As filed with the Securities and Exchange Commission on December 1, 2022

Registration No. 333-_____

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

OPGEN, INC.
(Exact name of registrant as specified in its charter)

Delaware	**8071**	**06-1614015**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

9717 Key West Avenue, Suite 100
Rockville, MD 20850
(301) 869-9683
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Oliver Schacht, Ph.D.
Chief Executive Officer
9717 Key West Avenue, Suite 100
Rockville, MD 20850
(301) 869-9683
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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New York, NY 10105
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box. [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [_]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [_]

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [_]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the 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 [X]	Smaller Reporting Company [X]
	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 to Section 7(a)(2)(B) of the Securities Act. [_]

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion: Dated [_____], 2022

Preliminary Prospectus

Up to [_____] Shares of Common Stock

[____] Common Warrants to Purchase Up to [_____] Shares of Common Stock

Up to [_____] Pre-Funded Warrants to Purchase Up tp [_____] Shares of Common Stock

Up to [_____] Shares of Common Stock Underlying the Common Warrants and Pre-Funded Warrants

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We are offering up to [_____] shares of our common stock together with warrants to purchase up to [_____] shares of common stock. The shares of common stock and warrants will be sold in a fixed combination, with each share of common stock accompanied by one warrant to purchase one share of common stock, or a common warrant. The shares of common stock and common warrants are immediately separable and will be issued separately in this offering, but must be purchased together in this offering. The assumed public offering price for each share of common stock and accompanying common warrant is $[__], which was the closing price of our common stock on The Nasdaq Capital Market on [_____], 2022. The common warrants will be immediately exercisable for a term of five years after the date of their issuance, at an exercise price of $ per share of common stock.

We are also offering to certain purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, pre-funded warrants, in lieu of shares of common stock that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. The public offering price of each pre-funded warrant and accompanying common warrant will be equal to the price at which one share of common stock and accompanying common warrant is sold to the public in this offering, minus $0.01, and the exercise price of each pre-funded warrant will be $0.01 per share. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. The pre-funded warrants and common warrants are immediately separable and will be issued separately in this offering, but must be purchased together in this offering. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis.

This offering will terminate on _____, unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date. We will have one closing for all the securities purchased in this offering. The combined public offering price per share (or pre-funded warrant) and common warrant will be fixed for the duration of this offering.

Our common stock is listed on The Nasdaq Capital Market under the symbol "OPGN". On [_____], 2022, the last reported sale price of our common stock on The Nasdaq Capital Market was $[___] per share. The public offering price per share of common stock and accompanying common warrant and per pre-funded warrant and accompanying common warrant will be determined between us and investors based on market conditions at the time of pricing, and may be at a discount to the then current market price of our common stock. The recent market price used throughout this prospectus may not be indicative of the actual offering price. The actual public offering price may be based upon a number of factors, including our history and our prospects, the industry in which we operate, our past and present operating results, the previous experience of our executive officers and the general condition of the securities markets at the time of this offering. There is no established public trading market for the pre-funded warrants and the common warrants and we do not expect a market to develop. Without an active trading market, the liquidity of the pre-funded warrants and the common warrants will be limited. In addition, we do not intend to list the pre-funded warrants or the common warrants on The Nasdaq Capital Market, any other national securities exchange or any other trading system.

We have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent in connection with this offering. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agent is not purchasing or selling any of the securities we are offering and the placement agent is not required to arrange the purchase or sale of any specific number of securities or dollar amount. We have agreed to pay to the placement agent the placement agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. There is no arrangement for funds to be received in escrow, trust or similar arrangement. There is no minimum offering requirement as a condition of closing of this offering. We will bear all costs associated with the offering. See "Plan of Distribution" on page [ ] of this prospectus for more information regarding these arrangements.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 6 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share and Common Warrant	Per Pre-Funded Warrant and Common Warrant	Total
Public offering price	$	$	$
Placement agent fees (1)	$	$	$
Proceeds, before expenses, to OpGen, Inc.	$	$	$

(1) We have also agreed to reimburse the placement agent for certain of its offering-related expenses, including a reimbursement for legal fees and expenses in the amount of up to $60,000, and for its clearing expenses in the amount of $15,950. For a description of the compensation to be received by the placement agent, see "Plan of Distribution" for more information.

The placement agent expects to deliver the securities to the purchasers on or about [___], 2022, subject to satisfaction of customary closing conditions.

H.C. WAINWRIGHT & CO.

Prospectus dated [___], 2022

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information other than the information that we have provided or incorporated by reference in this prospectus and your reliance on any unauthorized information or representation is at your own risk. This prospectus may be used only in jurisdictions where offers and sales of these securities are permitted. You should assume that the information appearing in this prospectus is accurate only as of the date of this prospectus and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, or any sale of our common stock. Our business, financial condition and results of operations may have changed since those dates.

The information appearing in this prospectus, the documents incorporated by reference in this prospectus and any free writing prospectus that we have authorized for use in connection with this offering is accurate only as of its respective date, regardless of the time of delivery of the respective document or of any sale of securities covered by this prospectus. You should not assume that the information contained in or incorporated by reference in this prospectus, or in any free writing prospectus that we have authorized for use in connection with this offering, is accurate as of any date other than the respective dates thereof.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporated by reference filed with the U.S. Securities and Exchange Commission (the "SEC") before the date of this prospectus, on the other hand, you should rely on the information in this prospectus. If any statement in a document incorporated by reference is inconsistent with a statement in another document incorporated by reference having a later date, the statement in the document having the later date modifies or supersedes the earlier statement.

Neither we nor the placement agent have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons who come into possession of this prospectus and any free writing prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus and any free writing prospectus applicable to that jurisdiction.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data and we do not make any representation as to the accuracy of the information.

Note Regarding Trademarks

We own various U.S. federal trademark registrations and applications and unregistered trademarks and service marks, including OpGen®, Curetis®, Unyvero®, ARES® and ARES GENETICS®, and Acuitas®. All other trademarks, servicemarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus 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.

PROSPECTUS SUMMARY

This summary highlights information contained in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. You should read the entire prospectus carefully before making an investment in our securities. You should carefully consider, among other things, our financial statements and the related notes and the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in, or incorporated by reference into, this prospectus. When we refer to OpGen, Inc., and its subsidiaries, we use the terms "OpGen," "the Company," "us," "we" and "our."

Overview

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

Our focus is on our combined broad portfolio of products, which include high impact rapid diagnostics and bioinformatics to interpret antimicrobial resistance (AMR) genetic data. We will continue to develop and seek FDA and other regulatory clearances or approvals, as applicable, for additional diagnostic tests. We 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 research use only (RUO) products to hospitals, public health departments, clinical laboratories, pharmaceutical companies and contract research organizations (CRO). We are also continuing to commercialize our CE-marked Unyvero Panels in Europe and other global markets through distributors.

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 in vitro diagnostics (IVD) platform 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 for hospitalized pneumonia, or HPN. As requested by the Chinese regulatory authority National Medical Products Administration (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. As a result of the Chinese regulatory atuhorities recent adoption of a new electronic submission regime, we plan to prepare a new submission BCB and their regulatory advisors for our pneumonia cartridge filing and currently expect to complete the process within 24 to 30 months.

- 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 an 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, presented positive data from an interim analysis in the first quarter of 2022, and completed enrollment at the end of the third quarter of 2022.

- The Unyvero Invasive Joint Infection, or IJI, test, which is a test specifically being developed for the U.S. market on the Unyvero A30 platform, has also been selected for analytical and clinical performance evaluation including clinical trials towards a future submission to the FDA. We anticipate such clinical trial not to commence before the second quarter of 2023. 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 the Unyvero IJI test 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 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 AMR patterns early and supports appropriate antibiotic treatment decisions in this indication. We have begun commercializing the Acuitas AMR Gene Panel for isolates to customers in the United States and have successfully signed the first two commercial contracts with customers and completed system installation and user training for such customers.

- We recently entered into a research and development collaboration with FIND, the global alliance for diagnostics, which will fund the development of the A30 *RQ* platform for use in low and middle income countries (LMICs). The initial project focuses on a feasibility study for the rapid detection of AMR from blood culture. The feasibility phase of this research and development project is set to conclude by the end of the first quarter of 2023 and funded by FIND with €700 thousand.

- 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.

- We commenced offering validated high quality sequencing and analysis services with rapid turnaround times for key applications in microbiology. The unique and differentiated offering for rapid and comprehensive genetic characterization of bacterial isolates and interpretive services include whole genome sequencing, taxonomic identification and typing, detection of plasmids, and other mobile elements, AMR and virulence markers. Furthermore, the RUO services provided by OpGen's laboratory in Rockville, MD, will provide prediction of phenotypic antibiotic susceptibility based on our ARESdb database as well as specialized software for bacterial outbreak analysis via our AREScloud web application.

Nasdaq Notice

On February 28, 2022, we received a notice from The Nasdaq Stock Market LLC, or Nasdaq, notifying us that, based upon the closing bid price of our common stock, for the 30 consecutive business days prior to the notice, the Company no longer met the requirement to maintain a minimum closing bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). The Company was originally granted 180 calendar days, or until August 29, 2022, to regain compliance with the minimum bid price rule. On August 30, 2022, Nasdaq notified the Company that it had been granted an additional 180-calendar day compliance period, or until February 27, 2023, to regain compliance with the Minimum Bid Price Rule. In connection with the grant of such additional compliance period, the Company provided notice to Nasdaq that it intended to cure the bid price deficiency by effecting a reverse stock split, if necessary, prior to the end of the compliance period. While we have until February 27, 2023 to regain such compliance, we do not believe we will be able to do so without implementing a reverse stock split. In order to regain compliance, the Company accordingly called a special meeting of stockholders that was held on November 30, 2022 at which our stockholders voted on and approved a proposal to amend our Amended and Restated Certificate of Incorporation, as amended, or, the Charter, to authorize a reverse stock split of the issued and outstanding shares of our common stock, at a ratio within a range of not less than five-to-one (5:1) and not more than twenty-to-one (20:1), such ratio and the implementation and timing of such reverse stock split to be determined in the discretion of our Board of Directors.

If we are not in compliance with the minimum bid price requirement by February 27, 2023, we can appeal Nasdaq's determination to a hearings panel in order to present a plan to regain compliance. There can be no assurances however that we will be granted any relief or additional time to regain compliance with the minimum bid price requirement and do not believe that any additional grace period will allow the Company to comply with the minimum closing bid price requirement unless a reverse stock split is not approved.

Reverse Stock Split

On November 30, 2022, at a special meeting of stockholders, or the Special Meeting, our stockholders approved an amendment to our Charter to effect a reverse stock split of our common stock, at a ratio of not less than five-to-one (5:1) and not more than twenty-to-one (20:1), with the final ratio and timing of such reverse stock split to be determined in the discretion of our Board of Directors. We intend to effect the reverse stock split prior to this offering.

Company Information

OpGen, Inc. was incorporated in Delaware in 2001. Our principal executive office is located at 9717 Key West Avenue, Suite 100, Rockville, MD 20850, and our telephone number is (301) 869-9683. We also have operations in Germany and Austria. Our website address is www.opgen.com. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

THE OFFERING

Securities offered by us	Up to [_____] shares of common stock and common warrants to purchase up to [_____] shares of common stock, or pre-funded warrants to purchase shares of common stock and common warrants to purchase shares of common stock. The shares of common stock or pre-funded warrants, respectively, and common warrants are immediately separable and will be issued separately in this offering, but must initially be purchased together in this offering. Each common warrant has an exercise price of $[____] per share of common stock and is immediately exercisable and will expire five years from the date of the issuance. See "Description of Securities". We are also registering [_____] shares of common stock issuable upon exercise of the pre-funded warrants and the common warrants pursuant to this prospectus.
Pre-funded warrants offered by us in this offering:	We are also offering to each purchaser whose purchase of shares in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded warrants (each pre-funded warrant to purchase one share of our common stock) in lieu of shares that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding common stock (or, at the election of the purchaser, 9.99%). The purchase price of each pre-funded warrant and accompanying common warrant will equal the price at which one share of common stock and accompanying warrant are being sold to the public in this offering, minus $0.01, and the exercise price of each pre-funded warrant will be $0.01 per share. The pre-funded warrants will be exercisable immediately and may be exercised at any time until all of the pre-funded warrants are exercised in full. For each pre-funded warrant we sell, the number of shares we are offering will be decreased on a one-for-one basis.
Term of the offering	This offering will terminate on [_____], unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date.
Common stock outstanding prior to this offering:	53,698,500 shares of common stock
Common stock outstanding after this offering:	[_____] shares, assuming no sale of pre-funded warrants, which, if sold, would reduce the number of shares of common stock that we are offering on a one-for-one basis, and no exercise of the common warrants issued in this offering.
Use of Proceeds:	We currently intend to use the net proceeds from this offering to: (i) continue commercialization of the FDA-cleared Acuitas AMR Gene Panel test for isolates in the U.S.; (ii) commercialize our other products with a focus on the Unyvero Platform and diagnostic tests; (iii) support further development and commercialization of the Ares Genetics database and service offerings; (iv) support directed sales and marketing efforts to the customers and collaborators for our products and services; (v) invest in manufacturing and operations infrastructure to support sales of products; and (vi) the repay certain outstanding indebtedness of the Company. We intend to use the remaining net proceeds for working capital and other general corporate purposes.

Risk Factors:	Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 6 of this prospectus and the other information included or incorporated by reference in this prospectus.
Nasdaq Capital Market symbol:	Our common stock is listed on The Nasdaq Capital Market under the symbol "OPGN." There is no established trading market for the warrants or the pre-funded warrants, and we do not expect a trading market to develop. We do not intend to list the warrants or the pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the warrants and pre-funded warrants will be extremely limited.

The number of shares of common stock to be outstanding immediately after this offering is based on 48,338,500 shares of our common stock outstanding as of September 30, 2022, and excludes:

- 2,160,027 shares of common stock issuable upon the exercise of outstanding options granted as of September 30, 2022, under our equity incentive plans at a weighted average exercise price of $4.73 per share;

- 16,164,183 shares of common stock issuable upon the exercise of outstanding warrants issued as of September 30, 2022, at a weighted average exercise price of $3.29 per share;

- 808,066 shares of common stock issuable upon vesting of outstanding restricted stock units granted as of September 30, 2022;

- 1,365,024 shares of common stock available for future issuance under our equity incentive plans as of September 30, 2022; and

- 5,360,000 shares of common stock issued at a price of $0.35 per share, 4,300,000 shares of common stock issuable upon the exercise of pre-funded warrants at an offering price of $0.34 per share and 9,660,000 shares of common stock issuable upon the exercise of common warrants with an exercise price of $0.377 per share, each of which was issued after September 30, 2022 as part of our registered direct offering of securities completed in October 2022.

The number of outstanding options, restricted stock units and shares of common stock available for future issuances under our equity incentive plans does not reflect:

- 50,000 shares of common stock issuable upon vesting of outstanding restricted stock unit grants since September 30, 2022; and

- 20,000 shares of common stock issuable upon the exercise of outstanding options granted since September 30, 2022, under our equity incentive plans at a weighted average exercise price of $0.18 per share.

Unless otherwise indicated, all information contained in this prospectus assumes (i) no exercise of options issued under our equity incentive plans and (ii) no exercise of warrants.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the risks and uncertainties described below, and incorporated by reference herein, together with all of the other information in, or incorporated by reference in, this prospectus, including our financial statements and related notes incorporated by reference herein, before making an investment decision. If any of these risks occur, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline and you could lose part or all of your investment.

Summary

Below is a summary of material factors that make an investment in our securities and this offering 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 prospectus 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 companies in the life sciences and biotechnology industry, and our business will suffer if we fail to compete effectively.
- We may never successfully develop new products or may not receive or be able to maintain regulatory clearance or approval for or commercialize our new and existing products.
- Our products and services may never achieve significant commercial market acceptance.
- We have significant indebtedness that, if we are unable to repay, would cause a material adverse effect on us.
- The COVID-19 pandemic has and may continue to 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, including our collaboration with FIND. If these collaborations are not successful, our business could be adversely affected.
- We may not be able to expand our customer base, which is crucial for our future success.
- If we are unable to protect our intellectual property effectively, our business will be harmed.
- We may suffer from adverse effects on our business condition and results of operations from general economic and market conditions and overall fluctuations in the United States and international markets, including deteriorating market conditions due to investor concerns regarding inflation and Russia’s war against Ukraine.

Risks Related to this Offering and Our Securities

We need to raise capital in this offering to support our operations. If we are unable to raise capital in this offering, our financial position will be materially adversely impacted.

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the three and nine months ended September 30, 2022, we had net losses of $14.1 million and $26.7 million, respectively. From our inception through September 30, 2022, we had an accumulated deficit of $262.3 million. We believe that current cash on hand is not sufficient to fund operations beyond the first quarter of 2023. In addition, 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. In the event we are unable to successfully raise sufficient capital in this offering, we will not have sufficient cash and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to 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. We have no additional 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 a material adverse effect on our business, financial condition and results of operations. 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.

We received deficiency notices from the Nasdaq Capital Market. If we are unable to cure these deficiencies 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 a notice from The Nasdaq Stock Market LLC, or Nasdaq, notifying us that, based upon the closing bid price of our common stock, for the 30 consecutive business days prior to the notice, the Company no longer met the requirement to maintain a minimum closing bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). The Company was originally granted 180 calendar days, or until August 29, 2022, to regain compliance with the minimum bid price rule. On August 30, 2022, Nasdaq notified the Company that it had been granted an additional 180-calendar day compliance period, or until February 27, 2023, to regain compliance with the Minimum Bid Price Rule. In connection with the grant of such additional compliance period, the Company provided notice to Nasdaq that it intended to cure the bid price deficiency by effecting a reverse stock split, if necessary, prior to the end of the compliance period. In order to regain compliance, the Company accordingly called and held a special meeting of stockholders on November 30, 2022 at which our stockholders voted on and approved a proposal to amend our Charter to authorize a reverse stock split of the issued and outstanding shares of our common stock, at a ratio within a range of not less than five-to-one (5:1) and not more than twenty-to-one (20:1), such ratio and the implementation and timing of such reverse stock split to be determined in the discretion of our Board of Directors.

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.

Management will have broad discretion as to the use of the net proceeds from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion as to the application of the net proceeds and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management may use the net proceeds for corporate purposes that may not increase our results of operations or the market value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development and approval of our products and cause the price of our common stock to decline.

If you purchase common stock sold in this offering, you will experience immediate dilution as a result of this offering.

Because the price per share of our common stock being offered may be higher than the net tangible book value per share of our common stock, you will experience dilution to the extent of the difference between the offering price per share of common stock you pay in this offering and the net tangible book value per share of our common stock immediately after this offering. Our net tangible book value as of September 30, 2022, was approximately $1.9 million, or $0.04 per share of common stock. Net tangible book value per share is equal to our total tangible assets minus total liabilities, all divided by the number of shares of common stock outstanding.

If you purchase our securities in this offering you may experience future dilution as a result of future equity offerings or other equity issuances.

In order to raise additional capital, we believe that we will offer and issue additional shares of our common stock or other securities convertible into or exchangeable for our common stock in the future. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in this offering.

In addition, we have a significant number of stock options, restricted stock units and warrants outstanding. To the extent that outstanding stock options or warrants have been or may be exercised or other shares issued, you may experience further dilution. Further, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

The market price of our common stock and the trading volume 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.

During the first three quarters of 2022, the market price of our Common Stock fluctuated from a high of $1.11 per share to a low of $0.286 per share, and our stock price continues to fluctuate. The market price and trading volume 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 or the market introduction of new products or product enhancements by us or our competitors;
- the trading volume of our common stock;
- 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;

- adverse effects on our business condition and results of operations from general economic and market conditions and overall fluctuations in the United States and international markets, including deteriorating market conditions due to investor concerns regarding inflation and Russia's war on Ukraine;
- the continued impact of the COVID-19 pandemic on our business and operations;
- future issuances of common stock or other securities;
- the addition or departure of key personnel;
- announcements by us or our competitors of acquisitions, investments or strategic alliances; and
- general market conditions and other factors, including factors unrelated to our operating performance.

Further, the stock market in general, and the market for health care and life sciences companies in particular, has recently experienced extreme price and volume fluctuations. The volatility of our common stock is further exacerbated due to its low trading volume. 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.

Trading of our common stock is limited, and trading restrictions imposed on us by applicable regulations may further reduce trading in our common stock, making it difficult for our stockholders to sell their shares; and future sales of common stock could reduce our stock price.

Trading of our common stock is currently conducted on the NASDAQ Capital Market. The liquidity of our common stock is limited, including in terms of the number of shares that can be bought and sold at a given price and reduction in security analysts' and the media's coverage of us, if any. These factors may result in different prices for our common stock than might otherwise be obtained in a more liquid market and could also result in a larger spread between the bid and asked prices for our common stock. In addition, in the absence of a large market capitalization, our common stock is less liquid than the stock of companies with broader public ownership, and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock. We cannot predict the prices at which our common stock will trade in the future, if at all.

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 November 30, 2022, we had outstanding warrants to acquire 30,124,183 shares of our common stock, and stock options to purchase 2,180,027 shares of our common stock. A significant number of such warrants have exercise prices above our common stock's recent trading prices, but the holders have the right to effect 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.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. We may also enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. For example, our loan agreement with the European Investment Bank (EIB) restricts our ability to declare or pay dividends. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for the foreseeable future.

There is no public market for the common warrants or pre-funded warrants to purchase shares of our common stock being offered by us in this offering.

There is no established public trading market for the common warrants or pre-funded warrants to purchase shares of our common stock that are being offered as part of this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the common warrants or pre-funded warrants on any national securities exchange or other nationally recognized trading system, including The Nasdaq Capital Market. Without an active market, the liquidity of the common warrants and pre-funded warrants will be limited.

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 September 30, 2022, we had an accumulated deficit of $262.3 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 2021 and 2022, including an at-the-market public offering which commenced in June 2022 (the "ATM Offering") and a registered direct financing in October 2022. The net proceeds from such financings were approximately $52.0 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 may not realize the growth and success that we expected from the combination of the OpGen and Curetis businesses.

Although we believe the combination of the OpGen and Curetis businesses provided a significant commercial opportunity for growth, we may not realize all of the synergies that we had anticipated and may not be successful in implementing our commercialization strategy across all products and platforms as well as all geographies. Our combined business is and continues to 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 achieve the expected benefits from 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-19 related product reviews. The FDA has not been able to provide any feedback in the form of presub meetings for either the Unyvero UTI or IJI panels and declined to host any presub meetings for the IJI panel 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 $202.0 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 NGS-based isolate sequencing 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 further grow our microbial isolate and antibiotic resistance genes knowledgebases and bioinformatics offerings;
- 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, ARESid, or ARESiss (Express) solutions 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 AMR testing. 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 RUO 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 internationanl government agencies or non-government organizations (NGO), 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 September 2022, we entered into a research and development collaboration with FIND, an NGO focused on innovative new diagnostics, for the potential use of the Unyvero A30 platform in low and middle income countries (LMICs).

In the future, we may seek to enter into additional agreements with governmental funding sources or contract with government healthcare organizations or NGOs to sell our products and services, such as our collaboration agreement with FIND. Under such agreements, we would rely on the continued performance by these government agencies and NGOs of their responsibilities under these agreements, including adequate continued funding of the agencies and NGOs 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 or NGOs may fail to perform their responsibilities under these agreements, which may cause them to be terminated by the government agencies or NGOs . In addition, we may fail to perform our responsibilities under these agreements. Any government agreements or NGO 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 and NGO 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 several 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, NGS 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 limited 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, including internally and at our distribution partners. Competition for such personnel is intense. We may not be able to attract and retain sufficient personnel to maintain an effective sales and marketing force. In addition, we will likely have less control over sales and marketing personnel of our distribution partners. The personnel at our distribution partners may therefore not be adequately trained with respect to our products or may not be sufficiently incentivized to sell our products. 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 are currently transferring to our Bodelshausen facility. 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. As a result, the manufacturing transfer of our Acuitas products to our Bodelshausen facility may not be completed when anticipated and may experience cost overruns. 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, 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 or using their own technologies that do not infringe our intellectual property rights.

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 the Centers for Medicare & Medicaid Services (CMS) 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 healthcare-associated infections (HAI), 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, ransomware attacks 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, ransomware attacks or other 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 Health Insurance Portability and Accountability Act, or 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 United States 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 United States. Failure to comply with the requirements of the GDPR, and the related national data protection laws of the European Union (EU) 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.

In addition, in the United States, there are state and federal laws relating to data privacy and security. As we expand our operations, these laws which vary from jurisdiction to jurisdiction, may increase our compliance costs and potential liability. In addition to California, Virginia and Maine, other states are beginning to propose similar laws, which may be the beginning of a trend toward more stringent privacy legislation in the United States that could increase our potential liability and adversely affect our business, results of operations and financial condition.

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 products and services. The further development and commercialization of additional diagnostic 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 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.

If our acquired in-process research and development costs or finite-lived tangible and intangible assets or any future goodwill become impaired in the future, we may be required to record non-cash charges to earnings, which could be material and could reduce stockholders' equity or otherwise adversely affect the Company's financial condition.

We review long-lived assets, including property and equipment and identifiable amortizing intangible assets, for impairment whenever changes in circumstances or events may indicate that the carrying amounts are not recoverable. If the fair value is less than the carrying amount of the asset, an impairment is recognized for the difference. Factors which may cause an impairment of long-lived assets include significant changes in the manner of use of these assets, negative industry or market trends, a significant underperformance relative to historical or projected future operating results, extended period of idleness or a likely sale or disposal of the asset before the end of its estimated useful life. For example, in 2021, the Company had determined that the right-of-use asset associated with the Company's San Diego, California office lease may not be recoverable, and, as a result, the Company recorded an impairment charge of $171 thousand during the six months ended June 30, 2021. There can be no assurance that our other long-lived assets and intangible assets will not be further impaired. If our property and equipment and identifiable amortizing intangible assets are determined to be impaired in the future, we may be required to record non-cash charges to earnings during the period in which the impairment is determined, which could be material and have an adverse effect on our financial position and results of operations.

In addition, we review and test goodwill for impairment at least annually and whenever changes in circumstances indicate that the carrying value of the goodwill may not be recoverable. The impairment test for goodwill consists of comparing the fair value of the reporting unit and acquired in-process research and development projects (IPR&D), which is estimated using both the income and market approach, to its carrying value. The process of impairment testing for our goodwill involves a number of judgments and estimates made by management including future cash flows, revenue growth rates, profitability assumptions, terminal growth rates and discount rates with regards to our reporting unit. Our internally generated long-range plan includes assumptions regarding pricing and operating forecasts for our products and technologies. For instance, based on the goodwill impairment assessment performed during the quarter ended September 30, 2022, and primarily due to recent changes in the Company's stock price and market capitalization, it was determined that goodwill was impaired. As a result, the Company recorded a one-time non-cash goodwill impairment charge in the full amount of $6,975,520 for the three and nine months ended September 30, 2022. Accordingly, if the judgments and estimates used in such analyses are not realized or are affected by external factors, our actual results may not be consistent with such judgments and estimates, and we may be required to record further impairment of the Company's assets in the future, which could be material, could reduce stockholders' equity and have an adverse effect on our financial position and results of operations.

Risks Related to Our Public Company Status

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

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

When we are no longer 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.

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, high 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 Russia's war on the Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts and wars, including the one on the 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 and high 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 Russia's war on the 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 and 2022 Annual Meetings of 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.

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 have limited 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 Quality System Regulations (QSR) 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 (PMA) of new products or modified products; (7) operating restrictions; (8) withdrawing granted De Novo classifications, 510(k) clearances or PMAs 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 PMAs or, in the future, new CE-IVD markings that comply with the new EU Regulation on In Vitro Diagnostic Medical Devices (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) was adopted. The IVDR became effective in May 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. The IVDR introduced 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 to these devices will increase considerably. Complying with the requirements of this regulation may result in the reclassification of existing CE-IVD marked products and will require additional filings with the notified body or competent authority by the time the extended transition periods have expired. 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, 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.

General Risk Factors

The COVID-19 pandemic has and other similar pandemic events may adversely impact our business, financial condition and results of operations.

The COVID-19 pandemic and more recently possible endemic has continued to impact the global economy and has impacted our operations in the United States and abroad (including, in particular, China), 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 or endemic 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 and staffing shortages with many hospitals and labs as well as our own personnel.

Healthcare providers, including our strategic partners worldwide, spend significant time dealing with COVID-19, and may be unable to initiate or continue to participate in our clinical activities. For example, some clinical trial sites, most notably in China, have imposed and continue to maintain restrictions on site visits by sponsors and CROs, the initiation of new or execution of ongoing 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 initiation 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 such as for example the supplemental clinical study in China. 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 and we did not receive responses to our most recent requests for pre-submission meetings.

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 coronavirus on our business and results of operations. As coronavirus and its mutations become endemimc, it could have a continued 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 successfully implemented 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 and remain endemic.

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 had 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, had 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 continue to 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.

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 September 30, 2022, we owed indebtedness of $14.2 million (€14.5 million) of principal (including deferred interest of $1.7 million (€1.8 million)) under a loan provided by the EIB with remaining maturities in June 2023 and June 2024. In particular, of the approximately $15 million of such indebtedness that was due to the EIB in April 2022, we had paid approximately $5 million and have agreed to amortize the remaining amount over a 12-month period in monthly installments of approximately $700 thousand each. While we continue evaluating options to restructure the remaining 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. 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 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 whether taking advantage of the reduced disclosure requirements applicable to these companies 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.

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 continued high 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.

The Company's Charter provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between the Company and its stockholders, which could limit its stockholders' ability to obtain a favorable judicial forum for disputes with the Company or its directors, officers or other employees.

The Company's Charter provides that, unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company or its stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or the Company's Certificate of Incorporation or Bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine. 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 of 1933, as amended, or the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction. The exclusive forum provision in the Company's Charter will not relieve the Company of its duties to comply with the federal securities laws and the rules and regulations thereunder, and stockholders of the Company will not be deemed to have waived the Company's compliance with these laws, rules and regulations.

This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with the Company or its directors, officers or other employees, which may discourage lawsuits against the Company and its directors, officers and other employees. In addition, stockholders who do bring a claim in the Court of Chancery of the State of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery of the State of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder would otherwise choose to bring the action, and such judgments or results may be more favorable to the Company than to its stockholders. However, 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 find this type of provision to be inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings. If a court were to find the exclusive forum provision contained in the Company's Charter to be inapplicable or unenforceable in an action, the Company might incur additional costs associated with resolving such action in other jurisdictions.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements" within the meaning of Section 27A of the Securities and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical fact, included or incorporated in this prospectus regarding our strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

- our liquidity and working capital requirements, including our cash requirements over the next 12 months;
- our use of proceeds from capital financing transactions;
- our ability to maintain compliance with the ongoing listing requirements for the Nasdaq Capital Market;
- 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 meet our obligations and extend our relationships under our collaboration agreements, including our collaboration agreement with the Foundation for Innovative New Diagnostics;
- our ability to obtain regulatory clearance for and commercialize our product and services offerings;
- our ability to establish a market for and sell our Acuitas AMR Gene Panel test for use with bacterial isolates;
- our ability to sustain or grow our customer base for our Unyvero IVD 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 successfully transfer, and realize the expected benefits of the transfer of, the manufacturing of our Acuitas AMR Gene Panel from our Rockville, Maryland facility to our Bodelshausen, Germany manufacturing facility;
- our ability to satisfy our debt obligations;
- the continued impact of the COVID-19 pandemic on our business and operations;
- adverse effects on our business condition and results of operations from general economic and market conditions and overall fluctuations in the United States and international markets, including deteriorating market conditions due to investor concerns regarding inflation and Russia's war on the Ukraine;
- anticipated trends and challenges in our business and the competition that we face;
- the execution of our business plan and our growth strategy;
- our expectations regarding the size of and growth in potential markets;
- our opportunity to successfully enter into new collaborative or strategic agreements;
- compliance with the U.S. and international regulations applicable to our business; and
- our expectations regarding future revenue and expenses.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. These risks should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to the risks described under the heading "Risk Factors." 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 prospectus 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.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the securities offered under this prospectus, after deducting placement agent's fees and estimated offering expenses payable by us will be approximately $[__] million. However, because this is a best efforts offering and there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, the placement agent's fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus.

We intend to use the net proceeds from the sale of the shares to: (i) support continued commercialization of our FDA-cleared Acuitas AMR Gene Panel test for isolates in the U.S.; (ii) commercialize our products with a focus on the Unyvero Platform and diagnostic tests; (iii) support further development and commercialization of the Ares Genetics database and service offerings; (iv) support directed sales and marketing efforts to the customers and collaborators for our products and services, (v) invest in manufacturing and operations infrastructure to support sales of products; and (vi) repay certain outstanding indebtedness of the Company and its subsidiaries. We intend to use the remaining net proceeds for working capital and other general corporate purposes.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. Our management will have broad discretion in the application of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management may use the net proceeds for corporate purposes that may not result in our being profitable or increase our market value.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2022 as follows:

- on an actual basis; and
- on an as adjusted basis to give effect to the sale by us of [____] shares in this offering at an assumed public offering price of $[___] per share, which is the last reported sale price of our common stock on the Nasdaq Capital Market on [____], 2022, after deducting the estimated underwriting discounts and commissions and estimated offering expenses, and assuming no sale of any pre-funded warrants in this offering.

The as adjusted information set forth below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this table in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in, or incorporated by reference into, this prospectus.

	As of September 30, 2022	
	Actual	As Adjusted
	(In thousands, except share and per share data)	
Cash and cash equivalents	$ 10,276	$
Debt	12,451	$
Stockholders' equity:		
Common stock, par value $0.01 per share: 100,000,000 shares authorized, 48,338,500 shares issued and outstanding as of September 30, 2022, actual; 100,000,000 shares authorized, [_____] issued and outstanding, as adjusted	483	
Preferred stock, par value $0.01 per share; 10,000,000 shares authorized, no shares outstanding, actual and no shares outstanding as adjusted	—	
Additional paid-in capital	277,407	
Accumulated other comprehensive loss	(1,662)	
Accumulated deficit	(262,290)	
Total stockholders' equity	13,938	
Total capitalization	$ 26,389	$

A $1.00 increase (decrease) in the assumed public offering price of $[____] per share would increase (decrease) the expected net proceeds to us from this offering by approximately $[____] million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and excluding the proceeds, if any, from the exercise of the pre-funded warrants issued pursuant to this offering.

Similarly, a 100,000 share increase or decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the net proceeds to us by approximately $[____] , assuming the assumed public offering price of $[____] per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and excluding the proceeds, if any, from the exercise of the pre-funded warrants issued pursuant to this offering.

The number of shares of common stock to be outstanding immediately after this offering is based on 48,338,500 shares of our common stock outstanding as of September 30, 2022, and excludes:

- 2,160,027 shares of common stock issuable upon the exercise of outstanding options granted as of September 30, 2022, under our equity incentive plans at a weighted average exercise price of $4.73 per share;

- 16,164,183 shares of common stock issuable upon the exercise of outstanding warrants issued as of September 30, 2022, at a weighted average exercise price of $3.29 per share;

- 808,066 shares of common stock issuable upon vesting of outstanding restricted stock units granted as of September 30, 2022;

- 1,365,024 shares of common stock available for future issuance under our equity incentive plans as of September 30, 2022; and

- 5,360,000 shares of common stock issued at a price of $0.35 per share, 4,300,000 shares of common stock issuable upon the exercise of pre-funded warrants at an offering price of $0.34 per share and 9,660,000 shares of common stock issuable upon the exercise of common warrants with an exercise price of $0.377 per share, each of which was issued after September 30, 2022 as part of our registered direct offering of securities completed in October 2022.

The number of outstanding options, restricted stock units and shares of common stock available for future issuances under our equity incentive plans does not reflect:

- 50,000 shares of common stock issuable upon vesting of outstanding restricted stock unit grants since September 30, 2022; and

- 20,000 shares of common stock issuable upon the exercise of outstanding options granted since September 30, 2022, under our equity incentive plans at a weighted average exercise price of $0.18 per share.

DILUTION

Our net tangible book value as of September 30, 2022 was approximately $1.9 million, or $0.04 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of September 30, 2022. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the assumed sale of [____] shares of our common stock in this offering at an assumed public offering price of $[____] per share of common stock, based on the last reported sale price of our common stock on the Nasdaq Capital Market on [____], 2022, assuming no sale of any pre-funded warrants in this offering and after deducting estimated placement agent fees and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2022 would have been approximately $[____] million, or $[____] per share. This represents an immediate increase in net tangible book value of $[____] per share to existing stockholders and immediate dilution of $ per share to investors purchasing our securities in this offering at the public offering price. The following table illustrates this dilution on a per share basis:

Assumed public offering price per share		$
Net tangible book value per share of as September 30, 2022	$ 0.04	
Increase in net tangible book value per share attributable to this offering	$	
As adjusted net tangible book value per share as of September 30, 2022, after giving effect to this offering		$
Dilution per share to new investors purchasing our common stock in this offering		$

A $1.00 increase or decrease in the assumed public offering price of $[___] per share of common stock, based on the last reported sale price for our common stock as reported on the Nasdaq Capital Market on [_____], 2022, would decrease or increase the number of shares of our common stock offered in this offering by approximately [____] shares.

We may also increase or decrease the number of shares of common stock we are offering. An increase of 100,000 in the number shares of common stock offered by us would increase our as adjusted net tangible book value by approximately $[__], or $[__] per share, and decrease the dilution per share to investors participating in this offering by $[___] per share, assuming the assumed offering price per share remains the same and after deducting the estimated underwriting fees and estimated offering expenses payable by us. Similarly, a decrease of 100,000 in the number of shares of common stock offered by us would decrease our as adjusted net tangible book value by approximately $[___] or $[____] per share, and increase the dilution per share to investors participating in this offering by $[__] per share, assuming the assumed offering price per share remains the same and after deducting the estimated underwriting fees and estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual offering price, the actual number of shares of common stock we offer in this offering, and other terms of this offering determined at pricing.

The number of shares of common stock to be outstanding immediately after this offering is based on 48,338,500 shares of our common stock outstanding as of September 30, 2022, and excludes:

- 2,160,027 shares of common stock issuable upon the exercise of outstanding options granted as of September 30, 2022, under our equity incentive plans at a weighted average exercise price of $4.73 per share;
- 16,164,183 shares of common stock issuable upon the exercise of outstanding warrants issued as of September 30, 2022, at a weighted average exercise price of $3.29 per share;
- 808,066 shares of common stock issuable upon vesting of outstanding restricted stock units granted as of September 30, 2022;
- 1,365,024 shares of common stock available for future issuance under our equity incentive plans as of September 30, 2022; and
- 5,360,000 shares of common stock issued at a price of $0.35 per share, 4,300,000 shares of common stock issuable upon the exercise of pre-funded warrants at an offering price of $0.34 per share and 9,660,000 shares of common stock issuable upon the exercise of common warrants with an exercise price of $0.377 per share, each of which was issued after September 30, 2022 as part of our registered direct offering of securities completed in October 2022.

The number of outstanding options, restricted stock units and shares of common stock available for future issuances under our equity incentive plans does not reflect:

- 50,000 shares of common stock issuable upon vesting of outstanding restricted stock unit grants since September 30, 2022; and

- 20,000 shares of common stock issuable upon the exercise of outstanding options granted since September 30, 2022, under our equity incentive plans at a weighted average exercise price of $0.18 per share.

BUSINESS

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 sequencing services, and the ARES Technology Platform including ARESdb, NGS technology and AI-powered bioinformatics solutions for AMR surveillance, outbreak analysis, and antibiotic response prediction including ARESiss, ARESid, and AREScloud, as well as the Curetis CE-IVD-marked Polymerase Chain Reaction, or PCR, based SARS-CoV-2 test kit. The Company exited its FISH business in early 2021, and the Company's corresponding 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 pneumonia in hospitalized patients. According to the National Center for Health Statistics (2018), pneumonia is a leading cause of admissions to the hospital and is associated with substantial morbidity and mortality. It also increases in elderly patients, transplant, cancer or other immunocompromised patients. 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 U.S. Centers for Disease Control and Prevention, or CDC.

- Following registration of the Unyvero instrument system as an in vitro diagnostics (IVD) platform 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 Hospitalized Pneumonia (HPN) test. As requested by the Chinese regulatory authority National Medical Products Administration (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. Due to continued impact of strict COVID-19 restrictions in China, this supplementary study has not yet been initiated and OpGen currently does not have visibility on the timelines for such a clinical study to start. In the third quarter of 2022, regulatory advisors to BCB informed OpGen that the NMPA has implemented a mandatory new electronic filing regime that requires the Company to re-submit its clinical trial plan under the new regime. The regulatory advisors estimate a total duration for the review and approval process to be between 24 to 30 months, and during that time, the clinical study is believed to take approximately 10 to 12 months.

- 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 and have recently completed enrollment of more than 1,800 patient samples. We currently expect to conclude reference testing in the coming months and expect unblinding in December 2022 as the next step towards a subsequent submission to the FDA.

- 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 on the Unyvero A30 platform including clinical trials towards a future submission to the FDA. Such clinical trial is not expected to start before the second quarter of 2023. 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 antimicrobial resistence, or 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 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 AMR patterns early and supports appropriate antibiotic treatment decisions in this indication. We signed two commercial customer contracts, and in October 2022, installed the first two systems for the Acuitas AMR Gene Panel for isolates and have a funnel of several additional commercial contract proposals that we expect to enter into during the coming quarters.

- On September 20, 2022, we signed a research and development collaboration agreement with the Foundation for Innovative New Diagnostics (FIND), the global alliance for diagnostics, which will fund the development of the Unyvero A30*RQ* platform for use in low- and middle-income countries (LMICs). The initial project focuses on a feasibility study for the rapid detection of AMR markers from blood culture. The feasibility phase of this research and development project is set to conclude in the first half of 2023 and is funded by FIND for €0.7 million.

- On October 25, 2022, we announced that our subsidiary Curetis and BioVersys AG, a Swiss biotech company developing novel antibiotics against drug resistant infections, signed a collaboration agreement. Under that collaboration agreement, BioVersys will be using the Unyvero systems and HPN test at all its sites for its upcoming BV100 phase II clinical trial.

- 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.

- We have started offering validated high-quality sequencing and analysis services with rapid turnaround times for key applications in microbiology. The unique and differentiated offering for rapid and comprehensive genetic characterization of bacterial isolates and interpretive services include whole genome sequencing, taxonomic identification and typing, detection of plasmids, and other mobile elements, AMR, and virulence markers. Furthermore, the RUO services provided by OpGen's lab in Rockville, MD, will provide prediction of phenotypic antibiotic susceptibility based on our ARESdb database as well as specialized software for bacterial outbreak analysis via our AREScloud web application.

OpGen has extensive offerings of additional IVD tests including CE-IVD-marked Unyvero tests for intra-abdominal 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 more than 90,000 bacterial isolates that have been sequenced using Next Generation Sequencing, or 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 as well as the Belgian national reference laboratory at the University Hospital Leuven 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 Artificial Intelligence, or 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' customers for such offerings include Siemens Technology Accelerator and academic, public health, and biotechnology institutions from various European countries as new customers.

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 verification and validation testing of the A30 *RQ* instruments and, in addition to the new collaboration with FIND, is actively engaged in ongoing partnering discussions and due diligence.

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 of the Unyvero A50 product line to currently 12 countries and Beijing Clear Biotech Co. Ltd. for Unyvero A50 product distribution in China. We have a network of other 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.

OpGen will continue to develop and seek FDA and other regulatory clearances or approvals, as applicable, for its Unyvero UTI and IJI products as well as for its Unyvero A30 *RQ* platform. 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 RUO products to hospitals, public health departments, clinical laboratories, pharmaceutical companies and CROs in the United States. Curetis continues its efforts in ensuring compliance with the new In-Vitro-Diagnostic Device Regulation (IVDR) in the European Union (EU), which officially went 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 former 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.

OpGen's Products and Products in Development

Through its wholly owned subsidiary Curetis GmbH, 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 by Curetis. 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 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 A50 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 A50 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, and Singapore), and has been rolled out commercially in the United States following De Novo clearance of the Unyvero A50 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 A50 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 A50 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 A50 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 September 30, 2022, the distribution network comprises 12 distributors covering 28 countries in those regions with regulatory clearance for the Unyvero A50 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 completion of enrollment of more than 1,800 patient samples into its clinical trial at the end of the third quarter of 2022. Data read out from that trial will be required for a subsequent submission to the FDA for clearance in 2023;
- 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 A50 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 A50 System and its 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 access the Unyvero A30 *RQ* for commercialization of their own assays on this platform, potentially even as legal manufacturer under their own branding.

The Unyvero A50 Platform

Curetis launched its CE-IVD-marked Unyvero A50 Platform with a first disposable Application Cartridge for pneumonia in 2012. The FDA cleared the Unyvero A50 System and LRT Application Cartridge in April 2018 and the LRT BAL Application Cartridge in December 2019.

The Unyvero A50 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 A50 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 intensive care units, or ICUs.

Unyvero A50 Platform, System Components and Workflow

The Unyvero A50 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 A50 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 A50 Platform. In addition, the Unyvero A50 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-formatted files via a USB key or to a connected printer. It also features built-in interfaces for possible future connectivity to standard hospital and laboratory information systems.

The Unyvero A50 Analyzer

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

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

Workflow

The Unyvero A50 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

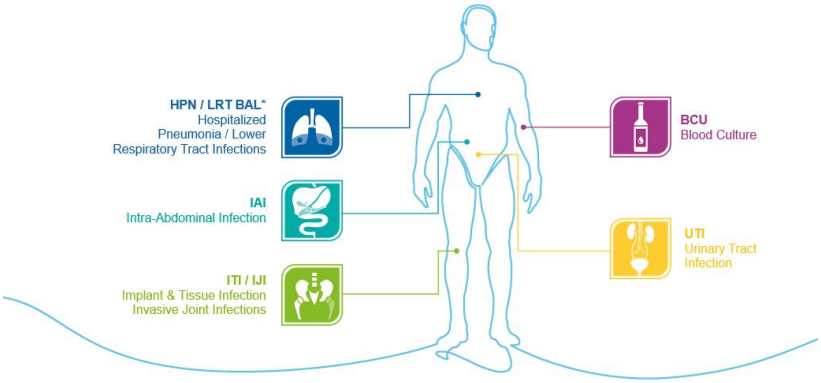

Figure 3: Currently available Application Cartridges

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 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 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 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 A50 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 Health Sciences Authority (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 United States 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 submission to the FDA for this Application Cartridge and initiated clinical trials in the third quarter of 2021. We completed enrollment of over 1,800 patient samples into a prospective multi-center clinical trial at the end of the third quarter of 2022. Data read out from that trial will be required for a subsequent submission to the FDA in 2023.

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, or Ares, 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 currently including data from over 90,000 sequenced isolates and phenotypic data on over 100 antibiotics. 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 in 2021 entered into 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 AMR database ARESdb and the ARES Technology Platform for data interpretation. OpGen also began offering Ares' services in the United States from its Rockville, Maryland-based lab.

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 has been 510(k)-cleared by the FDA on September 30, 2021 for testing bacterial isolates. This test had already been made available in the United States prior to FDA-clearance as an RUO test, 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 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

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 700 thousand to 1.27 million. 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 carbapenemase producing *Klebsiella pneumonia*, or 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 complicated urinary tract infections (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 12 distributors covering 28 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 A50 System and its DNA-based 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, NGS 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 A50 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™) and 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 developers of laboratory developed tests (LDT) have to be separately assessed by each application. OpGen believes that its Unyvero A50 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 A50 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 A50 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 A50 Platform. As the lysis is integrated into the workflow, hands-on time and potential handling errors are significantly reduced.

The Unyvero A50 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 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 submission to the FDA for clearance. 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 matrix assisted laser desorption ionization - time of flight mass spectrometry, or 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 turnaround times of 48 to 72 hours 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 antibiotic susceptibility testing, or AST, methods (Pattern Bioscience, Q-Linea ASTar, Lifescale, Specific Diagnostics Reveal, Gradientech, oCelloScope), as well as efforts to achieve AST with MALDI-TOF. While turnaround times for MALDI-TOF based testing is much faster, overall turnaround times 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 turnaround time, 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 turnaround time compared to conventional microbiology. Generally, providers of PCR-based molecular diagnostics are focusing on further reducing turnaround time to less than 30 minutes to one hour and/or increasing multi-plexing degree as well as reducing use of labor, lab space, and overall costs. The Company believes that its ability to quantitatively predict antibiotic susceptibility based on the pathogen's genetic profile complements PCR-based approaches detecting panels of genes and mutations as indicators of resistance.

Competition to Ares Genetics

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

Competition by Molecular Diagnostics – NGS

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

Competing AMR Databases & Bioinformatics Solutions

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

Research and Development

We intend to continue to invest in the development of additional Unyvero panels such as UTI for the Unyvero A50 platform, a Unyvero IJI panel for 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 including an IJI cartridge as well as the AMR panel from blood culture bottles under our research and development collaboration with FIND;
- Data read out from clinical trial that completed enrollment at the end of the third quarter of 2022 with more than 1,800 patient samples, and subsequent regulatory filing with the FDA for Unyvero UTI in the United States;
- Clinical trials and regulatory filings for Unyvero IJI in the United States (expected as De Novo with clinical trial at a minimum of three 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 12 distributors covering 28 countries.

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

Customers

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

Sales Process

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

OpGen expects that the entire sales process, from the introductory visit to the point in time when the hospital begins routinely purchasing Application Cartridges or Acuitas consumables, known as the push-pull triangle model, which includes the lab, the clinicians and the finance entity, will take around six to twelve months or longer, 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). Consequently, OpGen and its distribution partners aim to optimize the utilization of each placed hardware unit rather than solely maximizing the installed base of instruments. Therefore, OpGen, with its tests primarily targeting in-patients (hospitalized) with severe infections, is focusing its sales and commercialization efforts on laboratories in hospitals and independent laboratories serving larger hospitals.

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

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

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

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

Distribution Channels

To distribute the Unyvero A50 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 several countries of Europe, the Middle East, Asia, and Latin America (see section "Indirect Sales Markets" for a detailed list).

As of September 30, 2022, OpGen had an installed base of approximately 200 Unyvero A50 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 September 30, 2022, OpGen had an installed base of approximately 30 Unyvero A50 Analyzers across the United States and in different types of hospitals and laboratories.

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 32 countries. Distribution agreements usually feature minimal sales commitments and purchase commitments of the Unyvero A50 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:

- *A. Menarini Diagnostics S.r.l.*: Austria, Belgium, France, Germany, Greece, Italy, Luxemburg, Netherlands, Portugal, Spain, Switzerland, United Kingdom;
- *Ako Med d.o.o.*: Bosnia and Hercegovina, Croatia, Montenegro, North Macedonia, and Serbia;
- *Synttergy Consult LTD*: Romania
- *BioLine LLC*[1]: Kazakhstan, Russia, and Ukraine ;
- *BioLine BS LLC*[2]: Belarus; and
- *Kosova Export Import Supply Pharmaceutical (KEIS) Sh.p.k.*: Kosovo.

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

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

Outside of the EU, distribution agreements are in place for the following countries:

· *Future Horizons Scientific*: Egypt;
· *Advanced Technology Co. (ATC)*: Kuwait
· *Leader Medical Supplies Trading L.L.C.*: Qatar and the United Arab Emirates (UAE);
· *Acumen Research Laboratories Pte Ltd.*: Singapore;
· *Beijing Clear Bio-tech Co. Ltd. (BCB)*: China and Taiwan;;
· *Quimica Valaner*: Mexico; and
· *Annar Diagnostica Import SAS*: Colombia

The total contractual minimum purchase requirements of all current distributors are 372 Unyvero A50 Systems of which about 350 are part of BCB's commitment, which applies over an eight year period following market approval in China by the National Medical Products Association (NMPA), 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 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.

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[1] Distribution agreement currently suspended due to Russia's war on Ukraine.
[2] Distribution agreement currently suspended due to Russia's war on Ukraine.

Manufacturing

During 2022, we manufactured all our Unyvero products in Germany (Unyvero systems are manufactured by our German supplier Zollner Elektronik AG, or Zollner, and Unyvero cartridges and consumables at our own manufacturing facility in Bodelshausen, Germany), and all our FDA-cleared Acuitas AMR products at our new headquarters in Rockville, Maryland. The Acuitas AMR product manufacturing is currently being transferred to to Curetis in Germany, which transfer is expected to be completed in 2023.

Manufacturing of our CE-IVD-marked and FDA-cleared products is performed under the respective applicable relevant current standards – Quality System Regulation (QSR) 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 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 GmbH and certain components provided by Horst Scholz GmbH, or 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. The Company's management believes that manufacturing capacity will not become a bottleneck in the foreseeable future as inventory levels are sufficient to support anticipated demand for the coming years. 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 original equipment manufacturer (OEM) for the series production of the Unyvero A30 *RQ* systems. Unyvero A30 *RQ* systems are so far being produced in pilot batches by DMT Produktentwicklung GmbH as the current German development partner to Curetis.

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 and potential own MDx products of OpGen such as the Acuitas IVD products and/or potential products for the Unyvero A30 *RQ* will also be manufactured in Bodelshausen, in a dedicated manufacturing line module 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 A50 instrument 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. 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. 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 significant 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 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 in-patients with severe infections are typically covered under the DRG system. With DRG, hospitals receive a lump-sum payment, e.g., up to €22 thousand in Germany for a life-threatening case of ventilator-associated pneumonia (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 September 30, 2022, 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 three granted U.S. patents related to our Acuitas products.

As part of the Company's portfolio, there are two pending U.S. non-provisional patent applications and 8 issued U.S. patents related to our FISH products. These issued patents begin to expire in November 2024 and will be fully expired by October 2033. We are currently in the process of sunsetting our FISH intellectual property.

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

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

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

Regulation

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

Federal Oversight of Research-Use-Only Products

We currently offer for sale and sell some of our Unyvero 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 the second quarter of 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 the U.S. 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 has broad authority over the regulation of medical devices marketed for sale in the United States. The FDA regulates the research, clinical testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, promotion, distribution and production of medical devices. The FDA also regulates the export of medical devices manufactured in the United States to international markets.

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

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

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

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

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

510(k) Clearance Pathway

We are currently working to submit our Unyvero tests 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 for the 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 PMA, 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 PMA is obtained. If the FDA requires us to seek 510(k) clearance or PMA 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. While the Unyvero LRT Application has been subject to the De Novo process, both the LRT BAL Application as well as the Acuitas AMR Gene Panel have been FDA-cleared as 510(k) submissions. We currently expect that the Unyvero UTI and IJI will 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. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA 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 PMA.

Clinical Trials

Clinical trials are almost always required to support a De Novo or PMA application and are usually required to support non-exempt Class I and Class II 510(k) premarket submissions. Clinical trials may also be required to support certain marketing claims. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to file an investigational device exemption, or IDE application, with the FDA and obtain IDE approval prior to conducting the human clinical trials. The IDE application must be supported by appropriate data, such as analytical, animal and laboratory testing results, manufacturing information, and an Investigational Review Board, or IRB, approved protocol showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA prior to initiation of enrollment of human subjects. Clinical trials for a significant risk device may begin once the investigational device exemption application is approved by the FDA. If the clinical trial design is deemed to be "non-significant risk," the clinical trial may eligible for the "abbreviated" IDE requirements; in some instances IVD clinical trials may be exempt from the more burdensome IDE requirements if the test uses a noninvasive sampling method, does not introduce energy into the subject, and is not used in a diagnostic procedure without confirmation of the diagnosis by another established medically diagnostic procedure or product. All clinical trials conducted to support a PMA application 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 commenced transferring the manufacturing of the Acuitas products to Curetis and expect to complete such transfer in 2023. We and any third-party manufacturers are subject to announced and unannounced inspections by the FDA to determine our compliance with quality system regulation and other regulations.

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

After a medical device is placed on the market, numerous regulatory requirements apply. These include: all of the relevant elements of the QSR, labeling regulations, restrictions on promotion and advertising, the medical device reporting (which requires the manufacturer to report to the FDA if its devices 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 expensive 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 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 United States 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 September 30, 2022, we had 99 employees worldwide, with 22 employed at OpGen, Inc. in the United States, 62 employed at Curetis GmbH in Germany, and 15 employed at Ares Genetics GmbH in Austria. Of our 99 worldwide employees, 84 are full-time employees. Except for the managing director of Ares Genetics, our Austria-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 22 employees in the United States 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 and 2022, health and wellness was a key focus of the Company, especially in light of the COVID-19 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 has been a top priority. Ongoing safety measures were put into place at each of our locations including implementing pre-screening and social distancing requirements in addition to providing personal protective equipment and regular testing of staff wherever possible.

Glossary

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

“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.

“ATM offering” means at-the-market public offering.

“BCB” means Beijing Clear Biotech.

“BCU” means blood culture.

“CAP”-Community-Acquired Pneumonia.

“CCPA” means the California Consumer Privacy Act.

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

“CE” means Conformité Européenne.

“CLIA” means Clinical Laboratory Improvement Amendments.

“CMS” means the Centers for Medicare and Medicaid Services.

“CRE” means carbapenem-resistant Enterobacteriaceae, an MDRO.

“CRO” means contract research organization.

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

“DRG” means Diagnosis Related Group.

“EIB” means European Investment Bank.

“ESBL” means extended spectrum beta lactamase bacteria.

“EU” means European Union.

“FCPA” means the U.S. Foreign Corrupt Practices Act.

“FDA” means the U.S. Food and Drug Administration.

“FDAMA” means the U.S. Food and Drug Administration Modernization Act of 1997.

“FDC Act” means the U.S. Food, Drug, and Cosmetic Act.

“FIND” means Foundation for Innovative New Diagnostics.

“GDPR” means the General Data Protection Regulation in the EU.

“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.

“HHS” means the U.S. Department of Health and Human Services.

“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.

“ICU” means intensive care unit.

“IDE” means investigational device exemption.

“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.

“IOU” means investigational-use-only.

“IPR&D” means in-process research and development projects.

“IRB” means Investigational Review Board.

“ITI” means implant & tissue infection.

“IVD” means in vitro diagnostic.

“IVDD” means In-Vitro-Diagnostic Device Directive (Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices).

“IVDR” means In-Vitro-Diagnostic Device Regulation (Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices).

“KOL” means key opinion leader.

“KPC” means carbapenemase producing *Klebsiella pneumoniae*, an MDRO.

“LRT” means lower respiratory tract infection.

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

“MDRO” means a multidrug-resistant organism.

“MDx” means molecular diagnostics.

“ML” means machine learning.

“NGO” means non-governmental organization.

“NGS” means Next Generation Sequencing.

“NMPA” means National Medical Products Administration, the Chinese agency for regulating drugs and medical devices.

“NOL” means net operating loss.

“OEM” means original equipment manufacturer.

“PCR” means polymerase chain reaction.

“PMA” means premarket approval.

“QSR” means Quality System Regulation.

“RUO” means research-use-only.

"RoW” means the rest of the world.

“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, through its subsidiaries, 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 prospectus. 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.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain our future earnings, if any, for use in our business and therefore do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion.

MARKET AND INDUSTRY DATA

This prospectus and the documents incorporated by reference in this prospectus contain market data and industry statistics that are based on independent industry publications and other publicly available information. Although we believe that these sources are reliable, we do not guarantee the accuracy or completeness of the information and we have not independently verified this information. Although we are not aware of any misstatements regarding the market and industry data presented or incorporated by reference in this prospectus, these estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section titled “Risk Factors” or incorporated by reference herein, and any related free writing prospectus. Accordingly, investors should not place undue reliance on this information.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering up to [___] shares of our common stock and pre-funded warrants to purchase up to [___] shares of our common stock along with common warrants to purchase up to [___] shares of common stock. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis. We are also registering the shares of common stock issuable from time to time upon exercise of the pre-funded warrants offered hereby.

Common Stock

The description of our common stock offered by this prospectus is incorporated herein by reference to the description of such common stock included in our Annual Report on Form 10-K for the year ended December 31, 2021.

Common Warrants

The Company is also offering common warrants to purchase up to an aggregate of [_____] shares of our common stock.

Each common warrant issued in this offering represents the right to purchase up to one share of common stock at an initial exercise price of $[___] per share. Each common warrant may be exercised, in cash or by a cashless exercise at the election of the holder at any time following the date of issuance and from time to time thereafter through and including the five year anniversary of the initial exercise date.

The common warrants will be exercisable in whole or in part by delivering to the Company a completed instruction form for exercise and complying with the requirements for exercise set forth in the common warrant. Payment of the exercise price may be made in cash or pursuant to a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the common warrant.

No Fractional Shares

No fractional shares or scrip representing fractional shares shall be issued upon the exercise of the common warrant. As to any fraction of a share which the holder would otherwise be entitled to purchase upon such exercise, the number of shares of common stock to be issued shall be rounded up to the nearest whole number.

Failure to Timely Deliver Shares

If we fail to deliver to the holder a certificate representing shares issuable upon exercise of a common warrant or to credit the holder's balance account with Depository Trust Company for such number of shares of common stock to which the holder is entitled upon the holder's exercise of the common warrant, in each case, by the delivery date set forth in the common warrant, and if after such date the holder is required by its broker to purchase (in an open market transaction or otherwise) or the holder's brokerage firm otherwise purchases, shares of common stock to deliver in satisfaction of a sale by the holder of the warrant shares which the holder anticipated receiving upon such exercise, or a Buy-In, then we shall (A) pay in cash to the holder the amount, if any, by which (x) the holder's total purchase price (including brokerage commissions, if any) for the shares of common stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of warrant shares that we were required to deliver to the holder in connection with the exercise at issue, times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the holder, either reinstate the portion of the applicable warrant and equivalent number of warrant shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the holder the number of shares of common stock that would have been issued had we timely complied with our exercise and delivery obligations. In addition, if we fail to deliver to the holder any common stock pursuant to a validly-exercised common warrant, we will be required to pay liquidated damages in the amount of $10 per trading day for each $1,000 of the shares of common stock exercised but not delivered (and rising to $20 per trading day beginning the third trading day after the warrant share delivery date) until such time the shares of common stock are delivered or the holder rescinds such exercise.

Exercise Limitation

In general, a holder will not have the right to exercise any portion of a common warrant if the holder (together with its Attribution Parties (as defined in the common warrant)) would beneficially own in excess of 4.99% or 9.99%, at the election of the holder, of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrant. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us, provided that any increase in this limitation will not be effective until 61 days after such notice from the holder to us and such increase or decrease will apply only to the holder providing such notice.

Cashless Exercise

If, at the time a holder exercises its warrants, a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act, is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrant.

Adjustment for Stock Splits

The exercise price and the number of shares of common stock purchasable upon the exercise of the common warrants are subject to adjustment upon the occurrence of specific events, including sales of additional shares of common stock, stock dividends, stock splits, and combinations of our common stock.

Dividends or Distributions

If we declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of our common stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property, options, evidence of indebtedness or any other assets by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) at any time after the issuance of the common warrants, then, in each such case, the holders of the common warrants shall be entitled to participate in such distribution to the same extent that the holders would have participated therein if the holders had held the number of shares of common stock acquirable upon complete exercise of the common warrants.

Purchase Rights

If we grant, issue or sell any shares of our common stock or securities exercisable for, exchangeable for or convertible into our common stock, or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of our common stock, referred to as Purchase Rights, then each holder of the common warrants will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon complete exercise of the common warrant immediately before the record date, or, if no such record is taken, the date as of which the record holders of shares of common stock are to be determined, for the grant, issue or sale of such Purchase Rights.

Fundamental Transaction

If a Fundamental Transaction (as defined in the common warrants and described below) occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the common warrants with the same effect as if such successor entity had been named in the warrant itself. Additionally, upon consummation of a Fundamental Transaction pursuant to which holders of shares of our common stock are entitled to receive securities or other assets with respect to or in exchange for shares of our common stock, we will make appropriate provision to ensure that the holder will thereafter have the right to receive upon an exercise of the common warrants at any time after the consummation of the Fundamental Transaction but prior to the applicable expiration date of the common warrants, in lieu of shares of our common stock (or other securities, cash, assets or other property) purchasable upon the exercise of the common warrant prior to such Fundamental Transaction, at the option of each holder (without regard to any limitation in the common warrant on the exercise of the common warrants), the number of shares of common stock of the successor or acquiring corporation or of us, if we are the surviving corporation, and any additional consideration which the holder would have been entitled to receive upon the happening of such Fundamental Transaction had the common warrant been exercised immediately prior to such Fundamental Transaction.

If holders of our common stock are given a choice as to the securities, cash or property to be received in a Fundamental Transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the common warrants, following such Fundamental Transaction. These provisions apply similarly and equally to successive Fundamental Transactions and other corporate events described in the common warrants and will be applied without regard to any limitations on the exercise of the warrant.

In the event of a Fundamental Transaction, at the request of the holder, we or the successor entity shall purchase the unexercised portion of the common warrants from the holder by paying to the holder, on or prior to the second trading day after such request (or, if later, on the effective date of the Fundamental Transaction), cash in an amount equal to the Black-Scholes Value (as defined below) of the remaining unexercised portion of the common warrants on the date of such Fundamental Transaction.

Transferability

Subject to applicable laws, the common warrants may be offered for sale, sold, transferred or assigned. There is currently no trading market for the common warrants and a trading market is not expected to develop.

Rights as a Stockholder

Except as otherwise provided in the common warrants or by virtue of a holder's ownership of shares of our common stock, the holders of the common warrants do not have the rights or privileges of holders of our common stock, including any voting rights, unless and until they exercise their warrants.

Amendments

Each common warrant may be amended with the written consent of the holder of such common warrant and us.

Listing

There is no established public trading market for the common warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the common warrants on any national securities exchange.

Definitions

"Black Scholes Value" means the value of the common warrants based on the Black-Scholes Option Pricing Model obtained from the "OV" function on Bloomberg, L.P. ("Bloomberg") determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the trading day immediately following the public announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the greater of (i) the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (ii) the greater of (x) the last VWAP immediately prior to the public announcement of such Fundamental Transaction and (y) the last VWAP immediately prior to the consummation of such Fundamental Transaction and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, and (E) a zero cost of borrow.

"Fundamental Transaction" means (i) we, directly or indirectly, in one or more related transactions effect any merger or consolidation with or into another Person, (ii) we (and all of our subsidiaries, taken as a whole), directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of our assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by us or another Person) is completed pursuant to which holders of common stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding common stock, (iv) we, directly or indirectly, in one or more related transactions effect any reclassification, reorganization or recapitalization of our common stock or any compulsory share exchange pursuant to which our common stock is effectively converted into or exchanged for other securities, cash or property, or (v) we, directly or indirectly, in one or more related transactions consummate a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of our common stock (not including any shares of common stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination).

Pre-Funded Warrants

The following summary of certain terms and provisions of the pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration and Exercise Price

Each pre-funded warrant offered hereby will have an initial exercise price per share equal to $0.01. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

Exercisability

Each pre-funded warrant may be exercised, in cash or by a cashless exercise at the election of the holder at any time following the date of issuance and from time to time thereafter through and including the five year anniversary of the initial exercise date. The pre-funded warrants will be exercisable in whole or in part by delivering to the Company a completed instruction form for exercise and complying with the requirements for exercise set forth in the pre-funded warrant. Payment of the exercise price may be made in cash or pursuant to a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the pre-funded warrant.

Cashless Exercise

At the time a holder exercises its pre-funded warrants, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Transferability

Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the pre-funded warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Trading Market

There is no trading market available for the pre-funded warrants on any securities exchange or nationally recognized trading system.

Right as a Stockholder

Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants.

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.

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." There is no established public trading market for the pre-funded warrants or common warrants to be sold in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the common warrants or pre-funded warrants on any national securities exchange.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Pacific Stock Transfer, Inc. The transfer agent's address is 6725 Via Austi Parkway, Suite 300, Las Vegas, Nevada 89119.

PLAN OF DISTRIBUTION

We have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent to solicit offers to purchase the shares of our common stock, pre-funded warrants and common warrants offered by this prospectus. The placement agent is not purchasing or selling any such securities, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of such securities, other than to use its "reasonable best efforts" to arrange for the sale of such securities by us. Therefore, we may not sell all of the shares of common stock, pre-funded warrants and common warrants being offered. The terms of this offering were subject to market conditions and negotiations between us, the placement agent and prospective investors. The placement agent will have no authority to bind us by virtue of the engagement letter. We will enter into a securities purchase agreement directly with the institutional investors, at the investor's option, who purchase our securities in this offering. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering. The placement agent may retain sub-agents and selected dealers in connection with this offering.

Delivery of the shares of common shares, pre-funded warrants and common warrants offered hereby is expected to occur on or about [_____], [2022], subject to satisfaction of certain customary closing conditions.

We have agreed to pay the placement agent an aggregate fee equal to 6.0% of the gross proceeds received in the offering. In addition, we have agreed to reimburse the placement agent for its legal fees and expenses and other out-of-pocket expenses in an amount up to $60,000 and clearing expenses of $15,950.

We estimate the total expenses of this offering paid or payable by us, exclusive of the placement agent's cash fee of 6% of the gross proceeds and expenses, will be approximately $[_____]. After deducting the fees due to the placement agent and our estimated expenses in connection with this offering, we expect the net proceeds from this offering will be approximately $[____] million.

The following table shows the per share and total cash fees we will pay to the placement agent in connection with the sale of the common stock and shares of common stock underlying the pre-funded warrants pursuant to this prospectus.

	Per Common Share and Common Warrant	Per Pre-funded Warrant and Common Warrant	Total
Offering price	$	$	$
Placement agent fees	$	$	$
Proceeds before expenses to us	$	$	$

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in our engagement letter with the placement agent. We have also agreed to contribute to payments the placement agent may be required to make in respect of such liabilities.

Lock-up Agreements

We and each of our officers and directors have agreed with the placement agent to be subject to a lock-up period of ___ days following the date of closing of the offering pursuant to this prospectus. This means that, during the applicable lock-up period, we and such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any of our shares of common stock or any securities convertible into, or exercisable or exchangeable for, shares of common stock, subject to customary exceptions. The placement agent may waive the terms of these lock-up agreements in its sole discretion and without notice. In addition, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of our common stock or upon a specified or contingent event in the future or enter into any agreement to issue securities at a future determined price for a period of one year following the closing date of this offering, subject to an exception. The placement agent may waive this prohibition in its sole discretion and without notice.

Other Relationships

From time to time, the placement agent may provide in the future various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. However, except as disclosed in this prospectus, we have no present arrangements with the placement agent for any further services. The placement agent is currently acting as sales agent under our existing At the Market, or ATM, Offering, which commenced in June 2022, for which it receives compensation.

Regulation M Compliance

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the sale of our securities offered hereby by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent will be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Trading Market

Our common stock is listed on the Nasdaq Capital Market under the symbol “OPGN.” There is no established public trading market for the pre-funded warrants or common warrants to be sold in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the common warrants or pre-funded warrants on any national securities exchange.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following is a summary of the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock and pre-funded warrants, but does not purport to be a complete analysis of all the potential tax considerations relating thereto. Throughout this summary, all references to our common stock are meant to include our pre-funded warrants. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed or subject to differing interpretations, possibly with retroactive effect, with the resulting U.S. federal income tax consequences being different from those set forth below. We have not sought and will not seek any ruling from the Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This summary also does not address the tax considerations arising under the laws of any U.S. state or local or any non-U.S. jurisdiction, estate or gift tax, the 3.8% Medicare tax on net investment income or any alternative minimum tax consequences. In addition, this discussion does not address tax considerations applicable to a holder's particular circumstances or to a holder that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions;
- tax-exempt or government organizations;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than 5.0% of our capital stock;
- certain U.S. expatriates, citizens or former long-term residents of the United States;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction," synthetic security, other integrated investment, or other risk reduction transaction;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes);
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- pension plans;
- partnerships, or other entities or arrangements treated as partnerships for U.S. federal income tax purposes, or investors in any such entities;
- persons for whom our stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code;
- integral parts or controlled entities of foreign sovereigns;
- passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax; or
- persons that acquire our common stock as compensation for services.

In addition, if a partnership, including any entity or arrangement classified as a partnership for U.S. federal income tax purposes, holds our common stock, the tax treatment of a partner generally will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors regarding the U.S. federal income tax consequences to them of the purchase, ownership, and disposition of our common stock.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal estate or gift tax rules or under the laws of any U.S. state or local or any non-U.S. or other taxing jurisdiction or under any applicable tax treaty.

Definition of a U.S. Holder

For purposes of this summary, a "U.S. Holder" is any beneficial owner of our common stock that is a "U.S. person," and is not a partnership, or an entity treated as a partnership or disregarded from its owner, each for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

For purposes of this summary, a "Non-U.S. Holder" is any beneficial owner of our common stock that is not a U.S. Holder or a partnership, or other entity treated as a partnership or disregarded from its owner, each for U.S. federal income tax purposes.

Tax Consequences to U.S. Holders

Distributions on Common Stock

As discussed above under "Dividend Policy," we do not currently expect to make distributions on our common stock. In the event that we do make distributions of cash or other property, distributions paid on common stock, other than certain pro rata distributions of common stock, will be treated as a dividend to the extent paid out of our current or accumulated earnings and profits, if any, and will be includible in income by the U.S. Holder and taxable as ordinary income when received. If a distribution exceeds our current and accumulated earnings and profits, the excess will be first treated as a tax-free return of the U.S. Holder's investment, up to the U.S. Holder's tax basis in the common stock. Any remaining excess will be treated as a capital gain. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be eligible for taxation as "qualified dividend income" and therefore may be taxable at rates applicable to long-term capital gains. U.S. Holders should consult their tax advisers regarding the availability of the reduced tax rate on dividends in their particular circumstances. Dividends received by a corporate U.S. Holder will be eligible for the dividends-received deduction if the U.S. Holder meets certain holding period and other applicable requirements.

Sale or Other Disposition of Common Stock

For U.S. federal income tax purposes, gain or loss realized on the sale or other disposition of common stock will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the common stock for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the common stock disposed of and the amount realized on the disposition. Long-term capital gains recognized by non-corporate U.S. Holders will be subject to reduced tax rates. The deductibility of capital losses is subject to limitations.

Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, we believe a pre-funded warrant should be treated as common stock for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of our common stock, as described below. Accordingly, no gain or loss should be recognized upon the exercise of a pre-funded warrant and, upon exercise, the holding period of a pre-funded warrant should carry over to the common stock received. Similarly, the tax basis of the pre-funded warrant should carry over to the common stock received upon exercise, increased by the exercise price of $0.01 per share**.** However, our characterization of a pre-funded warrant is not binding on the IRS, and the IRS may treat our pre-funded warrants as warrants to acquire our common stock. If so, the amount and character of your gain with respect to an investment in our pre-funded warrants could change. Accordingly, each holder should consult his, her or its own tax advisor regarding the risks associated with the acquisition of pre-funded warrants pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that our characterization described above is respected for U.S. federal income tax purposes.

Tax Consequences to Non-U.S. Holders

Distributions

As discussed in the section entitled "Dividend Policy," we do not anticipate paying any dividends on our common stock in the foreseeable future. If we make distributions on our common, those payments will constitute dividends for U.S. federal income tax purposes to the extent we have current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce a Non-U.S. Holder's basis in our common stock, as applicable, but not below zero. Any excess will be treated as capital gain and will be treated as described below under the "—Gain on Sale or Other Disposition of Common Stock" section. Any such distributions would be subject to the discussions below regarding back-up withholding and the Foreign Account Tax Compliance Act, or FATCA.

Subject to the discussion below on effectively connected income, any dividend paid to a Non-U.S. Holder generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. To receive a reduced treaty rate, a Non-U.S. Holder must provide us or our agent with an IRS Form W-8BEN (generally including a U.S. taxpayer identification number), IRS Form W-8 BEN-E or another appropriate version of IRS Form W-8 (or a successor form), which must be updated periodically, and which, in each case, must certify qualification for the reduced treaty rate. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States and that are not eligible for relief from U.S. (net basis) income tax under an applicable income tax treaty, generally are exempt from the (gross basis) withholding tax described above. To obtain this exemption from withholding tax, the Non-U.S. Holder must provide the applicable withholding agent with an IRS Form W-8ECI or successor form or other applicable IRS Form W-8 certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States. Such effectively connected dividends, if not eligible for relief under a tax treaty, would not be subject to a withholding tax, but would be taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits and if, in addition, the Non-U.S. Holder is a corporation, may also be subject to a branch profits tax at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty).

If you are eligible for a reduced rate of withholding tax pursuant to a tax treaty, you may be able to obtain a refund of any excess amounts withheld if you timely file an appropriate claim for refund with the IRS.

Gain on Sale or Other Disposition of Common Stock

Subject to the discussion below regarding backup withholding and FATCA, a Non-U.S. Holder generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States and not eligible for relief under an applicable income tax treaty, in which case the Non-U.S. Holder will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and for a Non-U.S. Holder that is a corporation, such Non-U.S. Holder may be subject to the branch profits tax at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items;

- the Non-U.S. Holder is an individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met, in which case the Non-U.S. Holder will be required to pay a flat 30% tax on the gain derived from the sale, which tax may be offset by U.S. source capital losses (even though the Non-U.S. Holder is not considered a resident of the United States) (subject to applicable income tax or other treaties); or

- we are a "U.S. real property holding corporation" for U.S. federal income tax purposes, or a USRPHC, at any time within the shorter of the five-year period preceding the disposition or the Non-U.S. Holder's holding period for our common stock. We believe we are not currently and do not anticipate becoming a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to United States federal income tax if (a) shares of our common stock are "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, such as Nasdaq, and (b) the Non-U.S. Holder owns or owned, actually and constructively, 5% or less of the shares of our common stock throughout the five-year period ending on the date of the sale or exchange. If the foregoing exception does not apply, such Non-U.S. Holder's proceeds received on the disposition of shares will generally be subject to withholding at a rate of 15% and such Non-U.S. Holder will generally be taxed on any gain in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Information Reporting and Backup Withholding

Information returns may be filed with the IRS in connection with distributions on common, and the proceeds of a sale or other disposition of common stock. A non-exempt U.S. Holder may be subject to U.S. backup withholding on these payments if it fails to provide its taxpayer identification number to the withholding agent and comply with certification procedures or otherwise establish an exemption from backup withholding.

A Non-U.S. Holder may be subject to U.S. information reporting and backup withholding on these payments unless the Non-U.S. Holder complies with certification procedures to establish that it is not a U.S. person (within the meaning of the Code). The certification requirements generally will be satisfied if the Non-U.S. Holder provides the applicable withholding agent with a statement on the applicable IRS Form (or a suitable substitute or successor form), together with all appropriate attachments, signed under penalties of perjury, stating, among other things, that such Non-U.S. Holder is not a U.S. Person. Applicable Treasury Regulations provide alternative methods for satisfying this requirement. In addition, the amount of distributions on common stock paid to a Non-U.S. Holder, and the amount of any U.S. federal tax withheld therefrom, must be reported annually to the IRS and the holder. This information may be made available by the IRS under the provisions of an applicable tax treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides.

Payment of the proceeds of the sale or other disposition of common stock to or through a non-U.S. office of a U.S. broker or of a non-U.S. broker with certain specified U.S. connections generally will be subject to information reporting requirements, but not backup withholding, unless the Non-U.S. Holder certifies under penalties of perjury that it is not a U.S. person or an exemption otherwise applies. Payments of the proceeds of a sale or other disposition of common stock to or through a U.S. office of a broker generally will be subject to information reporting and backup withholding, unless the Non-U.S. Holder certifies under penalties of perjury that it is not a U.S. person or otherwise establishes an exemption.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment generally will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle the holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Accounts

The Code generally imposes a U.S. federal withholding tax of 30% on dividends and, subject to the discussion below regarding proposed regulations recently issued by the U.S. Treasury Department, the gross proceeds of a disposition of our securities paid to a "foreign financial institution" (as specifically defined for this purpose), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise qualifies for an exemption from these rules. A U.S. federal withholding tax of 30% also applies to dividends and, subject to the discussion below regarding proposed regulations recently issued by the U.S. Treasury Department, will apply to the gross proceeds of a disposition of our securities paid to a non-financial foreign entity (as defined in the Code), unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect. "United States owners" (as defined in the Code), provides information regarding each substantial United States owners of the entity, or otherwise qualifies for an exemption from these rules.

Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph.

The U.S. Treasury Department released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock. In its preamble to such proposed regulations, the U.S. Treasury Department stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. Prospective investors should consult their own tax advisors regarding the possible impact of these rules on their investment in our common stock, and the possible impact of these rules and the proposed regulations on the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of this 30% withholding tax.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR SECURITIES, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS. IN ADDITION, SIGNIFICANT CHANGES IN U.S. FEDERAL TAX LAWS WERE RECENTLY ENACTED. PROSPECTIVE INVESTORS SHOULD ALSO CONSULT WITH THEIR TAX ADVISORS WITH RESPECT TO SUCH CHANGES IN U.S. TAX LAW AS WELL AS POTENTIAL CONFORMING CHANGES IN STATE TAX LAWS.

LEGAL MATTERS

The validity of the securities being offered hereby will be passed upon Ballard Spahr LLP, Philadelphia, Pennsylvania. Certain legal matters will be passed upon for the placement agent by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The consolidated financial statements of OpGen, Inc. and its subsidiaries as of December 31, 2021 and 2020, and for the years then ended, have been incorporated by reference herein in reliance upon the report, also incorporated by reference herein, of CohnReznick LLP, an independent registered public accounting firm, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2021 consolidated financial statements contains an explanatory paragraph that states that the Company has experienced losses and negative cash flows from operations since its inception, has an accumulated deficit, and has debt obligations coming due which collectively raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We filed with the SEC a registration statement under the Securities Act of 1933 for the securities offered by this prospectus. This prospectus does not contain all of the information in the registration statement and the exhibits and schedule that were filed with the registration statement. For further information with respect to us and our securities, we refer you to the registration statement and the exhibits and schedule that were filed with the registration statement. Statements contained in this prospectus about the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and we refer you to the full text of the contract or other document filed as an exhibit to the registration statement. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding registrants that file electronically with the SEC. The address of the website is www.sec.gov.

We file periodic reports under the Securities Exchange Act of 1934, including annual, quarterly and special reports, and other information with the Securities and Exchange Commission. These periodic reports and other information are available for inspection and copying at the SEC regional offices, public reference facilities and on the website of the SEC referred to above.

We make available free of charge on or through our internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The information found on our website, www.opgen.com, other than as specifically incorporated by reference in this prospectus, is not part of this prospectus.

INCORPORATION BY REFERENCE

The SEC allows us to "incorporate by reference" in this prospectus the information in other documents that we file with it, which means that we can disclose important information to you by referring you to those documents containing such information. This prospectus is part of a registration statement we filed with the SEC. You should rely on the information incorporated by reference in this prospectus and the registration statement. The information incorporated by reference is considered to be part of this prospectus and information we file later with the SEC will automatically update and supersede this information and information contained in documents filed earlier with the SEC. We incorporate by reference the documents listed below, any filings made with the SEC after the date of the initial registration statement and prior to effectiveness of the registration statement, and any future filings made with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of the offering; provided, that we are not incorporating by reference any documents or information deemed to have been furnished and not filed in accordance with SEC rules. The documents we are incorporating by reference are:

- our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 30, 2022;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022, filed with the SEC on May 13, 2022, June 30, 2022, filed with the SEC on August 12, 2022, and September 30, 2022, filed with the SEC on November 14, 2022;
- our Current Reports on Form 8-K, filed with the Commission on March 3, 2022 (Item 3.01), April 25, 2022 (Items 8.01 and 9.01), May 24, 2022 (Items 1.01, 2.03 and 9.01), June 9, 2022 (Item 5.07), June 24, 2022 (Items 1.01, 1.02 and 9.01), August 31, 2022 (Items 3.01, 8.01 and 9.01), September 20, 2022 (Item 8.01 and 9.01), October 3, 2022 (Items 1.01, 3.02, 3.03, 5.03, 8.01 and 9.01), November 10, 2022 (but only with respect to Item 5.02 and not Item 2.02 or 9.01), and November 30, 2022;
- our Definitive Proxy Statement for the Company's 2022 Annual Meeting of Stockholders filed with the Commission on April 25, 2022; and
- the description of our common stock contained in the Registration Statement on Form 8-A filed on April 30, 2015 and any amendments to such Registration Statement filed subsequently thereto, including all amendments or reports filed for the purpose of updating such description.

We will furnish to you, on written or oral request, a copy of any or all of the documents that have been incorporated by reference, including exhibits to these documents. You may request a copy of these filings at no cost by writing or telephoning our Secretary at the following address and telephone number:

OpGen, Inc.
9717 Key West Avenue, Suite 100
Rockville, MD 20850
Attention: Albert Weber, Corporate Secretary
Telephone No.: (301) 869-9683

Up to [_____] Shares of Common Stock

Up to [_____] Warrants to Purchase Up to [_____] Shares of Common Stock

Up to [_____] Pre-Funded Warrants to Purchase [_____] Shares of Common Stock

Up to [_____] Shares of Common Stock Underlying the Pre-Funded Warrants and Common Warrants

PROSPECTUS

H.C. Wainwright & Co.

, 2022

PART II

Information Not Required in Prospectus

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the fees and expenses, other than underwriting fees and expenses, payable in connection with the registration of the common stock hereunder. All amounts are estimates except the SEC registration fee and the FINRA filing fee.

SEC registration fee	$
Legal fees and expenses	$
Accounting fees and expenses	$
FINRA filing fee	$
Transfer agent and registrar fees and expenses	$
Printer costs and expenses	$
	$

Item 14. Indemnification of Directors and Officers.

The Registrant maintains insurance providing for indemnification of its officers and directors and certain other persons against liabilities and expenses incurred by any of them in certain stated proceedings and under certain stated conditions.

Delaware Corporations

Section 145 of the Delaware General Corporation Law, or DGCL, provides that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. Section 145 further provides that a corporation similarly may indemnify any such person serving in any such capacity who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or such other court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Delaware Court of Chancery or such other court shall deem proper.

Certificate of Incorporation and Bylaws

The Registrant's amended and restated certificate of incorporation, as amended, provides that a director of the Registrant shall not be personally liable to the Registrant or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Registrant or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transaction from which the director derived an improper personal benefit. If the DGCL is hereafter amended to authorize the further elimination or limitation of the liability of directors, then the liability of the directors of the Registrant, in addition to the limitation on personal liability provided herein, shall be limited to the fullest extent permitted by the amended DGCL. Any repeal or modification of this paragraph by the stockholders of the Registrant shall be prospective only, and shall not adversely affect any limitation on the personal liability of a director of the corporation at the time of such repeal or modification. The Registrant's certificate of incorporation further provides that the Registrant's officers and directors shall be indemnified by the Registrant as provided in the Registrant's bylaws.

Under the provisions of the Registrant's bylaws, as amended, any person who is or was a party or is threatened to be made a party of any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Registrant) by reason of the fact that he or she is or was a director, officer, employee or agent of the Registrant or is or was serving at the Registrant's request as a director, officer, employee or agent of another company or other entity shall be indemnified by the Registrant against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action, suit or proceeding if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the Registrant's best interests, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The Registrant shall further indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Registrant to procure a judgment in its favor by reason of the fact that he is or was a director, officer, employee or agent of the Registrant or is or was serving at the request of the Registrant as a director, officer, employee or agent of another corporation or other entity against expenses (including attorneys' fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Registrant. Notwithstanding the foregoing, no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Registrant unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Delaware Court of Chancery or such other court shall deem proper.

The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he or she reasonably believed to be in, or not opposed to, the Registrant's best interests and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

In addition, to the extent that such a person is successful on the merits or otherwise in defense of any action, suit, or proceeding brought against him or her by reason of the fact that he or she is the Registrant's director, officer, employee or agent, he or she shall be indemnified against expenses, including attorneys' fees, actually and reasonably incurred in connection therewith.

The Registrant's bylaws, as amended, provide that expenses (including attorneys' fees) incurred by a director or officer in defending a civil, criminal, administrative, or investigative action, suit or proceeding may be paid by the Registrant in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of the director or officer to repay such amount if it shall ultimately be determined that he or she is not entitled to be indemnified by the Registrant. Such expenses, including attorneys' fees, incurred by other employees and agents may be paid upon such terms and conditions as the Board of Directors deems appropriate.

Any indemnification under the provisions summarized above (unless ordered by a court) shall be made by the Registrant only as authorized in each specific case upon a determination that indemnification of such person is proper under the circumstances because he or she has met the applicable standard of conduct set forth in the applicable provision. Such determination shall be made (1) by a majority vote of the Registrant's directors who are not parties to the action, suit or proceeding (even though less than a quorum), (2) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (3) by the stockholders.

The Registrant maintains director and officer insurance with respect to those claims described above in customary amounts.

The above discussion of the certificate of incorporation and bylaws of the Registrant and the DGCL is not intended to be exhaustive and is qualified in its entirety by such certificates of incorporation, bylaws and the DGCL.

The Registrant has entered into indemnification agreements with each of our directors and executive officers. These agreements provide that we will indemnify each of our directors, such executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us and/or in furtherance of our rights. Additionally, each of our directors may have certain rights to indemnification, advancement of expenses and/or insurance provided by their affiliates, which indemnification relates to and might apply to the same proceedings arising out of such director's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors are primary and any obligation of the affiliates of those directors to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information as to all securities we have sold since September 30, 2019, which were not registered under the Securities Act.

(1) On October 3, 2022, the Company closed a preferred stock offering, in which the Company issued 5,360,000 shares of common stock, 33,810 shares of Series C Mirroring Preferred Stock and pre-funded warrants to purchase an aggregate of 4,300,000 shares of common stock. Gross proceeds from the offering, before deducting the placement agent's fees and other estimated offering expenses, was approximately $3.34 million. Each share of common stock had a purchase price of $0.35, each share Preferred Stock had a purchase price of $0.01, and each pre-funded warrant had a purchase price of $0.34 per share of common stock underlying the pre-funded warrants. In connection with the offering, in a concurrent private placement, the Company issued warrants to purchase an aggregate amount of 9,660,000 shares of common stock, which warrants have an exercise price of $0.377 per share.

(2) On March 9, 2021, the Company entered into a Warrant Exercise Agreement (the "Exercise Agreement") with the institutional investor (the "Holder") from the Company's private placement of common stock, pre-funded warrants to purchase common stock, and warrants to purchase shares of common stock that was completed in November 2020 (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 initially had 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. In connection with the Company's October 2022 Offering, the exercise price of the institutional investor's 3,147,700 warrants was repriced to $0.377 per share.

(3) 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 initially had 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 were exercised. In connection with the Company's offering consummated in October 2022, the exercise price of the institutional investor's 4,166,666 warrants was repriced to $0.377 per share.

As of September 30, 2022, none of the warrants issued in these transactions have been exercised.

We deemed the offers, sales and issuances of the securities described in paragraphs (1) through (2) above to be exempt from registration under the Securities Act, in reliance on Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, regarding transactions by an issuer not involving a public offering. All purchasers of securities in transactions exempt from registration pursuant to Regulation D represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

All certificates representing the securities issued in the transactions described in this Item 15 included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transactions set forth in this Item 15.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits:

EXHIBIT INDEX

Exhibit Number	Description
1.1 **	Form of Securities Purchase Agreement
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)

Exhibit Number	Description
3.1.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of OpGen, Inc., filed with the Secretary of the State of Delaware on December 8, 2021 (incorporated by reference to Apendix A to the Registrant's definitive proxy statement filed on October 29, 2021)
3.1.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of OpGen, Inc., filed with the Secretary of the State of Delaware on December 9, 2021 (incorporated by reference to Apendix B to the Registrant's definitive proxy statement filed on October 29, 2021)
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	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)
3.5	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)
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series C Mirroring Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on October 3, 2022).
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)

Exhibit Number	Description
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)
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 Common Stock Purchase Warrant. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on October 3, 2022).
4.18	Form of Pre-Funded Common Stock Purchase Warrant. (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on October 3, 2022).
4.19	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.19 to the Registrants Annual Report on Form 10-K, filed on March 30, 2022)
4.20 **	Form of Pre-funded Warrant
4.21 **	Form of Common Warrant
5.1 **	Opinion of Ballard Spahr LLP
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 Item 5.02 of the Registrant's Current Report on Form 8-K filed on May 7, 2020)
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 !	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)

Exhibit Number	Description
10.6 !	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)
10.7 !	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)
10.8 !	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)
10.9	Common Stock and Note Purchase Agreement, dated as of July 14, 2015, between the Registrant and Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 16, 2015)
10.10	Senior Secured Promissory Note, dated as of July 14, 2015, between the Registrant and Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on July 16, 2015)
10.11	Second Amended & Restated Senior Secured Promissory Note, dated June 28, 2017, by and between the Registrant and Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, Amendment No. 1, filed on June 28, 2017)
10.12	Allonge, dated June 11, 2018, to the Second Amended and Restated Senior Secured Promissory Note, dated June 28, 2017, with a principal amount of $1,000,000 issued by OpGen, Inc. to Merck Global Health Innovation Fund, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on June 11, 2018)
10.13 !	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)
10.14	Assignment of the Agreement for the Issuance of and Subscription to Notes Convertible into Shares, dated February 24, 2020, among OpGen, Inc., YA II PN, LTD, and Curetis N.V. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on February 28, 2020)
10.15	Amended and Restated Interim Facility Agreement, dated as of March 18, 2020, by and among Curetis GmbH, as Borrower, Crystal GmbH, a wholly owned subsidiary of the Registrant, as Lender and Curetis N.V. (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K filed on March 24, 2020).
10.16 !	Amended and Restated Management Services Agreement, dated April 2, 2020, by and between OpGen, Inc. and Oliver Schacht (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed on April 2, 2020).
10.17 !	Amended and Restated Stock Option Plan, dated April 1, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 2, 2020).
10.18	Term Note between OpGen, Inc. and Silicon Valley Bank, dated April 22, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 28, 2020).
10.19	Term Note between Curetis USA Inc. and Silicon Valley Bank, dated April 22, 2020 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on April 28, 2020).
10.20 !	Managing Director's Employment Contract by and between Curetis GmbH and Oliver Schacht, Ph.D dated August 6, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 11, 2020).

Exhibit Number	Description
10.21 !	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).
10.22	Exclusive International Distributor Agreement, dated as of September 25, 2015, between Curetis AG and Beijing Clear Biotech Co. Ltd (incorporated by reference to Exhibit 10.32 to the Registrant's Form S-4/A filed on December 20, 2019).
10.23	Amendment 1 to the Exclusive International Distributor Agreement, dated as of October 11, 2018, between Curetis GmbH and Beijing Clear Biotech (incorporated by reference to Exhibit 10.32.2 to the Registrant's Form S-4/A filed on December 20, 2019).
10.24	Assumption of contract, dated as of May 30, 2016, by and between Curetis GmbH, Beijing Clear Bio-tech Co. Ltd and Technomed (Hong Kong) Ltd. (incorporated by reference to Exhibit 10.32.3 to the Registrant's Form S-4/A filed on December 20, 2019).
10.25	Non-Exclusive Patent License and Research Collaboration Agreement, dated as of October 5, 2015, between Acumen Research Laboratories Pte Ltd and Curetis AG (incorporated by reference to Exhibit 10.33 to the Registrant's Form S-4/A filed on December 20, 2019).
10.26	Exclusive International Distributor Agreement, dated as of October 5, 2015, between Curetis AG and Acumen Research Laboratories Pte Ltd (incorporated by reference to Exhibit 10.34.1 to the Registrant's Form S-4/A filed on December 20, 2019).
10.27	Amendment 1 to the Exclusive International Distributor Agreement, dated as of November 15, 2015, between Curetis GmbH and Acumen Research Laboratories Pte Ltd (incorporated by reference to Exhibit 10.34.2 to the Registrant's Form S-4/A filed on December 20, 2019).
10.28	Technology Transfer, Technical Cooperation and License Agreement, dated as of September 7, 2016, by and between Curetis GmbH and Siemens Technology Accelerator GmbH (incorporated by reference to Exhibit 10.35.1 to the Registrant's Form S-4/A filed on December 20, 2019).
10.29±	First Amendment Agreement to the Technology Transfer, Technical Cooperation and License Agreement, dated as of May 17, 2018, by and between Ares Genetics GmbH and Siemens Technology Accelerator GmbH (incorporated by reference to Exhibit 10.35.2 to the Registrant's Form S-4/A filed on December 20, 2019).
10.30	Memorandum of Understanding, dated as of September 12, 2017, between Curetis GmbH, Ares Genetics GmbH and MGI Tech Co., Ltd. (incorporated by reference to Exhibit 10.36 to the Registrant's Form S-4/A filed on December 20, 2019).
10.31	Authorization and Supply Agreement, dated as of January 10, 2018, between MGI Tech Co., Ltd. And Curetis GmbH (incorporated by reference to Exhibit 10.37 to the Registrant's Form S-4/A filed on December 20, 2019).
10.32	Technology Purchase Agreement, dated as of December 13, 2016, between Systec Elektronik und Software GmbH, Carpegen GmbH and Curetis GmbH (incorporated by reference to Exhibit 10.38 to the Registrant's Form S-4/A filed on December 20, 2019).
10.33	Services Frame Agreement, dated as of December 14, 2018, between Ares Genetics GmbH and Sandoz International GmbH (incorporated by reference to Exhibit 10.39.1 to the Registrant's Form S-4/A filed on December 20, 2019).
10.34	Work Order Agreement, dated as of December 14, 2018, between Ares Genetics GmbH and Sandoz International GmbH (incorporated by reference to Exhibit 10.39.2 to the Registrant's Form S-4/A filed on December 20, 2019).
10.35	License Agreement, dated as of February 18, 2019, between Ares Genetics GmbH and QIAGEN GmbH and the QIAGEN Affiliates (incorporated by reference to Exhibit 10.40.1 to the Registrant's Form S-4/A filed on December 20, 2019).

Exhibit Number	Description
10.36	First Amendment to License Agreement, dated as of September 18, 2019, between Ares Genetics GmbH and QIAGEN GmbH (incorporated by reference to Exhibit 10.40.2 to the Registrant's Form S-4/A filed on December 20, 2019).
10.37	Technology Evaluation Agreement, dated as of September 13, 2019, between Ares Genetics and [***] (incorporated by reference to Exhibit 10.41 to the Registrant's Form S-4/A filed on December 20, 2019).
10.38	Amendment and Restatement Agreement in relation to the Finance Contract, dated December 12, 2016, dated as of May 20, 2019, between Curetis GmbH, Curetis N.V., Curetis USA INC., Ares Genetics GmbH and European Investment Bank (incorporated by reference to Exhibit 10.42 to the Registrant's Form S-4/A filed on December 20, 2019).
10.39 !	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).
10.40 !	2020 Stock Options Plan, dated September 30, 2020 (incorporated by reference to Exhibit 10.3 to the Registrants Quarterly Report on Form 10-Q filed on November 16, 2020)
10.41 !	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)
10.42 !	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)
10.43	Lease Agreement, dated as of November 11, 2020, between the Registrant and Key West MD Owner, LLC (the "Landlord") (incorporated by reference to Exhibit 10.6 to the Registrants Quarterly Report on Form 10-Q filed on November 16, 2020)
10.44	Form of Securities Purchase Agreement, dated November 23, 2020, by and between OpGen, Inc. and the purchaser party thereto. for 2020 PIPE (incorporated by reference to Exhibit 10.1 to the Registrants Current Report on Form 8-K, filed on November 24, 2020)
10.45	Placement Agent Agreement, dated November 23, 2020, by and between OpGen, Inc. and Alliance Global Partners (incorporated by reference to Exhibit 10.2 to the Registrants Current Report on Form 8-K, filed on November 24, 2020)
10.46	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)
10.47	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)
10.48	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)
10.49	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)

Exhibit Number	Description
10.50 !	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)
10.51	Waiver and Amendment Letter, dated May 23, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 24, 2022).
10.52	At the Market Offering Agreement, dated June 24, 2022, by and between OpGen, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed on June 24, 2022).
10.53	Form of Securities Purchase Agreement, dated September 30, 2022, by and between OpGen, Inc. and the Investor. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on October 3, 2022).
10.54	Form of Warrant Amendment Agreement, dated September 30, 2022, by and between OpGen, Inc. and the Investor. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on October 3, 2022).
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021, filed on March 30, 2022)
23.1 *	Consent of CohnReznick LLP
23.2 **	Consent of Ballard Spahr LLP (included in Exhibit 5.1)
24.1 *	Power of attorney (included on signature page)
107 *	Filing Fee Table

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* Filed herewith

** To be filed by amendment

! Denotes management compensation plan or contract

± Confidential treatment has been requested for certain portions of this agreement pursuant to an application for confidential treatment filed with the Securities and Exchange Commission on June 19, 2017. Such provisions have been filed separately with the Commission.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of this registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high and of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission (the "Commission") pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in this registration statement;

provided, *however*, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

For purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.

For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Rockville, State of Maryland, on December 1, 2022.

OPGEN, INC.

By: /s/ Oliver Schacht
Name: Oliver Schacht
Title: Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENT, that each individual whose signature appears below hereby constitutes and appoints each of Oliver Schacht and Albert Weber as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement (or any Registration Statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement and Power of Attorney has been signed by the following persons in the capacities and on the date indicated.

Signature	Title	Date
/s/ Oliver Schacht Oliver Schacht	Chief Executive Officer and Director (principal executive officer)	December 1, 2022
/s/ Albert Weber Albert Weber	Chief Financial Officer (principal financial officer and principal accounting officer)	December 1, 2022
/s/ Mario Crovetto Mario Crovetto	Director	December 1, 2022
/s/ R. Donald Elsey R. Donald Elsey	Director	December 1, 2022
/s/ Prabhavathi Fernandes Prabhavathi Fernandes	Director	December 1, 2022
/s/ William Rhodes William Rhodes	Director	December 1, 2022
/s/ Yvonne Schlaeppi Yvonne Schlaeppi	Director	December 1, 2022

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in this Registration Statement on Form S-1 of OpGen, Inc. of our report, dated March 30, 2022, which includes an explanatory paragraph related to OpGen, Inc.'s ability to continue as a going concern, 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 the Annual Report on Form 10-K of OpGen, Inc for the year ended December 31, 2021 also incorporated by reference in the Registration Statement. We also consent to the reference to our firm under the caption "Experts" in the Registration Statement.

/s/ CohnReznick LLP

Tysons, Virginia
December 1, 2022

EXHIBIT 107

Calculation of Filing Fee Tables

FORM S-1
(Form Type)

OPGEN, INC.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

	Security Type	Security Class Title	Fee Calculation Rule	Amount Registered	Maximum Aggregate Offering Price(1)	Amount of Registration Fee
Fees to Be Paid	Equity	Common Stock, $0.01 par value	457(o)		$10,000,000.00	$1,102.00
	Total Offering Amounts:					$1,102.00

Calculated pursuant to Rule 457(o), based on the proposed maximum aggregate offering price.