Q-Linea ASTar, Lifescale, Specific Diagnostics Reveal, Gradientech, oCelloScope), as well as efforts to achieve AST with MALDI-TOF. While TATs for MALDI-TOF based testing are 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 players in the PCR-based molecular diagnostics market include bioMérieux, BD, Danaher, Roche, Qiagen, Abbott, Hologic, OpGen (including Curetis GmbH), amongst others. 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 predict phenotypic 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, and demonstrated capability to predict phenotypic antibiotic susceptibility.

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 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. Start-ups participating in this market include companies such as 1928 Diagnostics or Ridom developing bioinformatics software for surveillance and outbreak analysis.

Research and Development

We intend to continue to invest in the development of additional Unyvero panels such as UTI for the Unyvero A50 platform, a Unyvero IJI panel, and 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, ARESiss, ARESid, ARESupa etc.
- Development of Unyvero A30 *RQ* platform
- Clinical trials and regulatory filings for Unyvero UTI in the USA (expected 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 (expected 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 14 distributors covering 31 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 as well as sales of our tests for RUO purposes.

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 inpatients 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 and throughout the sales process.

Sales Process

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 six 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 of interest.

The focus is on high-volume consumable orders (Application Cartridges, Acuitas AMR Gene Panel kits and other consumables) instead of driving revenues and profits through hardware placements (Unyvero System or EZ1/QS5 installations for Acuitas). 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 inpatients (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 offer 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, 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 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 a 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, Switzerland, UK, France, Belgium, Netherlands, Luxemburg, Spain, Italy, Greece, Portugal, Austria, Serbia, Northern Macedonia, Bosnia and Herzegovina, Montenegro, Croatia, Russia, Belarus, Ukraine, Kazakhstan, Romania, Kuwait, Egypt and Asian countries such as Singapore, Vietnam, China, Taiwan and Hong Kong and other markets such as Central and Latin American markets such as Mexico and Colombia.

As of December 31, 2021, OpGen had an installed base of 195 Unyvero Analyzers across global 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, 2021, OpGen had an installed base of 30 Unyvero Analyzers across the United States and in different types of hospitals and labs.

Indirect Sales Markets

OpGen enters into a standard distribution agreement with most of its Unyvero distributors, which specifies the particular Unyvero products 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.

OpGen, through its subsidiary Curetis, has entered into distribution agreements with 12 distributors covering 31 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:

- Austria, Belgium, France, Germany, Greece, Italy, Luxemburg, Netherlands, Portugal, Spain, Switzerland, United Kingdom: A. Menarini Diagnostics;
- Romania: Synttergy Consult LTD;
- Russia, Ukraine, Kazakhstan: BioLine LLC;
- Belarus: BioLine BS LLC; and
- Bosnia and Hercegovina, Montenegro, Serbia, North Macedonia, Croatia: 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;
- fulfil their regulatory and quality management system obligations 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 also through distributors. Currently further distribution agreements are in place for the following countries:

- Kuwait: ATC;
- Singapore: Acumen Research Laboratories;
- China, Taiwan and Hong Kong: Beijing Clear Biotech/ Technomed (Hong Kong) Ltd;
- Egypt: Future Horizons Scientific;
- Mexico: Quimica Valaner;
- Colombia: Annar; and
- Vietnam: Quang Phat Technology

The total contractual minimum purchase requirements of all current distributors is 382 Unyvero Systems of which about 350 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 in some markets has established a concept of system replacement instead of onsite repair. In the event of system failure or required maintenance, systems in such markets 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. OpGen via its Curetis subsidiary has also trained field service engineers of several of our distribution partners so that they can perform certain repairs and services themselves. OpGen expects to establish a service maintenance arrangement where customers and distributors pay for support and repair based on what service package they have purchased.

Manufacturing

During 2021, 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 Acuitas AMR products in either our previous Gaithersburg, Maryland facility or at our new headquarters in Rockville, Maryland. The Acuitas AMR product manufacturing has been moved to the new site in Rockville, Maryland and is planned to get transferred to Curetis in Germany in 2022.

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. To date, no decision has been made on the selection of the OEM provider for the series production of the Unyvero A30 *RQ* systems. Unyvero A30 *RQ* systems are so far being produced in pilot batches by DMTPe as development partner to Curetis in Germany.

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 research and development 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 Horst Scholz GmbH & Co. KG, Kronach, Germany, or 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

Curetis is party to a supply agreement with a large single-source supplier 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 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 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 quality and regulatory affairs functions oversee the quality of our research and development 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 quality management systems 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, and Acuitas AMR Gene Panel tests are, 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 inpatients 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 as the causative agent of pneumonia but undetected by conventional microbiology, 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, 2021, OpGen had a patent portfolio of 55 granted patents and 12 patent applications. 32 of the granted patents and 4 of the pending patent applications are from Curetis and 20 of the granted patents and 8 of the pending patent applications are from Ares Genetics.

As part of such portfolio, we have 3 granted U.S. patents related to our Acuitas products.

As part of the Company's portfolio, there are 2 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.

We have ownership rights to 8 issued U.S. patents related to our legacy 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 tests to CROs, pharmaceutical companies, reference laboratories, hospitals and other health care facilities for research use only (RUO). 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 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 their 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

Where applicable, we are working towards submitting our Unyvero tests 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 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. The first Unyvero application cartridge product had 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 be 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 Rockville, Maryland facility is currently registered as a manufacturer with the FDA to manufacture our Acuitas products, whereas the Curetis facility in Bodelshausen, Germany 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 *De Novo* classification, 510(k) clearance or premarket approval of new products or modified products; (7) operating restrictions; (8) withdrawing granted *De* Novo classifications, 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.

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 and SARS CoV-2 test kits 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 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, 2021, we had 99 employees worldwide, with 31 employed in the United States, 54 employed in Germany at Curetis GmbH, and 14 employed in Austria at Ares Genetics GmbH. Of our 99 worldwide employees, 91 are full-time employees. Except for the managing director of Ares Genetics, our Austrian-based employees are subject to a collective bargaining agreement for employees of companies in the automated data processing and IT services industry. None of our other employees worldwide are subject to a collective bargaining arrangement. The 31 employees in the United States primarily work in our Rockville, 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 based on our shared core values at OpGen: Ownership, Performance, Generosity, Enthusiasm, Now! We support employee growth professionally and personally through formal and informal opportunities and leadership support.

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 2021, 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. Many 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 and regular testing of staff wherever possible.

Glossary

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

“Acuitas AMR Gene Panel” 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 a bioinformatics platform that we have discontinued following the integration of relevant datasets into our ARESdb.

“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.

"ARESiss” means ARES isolate sequencing service.

"ARESid” means ARES identification of pathogens.

“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 invasive & joint infections.

“bioinformatics” 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 (bio)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 “(bio)informatics products and services,” often interchangeably with “(bio)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.

“(bio)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 (bio)informatics platform, we are primarily referring to ARESdb and the Ares suite of AI powered and machine learning based tools.

“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 Rockville, Maryland. The Company also has operations in Germany, and Austria.

Available Information

The Company maintains a website at www.opgen.com. Our Code of Conduct 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 face. 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.

Summary

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. We encourage you to carefully review the full risk factors contained in this Annual Report in their entirety for additional information regarding the material factors that make an investment in our securities speculative or risky.

- 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.
- 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.

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, 2021 and 2020 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, 2021 and 2020, we had net losses of $34.8 million and $26.2 million, respectively. From our inception through December 31, 2021, we had an accumulated deficit of $235.5 million. The reports of our independent registered public accounting firm on our financial statements for the years ended December 31, 2021 and 2020 each contain explanatory language that substantial doubt exists about our ability to continue as a going concern. We completed a number of financings in 2020 and 2021, including an at-the-market public offering which commenced in February 2020 (the "ATM Offering"), a private placement in November 2020, a registered direct financing in February 2021, a warrant exercise and exchange transaction in March 2021, and a registered direct financing in October 2021. The net proceeds from such financings were approximately $82.0 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 additional 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 additional 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.

We believe that additional equity or debt 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 will be sufficient to fund operations into the fourth quarter of 2022, including repayment of the first tranche of the EIB loan facility of approximately $15 million due in April 2022. In the event we are unable to successfully raise additional capital during or before the fourth quarter of 2022, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to immediately reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until we are able to obtain sufficient financing. If such sufficient financing is not received 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.

Following the combination of the OpGen and Curetis businesses we may not see the growth and success of the combined OpGen 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 across all products and platforms as well as all geographies. 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. We were subject to extended delays for the FDA clearance of our Acuitas AMR Gene Panel test due to the national emergency situation caused by the COVID-19 pandemic and FDA prioritizing COVID related product reviews. The FDA has not yet been able to provide any feedback in the form of presub meetings for either the Unyvero UTI or IJI panels and has recently declined to host any presub meetings for IJI in early 2022. In addition, the time and expense needed to prepare future clinical trial data for submission to the FDA and reviewing and responding to the FDA's request for additional information may require significant resources and could impact other research and development project timelines, 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, 2021, we had approximately $202 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 have occurred 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;
- the willingness of hospitals and physicians to use our products and services; and
- the ability of hospitals and labs to pay for 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. We are subject to similar challenges with respect to 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 products that detect antibiotic resistance markers in under ninety minutes as well as four to five hours – and in the case of our NGS-based ARESupa or ARESiss several days to weeks - 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 some of 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. From 2018 through September 30, 2021, we were 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 several of our clinical and economic validation studies involving our products have been presented at major infectious disease and infection control society meetings and some have been published in peer reviewed scientific journals. 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 pathogen identification as well as AMR marker detection and possibly MDRO diagnosis 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 platforms and product offerings, including our bioinformatics products and services. Such collaborations are and may be with microbiology and IVD companies, pharmaceutical and biotech companies, CROs and CLIA labs, 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 the identity of the partner, financial details as well as details on 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, labs, 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 U.S. 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 stakeholders in inpatient 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 Rockville, Maryland, which we plan to move to the Bodelshausen facility in 2022. We do not have redundant facilities for these products. Our facilities and the equipment we use to 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 or fire, 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, Scholz, 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.

Our distributors, collaboration partner, and service providers may be impacted and could be delayed or suspended as a result of the military action by Russia in Ukraine.

We have distribution relationships with partners for the distribution of certain of our products in Russia and Ukraine as well as other neighboring territories. We also have relationships with other parties and service providers that may operate in or be impacted by conditions in Russia and Ukraine.

In February 2022, Russia commenced a military invasion of Ukraine. Russia's invasion and the ensuing response by Ukraine may disrupt our and our distribution partner's distribution efforts in such jurisdictions, impact the ability of certain service providers to perform and could increase our costs and disrupt future planned activities. For example, we believe our distribution partner will not be able to successfully distribute products in Ukraine or Russia during the conflict and Curetis has suspended its business support to our distributors and will not accept any purchase orders until the geopolitical situation has been resolved. Such disruption would significantly impact our ability to market, sell and distribute in such territories and could impact our ability to do so in nearby territories, which would increase our costs and slow down and jeopardize our commercialization efforts.

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 (a Danaher company), Becton-Dickinson, bioMérieux, Accelerate Diagnostics, T2 Biosystems, GenMark (a Roche company), Qiagen, Mobidiag (a Hologic company) and Luminex (a DiaSorin company).

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-genetics.cloud services 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 ares-genetics.cloud 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, could adversely affect our ability to operate our business. Any interruption in the operation of our ARESdb, 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, which may include 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, phishing attempts, 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 data 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 is 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 pathogens and AMR 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 longer. 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 inpatient 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 inpatient 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

We received a bid price deficiency notice from the Nasdaq Capital Market. If we are unable to cure this deficiency and meet the NASDAQ continued listing requirements, we could be delisted from the Nasdaq Capital Market, which would negatively impact the trading of our common stock.

On February 28, 2022, we received notice from Nasdaq that we had failed to maintain a bid price of at least $1.00 per share for 30 successive trading days. We have six months to regain compliance with the listing standard. We are currently considering our alternatives to restore the bid price, including a reverse stock split of our common stock. However, there can be no assurance that we will be able to maintain the Nasdaq Capital Market listing of our common stock in the future.

If our common stock is delisted by Nasdaq, our common stock may be eligible for quotation on an over-the-counter quotation system or on the pink sheets. Upon any such delisting, our common stock would become subject to the regulations of the SEC relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than $5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of stockholders to sell securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will be eligible for trading or quotation on any alternative exchanges or markets.

Delisting from Nasdaq could adversely affect our ability to raise additional financing through public or private sales of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

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 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 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, 2021, 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;
- the market entry of new 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 and/or unrelated to our industry.

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, 2021, we had outstanding warrants to acquire 16,217,946 shares of our common stock, and stock options to purchase 1,713,349 shares of our common stock. The expiration of the term of such options and warrants range from June 2022 to July 2031. 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.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, instability in inflation in U.S. and foreign markets, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions, including instability in inflation. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, distributors, manufacturers, and other partners may not survive an economic downturn or could be adversely affected by geopolitical events, such as the conflict in Ukraine, which could directly affect our ability to attain our operating goals on schedule and on budget.

A large base of individual stockholders may make it difficult for us to take action on certain corporate transactions and matters, which may limit the ability of the Company to enter into certain transaction.

We believe that we currently have a large base of individual stockholders instead of institutional investors. Procuring the vote of such stockholders in connection with certain corporate transactions and matters is difficult, time consuming and expensive. For example, in connection with the Company's 2021 Annual Meeting for stockholders, despite extensive efforts by the Company, we were unable to receive votes from a sufficient portion of our outstanding shares of common stock required to approve certain proposals submitted at such meeting, despite the fact that, of those shares that had voted on the proposals, such shares had supported the approval of such proposals.

We expect that we may continue to need stockholder approval of additional matters in the future, including, in connection with, amendments to the Company's amended and restated certificate of incorporation, as amended, and for certain other corporate transactions. If we are unable to obtain the requisite vote due to stockholder disinterest and apathy for engaging in corporate governance of the Company, we may be unable to take certain actions, which could prevent or limit our ability to further finance the Company in the future or enter into certain transactions.

Short sellers of our stock may be manipulative and may drive down the market price of our common stock.

Short selling is the practice of selling securities that a seller does not own but rather has borrowed, or intends to borrow, from a third party with the intention of buying identical securities at a later date to return to the lender. A short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's interest for the price of the stock to decline, some short sellers publish, or arrange for the publication of, opinions or characterizations regarding the relevant issuer, its business prospects and similar matters calculated to or which may create negative market momentum, which may permit them to obtain profits for themselves as a result of selling the securities short. The use of the Internet, social media, and blogging have allowed short sellers to publicly attack a company's credibility, strategy and veracity by means of so-called "research reports" that mimic the type of investment analysis performed by legitimate securities research analysts. Issuers with substantial retail stockholder bases can be particularly susceptible to higher volatility levels, and can be particularly vulnerable to such short attacks.

While we intend to strongly defend our public filings against any such short seller attacks, in many situations we could be constrained, for example, by principles of freedom of speech, applicable state law or issues of commercial confidentiality, in the manner in which we are able to proceed against the relevant short seller. Such short-seller attacks may cause, temporary or possibly long term, declines in the market price of our common stock.

We may be subject to litigation or government investigations for a variety of claims, which could adversely affect our operating results, harm our reputation or otherwise negatively impact our business.

We may be subject to litigation or government investigations. These may include claims, lawsuits, and proceedings involving securities laws, fraud and abuse, healthcare compliance, product liability, labor and employment, wage and hour, commercial and other matters. Any such litigation or investigations could result in substantial costs and a diversion of management's resources and attention. In addition, any adverse determination could expose us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Regulation of Our Business

There is no guarantee that the FDA will grant De Novo classification requests, 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 received 510(k) clearance from the FDA for our Acuitas AMR Gene Panel test as well as FDA clearances for Unyvero LRT and LRT BAL in the past. We have plans to submit additional *De Novo* classification requests for our Unyvero UTI test and our 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 RUO products to labs, CROs, diagnostics, pharmaceutical and biotech 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 our 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 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 *De Novo* classification, 510(k) clearance or premarket approval of new products or modified products; (7) operating restrictions; (8) withdrawing granted *De* Novo classifications, 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, De Novo classifications or PMA approvals or, in the future, new CE-IVD markings that comply with the new IVDR, 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 or new IVDR compliant product authorization.

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 under new IVDR, 510(k) submission, or file a De Novo classification request or 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 is expected to apply commencing on May 26, 2022, subject to certain extended transition periods for existing CE-IVD marked products until the 2025 to 2027 time frame, 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 will 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 continued to adversely impact our business, financial condition and results of operations.

The COVID-19 pandemic has continued to impact 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 years 2020 and 2021 as well as into 2022. 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 due to funding diverted to fight COVID-19 and reduced demand from research laboratories.

Healthcare providers, including our strategic partners worldwide, spend significant time dealing with COVID-19, and may be unable to continue to participate in our clinical activities. For example, some clinical trial sites have imposed and continue to maintain 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 may therefore 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 had paused new subject enrollment for most clinical trials during the earlier phase of the pandemic and might do so again.

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 in 2021 notified us that the agency would continue prioritizing emergency use authorization requests for diagnostic products intended to address the COVID-19 pandemic during 2021. Due to delays from such prioritization, we only received a clearance decision on our Acuitas AMR Gene Panel on September 30, 2021, which was originally targeted for a decision by mid-2020.

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 become more widespread, each day manufacturing closures, travel restrictions, quarantined staff 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 acceptance of vaccination by many individuals in the United States as well as in Europe and globally, 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 continued to have a subset of our office-based employee population in 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).

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, quarantine orders, 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 testing for the SARS-CoV-2 virus, 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, 2021, we owed indebtedness of $25.2 million of principal (including deferred interest of $4.8 million) under a loan provided by the European Investment Bank with maturities in April 2022, June 2023, and June 2024. In particular, approximately $15 million of such indebtedness is due to the European Investment Bank in April 2022. While we are evaluating options to restructure such indebtedness, we may not be able to do so, and in such event, 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 continue to 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 OpGen 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 continued 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 following our combination with Curetis the combined OpGen group 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.

We are dependent on the services of our management and other key personnel and members of our board of directors, and if we are not able to retain these individuals or recruit additional management, our business will suffer.

Our success depends in part on our continued ability to attract, retain, manage and motivate highly qualified management and other key personnel. We are highly dependent upon our senior management and other members of our management team. The loss of services of any of these individuals, such as the recent departure of our former chief financial officer and our former chairman and founder, could cause the loss of critical Company knowledge and information, delay or prevent the successful development of our products, initiation or completion of our preclinical studies and clinical trials or the commercialization of our products. Although we have executed employment agreements or offer letters with each member of our senior management team, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

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.

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 further integrating the businesses, including in connection with certain internal corporate restructuring matters. As such, 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;
- 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 so 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 leases 10,100 square feet of office and laboratory space at our headquarters in Rockville, Maryland. The lease term expires in February 2032. The Company had also leased 12,770 square feet of space at its facility in Woburn, Massachusetts under an operating lease that expired in January 2022. The Company entered into a sublease agreement for this space in February 2021 that expired 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 research and development, operations, and general and administrative purposes. The lease term expires in August 31, 2025, with a subsequent option to extend the term by another four years. Curetis' U.S. subsidiary leases 5,003 square feet of office space in San Diego, California under an operating lease that expires in May 2022. The Company entered into a sublease agreement for this space in October 2021 that also expires in May 2022.

Ares Genetics leases 1,299 square feet of office space in Vienna, Austria under an operating lease that expires in March 2025. 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, 2021 and 2020 were $1,019,785 and $1,154,927, 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, 2021, there were approximately 39 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. [Reserved]

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 our subsidiaries, Curetis GmbH and Ares Genetics GmbH, we are developing and commercializing molecular microbiology solutions helping to guide clinicians with more rapid and actionable information about life threatening infections to improve patient outcomes and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. Our current product portfolio includes Unyvero, Acuitas AMR Gene Panel, and the ARES Technology Platform including ARESdb, using NGS technology and AI-powered bioinformatics solutions for antibiotic response prediction, as well as the Curetis CE-IVD-marked PCR-based SARS-CoV-2 test kit. The Company exited its FISH business in early 2021, and the Company's license agreement with Life Technologies, a subsidiary of Thermo Fisher, was terminated as of June 30, 2021.

On April 1, 2020, the Company completed a business combination transaction whereby the Company acquired Curetis GmbH, a private limited liability company organized under the laws of the Federal Republic of Germany ("Curetis GmbH"). 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 business combination 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 (e.g. for bacterial pneumonias) is the first U.S. Food and Drug Administration, or FDA, cleared test that can be used for the detection of more than 90% of common causative agents of hospitalized pneumonia. According to the National Center for Health Statistics (2018), pneumonia is a leading cause of admissions to the hospital and is associated with substantial morbidity and mortality. The Unyvero LRT automated test detects 19 pathogens within less than five hours, with approximately two minutes of hands-on time and provides clinicians with a comprehensive overview of 10 genetic antibiotic resistance markers. We have commercialized the Unyvero LRT BAL test for testing bronchoalveolar lavage, or BAL, specimens from patients with lower respiratory tract infections following FDA clearance received by Curetis in December 2019. The Unyvero LRT BAL automated test simultaneously detects 20 pathogens and 10 antibiotic resistance markers, and it is the first and only FDA-cleared panel that also includes *Pneumocystis jirovecii*, a key fungal pathogen often found in immunocompromised patients (such as AIDS and transplant patients) that can be difficult to diagnose, as the 20th pathogen on the panel. We believe the Unyvero LRT and LRT BAL tests have the ability to help address a significant, previously unmet medical need that causes over $10 billion in annual costs for the U.S. healthcare system, according to the Centers for Disease Control, or CDC.

- Following registration of the Unyvero instrument system as an IVD for the Chinese market in early 2021, we are supporting our strategic partner BCB in pursuing execution of a supplemental clinical trial with the Unyvero HPN test. As requested by the Chinese regulatory authority NMPA, this study is geared towards generating additional data in China that will complement a larger data set with data from abroad compiled from other clinical and analytical studies performed in the past.

- The Unyvero Urinary Tract Infection, or UTI, test, which is CE-IVD marked in Europe, is currently being made available to laboratories in the United States 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. We initiated a prospective multi-center clinical trial for the Unyvero UTI in the United States in the third quarter of 2021.

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

- On September 30, 2021, we received clearance from the FDA for our Acuitas AMR Gene Panel for bacterial isolates. The Acuitas AMR Gene Panel detects 28 genetic antimicrobial resistance, or AMR, markers in isolated bacterial colonies from 26 different pathogens. We believe the panel provides clinicians with a valuable diagnostic tool that informs about potential antimicrobial resistance patterns early and supports appropriate antibiotic treatment decisions in this indication. We expect to commercialize the Acuitas AMR Gene Panel for isolates more broadly to customers in the United States.

- 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 IVD 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).

OpGen's combined AMR bioinformatics offerings, when and if such products are cleared for marketing, will offer important new tools to clinicians treating patients with AMR infections. OpGen's subsidiary 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 discontinued Acuitas Lighthouse into ARESdb to now cover > 78,000 bacterial isolates that have been sequenced using NGS technology and tested for susceptibility with applicable antibiotics from a range of over 100 antimicrobial drugs. In the fourth quarter of 2021, Ares Genetics entered into a strategic database access deal with one of the world's leading microbiology and IVD corporations for their non-exclusive access to approximately 1.1% of Ares Genetics' total database asset at the time of signing. Ares Genetics continues to explore various discussions with several interested parties in potential future collaboration or licensing opportunities. Additional partnerships with a U.S. CLIA lab, CRO and a major University Medical Center have been initiated and are ongoing and the collaboration master service agreement with Sandoz has recently been extended until January 2025.

In addition to potential future licensing and partnering, Ares Genetics intends to independently utilize the proprietary biomarker content in this database, as well as to build an independent business in NGS and AI based offerings for AMR research and diagnostics in collaboration with its current and potential future partners in the life science, pharmaceutical and diagnostics industries. Ares Genetics signed up Siemens Technology Accelerator and AGES (Austrian Agency for Health and Food Safety), as well as several other national institutions from various European countries as new customers.

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

The Company has extensive partner and distribution relationships to help accelerate the establishment of a global infectious disease diagnostic testing and informatics business. The Company's partners include A. Menarini Diagnostics S.r.l. for pan-European distribution to currently 12 countries and Beijing Clear Biotech Co. Ltd. for Unyvero A50 product distribution in China. We have a network of distributors covering countries in Europe, the Middle East and Africa, Asia Pacific and Latin America. With the discontinuation of our FISH products business in Europe, we have reduced our network of distributors to only those distributors actively commercializing our Unyvero line of products or CE-IVD-marked SARS-CoV-2 test kits.

OpGen will continue to develop and seek FDA and other regulatory clearances or approvals, as applicable, for our Unyvero UTI and IJI products. OpGen will continue to offer the FDA-cleared Unyvero LRT and LRT BAL Panels, and FDA-cleared Acuitas AMR Gene Panel tests, as well as the Unyvero UTI Panel as a RUO product to hospitals, public health departments, clinical laboratories, pharmaceutical companies and CROs. OpGen's subsidiary, Curetis, continues its preparations for achieving compliance with the upcoming European Union's In-Vitro-Diagnostic Device Regulation (IVDR), which officially will go into effect in May 2022. Given the lack of designated Notified Bodies at this time, and with the recently approved EU commission proposal to provide for generous multi-year grace periods for IVD products with current In-Vitro-Diagnostic Device Directive (IVDD) CE marking, it is now possible for Curetis to continue its portfolio of existing CE-IVD marked products until at least May 2025 and May 2026, respectively, as long as no material changes are being made to any of its products. Following May 2022, however, any new or changed CE marked products will be required to be IVDR compliant from the outset.

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

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 2020 and 2021:

- On February 11, 2020, the Company entered into an at-the-market sales agreement (the "ATM Agreement") with H.C. Wainwright & Co., 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 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, 2021, the Company sold 680,000 shares of its common stock under the ATM Offering resulting in aggregate net proceeds of approximately $1.48 million, and gross proceeds of $1.55 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 a public offering that we consummated in October 2019 were exercised, raising net proceeds of approximately $8.7 million.

- On February 11, 2021, the Company closed a registered direct offering (the "February 2021 Offering") with a single U.S.-based, healthcare-focused institutional investor for the purchase of (i) 2,784,184 shares of common stock and (ii) 5,549,149 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock. The Company also issued to the investor, in a concurrent private placement, unregistered common share purchase warrants to purchase 4,166,666 shares of the Company's common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of $3.00, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of $2.99. The pre-funded warrants were immediately exercisable, at an exercise price of $0.01, and could be exercised at any time until all of the pre-funded warrants are exercised in full. The common warrants have an exercise price of $3.55 per share, are exercisable commencing on the six-month anniversary of the date of issuance, and will expire five and one-half (5.5) years from the date of issuance. The February 2021 Offering raised aggregate net proceeds of $23.5 million, and gross proceeds of $25.0 million. As of December 31, 2021, all 5,549,149 pre-funded warrants issued in the February 2021 Offering have been exercised.

- On March 9, 2021, the Company entered into a Warrant Exercise Agreement (the "Exercise Agreement") with the institutional investor (the "Holder") from our 2020 PIPE. Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of the remaining 4,842,615 outstanding warrants acquired in the 2020 PIPE (the "Existing Warrants") for cash, pursuant to the terms of and subject to beneficial ownership limitations contained in the Existing Warrants, the Company agreed to issue to the Holder new warrants (the "New Warrants") to purchase 0.65 shares of common stock for each share of common stock issued upon such exercise of the Existing Warrants pursuant to the Exercise Agreement for an aggregate of 3,147,700 New Warrants. The terms of the New Warrants are substantially similar to those of the Existing Warrants, except that the New Warrants have an exercise price of $3.56. The New Warrants are immediately exercisable and will expire five years from the date of the Exercise Agreement. The Holder paid an aggregate of $255,751 to the Company for the purchase of the New Warrants. The Company received aggregate gross proceeds before expenses of approximately $9.65 million from the exercise of the remaining Existing Warrants held by the Holder and the payment of the purchase price for the New Warrants (together, the "2021 Warrant Exercise").

- On October 18, 2021, the Company closed a registered direct offering (the "October 2021 Offering") with a single healthcare-focused institutional investor of 150,000 shares of convertible preferred stock and warrants to purchase up to an aggregate of 7,500,000 shares of common stock. The shares of preferred stock had a stated value of $100 per share and were converted into an aggregate of 7,500,000 shares of common stock at a conversion price of $2.00 per share after the Company received stockholder approval for an increase to its number of authorized shares of common stock, which approval occurred at the Company's special meeting of stockholders held in December 2021. Thereafter, all preferred stock was converted into 7,500,000 common shares in December 2021 so that there were no shares of preferred stock outstanding as of December 31, 2021. The warrants have an exercise price of $2.05 per share, will become exercisable six months following the date of issuance, and will expire five years following the initial exercise date. The October 2021 Offering raised aggregate net proceeds of $13.9 million, and gross proceeds of $15.0 million.

Results of Operations for the Years Ended December 31, 2021 and 2020

Revenues

	Years Ended December 31,	
	2021	2020
Revenue		
Product sales	$ 2,656,669	$ 2,704,364
Laboratory services	813,210	167,736
Collaboration revenue	836,152	1,342,341
Total revenue	$ 4,306,031	$ 4,214,441

The Company's total revenue for the year ended December 31, 2021 increased 2%, to $4.3 million from $4.2 million, when compared to the same period in 2020. This increase is primarily attributable to:

- Product Sales: the decrease in revenue of approximately 2% in 2021 compared to 2020 is primarily attributable to the loss of FISH products revenue following the discontinuation of the FISH business, offset, in part, by an increase in the Company's Unyvero product sales and the non-exclusive access to a portion of the ARESdb content;

- Laboratory Services: the increase in revenue of approximately 385% in 2021 compared to 2020 is primarily attributable to an increase in Ares Genetics' laboratory services (approximately $361,000) as well as COVID testing services performed by the Company's Curetis subsidiary (approximately $438,000); and

- Collaboration Revenue: the decrease in revenue of approximately 38% in 2021 compared to 2020 is primarily attributable to the conclusion of non-recurring partnering revenues from a completed research and development collaboration with an IVD partner at Ares Genetics in 2020 and non-recurring milestone-based revenue from the NYS project.

Operating expenses

	Years Ended December 31,	
	2021	2020
Cost of products sold	$ 2,295,828	$ 3,360,280
Cost of services	552,620	488,211
Research and development	10,910,679	9,964,720
General and administrative	9,935,963	8,801,661
Sales and marketing	3,713,263	3,094,092
Transaction costs	—	471,522
Impairment of right-of-use asset	170,714	101,838
Impairment of intangible assets	—	750,596
Gain on sale of equipment	—	(100,000)
Total operating expenses	$ 27,579,067	$ 26,932,920

The Company's total operating expenses for the year ended December 31, 2021 increased 2%, to $27.6 million from $26.9 million, when compared to the same period in 2020. This increase is primarily attributable to:

- Costs of products sold: expenses for the year ended December 31, 2021 decreased approximately 32% when compared to the same period in 2020. The decrease in cost of products sold is primarily attributable to the discontinuance of the Company's FISH line of products, partially offset by increased costs due to the sale of Curetis products;

- Costs of services: expenses for the year ended December 31, 2021 increased approximately 13% when compared to the same period in 2020. The increase in cost of services is primarily attributable to an increase in laboratory service revenue in 2021;

- Research and development: expenses for the year ended December 31, 2021 increased approximately 9% when compared to the same period in 2020. The increase in research and development expenses is primarily attributable to the inclusion of four quarters of such expenses for Curetis and Ares Genetics in 2021 compared to only three quarters of such expenses in 2020, as a result of the Company's business combination transaction with Curetis closing at the beginning of April 2020;

- General and administrative: expenses for the year ended December 31, 2021 increased approximately 13% when compared to the same period in 2020, primarily due to the inclusion of four quarters of such expenses for Curetis and Ares Genetics in 2021 compared to only three quarters of such expenses in 2020, as a result of the Company's business combination with Curetis closing at the beginning of April 2020;

- Sales and marketing: expenses for the year ended December 31, 2021 increased approximately 20% when compared to the same period in 2020, primarily due to the inclusion of four quarters of such expenses for Curetis and Ares Genetics in 2021 compared to only three quarters of such expenses in 2020, as a result of the Company's business combination with Curetis closing at the beginning of April 2020, partially offset by lower travel costs;

- Transaction costs: transaction costs for the year ended December 31, 2020 represent one-time costs incurred as part of the business combination with Curetis;

- Impairment of right-of-use asset: impairment of right-of-use asset for the year ended December 31, 2021 represents the impairment of our San Diego, California ROU asset. Impairment of right-of-use asset for the year ended December 31, 2020 represents the impairment of our Woburn, Massachusetts ROU asset;

- 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; 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,	
	2021	2020
Gain on extinguishment of debt	$ 259,353	$ 884,970
Warrant inducement expense	(7,755,541)	—
Interest expense	(4,799,331)	(3,399,384)
Foreign currency transaction gains (losses)	891,223	(1,468,855)
Change in fair value of derivative financial instruments	(129,731)	517,680
Interest and other income	45,179	105,627
Total other expense	$ (11,488,848)	$ (3,359,962)

Other expense for the year ended December 31, 2021 increased to a net expense of $11,488,848 from a net expense of $3,359,962 in the same period in 2020. The increase was primarily due to warrant inducement expense recorded in 2021 and an increase in interest expense associated with the debt assumed as part of the Transaction with Curetis.

Liquidity and Capital Resources

At December 31, 2021, the Company had cash and cash equivalents of $36.1 million, compared to $13.4 million at December 31, 2020. The Company has funded its operations primarily through external investor financing arrangements and has raised significant funds in 2021 and 2020, including:

During the year ended December 31, 2020, we sold 7,521,610 shares of common stock under the ATM Agreement resulting in aggregate net proceeds to us of approximately $15.8 million, and gross proceeds of $16.7 million. During the year ended December 31, 2021, we sold 680,000 shares of common stock under the ATM Agreement resulting in aggregate net proceeds to us of approximately $1.48 million, and gross proceeds of $1.55 million.

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

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

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

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

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

We expect that we will need to obtain additional funding to sustain our future operations and while we have successfully raised capital in the past, the ability to raise capital in future periods is not assured. Based on our available cash as of December 31, 2021, we will need to raise additional capital in the next twelve months to continue as a going concern. Management's plan to obtain additional capital may include additional equity or debt financings.

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,	
	2021	2020
Net cash used in operating activities	$ (21,479,277)	$ (23,396,532)
Net cash used in investing activities	(1,983,614)	(1,063,505)
Net cash provided by financing activities	47,451,431	34,087,148

Net cash used in operating activities

Net cash used in operating activities in 2021 consisted primarily of our net loss of $34.8 million, reduced by certain non-cash items, including warrant inducement expense of $7.8 million, depreciation and amortization expense of $2.7 million, non-cash interest of $4.0 million, share-based compensation of $0.9 million, partially offset by gains on debt forgiveness of $0.3 million and the net change in operating assets and liabilities of $2.1 million. 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 $1.7 million.

Net cash used in investing activities

Net cash used in investing activities in 2021 consisted of the purchase of property and equipment. 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 financing activities

Net cash provided by financing activities in 2021 of $47.5 million consisted primarily of net proceeds from the February 2021 Offering, 2021 Warrant Exercise, October 2021 Offering, and our 2020 ATM Offering. 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 the issuance of debt.

Funding requirements

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

- the initiation, progress, timing, costs and results of research and development programs, including analytical 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 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.

We intend to spend substantial amounts on research and development activities, including product development, regulatory and compliance, clinical studies in support of our future product offerings, and commercial activities. In addition, as of December 31, 2021, we had approximately $25.2 million, including deferred interest of approximately $4.8 million, due under our senior, unsecured loan financing facility with the EIB. Approximately $15 million is due under such facility in April 2022. Management may repay such amount in cash or through the issuance of additional equity to the EIB or other restructuring transactions with the EIB. We cannot assure you that additional financing will not be required in the future to support our operations. We intend to use financing opportunities strategically to continue to strengthen our financial position.

Critical Accounting 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 (see Part II, Item 8 of this Form 10-K).

Revenue Recognition

The Company derives revenues from (i) the sale of Unyvero Application cartridges, Unyvero Systems, SARS CoV-2 tests, Acuitas AMR Gene Panel test products, (ii) providing laboratory services, (iii) providing collaboration services including funded software arrangements, and license arrangements, and (iv) granting access to a small subset of the proprietary ARESdb data asset.

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.

Finite-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, 2021 and 2020, the Company did not have any off-balance sheet arrangements.

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 officer, 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, 2021. 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, 2021.

Changes in Internal Control over Financial Reporting

For the quarter ended December 31, 2021, there have been no changes in the Company's internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal controls over financial reporting.

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, 2021. 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, 2021, 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.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

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 2022 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 2022 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 2022 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 2022 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 2022 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, 2021 and 2020, 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)
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)
3.4	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock., (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on October 15, 2021)
3.5	Amendment to the Amended and Restated Bylaws of OpGen, Inc., dated October 15, 2021 (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on October 15, 2021)
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 15, 2019)

Exhibit Number	Description
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 15, 2019)
4.13	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)
4.14	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)
4.15	Form of Common Stock Purchase Warrant for 2021 Offering (incorporated by reference to Exhibit 4.2 to the Registrants, Current Report on Form 8-K, filed on February 10, 2021)
4.16	Form of Pre-Funded Common Stock Purchase Warrant for 2021 Offering (incorporated by reference to Exhibit 4.1 to the Registrants, Current Report on Form 8-K, filed on February 10, 2021)
4.17	Form of New Warrant (incorporated by reference to Exhibit 4.1 to the Registrants, Current Report on Form 8-K, filed on March 9, 2021)
4.18	Form of Common Stock Purchase Warrant for October 2021 Offering (incorporated by reference to Exhibit 4.1 to the Registrants Form 8-K, filed on October 15, 2021)
4.19*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
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)
10.10 !	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)
10.20 !	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).
10.38 !	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)

Exhibit Number	Description
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	Form of Securities Purchase Agreement, dated February 9, 2021, by and between OpGen, Inc. and the purchaser party thereto for 2021 Offering (incorporated by reference to Exhibit 10.1 to the Registrants, Current Report on Form 8-K, filed on February 10, 2021)
10.43	Placement Agent Agreement, dated February 9, 2021, by and between OpGen, Inc. and A.G.P./Alliance Global Partners for 2021 Offering (incorporated by reference to Exhibit 10.2 to the Registrants, Current Report on Form 8-K, filed on February 10, 2021)
10.44	Form of Warrant Exercise Agreement, dated as of March 9, 2021, by and between OpGen, Inc. and the Holder (incorporated by reference to Exhibit 10.1 to the Registrants, Current Report on Form 8-K, filed on March 9, 2021)
10.45	Letter Agreement, dated as of March 9, 2021, by and between A.G.P./Alliance Global Partners and OpGen Inc. (incorporated by reference to Exhibit 10.2 to the Registrants, Current Report on Form 8-K, filed on March 9, 2021)
10.46	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, dated October 13, 2021 by and between OpGen, inc. and the purchaser party thereto (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on October 15, 2021)
10.47!	Executive Employment Agreement by and between the Company and Albert Weber, dated as of November 11, 2021. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on November 4, 2021)
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 30, 2022

By: /s/ Albert Weber
Albert Weber
Chief Financial Officer

Date: March 30, 2022

POWER OF ATTORNEY

We, the undersigned officers and directors of OpGen, Inc., hereby severally constitute and appoint Oliver Schacht and Albert Weber, 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 30, 2022
/s/ Albert Weber Albert Weber	Chief Financial Officer (principal financial officer and principal accounting officer)	March 30, 2022
/s/ Mario Crovetto Mario Crovetto	Director	March 30, 2022
/s/ R. Donald Elsey R. Donald Elsey	Director	March 30, 2022
/s/ Prabha Fernandes Prabha Fernandes	Director	March 30, 2022
/s/ William Rhodes William Rhodes	Director	March 30, 2022

OPGEN, INC.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of 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, 2021 and 2020, 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 "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, 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 accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred recurring losses from operations since inception and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 audit to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of Inventory

As of December 31, 2021, the Company had $4.7 million of inventory which included $0.9 million of raw materials and supplies, $0.1 million in work-in-process and $3.7 million in finished goods. As disclosed in Note 3 to the financial statements, inventories are stated at the lower of cost or net realizable value. The Company assesses its inventory levels along with its purchase commitments each reporting period that is either expected to be at risk of expiration prior to sale or has a cost basis in excess of its net realizable value. The Company's evaluation takes into consideration historic usage, forecasted demand, probability of regulatory approval and anticipated sales price. The Company uses the most recently developed sales forecast to refine the estimated demand to adjust for circumstances in which historical sales are not expected to be representative of future demand including new products with little or no historical demand, products being replaced or discontinued for which demand is expected to decrease, or other customer specific or economic factors.

We identified the valuation of inventory as a critical audit matter. Management's estimates for excess and obsolete inventory involved complex judgments about future market, regulatory and economic conditions outside the Company's control. In particular, the excess inventory calculations are sensitive to significant assumptions, including the expected demand for the Company's products, including the effect on demand of competitive products and the changes in economic, regulatory and market conditions. Given these factors, the related audit effort in evaluating management's judgements was especially challenging, subjective, and complex and required a high degree of auditor judgment.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. We obtained an understanding and evaluated the design of internal controls over the Company's excess or obsolete inventory estimation process, including management's assessment of the assumptions and data underlying the excess or obsolete inventory reserves. Our substantive audit procedures included, among others, evaluating the significant assumptions stated above and the reasonableness of the underlying data used in management's excess or obsolete inventory assessment. We compared on-hand inventories to demand forecasts, assessed the reasonableness of management's demand forecasts through testing historical sales quantities, and evaluated adjustments to demand forecasts for specific product considerations, such as specific customer demand.

Impairment Assessments—Goodwill, Acquired In-Process Research and Development Costs and Finite-lived Intangibles

As disclosed in Note 3 to the financial statements, the Company's goodwill, acquired in-process research and development costs ("IPR&D") and finite-lived intangibles balances were $7.5 million, $5.9 million and $8.6 million, respectively, as of December 31, 2021. These assets are assessed for impairment at least annually, as of the last day of the Company's fourth fiscal quarter, and as triggering events occur. The impairment test for goodwill consists of comparing the fair value of the reporting unit and acquired IPR&D, which is estimated using both the income and market approach, to its carrying value. If the carrying value exceeds the fair value, an impairment loss is recognized in an amount equal to such excess. The Company evaluates finite-lived intangible assets for potential impairment by comparing estimated future undiscounted net cash flows to the carrying amount of the assets. If the carrying amount of the assets exceeds the estimated future undiscounted net cash flows, impairment is measured based on the difference between the carrying amount of the asset and its fair value. The determination of these fair values is primarily based on discounted future cash flows projected to be generated from these assets, including the estimation of future development costs, the probability of success in various phases of development programs and potential post-launch cash flows. In performing both the discounted and undiscounted cash flow analyses, management makes various judgments, estimates and assumptions, the most significant of which are the assumptions related to revenue growth rates, operating profit margin rates, terminal growth rates, and discount rates. Rates used to discount cash flows are dependent upon interest rates and the cost of capital at a point in time. The market approach requires use of market price data of guideline public companies to estimate the fair value of the reporting unit. Changes in these assumptions could have a significant impact on either the fair value, the amount of any impairment charges, or both.

We identified the impairment assessments for goodwill and intangibles as a critical audit matter. Management's estimates for future cash flows projected to be generated from these assets involved complex judgments. In particular, the fair value measurement of the reporting unit and intangibles are sensitive to significant assumptions, including revenue growth rates, operating profit margin rates, terminal growth rates, and discount rates. Given these factors, the related audit effort in evaluating management's judgements was especially challenging, subjective, and complex and required a high degree of auditor judgment and involved the use of professionals with specialized valuation skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. We obtained an understanding and evaluated the design of internal controls over the Company's impairment assessments, including management's assessment of the assumptions and data underlying the projected future cash flows. Our substantive audit procedures included, among others, (i) testing management’s process for developing the fair value estimate of the reporting unit and intangibles; (ii) evaluating the appropriateness of the discounted and undiscounted cash flow analyses; (iii) testing the reasonableness of underlying data used in the analyses; and (iv) evaluating the significant assumptions used by management related to the revenue growth rates, operating profit margin rates, terminal growth rates, and discount rates. Evaluating management’s assumptions related to revenue growth rates, operating profit margin rates, and terminal growth rates involved evaluating whether the assumptions were reasonable considering (i) the current and past performance of the reporting unit and products and technologies associated with the intangibles; (ii) the consistency with external market and industry data; and (iii) whether these assumptions were consistent with evidence obtained in other areas of the audit. In addition, we tested the reconciliation of the fair value of the reporting unit developed by management to the market capitalization of the Company as of the valuation date and evaluated the implied control premium for reasonableness. Professionals with specialized valuation skill and knowledge were used to assist in the evaluation.

/s/ CohnReznick LLP

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

Tysons, Virginia
March 30, 2022

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

	2021	2020
Assets		
Current assets		
Cash and cash equivalents	$ 36,080,392	$ 13,360,463
Accounts receivable, net	1,172,396	653,104
Inventory, net	1,239,456	1,485,986
Prepaid expenses and other current assets	1,250,331	1,388,090
Total current assets	**39,742,575**	**16,887,643**
Property and equipment, net	4,011,748	3,259,487
Finance lease right-of-use assets, net	90,467	449,628
Operating lease right-of-use assets	1,814,396	2,082,300
Goodwill	7,453,007	8,024,729
Intangible assets, net	14,530,209	16,580,963
Strategic inventory	3,472,337	1,686,342
Other noncurrent assets	551,794	779,953
Total assets	**$ 71,666,533**	**$ 49,751,045**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,307,081	$ 1,868,666
Accrued compensation and benefits	1,621,788	2,126,511
Accrued liabilities	1,965,845	1,437,141
Deferred revenue	—	9,808
Short-term notes payable	14,519,113	699,000
Short-term finance lease liabilities	43,150	266,470
Short-term operating lease liabilities	459,792	964,434
Total current liabilities	**19,916,769**	**7,372,030**
Note payable	7,176,251	19,378,935
Derivative liabilities	228,589	112,852
Long-term finance lease liabilities	3,644	46,794
Long-term operating lease liabilities	2,977,402	1,492,544
Other long-term liabilities	146,798	156,635
Total liabilities	**30,449,453**	**28,559,790**
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, 2021 and 2020, respectively	—	—
Common stock, $0.01 par value; 100,000,000 shares authorized; 46,450,250 and 25,085,534 shares issued and outstanding at December 31, 2021 and 2020, respectively	464,503	250,855
Additional paid-in capital	275,708,490	219,129,045
Accumulated deficit	(235,541,539)	(200,735,827)
Accumulated other comprehensive income	585,626	2,547,182
Total stockholders' equity	**41,217,080**	**21,191,255**
Total liabilities and stockholders' equity	**$ 71,666,533**	**$ 49,751,045**

See accompanying notes to consolidated financial statements.

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

	2021	2020
Revenue		
Product sales	$ 2,656,669	$ 2,704,364
Laboratory services	813,210	167,736
Collaboration revenue	836,152	1,342,341
Total revenue	**4,306,031**	**4,214,441**
Operating expenses		
Cost of products sold	2,295,828	3,360,280
Cost of services	552,620	488,211
Research and development, net	10,910,679	9,964,720
General and administrative	9,935,963	8,801,661
Sales and marketing	3,713,263	3,094,092
Transaction costs	—	471,522
Impairment of right-of-use asset	170,714	101,838
Impairment of intangible assets	—	750,596
Gain on sale of equipment	—	(100,000)
Total operating expenses	**27,579,067**	**26,932,920**
Operating loss	**(23,273,036)**	**(22,718,479)**
Other expense		
Gain on extinguishment of debt	259,353	884,970
Warrant inducement expense	(7,755,541)	—
Interest and other income, net	45,179	105,627
Interest expense	(4,799,331)	(3,399,384)
Foreign currency transaction gains/(losses)	891,223	(1,468,855)
Change in fair value of derivative financial instruments	(129,731)	517,680
Total other expense	**(11,488,848)**	**(3,359,962)**
Loss before income taxes	**(34,761,884)**	**(26,078,441)**
Provision for income taxes	43,828	132,403
Net loss	**$** (34,805,712)	$ (26,210,844)
Deemed dividend on beneficial conversion feature	(7,166,752)	—
Net loss available to common stockholders	**$ (41,972,464)**	**$ (26,210,844)**
Basic and diluted net loss per share attributable to common stockholders	**$ (1.14)**	**$ (1.66)**
Weighted average shares outstanding - basic and diluted	36,674,083	15,800,781
Net loss	$ (34,805,712)	$ (26,210,844)
Other comprehensive (loss) income - foreign currency translation	(1,961,556)	2,564,497
Comprehensive loss	**$ (36,767,268)**	**$ (23,646,347)**

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 Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount				
Balances at December 31, 2019	**5,582,280**	**$ 55,823**	**—**	**$ —**	**$178,779,814**	**$ (17,315)**	**$(174,524,983)**	**$ 4,293,339**
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**
Offering of common stock and warrants, net of issuance costs	8,333,333	83,334	—	—	23,390,628	—	—	23,473,962
Offering of preferred stock and warrants, net of issuance costs	—	—	150,000	1,500	13,849,759	—	—	13,851,259
Conversion of preferred stock into common stock	7,500,000	75,000	(150,000)	(1,500)	(73,500)	—	—	—
Beneficial conversion option on convertible preferred stock	—	—	—	—	7,166,752	—	—	7,166,752
Deemed dividend on convertible preferred stock	—	—	—	—	(7,166,752)	—	—	(7,166,752)
At the market offering, net of offering costs	680,000	6,800	—	—	1,477,033	—	—	1,483,833
Warrant exercises	4,847,615	48,476	—	—	9,045,696	—	—	9,094,172
Proceeds from the issuance of warrants	—	—	—	—	255,751	—	—	255,751
Warrant inducement	—	—	—	—	7,755,541	—	—	7,755,541
Issuance of RSUs	3,768	38	—	—	(38)	—	—	—
Stock compensation expense	—	—	—	—	878,575	—	—	878,575
Foreign currency translation	—	—	—	—	—	(1,961,556)	—	(1,961,556)
Net loss	—	—	—	—	—	—	(34,805,712)	(34,805,712)
Balances at December 31, 2021	**46,450,250**	**$ 464,503**	**—**	**$ —**	**$275,708,490**	**$ 585,626**	**$(235,541,539)**	**$ 41,217,080**

See accompanying notes to consolidated financial statements.

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

	2021	2020
Cash flows from operating activities		
Net loss	$ (34,805,712)	$ (26,210,844)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	2,713,907	2,334,739
Noncash interest expense	3,988,755	2,632,241
Noncash interest income	—	(87,233)
Stock compensation expense	878,575	316,086
Gain on sale of equipment	—	(100,000)
Gain on extinguishment of debt	(259,353)	(884,970)
Warrant inducement expense	7,755,541	—
Change in fair value of derivative financial instruments	129,731	(517,680)
Impairment of right-of-use asset	170,714	101,838
Impairment of intangible assets	—	750,596
Changes in operating assets and liabilities, net of acquisition		
Accounts receivable	(575,123)	438,284
Inventory	(2,336,714)	(410,341)
Other assets	739,429	1,152,200
Accounts payable	(471,824)	(481,453)
Accrued compensation and other liabilities	602,605	(1,559,881)
Deferred revenue	(9,808)	(870,114)
Net cash used in operating activities	**(21,479,277)**	**(23,396,532)**
Cash flows from investing activities		
Acquisition of business net of cash acquired	—	1,266,849
Note receivable	—	(2,200,000)
Purchases of property and equipment	(1,983,614)	(130,354)
Net cash used in investing activities	**(1,983,614)**	**(1,063,505)**
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	1,483,833	15,821,922
Proceeds from issuance of common stock warrants	255,751	—
Proceeds from issuance of common stock and pre-funded warrants in private placement, net of selling costs	—	9,289,129
Proceeds from issuance of common stock and pre-funded warrants in registered direct offering, net of selling costs	23,473,962	—
Proceeds from the exercise of common warrants	9,094,172	8,682,000
Proceeds from issuance of preferred stock and warrants, net of issuance costs	13,851,259	—
Proceeds from debt, net of issuance costs	—	1,871,308
Payments on debt	(441,076)	(998,182)
Payments on finance lease obligations	(266,470)	(579,029)
Net cash provided by financing activities	**47,451,431**	**34,087,148**
Effects of exchange rates on cash	(1,463,609)	1,586,541
Net increase in cash, cash equivalents and restricted cash	22,524,931	11,213,652
Cash and cash equivalents and restricted cash at beginning of year	14,107,255	2,893,603
Cash and cash equivalents and restricted cash at end of year	**$ 36,632,186**	**$ 14,107,255**
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 895,200	$ 952,050
Supplemental disclosures of noncash investing and financing activities		
Right-of-use assets acquired through operating leases	$ 615,761	$ 1,008,039
Deemed dividend – beneficial conversion option on preferred stock	$ 7,166,752	$ —
Inventory transferred to property and equipment	$ 530,638	$ —
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 (the "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 to the "Company" include OpGen and its wholly-owned subsidiaries. The Company's headquarters are in Rockville, Maryland and the Company's principal operations are in Rockville, Maryland; Holzgerlingen and Bodelshausen, Germany; and Vienna, Austria. The Company operates in one business segment.

OpGen Overview

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

Following its initial announcement in October 2020, the Company discontinued its QuickFISH and PNA FISH product portfolio in its entirety during the first quarter of 2021 (see Note 12). The Company's FISH customers and distribution partners have been informed accordingly and last orders were received and processed in the first quarter of 2021. The discontinuance of these product lines did not qualify for discontinued operations reporting.

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

Note 2 - Going Concern and Management's Plans

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Since inception, the Company has incurred, and continues to incur, significant losses from operations and negative operating cash flows and has a significant amount of debt coming due in 2022. The Company has funded its operations primarily through external investor financing arrangements and significant actions taken by the Company, including the following:

- On October 18, 2021, the Company closed a registered direct offering (the "October 2021 Offering") with a single healthcare-focused institutional investor of 150,000 shares of convertible preferred stock and warrants to purchase up to an aggregate of 7,500,000 shares of common stock. The shares of preferred stock had a stated value of $100 per share and were converted into an aggregate of 7,500,000 shares of common stock at a conversion price of $2.00 per share after the Company received stockholder approval for an increase to its number of authorized shares of common stock, which approval occurred at the Company's special meeting of stockholders held in December 2021. Thereafter, all preferred stock was converted into 7,500,000 common shares in December 2021 so that there were no shares of preferred stock outstanding as of December 31, 2021. The warrants have an exercise price of $2.05 per share, will become exercisable six months following the date of issuance, and will expire five years following the initial exercise date. The October 2021 Offering raised aggregate net proceeds of $13.9 million, and gross proceeds of $15.0 million.

- On March 9, 2021, the Company entered into a Warrant Exercise Agreement (the "Exercise Agreement") with the institutional investor (the "Holder") from our 2020 PIPE financing (see discussion below for a description of the 2020 PIPE). Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of the remaining 4,842,615 outstanding warrants acquired in the 2020 PIPE (the "Existing Warrants") for cash, pursuant to the terms of and subject to beneficial ownership limitations contained in the Existing Warrants, the Company agreed to issue to the Holder new warrants (the "New Warrants") to purchase 0.65 shares of common stock for each share of common stock issued upon such exercise of the Existing Warrants pursuant to the Exercise Agreement for an aggregate of 3,147,700 New Warrants. The terms of the New Warrants are substantially similar to those of the Existing Warrants, except that the New Warrants have an exercise price of $3.56. The New Warrants are immediately exercisable and will expire five years from the date of the Exercise Agreement. The Holder paid an aggregate of $255,751 to the Company for the purchase of the New Warrants. The Company received aggregate gross proceeds before expenses of approximately $9.65 million from the exercise of the remaining Existing Warrants held by the Holder and the payment of the purchase price for the New Warrants (together, the "2021 Warrant Exercise"). As additional compensation, A.G.P./Alliance Global Partners, the Company's placement agent for such warrant exchange, will receive a cash fee equal to $200,000 upon the cash exercise in full of the New Warrants.

- On February 11, 2021, the Company closed a registered direct offering (the "February 2021 Offering") with a single U.S.-based, healthcare-focused institutional investor for the purchase of (i) 2,784,184 shares of common stock and (ii) 5,549,149 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock. The Company also issued to the investor, in a concurrent private placement, unregistered common share purchase warrants to purchase 4,166,666 shares of the Company's common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of $3.00, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of $2.99. The pre-funded warrants were immediately exercisable, at an exercise price of $0.01, and could be exercised at any time until all of the pre-funded warrants are exercised in full. The common warrants have an exercise price of $3.55 per share, are exercisable commencing on the six-month anniversary of the date of issuance, and will expire five and one-half (5.5) years from the date of issuance. The February 2021 Offering raised aggregate net proceeds of $23.5 million, and gross proceeds of $25.0 million. As of December 31, 2021, all 5,549,149 pre-funded warrants issued in the February 2021 Offering have been exercised.

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

- On February 11, 2020, the Company entered into an At the Market Common Offering (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), which was amended and restated on November 13, 2020 to add BTIG, LLC ("BTIG"), pursuant to which the Company may offer and sell from time to time in an "at the market offering", at its option, up to an aggregate of $22.1 million of shares of the Company's common stock through the sales agents (the "2020 ATM Offering"). During the year ended December 31, 2020, the Company sold 7,521,610 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately $15.8 million, and gross proceeds of $16.7 million. During the year ended December 31, 2021, the Company sold 680,000 shares of its common stock under the 2020 ATM Offering, resulting in aggregate net proceeds to the Company of approximately $1.48 million, and gross proceeds of approximately $1.55 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, will be sufficient to repay or refinance the current portion of the Company's debt and fund operations into the fourth quarter of 2022. This has led management to conclude that there is substantial doubt about the Company's ability to continue as a going concern. In the event the Company is unable to successfully raise additional capital during or before the end of the fourth quarter of 2022, the Company will not have sufficient cash flows and liquidity to finance its business operations as currently contemplated. Accordingly, in such circumstances, the Company would be compelled to immediately reduce general and administrative expenses and delay research and development projects, pause or abort clinical trials including the purchase of scientific equipment and supplies, until it is able to obtain sufficient financing. If such sufficient financing is not received on a timely basis, the Company would then need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

Note 3 - Summary of Significant Accounting Policies

Basis of Presentation

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, 2021 and 2020.

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

Use of Estimates

In preparing financial statements in conformity with GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, liquidity assumptions, revenue recognition, inducement expense related to warrant repricing, 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, 2021 and 2020, the Company had funds totaling $551,794 and $746,792, respectively, which are required as collateral for letters of credit benefiting its landlords and for credit card processors. These funds are reflected in other noncurrent assets on the accompanying consolidated balance sheets.

The following table provides a reconciliation of cash and 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, 2021	December 31, 2020
Cash and cash equivalents	$ 36,080,392	$ 13,360,463
Restricted cash	551,794	746,792
Total cash and cash equivalents and restricted cash in the consolidated statements of cash flows	$ 36,632,186	$ 14,107,255

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 $0 and $20,753 as of December 31, 2021 and 2020, respectively.

At December 31, 2021, the Company had accounts receivable from two customers which individually represented 52% and 14% of total accounts receivable, respectively. At December 31, 2020, the Company had accounts receivable from one customer which individually represented 20% of total accounts receivable. For the year ended December 31, 2021, revenue earned from three customers represented 15%, 13%, and 12% of total revenues, respectively. For the year ended December 31, 2020, revenue earned from one customer represented 21% 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,	
	2021	2020
Raw materials and supplies	$ 866,963	$ 773,021
Work-in-process	100,801	87,159
Finished goods	3,744,029	2,312,148
Total	$ 4,711,793	$ 3,172,328

Inventory includes Unyvero instrument systems, Unyvero cartridges, reagents and components for Unyvero, Acuitas, Curetis SARS CoV-2 test kits, and reagents and supplies used for the Company's laboratory services. Inventory reserves for obsolescence and expirations were $98,064 and $288,378 at December 31, 2021 and 2020, respectively.

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

The Company classifies finished 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 $1,541,561 and $1,152,954 for the years ended December 31, 2021 and 2020, respectively. Property and equipment consisted of the following at December 31, 2021 and 2020:

	December 31,	
	2021	2020
Laboratory and manufacturing equipment	$ 4,613,324	$ 6,317,340
Office furniture and equipment	810,574	1,259,838
Computers and network equipment	491,183	1,692,154
Leasehold improvements	1,634,692	752,493
	7,549,773	10,021,825
Less accumulated depreciation	(3,538,025)	(6,762,338)
Property and equipment, net	$ 4,011,748	$ 3,259,487

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, 2021 and 2020, 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. During the year ended December 31, 2021, the Company determined that the ROU asset associated with its San Diego, California office lease may not be recoverable. As a result, during the year ended December 31, 2021, the Company recorded an impairment charge of $170,714. The Company also recorded an 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, 2021 consist of finite-lived and indefinite-lived intangible assets and goodwill.

Finite-lived and indefinite-lived intangible assets

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

		December 31, 2021				December 31, 2020			
	Subsidiary	Cost	Accumulated Amortization and Prior Year Impairment	Effect of Foreign Exchange Rates	Net Balance	Accumulated Amortization	Impairment	Effect of Foreign Exchange Rates	Net Balance
Trademarks and tradenames	AdvanDx	$ 461,000	$ (461,000)	$ —	$ —	$ (217,413)	$ (243,587)	$ —	$ —
Developed technology	AdvanDx	458,000	(458,000)	—	—	(308,526)	(149,474)	—	—
Customer relationships	AdvanDx	1,094,000	(1,094,000)	—	—	(736,465)	(357,535)	—	—
Trademarks and tradenames	Curetis	1,768,000	(316,930)	43,015	1,494,085	(147,161)	—	194,119	1,814,958
Distributor relationships	Curetis	2,362,000	(282,277)	57,465	2,137,188	(131,070)	—	259,336	2,490,266
A50 - Developed technology	Curetis	349,000	(89,384)	8,492	268,108	(41,504)	—	38,319	345,815
Ares - Developed technology	Curetis	5,333,000	(682,833)	129,745	4,779,912	(317,060)	—	585,536	5,601,476
A30 - In-Process Research & Development	Curetis	5,706,000	—	144,916	5,850,916	—	—	622,448	6,328,448
		$ 17,531,000	$ (3,384,424)	$ 383,633	$ 14,530,209	$ (1,899,199)	$ (750,596)	$ 1,699,758	$ 16,580,963

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 $813,184 and $672,823 for the years ended December 31, 2021 and 2020, respectively. Expected future amortization of intangible assets is as follows:

Year Ending December 31,		
2022	$	783,669
2023		783,669
2024		783,669
2025		783,669
2026		783,669
Thereafter		4,760,948
Total	$	8,679,293

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. During 2021, events and circumstances indicated the Company's intangible assets might be impaired. However, management's estimate of undiscounted cash flows indicated that such carrying amounts were expected to be recovered. Nonetheless, it is reasonably possible that the estimate of undiscounted cash flows may change in the near term, resulting in the need to write down those assets to fair value.

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, 2021 and 2020 was $7,453,007 and $8,024,729, respectively.

The changes in the carrying amount of goodwill as of December 31, 2021, and since December 31, 2019, were as follows:

Balance as of December 31, 2019	$	600,814
Acquisition of Curetis		6,688,652
Changes in currency translation		735,263
Balance as of December 31, 2020		8,024,729
Changes in currency translation		(571,722)
Balance as of December 31, 2021	$	7,453,007

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, 2021 and 2020, the Company determined that its goodwill was not impaired.

Revenue recognition

The Company derives revenues from (i) the sale of Unyvero Application cartridges, Unyvero Systems, SARS CoV-2 tests, Acuitas AMR Gene Panel test products, (ii) providing laboratory services, (iii) providing collaboration services including funded software arrangements, and license arrangements, and (iv) granting access to a small subset of the proprietary ARESdb data asset.

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 European 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, 2021, the Company recognized $692,701 as a reduction of research and development expense related to government grant arrangements. 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. As of December 31, 2021 and 2020, the Company had earned but not yet received $396,365 and $413,530, respectively 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, development materials, 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

The Company uses the quoted market price of its common stock as its fair value.

Expected volatility

Through 2020, since OpGen did not have sufficient history to estimate the expected volatility of its common stock price, expected volatility was based on the volatility of peer public entities that were similar in size and industry. Beginning in 2021, for stock options with an expected term where there is sufficient history available, expected volatility is based on the volatility of OpGen's common stock.

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 $202,015,062 and $196,511,928 at December 31, 2021 and 2020, 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 $170,607,782 at December 31, 2021 from their foreign subsidiaries. $147,313,786 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 18.2 million shares and 7.5 million shares as of December 31, 2021 and 2020, respectively.

Adopted accounting pronouncements

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

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

Recently issued accounting standards

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

Note 4 - Business Combination

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

At the closing, the Company assumed all of the liabilities of the Seller solely and exclusively related to the acquired business, which is providing innovative solutions, through development of proprietary platforms, diagnostic content, applied bioinformatics, lab services, research services and commercial collaborations and agreements, for molecular microbiology, diagnostics designed to address the global challenge of detecting severe infectious diseases and identifying antibiotic resistances in hospitalized patients. Pursuant to the Implementation Agreement, the Company also assumed and adopted the Seller Stock Option Plan as an Amended and Restated Stock Option Plan of the Company. In connection with the foregoing, the Company assumed all awards thereunder that were outstanding as of the closing date and converted such awards into options to purchase shares of the Company's common stock pursuant to the terms of the applicable award. In addition, the Company assumed, at the closing, all of the outstanding convertible notes issued by 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 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, 2020. Pro forma information primarily reflects adjustments relating to the amortization of intangibles acquired and elimination of interest expense due under the interim facility. The pro forma amounts do not purport to be indicative of the results that would have actually been obtained if the acquisition occurred as of January 1, 2020 or that may be obtained in the future.

Unaudited pro forma results	Year ended December 31,
	2020
Revenues	$ 5,239,192
Net loss	(29,319,303)
Net loss per share	(1.86)

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,	
	2021	2020
Product sales	$ 2,656,669	$ 2,704,364
Laboratory services	813,210	167,736
Collaboration revenue	836,152	1,342,341
Total revenue	$ 4,306,031	$ 4,214,441

Revenues by geography are as follows:

	Years Ended December,	
	2021	2020
Domestic	$ 1,203,748	$ 1,917,367
International	3,102,283	2,297,074
Total revenue	$ 4,306,031	$ 4,214,441

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 period from amounts acquired from Curetis		(870,114)
Effect of foreign exchange rates		40,839
Balance at December 31, 2020		9,808
New deferrals, net of amounts recognized in the current period		—
Amounts returned to customers		(9,808)
Effect of foreign exchange rates		—
Balance at December 31, 2021	$	—

Contract assets

The Company had approximately $0 and $18,000 of contract assets as of December 31, 2021 and 2020 respectively, which are generated when contractual billing schedules differ from revenue recognition timing. Contract assets represent a conditional right to consideration for satisfied performance obligations that becomes a billed receivable when the conditions are satisfied.

Unsatisfied performance obligations

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

Note 6 - Fair value measurements

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

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

For the year ended December 31, 2021, the Company has not transferred any assets between fair value measurement levels.

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

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

In June 2019, Curetis drew down a third tranche of EUR 5.0 million from the 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 was 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 years ended December 31, 2021 and 2020 was as follows:

Description	Balance at December 31, 2020	Change in Fair Value	Effect of Foreign Exchange Rates	Balance at December 31, 2021
Participation percentage interest liability	$ 112,852	$ 129,731	$ (13,994)	$ 228,589
Total revenue	$ 112,852	$ 129,731	$ (13,994)	$ 228,589

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). During the year ended December 31, 2021, the Company recorded impairment expense of $170,714 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, 2021 and 2020:

	December 31,	
	2021	2020
EIB	$ 25,161,855	$ 25,936,928
PPP	—	259,353
MGHIF	—	331,904
Insurance financings	—	107,742
Total debt obligations	25,161,855	26,635,927
Unamortized debt discount	(3,466,491)	(6,557,992)
Carrying value of debt	21,695,364	20,077,935
Less current portion	(14,519,113)	(699,000)
Long-term debt	$ 7,176,251	$ 19,378,935

MGHIF financing

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

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

On June 11, 2018, the Company executed an Allonge to the MGHIF Note. The Allonge provided that accrued and unpaid interest of $285,512 due as of July 14, 2018, the original maturity date, be paid through the issuance of shares of OpGen's common stock in a private placement transaction. In addition, the Allonge revised and extended the maturity date for payment of the MGHIF Note to six semi-annual payments of $166,667 plus accrued and unpaid interest beginning on January 2, 2019 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 were deferred and amortized as incremental expense over the term of the MGHIF Note. During the year ended December 31, 2021, the Company made the final payment under the MGHIF Note and the lien on the Company's assets was released.

Yorkville Convertible Notes

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

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

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

EIB Loan Facility

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

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

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

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

On July 10, 2020, EIB agreed to defer total interest payments of €720k due in April and June 2020 under the first three tranches of the debt financing facility until December 31, 2021. 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, 2021, the outstanding borrowings under all tranches were €22,216,012 (approximately USD $25,161,855), including deferred interest payable at maturity of €4,216,012 (approximately USD $4,775,055).

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 were dated April 22, 2020. The principal amount of the Company Note was $879,630, and the principal amount of the Subsidiary Note was $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. The Company Note was forgiven in November 2020. In May 2021, the Subsidiary Note was forgiven.

Total interest expense (including accretion of fair value to face value and amortization of debt discounts and financing fees) on all debt instruments was $4,799,331 and $3,399,984 for the years ended December 31, 2021 and 2020, respectively.

Note 8 - Stockholders' Equity

As of December 31, 2021, the Company has 100,000,000 shares of authorized common shares and 46,450,250 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 December 8, 2021, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to increase the authorized shares of common stock from 50,000,000 to 100,000,000 shares.

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. 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 Annual Report have been adjusted to reflect the reverse stock splits.

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

On February 11, 2020, the Company entered into an ATM Agreement with Wainwright, which we amended and restated on November 13, 2020 to add BTIG, LLC pursuant to which the Company may offer and sell from time to time in an "at the market offering," at its option, up to an aggregate of $22.1 million of shares of the Company's common stock through the sales agents. 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. During the year ended December 31, 2021, the Company sold 680,000 shares of its common stock under the 2020 ATM Offering resulting in aggregate net proceeds to the Company of approximately $1.48 million, and gross proceeds of $1.55 million. As of December 31, 2021, remaining availability under the ATM Agreement is $3.9 million.

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

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

On February 11, 2021, the Company closed the February 2021 Offering with a single U.S.-based, healthcare-focused institutional investor for the purchase of (i) 2,784,184 shares of common stock and (ii) 5,549,149 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock. The Company also issued to the investor, in a concurrent private placement, unregistered common warrants to purchase 4,166,666 shares of the Company's common stock. Each share of common stock and accompanying common warrant were sold together at a combined offering price of $3.00, and each pre-funded warrant and accompanying common warrant were sold together at a combined offering price of $2.99. The pre-funded warrants are immediately exercisable, at an exercise price of $0.01, and may be exercised at any time until all of the pre-funded warrants are exercised in full. The common warrants will have an exercise price of $3.55 per share, will be exercisable commencing on the six-month anniversary of the date of issuance, and will expire five and one-half (5.5) years from the date of issuance. The February 2021 Offering raised aggregate net proceeds of $23.5 million, and gross proceeds of $25.0 million. As of December 31, 2021, all pre-funded warrants issued in the February 2021 Offering have been exercised.

On March 9, 2021, the Company entered into an Exercise Agreement with the Holder from our 2020 PIPE financing. Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of the remaining 4,842,615 Existing Warrants for cash, pursuant to the terms of and subject to beneficial ownership limitations contained in the Existing Warrants, the Company agreed to issue to the Holder, New Warrants to purchase 0.65 shares of common stock for each share of common stock issued upon such exercise of the remaining Existing Warrants pursuant to the Exercise Agreement for an aggregate of 3,147,700 New Warrants. The terms of the New Warrants are substantially similar to those of the Existing Warrants, except that the New Warrants have an exercise price of $3.56. The New Warrants are immediately exercisable and will expire five years from the date of the Exercise Agreement. The Holder paid an aggregate of $255,751 to the Company for the purchase of the New Warrants. The Company received aggregate gross proceeds before expenses of approximately $9.65 million from the exercise of the remaining Existing Warrants held by the Holder and the payment of the purchase price for the New Warrants. The Company recognized approximately $7.8 million of non-cash warrant inducement expense during year ended December 31, 2021 related to this transaction representing the fair value of the New Warrants issued to induce the exercise. The fair values were calculated using the Black-Scholes option pricing model.

On October 18, 2021, the Company closed the October 2021 Offering with a single healthcare-focused institutional investor of 150,000 shares of convertible preferred stock and warrants to purchase up to an aggregate of 7,500,000 shares of common stock. The shares of preferred stock had a stated value of $100 per share and were converted into an aggregate of 7,500,000 shares of common stock at a conversion price of $2.00 per share after the Company received stockholder approval for an increase to its number of authorized shares of common stock, which approval occurred at the Company's special meeting of stockholders held in December 2021. The warrants have an exercise price of $2.05 per share, will become exercisable six months following the date of issuance, and will expire five years following the initial exercise date. The warrants are classified as permanent equity at December 31, 2021. In connection with the issuance of convertible preferred stock, the Company recognized a beneficial conversion feature of $7,166,752 as a deemed dividend to the preferred stockholders.

On December 8, 2021, the Company received shareholder approval to increase the number of authorized shares of common stock of the Company. As of December 31, 2021, all 150,000 shares of convertible preferred stock were converted into an aggregate of 7,500,000 shares of common stock. The October 2021 Offering raised aggregate net proceeds of $13.9 million, and gross proceeds of $15.0 million.

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, 2021, 465,586 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 1,300,000 shares of the Company's common stock would be made by the Board of Directors of the Company outside of the stockholder-approved equity incentive plan to its executive officers and non-employee directors (the "2020 Stock Options Plan"). The 2020 Stock Options Plan and the grant made thereunder were approved by the Board of Directors on August 6, 2020, subject to receipt of stockholder approval at the 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 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. As of December 31, 2021, no shares remain available for 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, 2021 and 2020, the Company recognized stock compensation expense as follows:

	Years Ended December 31,	
	2021	2020
Cost of services	$ 10,299	$ 2,927
Research and development	232,319	62,783
General and administrative	553,557	231,010
Sales and marketing	82,400	19,366
	$ 878,575	$ 316,086

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, 2021, the Company had unrecognized expense related to its stock options of $1.0 million, which will be recognized over a weighted average period of 2.5 years.

A summary of the status of options granted is presented below as of and for the years ended December 31, 2021 and 2020:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
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	$ —
Granted	415,000	$ 1.99		
Exercised	—	$ —		
Forfeited	(363,554)	$ 2.17		
Expired	(2,619)	$ 544.38		
Outstanding at December 31, 2021	1,713,349	$ 6.88	8.5	$ —
Vested and expected to vest	1,713,349	$ 6.88	8.5	$ —
Exercisable at December 31, 2021	731,090	$ 10.45	8.0	$ —

The total fair value of options vested in the years ended December 31, 2021 and 2020 was $622,757 and $549,341, 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,	
	2021	2020
Annual dividend	—	—
Expected life (in years)	5.75 - 6.00	5.25 - 6.25
Risk free interest rate	0.9% - 1.1%	0.3% - 0.5%
Expected volatility	121.3% - 123.1%	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, 2021 and 2020:

	Number of Units	Weighted-Average Grant Date Fair Value
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
Granted	360,000	$ 1.99
Vested	(3,768)	$ 8.94
Forfeited	(78,085)	$ 2.23
Unvested at December 31, 2021	286,265	$ 2.03

As of December 31, 2021, there was approximately $320,000 of unrecognized compensation cost related to restricted stock units, which is expected to be recognized over a weighted average period of 1 years.

Stock purchase warrants

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

Issuance	Exercise Price	Expiration	Outstanding at December 31, 2021 (1)	Outstanding at December 31, 2020 (1)
November 2011	$ 3,955.00	November 2021	—	15
December 2011	$ 3,955.00	December 2021	—	2
February 2015	$ 3,300.00	February 2025	451	451
May 2016	$ 656.20	May 2021	—	9,483
June 2016	$ 656.20	May 2021	—	4,102
June 2017	$ 390.00	June 2022	938	938
July 2017	$ 345.00	July 2022	318	318
July 2017	$ 250.00	July 2022	2,501	2,501
July 2017	$ 212.60	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	354,000	359,000
October 2019	$ 2.60	October 2024	235,000	235,000
November 2020	$ 1.94	May 2026	—	4,842,615
November 2020	$ 2.68	May 2026	242,130	242,130
February 2021	$ 3.55	August 2026	4,166,666	—
February 2021	$ 3.90	August 2026	416,666	—
March 2021	$ 3.56	March 2026	3,147,700	—
October 2021	$ 2.05	April 2027	7,500,000	—
			16,217,946	5,848,131

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 $34.8 million and $26.1 million for the years ended December 31, 2021 and 2020, respectively.

The Company's provision for income taxes consists of the following for the years ended December 31, 2021 and 2020:

	December 31, 2021	December 31, 2020
Current income tax provision		
Federal	$ 36,084	$ —
State	7,744	—
Foreign	—	132,403
Total	43,828	132,403
Deferred income tax provision		
Federal	—	—
State	—	—
Foreign	—	—
Total	—	—
Total provision for income taxes	$ 43,828	$ 132,403

At December 31, 2021 and 2020, the Company had deferred tax assets of $106,839,267 and $103,185,302, 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, 2021 and 2020 have been offset by a valuation allowance of $106,088,316 and $98,874,420, 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, 2021 and 2020 are as follows:

	December 31,	
	2021	2020
Deferred tax assets:		
NOL carryforward	$ 102,388,393	$ 98,165,790
R&D credit carryforward	2,559,479	2,559,479
Share-based compensation	498,658	319,397
Depreciation	—	100,157
Interest expense	502,575	1,233,203
ROU liabilities	567,624	475,645
Accruals and other	322,538	331,631
Total deferred tax assets	106,839,267	103,185,302
Valuation allowance	(106,088,316)	(98,874,420)
Deferred tax liabilities:		
Intangible assets	(178,478)	(3,885,485)
ROU assets	(225,057)	(425,397)
Depreciation	(347,416)	—
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:

	2021	2020
Federal income tax benefit at statutory rates	21.0%	21.0%
Permanent adjustment	(4.4)%	0.6%
Provision to return adjustment	(0.1)%	—
State income tax benefit, net of federal benefit	1.6%	3.5%
Foreign rate differential	2.4%	2.8%
Change in valuation allowance	(20.6)%	(28.4)%
	(0.1)%	(0.5)%

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, 2021 and 2020. Accordingly, a valuation allowance of $106.1 million and $98.9 million has been recorded to offset the net deferred tax assets.

The Company has federal NOL carryforwards of $202,015,062 and $196,511,928 at December 31, 2021 and 2020, respectively. The Company also has total Foreign NOL carryforwards at December 31, 2021 of $170,607,782 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 Code, defined earlier. 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 Code, 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.

On March 27, 2020, the United States enacted the 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, 2021, the Company had acquired twenty-four QuantStudio 5s including none during the year ended December 31, 2021. As of December 31, 2021, the Company has not committed to acquiring additional QuantStudio 5s in the next three months.

Curetis places frame-work orders for Unyvero-Systems and for raw materials for its cartridge manufacturing to ensure availability during commercial ramp-up-phase and also to gain volume-scale-effects with regards to purchase prices. Some of the electronic parts used for the production of Unyvero-Systems have lead times of 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 $0.9 million.

COVID-19 Impact

In December 2019 and early 2020, the coronavirus known as COVID-19 was reported to have surfaced in China. The spread of this virus including its variants and mutations globally in 2020 and 2021 as well as into 2022 has caused significant business disruption domestically in the United States and in Europe, as well as China, the areas in which the Company primarily operates or has significant business interest. While the disruption is currently expected to be temporary, such disruption is still ongoing and there remains considerable uncertainty around the duration of this disruption. Therefore, while the Company expects that this matter will continue to impact the Company’s financial condition, results of operations, or cash flows, the extent of the financial impact and duration cannot be reasonably estimated at this time.

Note 11 - Leases

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

Lease Classification	December 31, 2021	December 31, 2020
ROU Assets:		
Operating	$ 1,814,396	$ 2,082,300
Financing	90,467	449,628
Total ROU assets	$ 1,904,863	$ 2,531,928
Liabilities		
Current:		
Operating	$ 459,792	$ 964,434
Finance	43,150	266,470
Noncurrent:		
Operating	2,977,402	1,492,544
Finance	3,644	46,794
Total lease liabilities	$ 3,483,988	$ 2,770,242

Maturities of lease liabilities as of December 31, 2021 by year are as follows:

Maturity of Lease Liabilities	Operating	Finance	Total
2022	$ 745,850	$ 44,850	$ 790,700
2023	639,172	3,364	642,536
2024	648,767	280	649,047
2025	544,080	—	544,080
2026	378,279	—	378,279
Thereafter	2,126,371	—	2,126,371
Total lease payments	5,082,519	48,494	5,131,013
Less: Interest	(1,645,325)	(1,700)	(1,647,025)
Present value of lease liabilities	$ 3,437,194	$ 46,794	$ 3,483,988

Consolidated statements of operations classification of lease costs as of the years ended December 31, 2021 and 2020 are as follows:

		Years ended December 31,	
Lease Cost	Classification	2021	2020
Operating	Operating expenses	$ 1,055,595	$ 1,205,551
Finance:			
Amortization	Operating expenses	359,162	508,962
Interest expense	Other expenses	15,481	57,247
Total lease costs		$ 1,430,238	$ 1,771,760

Other lease information as of December 31, 2021 is as follows:

Other Information	Total
Weighted average remaining lease term (in years)	
Operating leases	7.6
Finance leases	0.9
Weighted average discount rate:	
Operating leases	8.9%
Finance leases	9.1%

Supplemental cash flow information for the years ended December 31, 2021, and 2020 is as follows:

Supplemental Cash Flow Information	2021	2020
Cash paid for amounts included in the measurement of lease liabilities		
Cash used in operating activities		
Operating leases	$ 1,055,595	$ 1,205,551
Finance leases	$ 15,481	$ 57,247
Cash used in financing activities		
Finance leases	$ 266,470	$ 579,029
ROU assets obtained in exchange for lease obligations:		
Operating leases	$ 615,761	$ 1,008,039
Finance leases	$ —	$ —

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. ILÚM has since been acquired by Infectious Disease Connect, Inc. ("IDC"), a University of Pittsburgh Medical Center ("UPMC") Enterprise company. The Company is working together with DOH's Wadsworth Center and IDC to continue development of an infectious disease digital health and precision medicine platform that connects healthcare institutions to DOH and uses genomic microbiology for statewide surveillance and control of antimicrobial resistance. As part of the collaboration, the Company received approximately $1.6 million over the 15-month demonstration portion of the project. The demonstration project began in early 2019 and was completed in the first quarter of 2020. In April 2020, the Company began a second-year expansion phase to build on the successes and experience of the first-year pilot phase while focusing on accomplishing the goal of the effort to improve patient outcomes and save healthcare dollars by integrating real-time epidemiologic surveillance with rapid delivery of antibiotic resistance results to care-givers via web-based and mobile platforms. The second-year contract included a quarterly retainer-based project fee as well as volume-dependent per test fees for a total contract value of up to $450,000 to OpGen. In April 2021, the Company extended its second-year expansion phase by another six months through September 30, 2021 at which point the project was completed and has ended. The six-month extension and expansion contract included a quarterly retainer-based project fee as well as volume-dependent per test fees for a total contract value of up to an additional $540,000. During the years ended December 31, 2021 and 2020, the Company recognized $558,000 and $388,000 of revenue related to the contract, respectively.

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 had an initial term of 36 months and recently been extended to end January 31, 2025, Ares Genetics and Sandoz intend to develop a digital anti-infectives platform, combining established microbiology laboratory methods with advanced bioinformatics and artificial intelligence methods to support drug development and life-cycle management. The collaboration, in the short- to mid-term, aims to both rapidly and cost-effectively re-purpose existing antibiotics and design value-added medicines with the objective of expanding indication areas and to overcome antibiotic resistance, in particular with regards to infections with bacteria that has already developed resistance against multiple treatment options. In the longer-term, the platform is expected to enable surveillance for antimicrobial resistant pathogens to inform antimicrobial stewardship and the development of novel anti-infectives that are less prone to encounter resistance and thereby preserve antibiotics as an effective treatment option.

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

Qiagen

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

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

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

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. A license was not executed and the collaboration ended in early 2021.

The Company recognized approximately $0 and $870,000 of revenue related to the contract during the years ended December 31, 2021 and 2020, respectively.

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, 2021 in conjunction with its announced exit of the FISH business in June 2021. The Company paid a one-time settlement fee of $350,000 and paid a 10% royalty on the sale of eligible products through June 2021 but is no longer subject to any minimum royalty obligations. The Company recognized net royalty expense related to this license of $11,721 and $(68,854) for the years ended December 31, 2021 and 2020, respectively.

Siemens

In 2016, Ares Genetics acquired the GEAR assets from Siemens Technology Accelerator GmbH (STA), providing the original foundation to ARESdb. Under the agreement with STA, Ares Genetics incurs royalties on revenues from licensed product sales or sublicensing proceeds. Royalty rates under the Siemens agreement range from 1.3% to 40% depending on the specifics of the licenses and rights provided by Ares Genetics to third parties and whether such third parties may have been originally introduced by Siemens to Ares Genetics. The total net royalty expense related to this agreement was $146,375 and $2,775 for the years ended December 31, 2021 and 2020, 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

The Company’s management reviewed all material events through the date the consolidated financial statements were issued for subsequent event disclosure consideration, and none were noted.

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, 2021, our authorized capital stock consists of 100,000,000 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 10,000,000 shares are available for future issuance. As of March 25, 2022, 46,557,750 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.

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. 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 10,000,000 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.

OPGEN, INC.

The following is a list of subsidiaries of OpGen, Inc. as of December 31, 2021:

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. 333-256821, 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 No. 333-258646, No. 333-256820, 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 30, 2022, on our audits of the consolidated financial statements of OpGen, Inc. as of December 31, 2021 and 2020 and for the years then ended, included in this Annual Report on Form 10-K of OpGen, Inc. for the year ended December 31, 2021.

/s/ CohnReznick LLP

Tysons, Virginia
March 30, 2022

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 30, 2022

/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, Albert Weber, 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 30, 2022

/s/ Albert Weber
Albert Weber
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, 2021 (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 30, 2022

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

Date: March 30, 2022

/s/ Albert Weber
Albert Weber
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.