OpGen

Financial update

Q121 results

Pharma & biotech

OpGen reported Q121 sales of $0.8m, up 35% compared to Q120, with growth mainly due to the April 2020 business combination with Curetis. The company expects to be able to build on this level with the help of the future 510(k) clearance of its Acuitas AMR Gene Panel test in bacterial isolates as well as potential approvals for the Unyvero platform in China and Colombia. To maintain the momentum, OpGen plans to initiate a clinical trial program for complicated urinary tract infections (cUTI) with the Unyvero platform in the summer and invasive joint infections (IJI) later in the year.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/19	3.5	(11.9)	(7.38)	0.0	N/A	N/A
12/20	4.2	(25.3)	(1.57)	0.0	N/A	N/A
12/21e	10.5	(25.5)	(0.70)	0.0	N/A	N/A
12/22e	26.4	(14.1)	(0.35)	0.0	N/A	N/A

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

Bacterial isolates 510(k) clearance possible in August

The FDA has resumed the review of the 510(k) submission for the Acuitas AMR Gene Panel test in bacterial isolates, which had been put on hold due to COVID-19. The agency has also informed OpGen that it intends to provide feedback on certain documents by the end of May and to complete its review by the end of August. However, these timelines are not written in stone and will depend on the FDA's workload with regards to COVID-19.

Strategic collaboration with New York extended

OpGen and the New York State Department of Health have extended and expanded their strategic collaboration for another six months, until 30 September 2021. The focus during this period will be to expand the reach of the platform, increase testing volume and enhance data collection.

Waiting on Chinese NMPA cartridge approval

In March, OpGen announced that the Chinese National Medical Products Administration (NMPA) approved the Unyvero instrument system for use in China. Next up would be an approval for the Unyvero A50 pneumonia cartridge, which is necessary for a product launch. As a reminder, OpGen partner Beijing Clear Biotech has significant minimum purchase requirements over the eight-year deal, totaling €150m in revenue to OpGen over that period.

Valuation: $102m or $2.67 per share

We have slightly adjusted our valuation from $103m or $2.68 per basic share to $102m or $2.67 per share. The change in the valuation is mainly due to a decrease in net cash. The company had $39.4m in gross cash at the end of Q121. We forecast that OpGen will need to raise $20m in additional capital to reach profitability though this will be dependent on timely Chinese and FDA approvals.

19 May 2021

Price	**US$2.0**
Market cap	**US$77m**

Net cash ($m) at 31 March 2021	19.3
Shares in issue	38.3m
Free float	72.5%
Code	OPGN
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(13.2)	(32.4)	1.0
Rel (local)	(11.9)	(35.9)	(27.7)
52-week high/low	US$3.55		US$1.7

Business description

OpGen is a diagnostic company focused on revolutionizing the identification and treatment of bacterial infections. Following the business combination 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	H221
NMPA approval for pneumonia	2021

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Waiting on regulators

OpGen is currently waiting on regulators for a variety of approvals/clearances. Most important will be Chinese NMPA approval for the Unyvero A50 pneumonia cartridge, though timing of this is uncertain. OpGen is partnered in China with Beijing Clear Biotech (BCB), which has agreed to 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 NMPA. Based on previously agreed transfer price levels, this volume equates to €60m in cumulative revenues from China over the first five years for OpGen and then €30m annually over the following three years (note that these are minimum purchase levels and actual revenues could be higher).

Additionally, as previously announced, the FDA has resumed the review of the 510(k) submission for the Acuitas AMR Gene Panel test in bacterial isolates, which had been put on hold due to COVID-19. The agency has also informed OpGen that the agency intends to provide feedback on certain documents by the end of May and to complete its review by the end of August. However, these timelines will depend on the FDA's workload with regards to COVID-19.

OpGen is also seeking approval in Colombia. In January, OpGen announced a distribution agreement with Annar Health Technologies for Colombia. Annar is responsible for product registration (and is working towards an accelerated preliminary registration), which is expected to complete in H221. Annar has agreed to purchase a minimum of 10 Unyvero systems over the three-year term following approval.

Valuation

We have slightly adjusted our valuation from $103m or $2.68 per basic share, to $102m or $2.67 per share. The change in the valuation is mainly due to a decrease in net cash.

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%	82.8
Total								82.8
Net cash (Q121)								19.3
Total firm value								**102.1**
Total basic shares (m)								38.3
Value per basic share ($)								**2.67**
Options (m)								11.0
Total number of shares (m)								49.3
Diluted value per share ($)								2.07

Source: Edison Investment Research

Financials

OpGen reported revenue of $0.8m for Q121, up 35% compared to $0.6m in Q121, mainly due to the inclusion of Curetis products following the April 2020 business combination with Curetis. Product sales were up 67% to $0.6m, while collaboration revenue fell from $0.25m to $0.118m due to lower revenue from the New York State collaboration. Laboratory services were $0.098m, up from zero in Q120 due to the inclusion of Ares Genetics' laboratory services after the combination with Curetis. R&D expenses increased from $1.2m in Q120 to $2.8m in Q121, while SG&A

expenses were up from $2.2m to $3.6m (in Q121) mainly due to the Curetis business combination. OpGen's net loss for the quarter was $14.9m compared to $3.9m in the same quarter a year ago. $7.8m of that increase in net loss was due to a one-time $7.8m non-cash warrant inducement expense related to the 2021 warrant exercise. The Q121 operating cash burn rate was $4.97m. Following these results, we are maintaining our revenue estimates. We have slightly adjusted our 2021 R&D and SG&A estimates. We have reduced our 2021 R&D estimate by $0.7m and increased our corresponding 2021 SG&A estimate by $0.9m.

The company had $39.4m in gross cash (and $19.7m in debt) at the end of Q121. We forecast that OpGen will need to raise approximately $20m in additional capital to reach profitability, currently expected in 2023. This amount will depend on the timing of Chinese and FDA approvals and whether they use cash on hand to repay the $25.1m in long term debt obligations owed to the European Investment Bank (EIB) prior to sustainable profitability (repayments related to the €10m first tranche of the EIB loan taken in April 2017 are due in April 2022 and will also include deferred interest). Note these long-term debt obligations are higher than the carrying value on the balance sheet due to an unamortized debt discount.

Exhibit 2: Financial summary

$'000s	2019	2020	2021e	2022e
Year end 31 December	GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS				
Revenue	3,499	4,214	10,497	26,406
Cost of Sales	(1,632)	(3,848)	(5,511)	(7,922)
Gross Profit	1,867	366	4,986	18,484
Sales, General and Administrative Expenses	(8,496)	(12,367)	(14,467)	(18,794)
Research and Development Expense	(5,121)	(9,965)	(11,424)	(11,538)
EBITDA	(11,741)	(21,966)	(20,905)	(11,848)
Operating Profit (before amort. and except.)	(11,741)	(21,966)	(20,905)	(11,848)
Intangible Amortisation	0	0	0	0
Other	10	0	0	0
Exceptionals	(521)	(752)	(55)	0
Operating Profit	(12,261)	(22,718)	(20,960)	(11,848)
Net Interest	(188)	(3,294)	(4,620)	(2,251)
Other	2	(66)	(7,429)	0
Profit Before Tax (norm)	(11,928)	(25,260)	(25,525)	(14,099)
Profit Before Tax (reported)	(12,446)	(26,078)	(33,010)	(14,099)
Tax	0	(132)	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(11,928)	(25,392)	(25,525)	(14,099)
Profit After Tax (reported)	(12,446)	(26,211)	(33,010)	(14,099)
Average Number of Shares Outstanding (m)	1.6	15.8	36.4	40.6
EPS - normalised ($)	(7.38)	(1.57)	(0.70)	(0.35)
EPS - Reported ($)	(7.70)	(1.66)	(0.91)	(0.35)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	3,755	32,863	34,309	37,092
Intangible Assets	1,418	24,606	25,311	27,253
Tangible Assets	2,133	5,791	6,339	7,180
Other	203	2,466	2,659	2,659
Current Assets	6,667	16,888	24,823	16,791
Stocks	473	1,486	1,417	1,417
Debtors	568	653	486	2,641
Cash	2,708	13,360	21,447	11,260
Other	2,918	1,388	1,473	1,473
Current Liabilities	(4,939)	(7,372)	(22,091)	(9,941)
Creditors	(4,565)	(6,673)	(6,291)	(6,291)
Short term borrowings	(374)	(699)	(15,800)	(3,650)
Long Term Liabilities	(1,190)	(21,188)	(12,551)	(29,192)
Long term borrowings	(329)	(19,379)	(9,431)	(25,781)
Other long term liabilities	(860)	(1,809)	(3,120)	(3,412)
Net Assets	4,293	21,191	24,490	14,750
CASH FLOW				
Operating Cash Flow	(11,505)	(23,397)	(20,916)	(11,122)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(32)	(130)	(851)	(885)
Acquisitions/disposals	0	1,267	0	0
Financing	13,062	33,793	32,824	0
Dividends	0	0	0	0
Other	(3,836)	0	0	0
Net Cash Flow	(2,310)	11,533	11,057	(12,007)
Opening net debt/(cash)	(3,514)	(2,005)	6,717	3,784
HP finance leases initiated	0	0	0	0
Exchange rate movements	4	(1,587)	629	0
Other	798	(18,669)	(8,753)	(2,380)
Closing net debt/(cash)	(2,005)	6,717	3,784	18,171

Source: Company reports, Edison Investment Research

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