EDISON

OpGen

Financial update

First 510(k) filed with the FDA

Healthcare equipment & services

OpGen has announced that it has filed for 510(k) clearance of its Acuitas AMR Gene Panel test in bacterial isolates with the FDA, with clearance expected by the end of the year. The company continues to expect to file a follow-on *De Novo* 510(k) submission in Q419 for approval of the Acuitas AMR Gene Panel test in urine samples, with another *De Novo* 510(k) submission for the Acuitas Lighthouse software soon thereafter or at approximately the same time.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/17	3.2	(15.6)	(9.81)	0.0	N/A	N/A
12/18	2.9	(13.4)	(1.68)	0.0	N/A	N/A
12/19e	4.0	(13.6)	(0.87)	0.0	N/A	N/A
12/20e	5.0	(15.5)	(0.87)	0.0	N/A	N/A

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

Accelerating the identification of antibiotic resistance

The Acuitas AMR Gene Panel molecular test, in combination with the Acuitas Lighthouse bioinformatics product, allows for the detection of five pathogens as well as 47 resistance genes and mutations, while also predicting the resistance for 14 antibiotics in less than three hours, a major improvement over the two to three days current methods require. It will first focus on complicated urinary tract infections (cUTI), of which there are around one million cases per year.

Milestone achieved with New York State

OpGen is collaborating with the New York State Department of Health and Merck's ILUM Health Solutions to develop a tool to track infectious disease and antimicrobial resistance across New York State. In Q119, the company was able to hit a $500,000 milestone as it installed Acuitas systems in three New York City metro area health systems. Further milestones will be achieved as software development and validations are completed. The company expects to receive up to $1.6m total over the first 12 months during the demonstration portion, with full implementation expected over the next five years.

Revenue growth in the first quarter

OpGen reported revenue of $1.0m for the quarter, up 20.6% compared to last year, though half the revenue came from a milestone payment related to the New York State Infectious Disease Digital Health Initiative. Product sales, which are mainly for the legacy FISH-based tests, were down 17.9%.

Valuation: $43.9m or $2.49 per share

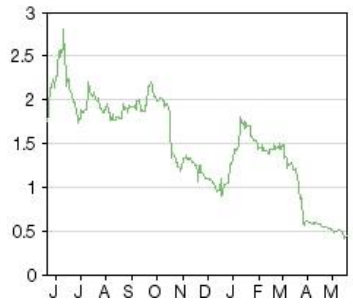
We have adjusted our valuation from $47.3m or $2.68 per basic share to $43.9m or $2.49 per share, which has been driven exclusively by a lower level of net cash. Key valuation inflection points over the next 12–18 months will be FDA 510(k) clearances for the key products as well as the subsequent commercial launch. We continue to expect the company to require $41m in financing before profitability in 2023.

20 May 2019

Price	**US$0.44**
Market cap	**US$8m**

Net cash ($m) at 31 March 2019	5.2
Shares in issue	17.6m
Free float	94.5%
Code	OPGN
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(21.1)	(69.1)	(75.4)
Rel (local)	(19.9)	(70.0)	(76.6)

52-week high/low	US$2.80	US$0.41

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

Acuitas Gene Panel (isolates) 510(k) clearance	Q419
Acuitas Gene Panel (urine) 510(k) filing	Q419
Acuitas Lighthouse 510(k) filing	Q419/Q120

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Edison profile page

Bacterial isolates clearance application submitted

OpGen has announced that it has filed for 510(k) clearance of its Acuitas AMR Gene Panel test in bacterial isolates (samples that have already been cultured from the original specimen that may have been blood, urine, etc) with the FDA. As a reminder, the 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. In the US, there are approximately one million cases of cUTI per year, with 70–80% attributable to indwelling catheters found in hospitals.[1]

The bacterial isolates submission is a standard 510(k) and typically the FDA takes around six months to review such an application with a clearance rate that has historically been around 85%, according to FDA statistics. We believe there is a high probability of clearance, especially as previously released data in 417 samples indicated that the test correctly identified the pathogen species in 99.5% of cases. The company did indicate, however, that this will be a more complex submission than the FDA typically sees as it had to use whole genome sequencing on virtually every sample, leading to a very high number of data points. So while the company expects a timely review, it believes it is likely that there will be some back and forth with the agency, possibly with some requests to recut the data.

OpGen expects to file a follow-on *De Novo* 510(k) submission in Q419 for clearance of the Acuitas AMR Gene Panel test in urine samples. The difference between a standard 510(k) submission and a *De Novo* 510(k) submission is that the *De Novo* pathway is for devices that do not have a valid predicate. *De Novo* applications are associated with somewhat lower clearance rates and longer review periods. Clearance of this application would allow for testing directly from urine so that the results would not require a sample to be cultured (which can add 15+ hours to the process) and OpGen can then truly differentiate itself from current methods (as well as the newer molecular entrants, which also typically depend on the samples already being cultured) by providing an answer in three hours. A direct from urine sample is especially important as the company will initially focus on urinary tract infections. That application will be based on 1,500 fresh urine samples and around 300 contrived urine samples from eight sites. The clinical studies to support the application are expected to begin before the end of the second quarter and mostly be completed during Q3.

In the months following the urine *De Novo* 510(k) submission, the company expects to file a *De Novo* 510(k) submission for the Acuitas Lighthouse software, though there is a chance it may either leapfrog ahead of the urine submission or be filed relatively simultaneously. Importantly, while the Acuitas AMR Gene Panel is a sound product on its own, what truly sets the OpGen solution apart from others is the Acuitas Lighthouse software. The Lighthouse Prediction Engine 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). Typically, this prediction of antibiotic resistance is the part of the pathogen testing process that takes the longest and it is where the speed of the Lighthouse software is most value added.

It is important to note that a key foundation of the Lighthouse system is the Lighthouse Knowledgebase, populated by data from the Merck Study for Monitoring Antimicrobial Resistance

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

Trends (SMART) archive, which has collected more than 250,000 bacterial pathogens over the last 15+ years as well as thousands of additional pathogens from other sources. The Knowledgebase is constantly growing, as every time the test is used, data from that specific case of infection are added to it. As the Knowledgebase grows, we would expect the Lighthouse Prediction Engine to make better predictions over time.

New York Department of Health Initiative milestone achieved

OpGen is collaborating with the New York State Department of Health and Merck's ILUM Health Solutions (the collaboration is called the New York State Infectious Disease Digital Health Initiative) to develop a tool to detect, track and manage infectious disease and antimicrobial resistance across the state. Importantly, this collaboration is not dependent on any FDA approval as it is considered to be a research use. In Q119, the company was able to hit a $500,000 milestone as it installed Acuitas systems in three New York City metro area health systems that include a total of 35 hospitals and 12,000 beds. Further milestones will be achieved as software development and validations are completed.

As a reminder, the first portion is a 12-month development project in which OpGen will work with the Department of Health's Wadsworth Center and ILUM to develop an infectious disease tracking platform that connects hospitals to the Department of Health to facilitate state-wide surveillance. The company expects to receive up to $1.6m total over the first 12 months during the demonstration portion, which has already started, with full implementation in New York State's more than 170 hospitals expected over the next five years. Depending on the outcome of this collaboration, additional states may come up with their own similar surveillance initiatives, which could accelerate the commercial adoption of OpGen's systems.

Valuation

We have adjusted our valuation from $47.3m or $2.68 per basic share to $43.9m or $2.49 per share, which has been driven exclusively by a lower level of net cash. Key valuation inflection points over the next 12–18 months will be FDA 510(k) clearances for the key products as well as the subsequent commercial launch.

Exhibit 1: 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%	2019	174	2039	100.0%	38.8
Total								38.8
Net cash (Q119)								5.2
Total firm value								**43.9**
Total basic shares (m)								17.6
Value per basic share ($)								**2.49**
Options (Q418, m)								3.5
Total number of shares (m)								21.2
Diluted value per share ($)								**2.08**

Source: Edison Investment Research

Financials

OpGen reported revenue of $1.0m for the quarter, up 20.6% compared to last year, though half the revenue came from a milestone payment related to the New York State Infectious Disease Digital Health Initiative. Product sales, which are mainly for the legacy FISH-based tests, were down 17.9%. R&D expenses grew 44.4% from $1.2m to $1.8m due to clinical development associated with the Acuitas AMR Gene Panel. The company expects R&D expenses to fall in Q2 but then increase again in Q3 as the urine test clinical trial gets into full swing. It expects the trial to cost a total of $1.2m. SG&A expenses were $2.1m for the quarter, essentially flat with the same quarter last year. OpGen's 2018 post-tax loss was $3.9m, up from a loss of $3.0m in Q118, primarily due to increased R&D expenses. While we have left revenue and SG&A expense estimates largely the same, we have increased our R&D estimate by $0.5m for 2019. This was largely offset by a lower cost of goods estimate due to a lower than expected run rate and higher gross profit margin.

OpGen reported $6.0m in cash and cash equivalents at the end of Q119, which we believe is enough to fund the company into Q419. We continue to model an additional $5m worth of financing for 2019, and $41m in total through to profitability in 2023. Per Edison policy, we assume future financings are to be funded with debt.

Exhibit 2: Financial summary

$000s	2017	2018	2019e	2020e
Year end 31 December	GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS				
Revenue	3,211	2,946	4,010	5,032
Cost of Sales	(2,133)	(1,848)	(1,486)	(1,902)
Gross Profit	1,078	1,098	2,524	3,130
Sales, General and Administrative Expenses	(9,460)	(8,601)	(9,487)	(12,280)
Research and Development Expense	(6,883)	(5,677)	(6,377)	(6,141)
EBITDA	(15,266)	(13,180)	(13,341)	(15,290)
Operating Profit (before amort. and except.)	(15,266)	(13,180)	(13,341)	(15,290)
Intangible Amortization	0	0	0	0
Other	0	0	0	0
Exceptionals	0	0	(521)	0
Operating Profit	(15,266)	(13,180)	(13,862)	(15,290)
Net Interest	(321)	(186)	(244)	(229)
Other	167	(2)	(10)	0
Profit Before Tax (norm)	(15,587)	(13,366)	(13,585)	(15,519)
Profit Before Tax (FRS 3)	(15,419)	(13,368)	(14,116)	(15,519)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(15,587)	(13,366)	(13,585)	(15,519)
Profit After Tax (FRS 3)	(15,419)	(13,368)	(14,116)	(15,519)
Average Number of Shares Outstanding (m)	1.6	8.0	15.6	17.9
EPS - normalized ($)	(9.81)	(1.68)	(0.87)	(0.87)
EPS - Reported ($)	(9.80)	(1.68)	(0.90)	(0.87)
Dividend per share ($)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	3,118	3,167	4,578	4,514
Intangible Assets	1,954	1,686	1,485	1,307
Tangible Assets	836	1,222	2,862	2,977
Other	329	259	230	230
Current Assets	3,190	5,490	2,754	6,967
Stocks	533	544	499	544
Debtors	810	374	813	423
Cash	1,847	4,572	1,442	6,000
Other	0	0	0	0
Current Liabilities	(2,882)	(2,438)	(3,310)	(3,136)
Creditors	(1,871)	(2,039)	(2,962)	(2,962)
Short term borrowings	(1,011)	(399)	(348)	(174)
Long Term Liabilities	(429)	(1,260)	(7,095)	(24,772)
Long term borrowings	0	(660)	(5,320)	(22,820)
Other long term liabilities	(429)	(600)	(1,775)	(1,952)
Net Assets	2,997	4,960	(3,073)	(16,427)
CASH FLOW				
Operating Cash Flow	(14,304)	(11,074)	(11,237)	(13,671)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(277)	(137)	(127)	(132)
Acquisitions/disposals	0	0	0	0
Financing	12,640	14,128	4,783	0
Dividends	0	0	0	0
Other	(205)	(293)	(508)	0
Net Cash Flow	(2,146)	2,624	(7,090)	(13,803)
Opening net debt/(cash)	(3,094)	(836)	(3,514)	4,226
HP finance leases initiated	0	0	0	0
Exchange rate movements	38	(13)	(4)	0
Other	(150)	66	(646)	1035
Closing net debt/(cash)	(836)	(3,514)	4,226	16,994

Source: Edison Investment Research, company reports

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