EDISON

OpGen

Financial update

Shareholder votes on Curetis merger coming

Pharma & biotech

In September, OpGen announced a merger with Curetis, a Germany-based molecular diagnostics company with a similar focus on infectious disease. Curetis has two main business lines, the Unyvero A50 high-plex polymerase chain reaction (PCR) platform for the diagnosis of infectious disease in hospital patients and the ARES AMR database (ARESdb), which includes data on 40,000 sequenced strains with a focus on resistant pathogens. Closure is dependent on certain conditions including approval by both OpGen and Curetis shareholders, currently expected by the end of January 2020.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/17	3.2	(15.6)	(196.25)	0.0	N/A	N/A
12/18	2.9	(13.4)	(33.51)	0.0	N/A	N/A
12/19e	3.5	(12.6)	(6.43)	0.0	N/A	N/A
12/20e	5.3	(15.8)	(2.81)	0.0	N/A	N/A

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

Combined company revenue set to double in 2020

Guidance is for combined company revenue to increase from $5–6m in 2019 to $10–15m in 2020. Growth is expected to come from all areas as OpGen is expected to gain 510(k) clearance for the Acuitas AMR Gene Panel while penetration increases for the Unyvero analyzer and the ARESdb business grows.

Expanding commercial reach

Historically, OpGen has been a very US-focused company. Following the merger, the company will have a combined team of 12 direct salespeople in the US, an additional 10 commercial operations team members in the EU and Latin America, European distribution through Menarini Diagnostics and distribution in China through Beijing Clear Biotech.

Bacterial isolates 510(k) process progressing

In May, OpGen announced that it filed for 510(k) clearance of its Acuitas AMR Gene Panel test in bacterial isolates with the FDA. It received a formal request for additional information in July and has been working towards responses to the FDA's questions/comments. It expects to submit its formal response in early January with clearance likely a few months later.

Valuation: $46.9m or $8.39 per share

We have adjusted our valuation to $46.9m or $8.39 per basic share, from $43.9m or $2.49 per share. The total valuation increased due to a higher net cash level following a capital raise in October 2019 with $8.3m in net proceeds. The per share value increased due to a one-for-20 reverse stock split in August, which lowered the share count. This was offset in part by the financing, which increased the number of shares outstanding. We do not currently include Curetis in our forecasts but will do so following closure of the merger.

3 December 2019

Price	**US$1.25**
Market cap	**US$7m**

Net cash ($m) at 30 September 2019 + offering	8.1
Shares in issue	5.6m
Free float	99.6%
Code	OPGN
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(8.1)	(82.9)	(94.3)
Rel (local)	(9.5)	(83.9)	(94.9)

52-week high/low	US$36.00 US$1.02

Business description

OpGen is a diagnostic company focused on revolutionizing the identification and treatment of bacterial infections. The Acuitas AMR Gene Panel molecular test, in combination with the Acuitas Lighthouse bioinformatics product, detects multiple pathogens and predicts antibiotic resistance in less than three hours, a major improvement on the two to three days that current methods require.

Next events

Curetis merger closure	Q120
Acuitas Gene Panel (isolates) 510(k) clearance	Q120

Analysts

Maxim Jacobs	+1 646 653 7027
Wiktoria O'Hare	+1 646 653 7028

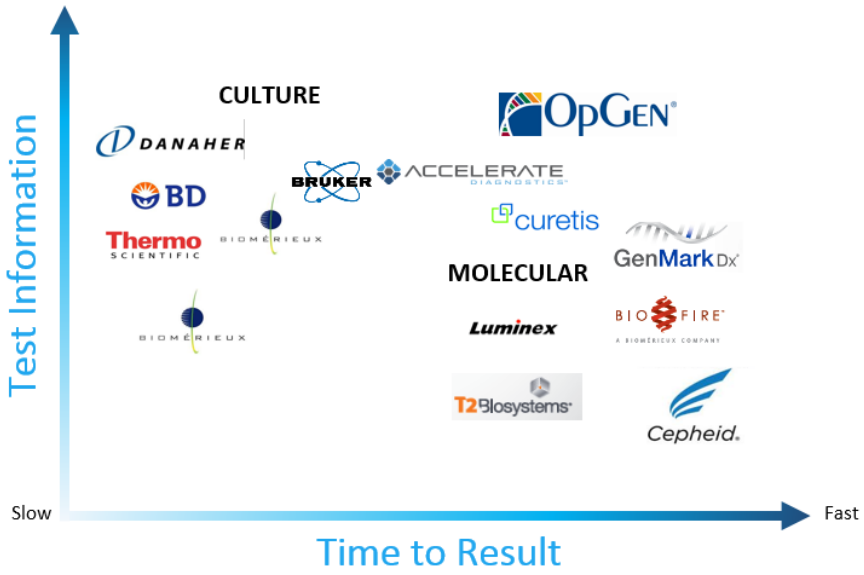
healthcare@edisongroup.com

Edison profile page

Curetis merger

OpGen's proposed merger with Curetis would combine two complementary companies in the molecular diagnostic space that are focused on accelerating the speed of the detection of pathogens and treatment of infectious disease. The initial disease focus will be on complicated urinary tract infections (cUTI) with OpGen's Acuitas platform and on lower respiratory tract infections with Curetis's Unyvero platform.

Exhibit 1: Competitive landscape



Source: OpGen

As a reminder, Opgen's Acuitas AMR Gene Panel is a qualitative and semi-quantitative nucleic acid-based in vitro diagnostic test that is currently optimized for the cUTI market, which will be the initial focus commercially, as the five pathogens it detects (namely *E. coli, E. faecalis, K. pneumoniae, P. mirabilis* and *P. aeruginosa*) represent approximately 88% of all cUTIs. Importantly, the test is able to detect resistance genes regardless of the original pathogen, so the resistance data are not limited to the five target pathogens. With regards to market size, there are approximately one million cases of cUTI per year, with 70–80% attributable to indwelling catheters found in hospitals.[1]

The Unyvero A50 from Curetis is a high-plex PCR platform for the diagnosis of infectious disease in hospital patients. It tests for up to 130 diagnostic targets, both pathogens and resistance genes, in less than five hours with approximately only two minutes of hands-on time and importantly does not require any culturing of the samples. The system first received a CE-IVD mark (which is a CE mark especially for in vitro diagnostic products) in 2012 and gained a 510(k) *De Novo* clearance in 2018 along with the Unyvero LRT test, which Curetis believes covers more than 90% of infection cases of hospitalized pneumonia through testing for 36 pathogens and 10 resistance genes. Importantly, the LRT test provides the broadest coverage of carbapenem resistance and is the only molecular pneumonia panel that covers resistance to penicillin. According to the Agency for Healthcare Research and Quality, pneumonia is the cause of 1.1 million stays in hospitals in the US per year. The company has developed several other tests, which currently have a CE-IVD mark in the EU

1 Flores-Mireles et al., Urinary tract infections: epidemiology, mechanisms of infection and treatment options. *Nature Reviews Microbiology*. 2015 May; 13(5): 269–284.

and approval in additional countries in some cases (see Exhibit 2). It has also developed a new platform, the Unyvero A30 RQ, which is designed for low-mid plex markets and tests for five to 30 DNA targets with results in 45–90 minutes with only two to three minutes of hands-on time. It has a smaller footprint and has attractive cost of goods. Launch in the EU is possible in 2020.

Exhibit 2: Curetis cartridge product portfolio

Cartridge	Indication	Number of pathogens tested for	Number of antibiotic resistance markers tested for	Sample types	Status
LRT	Lower respiratory tract infections/pneumonia	36	10	Tracheal aspirates	FDA clearance. 510(k) submission filed for bronchoalveolar lavage sample types in July 2019
HPN	Severe cases of pneumonia	29	19	Sputum, bronchoalveolar lavage, tracheal aspirate	CE-IVD marked plus clearance in Singapore, Thailand and Malaysia
ITI	Severe cases of implant and tissue infections	85	17	Sonication fluid, swabs, tissue, pus, aspirate/exudate	CE-IVD marked
BCU	Bloodstream infections	86	17	Positively flagged blood cultures	CE-IVD marked plus clearance in Singapore and Thailand
IAI	Severe intra-abdominal infections	108 (including 3 toxins)	22	Paracentesis fluids, biliary fluids, peritoneal fluids, drainage fluids, retroperitoneal fluids, pus, swabs, other samples	CE-IVD marked
UTI	Severe urinary tract infections	88	15	Midstream urine, suprapubic aspiration, tissue	CE-IVD marked

Source: Curetis

In addition to these platforms, both companies have antimicrobial resistance bioinformatics solutions. OpGen's Lighthouse is cloud-hosted and includes a few key components: the Acuitas Lighthouse portal, which is a web application, the Acuitas Lighthouse Prediction Engine, data analysis software that draws from Lighthouse Knowledgebase, a relational database management system. Data from the Acuitas AMR Gene Panel is input into the Lighthouse portal and the Prediction Engine component indicates whether there is evidence of resistance due to the presence of certain genes and if there is any known intrinsic resistance to certain drugs (up to 14 antibiotics across nine antibiotic classes, including Aminoglycosides, Carbapenems, Cephalosporins, Fluoroquinolones, Polymyxins, Penicillins, Sulfonamides, Trimethoprim and Vancomycin). The final results are reported in a Prediction Report and the Resistance Dashboard interface in the portal. A key foundation of the Lighthouse system is the Lighthouse Knowledgebase, populated by data from the Merck Study for Monitoring Antimicrobial Resistance Trends (SMART) archive, which includes data on approximately 15,000 bacterial isolates.

Curetis ARESdb is a comprehensive genetic and phenotypic database, which includes information on 40,000 sequenced strains and phenotypic correlation data against over 100 antibiotics. Qiagen and Sandoz currently have collaborations with Curetis involving ARESdb and the company recently signed an R&D and option agreement with an un-named leading global IVD corporation. The purpose of that collaboration is to jointly develop diagnostics for infectious disease based on next-generation sequencing (NGS) technology.

Hence, on the technology side, we believe OpGen and Curetis have complementary/synergistic solutions. There are also synergies with regards to commercialization. Following the merger, the company will have a combined team of 12 direct salespeople in the US with the ability to sell each other's products. Curetis also brings an additional 10 commercial operations team members in the EU and Latin America. In addition, Curetis has international distribution through 18 distributors across 43 countries, including Menarini Diagnostics for Europe and Beijing Clear Biotech for China. With regards to China, the current agreement with Beijing Clear Biotech includes minimum purchase levels of 360 Unyvero A50 systems as well as over 1.5m Unyvero cartridges over the duration of the agreement following regulatory clearance by the National Medical Products Administration (NMPA), which may occur in 2020. Based upon previously agreed transfer price levels, this volume equates to €60m in cumulative revenues from China over the first five years for Curetis and then €30m annually over the following three years.

The merger is currently expected to close by the end of January 2020 with closure mainly depending on the approval of shareholders of both companies. One complication is that, because of OpGen's recent offering in October 2019, the stock price has fallen so that now the 2.7m shares that would be issued to Curetis shareholders are only worth around $3m while the current Curetis market capitalization is around €9.5m (over $10m). However, OpGen is also currently acting as lender to Curetis and agreed to provide up to $4m in capital through the closure of the merger and without that capital, Curetis would need to do a raise of its own or go bankrupt, either of which could have a major impact on the share price of that company.

510(k) update

As a reminder, OpGen announced in May that it filed for 510(k) clearance of its Acuitas AMR Gene Panel test in bacterial isolates with the FDA. It received a formal request for additional information in July and has been working towards responses to the FDA's questions/comments. It expects to submit its formal response in early January with clearance likely a few months later. The company is also beginning a trial that will enable a 510(k) De Novo submission for testing urine samples in the Acuitas AMR Gene Panel. Nine sites are under contract and the trial will involve 1,500 samples.

Valuation

We have adjusted our valuation to $46.9m or $8.39 per basic share, from $43.9m or $2.49 per share. The total valuation increased due to a higher net cash level following a capital raise with $8.3m in net proceeds. The per share value increased due to a one-for-20 reverse stock split in August, which lowered the share count. This was offset in part by the financing, which increased the number of shares outstanding. We do not currently include Curetis in our forecasts but will do so following closure of the merger.

Exhibit 3: OpGen valuation table

Product	Main Indication	Status	Probability of successful commercialization	Launch year	Peak sales ($m)	Patent protection	Economics	rNPV ($m)
OpGen Diagnostic Platform	cUTI, lower respiratory	Market (RUO)/ Registration	40%	2020	174	2039	100.0%	38.8
Total								38.8
Net Cash (Q319 + net proceeds of raise)								8.1
Total firm value								46.9
Total basic shares (m)								5.6
Value per basic share ($)								8.39
Options (Q319, m)								0.2
Total number of shares (m)								5.8
Diluted value per share ($)								8.14

Source: Edison Investment Research

Financials

OpGen reported revenue of $0.65m for the third quarter, up 17.4% compared to the $0.55m last year. Product sales, which are mainly for the legacy FISH-based tests, were down 6.1% to $0.57m. There was also a milestone payment of $75,000 related to the New York State Infectious Disease Digital Health Initiative. R&D expenses fell 11.4% from $1.29m to $1.14m as some of the expenses associated with the New York State initiative were moved from R&D to cost of services. SG&A expenses were $2.48m for the quarter, up 17.6% compared to the same quarter last year mainly due to the $0.54m in transaction costs related to the Curetis merger. OpGen's Q319 post-tax loss was $3.48m, up 7.2% from a loss of $3.26m in Q318, primarily due to the same transaction costs. We have lowered our 2019 revenue estimate by $0.54m and increased our 2020 estimate by

$0.25m, mainly as some of the New York State initiative milestone payments have shifted to next year and due to lower product sales forecasts. We lowered the R&D expense for 2019 to $5.44m compared to $6.38m previously due to a lower run rate and due to some of the urine test expenses shifting to next year, which had estimates increase by $0.61m. We also lowered SG&A estimates by $0.68m for 2019 due to a lower than expected run rate. Note these estimates do not include Curetis revenue or expense forecasts, which will be included once the deal closes. Through the first nine months of 2019, Curetis reported €1.38m in revenue, €8.63m in SG&A and €6.15m in R&D with an operating loss of €15.2m.

OpGen reported $0.63m in cash and cash equivalents and $0.84m in debt at the end of Q319 and raised approximately $8.3m net in capital through an offering in October. In November, the company entered into an interim facility agreement, which would provide up to $4m in capital to Curetis through closure. The company currently believes it has funding into Q220. We model an additional financing need of $36m in total through to profitability in 2023 (reduced from $41m previously due to the raise). Per Edison policy, we assume future financings are to be funded with debt.

Exhibit 4: Financial summary

$000s	2017	2018	2019e	2020e
Year end 31 December	GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS				
Revenue	3,211	2,946	3,472	5,282
Cost of Sales	(2,133)	(1,848)	(1,578)	(1,902)
Gross Profit	1,078	1,098	1,895	3,380
Sales, General and Administrative Expenses	(9,460)	(8,601)	(8,810)	(12,280)
Research and Development Expense	(6,883)	(5,677)	(5,437)	(6,755)
EBITDA	(15,266)	(13,180)	(12,336)	(15,654)
Operating Profit (before amort. and except.)	(15,266)	(13,180)	(12,336)	(15,654)
Intangible Amortisation	0	0	0	0
Other	0	0	16	0
Exceptionals	0	0	(521)	0
Operating Profit	(15,266)	(13,180)	(12,856)	(15,654)
Net Interest	(321)	(186)	(214)	(193)
Other	167	(2)	(9)	0
Profit Before Tax (norm)	(15,587)	(13,366)	(12,550)	(15,848)
Profit Before Tax (FRS 3)	(15,419)	(13,368)	(13,080)	(15,848)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(15,587)	(13,366)	(12,550)	(15,848)
Profit After Tax (FRS 3)	(15,419)	(13,368)	(13,080)	(15,848)
Average Number of Shares Outstanding (m)	0.1	0.4	2.0	5.6
EPS - normalised ($)	(196.25)	(33.51)	(6.43)	(2.81)
EPS - Reported ($)	(195.95)	(33.54)	(6.70)	(2.81)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	3,118	3,167	4,413	4,327
Intangible Assets	1,954	1,686	1,438	1,253
Tangible Assets	836	1,222	2,548	2,647
Other	329	259	427	427
Current Assets	3,190	5,490	6,912	9,714
Stocks	533	544	468	544
Debtors	810	374	377	423
Cash	1,847	4,572	6,066	8,747
Other	0	0	0	0
Current Liabilities	(2,882)	(2,438)	(4,006)	(3,672)
Creditors	(1,871)	(2,039)	(3,498)	(3,498)
Short term borrowings	(1,011)	(399)	(508)	(174)
Long Term Liabilities	(429)	(1,260)	(1,553)	(19,175)
Long term borrowings	0	(660)	(329)	(17,829)
Other long term liabilities	(429)	(600)	(1,224)	(1,346)
Net Assets	2,997	4,960	5,765	(8,806)
CASH FLOW				
Operating Cash Flow	(14,304)	(11,074)	(10,876)	(14,539)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(277)	(137)	(113)	(117)
Acquisitions/disposals	0	0	0	0
Financing	12,640	14,128	13,083	0
Dividends	0	0	0	0
Other	(205)	(293)	(1,054)	0
Net Cash Flow	(2,146)	2,624	1,039	(14,656)
Opening net debt/(cash)	(3,094)	(836)	(3,514)	(5,229)
HP finance leases initiated	0	0	0	0
Exchange rate movements	38	(13)	(5)	0
Other	(150)	66	681	172
Closing net debt/(cash)	(836)	(3,514)	(5,229)	9,255

Source: Edison Investment Research, company reports

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 £49,500 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 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.

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
1,185 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