

OpGen

Clinical update

Test menu expansion opportunity with positive data

OpGen has announced encouraging final data from its Unyvero Urinary Tract Infection (UTI) panel, a diagnostic test designed to detect pathogens and antimicrobial resistance markers related to UTI, from native urine specimens without the need for culturing. The study, which recruited over 1,800 patient samples across four trial sites in the United States, met its primary endpoint with an overall weighted average sensitivity of 96.4% and specificity of 97.4% in preliminary analysis. The favourable data should support an FDA De Novo application, which we anticipate in Q123 followed by likely launch in 2024, provided FDA clearance is received. The company also plans to submit the data for a peer review publication, which we believe would further strengthen the credibility and visibility of the UTI panel. We see this development as supporting potential test menu expansion for the company's flagship Unyvero systems in the United States. The market has reacted positively to this news with the stock closing 85% higher in trading.

Year end	Revenue (\$m)	EBITDA* (\$m)	PBT* (\$m)	EPS* (\$)	P/revenue (x)	P/E (x)	Net debt (\$m)
12/20	4.2	(19.6)	(24.7)	(1.6)	3.0	N/A	6.7
12/21	4.3	(20.4)	(35.7)	(1.0)	2.9	N/A	(14.4)

Note: *EBITDA, PBT and EPS are normalised, excluding amortization of acquired intangibles, exceptional items and share-based payments.

The UTI clinical trial, initiated in Q321, was conducted on 1,858 prospective patient samples across four US sites with over 3,300 Unyvero UTI cartridges used, including for controls. The primary objective was to test the effectiveness of the Unyvero UTI panel in identifying urinary tract infections using clean-catch or catheter-related urine samples. The primary endpoint was met with overall weighted average sensitivity and specificity of 96.4% and 97.4%, respectively, when compared with the trial sites' standard of care microbiology results.

Complicated UTIs are one of the most prevalent hospital-acquired infections, with a rising number of infections caused by antibiotic-resistant bacteria. The Unyvero UTI panel tests for a broad range of bacterial and fungal pathogens as well as antimicrobial resistance markers (25 pathogens and 15 resistance genes) directly from native urine specimens, without the need for culturing, resulting in much quicker turnaround times (four to five hours versus days in the case of culture-based tests). This is a key advantage in our opinion as early diagnosis remains crucial for effective treatment and should lead to more optimal usage of available antibacterial treatments, decreased hospital stays and lower healthcare costs.

OpGen plans to file for FDA submission under the De Novo classification, which we anticipate in Q123. In parallel, the company is also working on next-generation sequencing data at its Rockville (US) laboratory to study genotypic correlation of antibiotic resistance markers identified in the study, which will generate additional data for low prevalence strains and antibiotic resistance markers. We view the FDA clearance as likely, which would further validate the company's Unyvero platform. Note that the Unyvero UTI panel is already available in the United States as a research use only product to hospitals, public health departments, clinical laboratories, pharmaceutical companies and CROs.

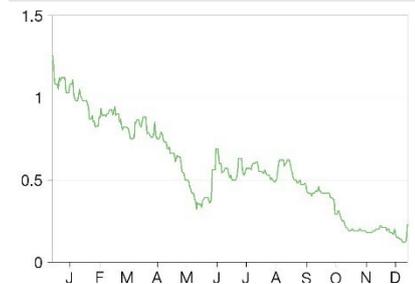
Pharma and biotech

14 December 2022

Price **US\$0.23**
Market cap **US\$12m**

Gross cash including net funding proceeds at 3 October 2022	US\$13.3m
Shares in issue	53.7m
Free float	92.5%
Code	OPGN
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance



Business description

OpGen is primarily a lab diagnostic manufacturer focused on identifying and treating bacterial infections. With the acquisition of Curetis in H120, management has the technology necessary to detect pathogens and predict resistance. Through the dual platform offering of the AMR Gene Panel and Unyvero, the company can provide diagnostic results in hours instead of days under legacy technologies.

Analysts

Soo Romanoff	+44 (0)20 3077 5700
Jyoti Prakash, CFA	+44 (0)20 3077 5700
Nidhi Singh	+44 (0)20 3077 5700

healthcare@edisongroup.com

[Edison profile page](#)

**OpGen is a research client of
 Edison Investment Research
 Limited**

General disclaimer and copyright

This report has been commissioned by OpGen and prepared and issued by Edison, in consideration of a fee payable by OpGen. Edison Investment Research standard fees are £60,000 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out of or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Copyright: Copyright 2022 Edison Investment Research Limited (Edison).

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia