EDISON

OpGen

Financial update

Q220 results

Pharma & biotech

OpGen recently reported its Q220 results. Sales were $1.2m, up 18% from Q219, thanks to the inclusion of the Curetis business. Importantly, the company announced in June that it has extended its partnership with the New York State Department of Health for a second year, which will have a contract value of up to $450,000. OpGen also recently announced a strategic partnership with Menarini Silicon Biosystems to co-promote COVID-19 related products in North America.

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	4.6	(25.8)	(1.63)	0.0	N/A	N/A
12/21e	12.5	(21.2)	(1.05)	0.0	N/A	N/A

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

Progress continues for Ares Genetics

OpGen has an R&D and option agreement for ARESdb with an unnamed leading global in vitro diagnostic (IVD) corporation. Ares has completed all three phases of the R&D program and successfully improved molecular antibiotic susceptibility prediction performance. Importantly, the company has signed a second technology evaluation agreement with another global IVD corporation.

Developing its COVID-19 business

OpGen recently announced a strategic partnership with Menarini Silicon Biosystems to co-promote COVID-19 related products, including an antibody test that provides results in less than 10 minutes. Additionally, Curetis has successfully completed the verification and clinical validation testing of its proprietary, rapid COVID-19 test, which should provide results in less than an hour. Curetis expects to pursue a CE Mark for its product.

510(k) clearance update

In May 2019, OpGen announced it had filed for 510(k) clearance of its Acuitas AMR Gene Panel test in bacterial isolates with the FDA. The process appears to be nearing completion, although there have been delays related to COVID-19. The next deadline for submission of responses to information requests is 13 October 2020. The trial to enable a 510(k) De Novo submission for testing urine samples has been on hold since March, although some sites have recently restarted enrollment.

Valuation: $68.4m or $3.47 per share

We have adjusted our valuation to $68.4m or $3.47 per basic share from $58.7m or $3.91 per share. The total valuation increased mainly due to lower net debt, while the per-share value decreased due to an increase in the number of shares outstanding. The company had $12.9m in gross cash at the end of the quarter and added an additional $3.6m through an at-the-market (ATM) offering and $0.4m through warrant exercises after the end of the quarter.

19 August 2020

Price	**US$2.1**
Market cap	**US$41m**

Net debt ($m) at 30 June 2020 plus post-quarter end changes	0.8
Shares in issue	19.7m
Free float	85.2%
Code	OPGN
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(4.2)	5.6	(60.8)
Rel (local)	(8.8)	(8.0)	(66.6)

52-week high/low	US$8.0	US$1.0

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 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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Edison profile page

Quarterly update

OpGen reported revenue of $1.2m for Q220, up 18% compared to $1.0m reported in the same quarter last year. Product sales were up 19% to $0.6m, mainly due to the inclusion of sales of Curetis products (although the company did not break down sales attributable to Curetis vs the organic business). The COVID-19 pandemic hampered sales during the quarter as there were fewer elective procedures at hospitals. Collaboration revenue was up 12%, mainly due to Ares Genetics, which contributed $456,000 through its partnership with a global IVD corporation. Collaboration revenue should improve as the New York State Infectious Disease Digital Health Initiative was renewed for a second year.

R&D expenses increased from $1.2m to $3.0m, while SG&A expenses were up from $2.0m to $3.8m (including $225,000 in Curetis merger transaction costs). OpGen's Q220 operating loss was $6.5m (vs $4.0m in Q120 and $2.6m in Q219) and the post-tax loss was $7.5m, up from $2.6m in the same quarter last year.

The company announced in June that it had extended its partnership (the New York State Infectious Disease Digital Health Initiative) with the New York State Department of Health for a second year. Up to an additional 3,500 AMR Gene Panel tests are expected to be run and the contract value will be up to $450,000. Testing was put on hold in June due to the pandemic, but participating hospitals are expected to restart testing sometime in Q3.

OpGen recently announced a strategic partnership with Menarini Silicon Biosystems to co-promote COVID-19 related products in the US, Canada and Mexico. The partnership will focus on promoting Menarini's CELLSEARCH system for the enrichment and enumeration of circulating endothelial cells (CEC) from whole blood. CEC count is used to measure the progression of COVID-19 and potentially in identifying patients at risk of developing more severe complications. Included in this partnership is an antibody test that provides results in less than 10 minutes. The test has received an emergency use authorization from the FDA for use by authorized laboratories. Additionally, Curetis has successfully completed the verification and clinical validation testing of its own proprietary, rapid COVID-19 test, which should provide results in less than an hour. The company expects to pursue a CE Mark for its product and hence it appears that this offering will be focusing on different geographies from the Menarini-based products (co-promotion agreement directed at North America).

Subsidiary Ares Genetics also continues to make progress. It has an R&D and option agreement for its ARESdb platform with an unnamed leading global IVD corporation. The company has now completed all three phases of the R&D program and successfully improved molecular antibiotic susceptibility prediction performance. The partner may now exercise an option for a 90-day exclusive negotiation period for certain partnering, licensing and commercial rights (the option expires in mid-October). Importantly, Ares Genetics has signed a second technology evaluation agreement with another global IVD corporation.

With regards to the Acuitas 510(k) submissions, OpGen announced in May 2019 that it had filed for 510(k) clearance of its Acuitas AMR Gene Panel test in bacterial isolates with the FDA. The process appears to be nearing completion, although there have been delays related to COVID-19. The next deadline for submission of responses to information requests is 13 October 2020.

With regards to the 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 is expected to involve 1,500 samples. By early March, completion of the clinical trial had been anticipated by mid-spring given the rate of accruals, but was put on hold due to the pandemic. Some sites have recently

restarted enrollment, although the exact timing for completion of the trial is uncertain (as the progression of the pandemic and its future impact on the healthcare system is uncertain).

One potential issue that has emerged is that the German Federal Ministry for Economic Affairs and Energy (BMWi) has initiated an investigation into the merger with Curetis due to its potential impact on German national healthcare interests in light of the pandemic. The company has responded to all questions and will seek swift completion of the process. While it is theoretically possible for BMWi to try to undo the merger, such actions are extremely rare and seem unlikely in this case as Curetis was having trouble funding itself prior to the merger.

Valuation

We have adjusted our valuation to $68.4m or $3.47 per basic share from $58.7m or $3.91 per share. The total valuation increased mainly due to lower net debt, while the per-share value decreased due to an increase in the number of shares outstanding, as described below.

Exhibit 1: OpGen valuation table

Product	Main Indication	Status	Probability of successful commercialization	Launch year	Peak sales ($m)	Patent protection	Economics	rNPV ($m)
OpGen/Curetis Diagnostic Platform	cUTI, lower respiratory	Market (RUO)/registration	40%	2020	183	2039	100.0%	69.2
Total								69.2
Net debt (Q220 plus ATM, warrant exercise and convertible debt conversion)								0.8
Total firm value								68.4
Total basic shares (m)								19.7
Value per basic share ($)								3.47
Options (m)								1.0
Total number of shares (m)								20.7
Diluted value per share ($)								3.30

Source: Edison Investment Research

Financials

Our FY20 revenue estimate has decreased from $7.1m to $4.6m, mainly due to uncertainty regarding the continued impact of the COVID-19 pandemic on product sales, as well as the timeline for 510(k) clearance from the FDA for the Acuitas AMR Gene Panel test in bacterial isolates. We have also made changes to our operating expense estimates for FY20. We have decreased our SG&A estimate by $1.4m due to continued expense controls in this area and increased our R&D estimate by $0.6m. We are largely maintaining our FY21 estimates, which assume a pick-up in the base business as elective surgery volumes recover from COVID-19, as well as new products, such as the Acuitas AMR Gene Panel tests in bacterial isolates and urine.

During Q220, the company raised $5.9m (net) through the issuance of 2.74m shares under its at-the-market (ATM) facility. The company had $12.9m in gross cash at the end of the quarter and subsequent to quarter-end, added an additional $3.6m (net) through the ATM offering and $0.4m through warrant exercises. There is also $18.2m in Q220 debt on the balance sheet. Also, following the end of the quarter, the company issued 0.3m shares following the conversion of $550,000 worth of convertible notes.

Subsequent to the end of the quarter, the company concluded an amendment to its European Investment Bank (EIB) financing facility for an additional €5m tranche. This tranche can be drawn down over the next nine months, and will have a five-year term and 10% interest, which will be payable at maturity. Additionally, on maturity, the EIB will be entitled to an additional equity-linked payment equivalent to 0.7% of the then total equity value of OpGen.

We model an additional financing need of $32.4m ($36m previously) in total through to profitability in FY23 (including $7.4m through the end of FY20 and an additional $12.5m in FY21). As per our policy, we assume future financings are to be funded with illustrative debt.

Exhibit 2: Financial summary

$'000s	2018	2019	2020e	2021e
Year end 31 December	GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS				
Revenue	2,946	3,499	4,567	12,482
Cost of Sales	(1,848)	(1,632)	(2,900)	(4,142)
Gross Profit	1,098	1,867	1,666	8,341
Sales, General and Administrative Expenses	(8,601)	(8,496)	(13,172)	(15,971)
Research and Development Expense	(5,677)	(5,121)	(11,197)	(10,316)
EBITDA	(13,180)	(11,741)	(22,702)	(17,947)
Operating Profit (before amort. and except.)	(13,180)	(11,741)	(22,702)	(17,947)
Intangible Amortisation	0	0	0	0
Other	0	10	0	0
Exceptionals	0	(521)	(751)	0
Operating Profit	(13,180)	(12,261)	(23,453)	(17,947)
Net Interest	(186)	(188)	(3,091)	(3,215)
Other	(2)	2	89	0
Profit Before Tax (norm)	(13,366)	(11,928)	(25,793)	(21,162)
Profit Before Tax (FRS 3)	(13,368)	(12,446)	(26,455)	(21,162)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(13,366)	(11,928)	(25,793)	(21,162)
Profit After Tax (FRS 3)	(13,368)	(12,446)	(26,455)	(21,162)
Average Number of Shares Outstanding (m)	0.3	1.6	15.6	20.1
EPS - normalised ($)	(44.45)	(7.38)	(1.63)	(1.05)
EPS - Reported ($)	(44.49)	(7.70)	(1.69)	(1.05)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	3,167	3,755	29,184	30,994
Intangible Assets	1,686	1,418	22,943	24,775
Tangible Assets	1,222	2,133	5,932	5,910
Other	259	203	309	309
Current Assets	5,783	6,667	14,023	5,477
Stocks	544	473	2,898	2,898
Debtors	374	568	231	243
Cash	4,572	2,708	10,894	2,336
Other	293	2,918	0	0
Current Liabilities	(4,381)	(4,939)	(10,524)	(9,705)
Creditors	(3,983)	(4,565)	(9,705)	(9,705)
Short term borrowings	(399)	(374)	(819)	0
Long Term Liabilities	(1,260)	(1,190)	(31,686)	(44,316)
Long term borrowings	(660)	(329)	(30,386)	(42,886)
Other long term liabilities	(600)	(860)	(1,300)	(1,430)
Net Assets	3,309	4,293	998	(17,549)
CASH FLOW				
Operating Cash Flow	(11,074)	(11,505)	(22,826)	(18,572)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(137)	(32)	(23)	(24)
Acquisitions/disposals	0	0	1,267	0
Financing	14,128	13,062	23,488	0
Dividends	0	0	0	0
Other	(293)	(3,836)	0	0
Net Cash Flow	2,624	(2,310)	1,905	(18,596)
Opening net debt/(cash)	(836)	(3,514)	(2,005)	20,311
HP finance leases initiated	0	0	0	0
Exchange rate movements	(13)	4	(326)	0
Other	66	798	-23896	-1643
Closing net debt/(cash)	(3,514)	(2,005)	20,311	40,550

Source: company reports, Edison Investment Research

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