EDISON

OpGen

Financial update

Merger with Curetis closes

Pharma & biotech

Following approval from both OpGen and Curetis shareholders, the merger between the two companies has now closed. Curetis is a Germany-based molecular diagnostics company with a focus on infectious disease. It 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. Together, OpGen and Curetis had around $6.0m in sales in 2019, up 33% compared to the combined sales of the previous year and at the top end of the original $5–6m guidance for 2019 (given at the time of the merger announcement).

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/18	2.9	(13.4)	(44.45)	0.0	N/A	N/A
12/19	3.5	(11.9)	(7.38)	0.0	N/A	N/A
12/20e	7.1	(21.6)	(1.39)	0.0	N/A	N/A
12/21e	12.5	(18.1)	(1.16)	0.0	N/A	N/A

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

High demand for coronavirus test kit

In March, Curetis announced that it had started offering a real-time PCR test kit that was developed by its Chinese partner, BGI Group, for the SARS-Cov2 pathogen (the underlying cause of the coronavirus pandemic) in Europe. The company has received orders for thousands of tests with significant interest across regions.

Bacterial isolates 510(k) process continuing

In May 2019, OpGen announced that it had 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, responded in early January and received additional questions a couple of weeks later. OpGen believes the process is near completion but the exact timing is unknown due to the ongoing pandemic.

Urine 510(k) clinical trial on hold

In December, the company began 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. By early March, completion of the clinical trial was anticipated by mid-spring given the rate of accruals, but it is now on hold due to the pandemic, likely into the summer.

Valuation: $58.7m or $3.91 per share

We have adjusted our valuation from $46.9m or $8.39 per basic share to $58.7m or $3.91 per share. The total valuation increased due to the addition of the Curetis business although this was mitigated somewhat by debt acquired in the acquisition. The reduction in the per share value is mainly due to an at-the-market (ATM) offering and the exercise of warrants related to the October 2019 capital raise.

16 April 2020

Price	**US$2.3**
Market cap	**US$35m**

Net debt ($m) as at 31 December 2019 plus offering and Curetis debt	10.8
Shares in issue	15.0m
Free float	99.8%
Code	OPGN
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	14.4	47.4	(79.8)
Rel (local)	11.5	74.2	(78.9)
52-week high/low	US$12		US$1

Business description

OpGen is a diagnostic company focused on revolutionizing the identification and treatment of bacterial infections. Following the merger with Curetis, the company has technology platforms with which to detect pathogens and predict resistance. Importantly, both the AMR Gene Panel and Unyvero platforms have the ability to provide results in hours instead of days like current methods require.

Next events

Acuitas Gene Panel (isolates) 510(k) clearance	2020

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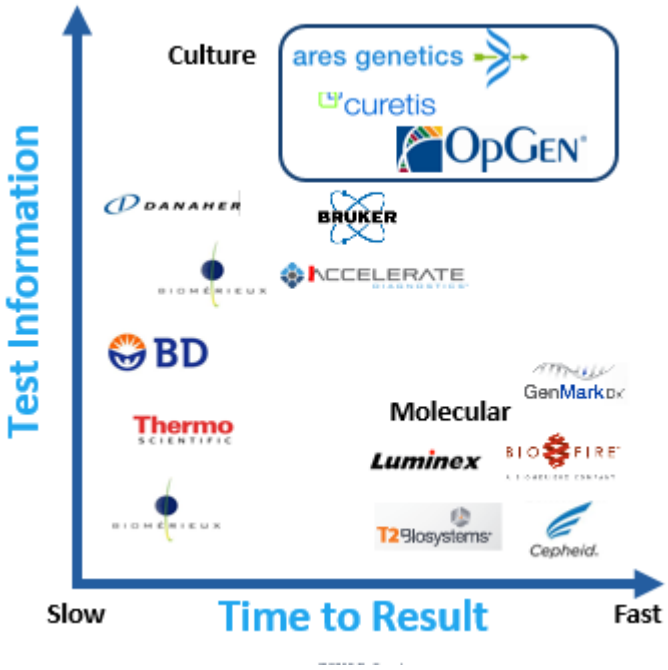
OpGen and Curetis

OpGen's merger with Curetis has combined two complementary companies in the molecular diagnostic space focused on accelerating the speed of the detection of pathogens and the treatment of infectious disease.

Exhibit 1: Competitive landscape



Source: OpGen, Edison Investment Research

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 complicated urinary tract infection (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, crucially, it 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 the company believes covers more than 90% of infection cases of hospitalized pneumonia through testing for 36 pathogens and 10 resistance genes (an additional clearance for bronchoalveolar lavage sample types was obtained in December 2019). 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

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

per year. The company has developed several other tests, which currently have a CE-IVD mark in the EU 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, bronchoalveolar lavage	FDA clearance. 510(k) clearance for bronchoalveolar lavage sample types in December 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 (now OpGen) and then €30m annually over the following three years.

In February, Curetis announced a distribution partnership with Quaphaco for the Unyvero A50 system for Vietnam. The agreement has an initial term of three years and can be extended by two-year increments. Quaphaco has committed to minimum purchases of instruments and cartridges over the initial term amounting to approximately €1.9m in revenue to Curetis (now OpGen). Product registration for Vietnam is expected in Q2.

Also, in March, Curetis announced that it had started offering a real-time PCR test kit that was developed by its Chinese partner, BGI Group, for the SARS-Cov2 pathogen (the underlying cause for the coronavirus pandemic) in Europe. OpGen management indicates that Curetis has received orders for thousands of tests with significant interest across Europe, the Middle East, Africa and Asia. Ultimately though, this will be a very competitive area likely dominated by the large players. The company believes it can have commercial success targeting the 'middle market' (eg facilities with lower- to medium-volume processing needs compared to the larger high-throughput central labs) with a focus on eastern Europe. As the economics of this part of the business is unclear and it is still a developing market, we have not included them in our forecasts.

Pandemic puts programs into a holding pattern

As a reminder, OpGen announced in May 2019 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 responded to the comments in early January. In mid-January 2020, OpGen received additional requests for information. The company believes the process is near completion, but the exact timing is unknown due to the ongoing pandemic.

Also, in December, OpGen began 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. By early March completion of the clinical trial was anticipated by mid-spring given the rate of accruals, but it is now on hold due to the pandemic. This hold is likely to last into the summer and the exact timing will likely depend on how long it takes for the pressure that the virus has put on the US healthcare system to abate.

Finally, with regards to the New York State Infectious Disease Digital Health Initiative, the company completed the pilot phase of the program. Unfortunately, further testing has been put on hold by the participating hospitals due to the pandemic.

Valuation

We have adjusted our valuation from $46.9m or $8.39 per basic share to $58.7m or $3.91 per share. The total valuation increased due to the addition of the Curetis business, although this was mitigated somewhat by debt acquired in the acquisition (Curetis had $2.2m in short-term notes payable and $21.6m in long-term debt as of the end of Q319, with $1.4m of the debt converted into shares as part of the merger). The per share value fell due to an ATM offering totaling $5.8m, the exercise of warrants related to the October 2019 offering, which provided $8.1m in gross proceeds, and 2.7m shares issued to purchase Curetis.

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	183	2039	100.0%	69.5
Total								69.5
Net cash/(debt) (Q120 less acquired Curetis long-term debt)								(10.8)
Total firm value								58.7
Total basic shares (m)								15.0
Value per basic share ($)								3.91
Options (m)								0.6
Total number of shares (m)								15.6
Diluted value per share ($)								3.76

Source: Edison Investment Research

Financials

OpGen reported revenue of $3.5m for FY19, up 18.7% compared to the $2.9m reported last year. Product sales, which are mainly for the legacy FISH-based tests, were down 9.5% to $2.2m. There was $1.3m in collaboration revenue related to the New York State Infectious Disease Digital Health Initiative. Operating expenses for the company were down due to effective control of costs. R&D expenses fell 9.8% from $5.7m to $5.1m and SG&A expenses were $8.5m for FY19, down 1.2% compared to the prior year despite including $0.8m in transaction costs related to the Curetis merger. OpGen's 2019 post-tax loss was $12.4m, down 6.9% from a loss of $13.4m in FY18. Curetis reported revenue of €2.3m for FY19, up 64% compared to FY18. Additionally, contract orders for Curetis more than tripled from €1.1m last year to €3.4m in FY19. The FY19 operating loss was €17.2m compared to €21.6m in FY18. In April, OpGen reported that Q1 revenues (not including Curetis) were $617,000, down 39.5% compared to Q119 due to 49.2% lower collaboration revenue from the New York State Infectious Disease Digital Health Initiative and legacy FISH-based test revenue falling by 30.2%.

With the closing of the merger we now include Curetis in our estimates. Our FY20 revenue estimate has increased from $5.3m to $7.1m. Curetis is responsible for a $4.1m increase in our estimate, which more than counteracted a reduction in our estimates for pre-merger OpGen due to the delays for the 510(k) programs and the New York Department of Health Initiative. Without Curetis, our FY20 OpGen revenue estimate would be $3.1m for the year. We have increased our FY20 SG&A estimate to $14.6m from $12.3m. The increase is relatively small as much of the SG&A ramp we previously expected does not need to happen due to existing sales resources at Curetis, plus there are likely significant synergies in G&A. We have increased our R&D expenses from $6.8m to $10.6m, which also includes significant synergies. We have also introduced FY21 estimates, which include revenues of $12.5m (up 74.8% compared to FY20 driven by a ramp in the Acuitas testing as well as growth in the Curetis business) and a net loss of $18.1m.

OpGen reported $2.7m in cash and cash equivalents and $0.7m in debt at the end of 2019. In April, the company reported it had $11.5m in cash at the end of Q120. It raised approximately $13.9m through an ATM offering ($5.8m) and the exercise of warrants ($8.1m). OpGen has approximately $11m remaining under the ATM. Curetis unfortunately did not report full year 2019 financials and hence the exact state of the balance sheet is unknown at present. We are assuming minimal cash and are using $22.4m (which was the debt total as of the end of September, less the $1.4m that was converted into shares) as the level of debt.

We model an additional financing need of $36m in total through to profitability in FY23. Per Edison policy, we assume future financings are to be funded with debt.

Exhibit 4: Financial summary

$'000s	2018	2019	2020e	2021e
Year end 31 December	GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS				
Revenue	2,946	3,499	7,139	12,482
Cost of Sales	(1,848)	(1,632)	(3,285)	(4,142)
Gross Profit	1,098	1,867	3,854	8,341
Sales, General and Administrative Expenses	(8,601)	(8,496)	(14,608)	(15,971)
Research and Development Expense	(5,677)	(5,121)	(10,628)	(10,316)
EBITDA	(13,180)	(11,741)	(21,382)	(17,947)
Operating Profit (before amort. and except.)	(13,180)	(11,741)	(21,382)	(17,947)
Intangible Amortisation	0	0	0	0
Other	0	10	0	0
Exceptionals	0	(521)	0	0
Operating Profit	(13,180)	(12,261)	(21,382)	(17,947)
Net Interest	(186)	(188)	(189)	(197)
Other	(2)	2	0	0
Profit Before Tax (norm)	(13,366)	(11,928)	(21,571)	(18,143)
Profit Before Tax (FRS 3)	(13,368)	(12,446)	(21,571)	(18,143)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(13,366)	(11,928)	(21,571)	(18,143)
Profit After Tax (FRS 3)	(13,368)	(12,446)	(21,571)	(18,143)
Average Number of Shares Outstanding (m)	0.3	1.6	15.5	15.7
EPS - normalized ($)	(44.45)	(7.38)	(1.39)	(1.16)
EPS - Reported ($)	(44.49)	(7.70)	(1.39)	(1.16)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	3,167	3,755	17,283	17,115
Intangible Assets	1,686	1,418	9,226	9,042
Tangible Assets	1,222	2,133	7,668	7,684
Other	259	203	389	389
Current Assets	5,783	6,667	18,176	13,832
Stocks	544	473	5,769	5,769
Debtors	374	568	1,457	1,530
Cash	4,572	2,708	10,950	6,534
Other	293	2,918	0	0
Current Liabilities	(4,381)	(4,939)	(8,244)	(8,070)
Creditors	(3,983)	(4,565)	(8,070)	(8,070)
Short term borrowings	(399)	(374)	(174)	0
Long Term Liabilities	(1,260)	(1,190)	(41,263)	(53,946)
Long term borrowings	(660)	(329)	(39,429)	(51,929)
Other long term liabilities	(600)	(860)	(1,833)	(2,017)
Net Assets	3,309	4,293	(14,048)	(31,069)
CASH FLOW				
Operating Cash Flow	(11,074)	(11,505)	(22,962)	(16,708)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(137)	(32)	(33)	(34)
Acquisitions/disposals	0	0	0	0
Financing	14,128	13,062	13,900	0
Dividends	0	0	0	0
Other	(293)	(3,836)	0	0
Net Cash Flow	2,624	(2,310)	(9,095)	(16,743)
Opening net debt/(cash)	(836)	(3,514)	(2,005)	28,653
HP finance leases initiated	0	0	0	0
Exchange rate movements	(13)	4	0	0
Other	66	798	(21,563)	0
Closing net debt/(cash)	(3,514)	(2,005)	28,653	45,396

Source: Company reports, Edison Investment Research

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