EDISON

OpGen

Financial update

AMR Gene Panel clearance expected shortly

Pharma & biotech

OpGen has announced that it submitted an updated 510(k) summary of its Acuitas AMR Gene Panel test in bacterial isolates to the FDA in June and believes that the review of the 510(k) clearance should be completed by the end of August (a timeline previously communicated to the company by the FDA). That said, given the ongoing pandemic, this timeline is not guaranteed. Also, OpGen continues to plan to initiate a clinical trial program for complicated urinary tract infections (cUTI) with the Unyvero platform in the coming weeks and for 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	3.3	(32.5)	(0.90)	0.0	N/A	N/A
12/22e	16.6	(21.1)	(0.52)	0.0	N/A	N/A

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

Local study necessary for NMPA approval

OpGen has announced that the Chinese National Medical Products Administration (NMPA) has requested additional clinical data (to be generated in China) prior to approval for the Unyvero A50 pneumonia cartridge. The company believes this will be a small-scale study of around 600 samples, which should only take a few months to conduct. As a reminder, OpGen partner Beijing Clear Biotech (BCB) has significant minimum purchase requirements over the eight-year deal, totaling €150m in revenue to OpGen over that period.

Discussions with New York State ongoing

As a reminder, in April, OpGen and the New York State Department of Health extended and expanded their strategic collaboration until 30 September 2021. Discussions on extending the relationship past this point are ongoing. The previous agreement ran to the end of March, but was only renewed well into April so a similar delay may occur here.

Unyvero A30 *RQ* analyzers hit milestone

OpGen has successfully completed the assembly of 10 final, pre-series release Unyvero A30 *RQ* analyzers, which have commenced final verification and validation testing. Once completed, they can be made available to development and commercialization partners. Discussions are currently underway.

Valuation: $91m or $2.38 per share

We have adjusted our valuation to $91m or $2.38 per share from $102m or $2.67 per share. The change in valuation is mainly due to a decrease in net cash, but also in part because of lower near-term revenue expectations following the announcement of an additional study required prior to Chinese approval.

18 August 2021

Price	**US$2.45**
Market cap	**US$94m**
Net cash ($m) at 30 June 2021	10.5
Shares in issue	38.3m
Free float	94.0%
Code	OPGN
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	12.4	25.6	15.6
Rel (local)	9.3	17.6	(12.1)
52-week high/low	US$3.6	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.

Next events

Acuitas Gene Panel (isolates) 510(k) clearance	Q321

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Edison profile page

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Waiting on governments

The FDA is continuing the review of the 510(k) submission for the Acuitas AMR Gene Panel test in bacterial isolates, with the expectation of completing the review by the end of August. In June, OpGen submitted an updated 510(k) summary of its Acuitas AMR Gene Panel test in bacterial isolates to the FDA and believe that the review for the 510(k) clearance should be completed by the previously announced timeline, although of course this timing is not guaranteed.

The company is also seeking to extend the strategic collaboration with the New York State Department of Health, a collaboration currently set to expire at the end of September. Note that the previous agreement ran to the end of March but was only renewed well into April so a similar delay may occur here.

With regards to China, OpGen has announced that the Chinese NMPA has requested additional clinical data (to be generated in China) prior to approval for the Unyvero A50 pneumonia cartridge. The company stated on its earnings call that this will likely be a small-scale study of around 600 samples, which should only take a few months to conduct. However, timing for the review following the submission of the data is unknown and will likely run into 2022. As a reminder, OpGen is partnered in China with BCB, which has agreed to minimum purchase levels of 360 Unyvero A50 systems as well as more than 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).

Valuation

We have adjusted our valuation to $91m or $2.38 per share from $102m or $2.67 per share. The change in the valuation is mainly due to a decrease in net cash, but also in part because of lower near-term revenue expectations following the announcement of an additional study prior to Chinese approval. We have made no changes to our long-term forecasts. Additionally, we expect to review our valuation following FDA clearance for the AMR Gene Panel in bacterial isolates as well as NMPA approval.

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%	80.6
Total								80.6
Net cash (Q221)								10.5
Total firm value								91.1
Total basic shares (m)								38.3
Value per basic share ($)								2.38
Options (m)								11.0
Total number of shares (m)								49.3
Diluted value per share ($)								1.85

Source: Edison Investment Research

Financials

OpGen reported Q221 sales of $0.8m, down 32% compared to the prior year mainly due to its exit from the fluorescence in situ hybridization (FISH) business at the end of Q121. Product sales were down 49% to $0.3m (primarily due to the exit from FISH), while collaboration revenue fell 58% from $0.6m to $0.2m due to the conclusion of a non-recurring R&D collaboration between Ares Genetics and an in vitro diagnostic partner in 2020. Laboratory services increased 926% to $0.3m, partially due to COVID testing services. R&D expenses were down slightly from $3.0m in Q220 to $2.9m this quarter, while SG&A expenses were $3.5m, down from $3.8m in the same period a year ago (and which had included $0.2m in merger transaction costs). OpGen's net loss for the quarter was $7.1m, an improvement from the $7.5m loss seen in Q220. Following these results, we have lowered our FY21 revenue expectations by $7.2m and our FY22 estimate by $9.8m, mainly due to the delay of Chinese approval for the Unyvero A50 pneumonia cartridge, which we had expected at the end of this year. We have slightly adjusted our 2021 R&D and SG&A estimates. We have increased our 2021 R&D estimate by less than $0.1m, and correspondingly decreased 2021 our SG&A estimate by $0.3m.

The company had $31.2m in gross cash (and $20.7m in debt) at the end of Q221. We forecast that OpGen will need to raise approximately $30m in additional capital to reach profitability (up from $20m previously), which we currently expect in 2023. This amount will depend on the timing of Chinese and FDA approvals, and whether they use cash on hand to repay the $25.8m 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 out in April 2017 are due in April 2022 and will also include deferred interest). Note that 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

$'000s	2019	2020	2021e	2022e
Year end 31 December	GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS				
Revenue	3,499	4,214	3,300	16,601
Cost of Sales	(1,632)	(3,848)	(5,511)	(4,980)
Gross Profit	1,867	366	(2,211)	11,621
Sales, General and Administrative Expenses	(8,496)	(12,367)	(14,153)	(18,794)
Research and Development Expense	(5,121)	(9,965)	(11,478)	(11,593)
EBITDA	(11,741)	(21,966)	(27,842)	(18,767)
Operating Profit (before amort. and except.)	(11,741)	(21,966)	(27,842)	(18,767)
Intangible Amortisation	0	0	0	0
Other	10	0	0	0
Exceptionals	(521)	(752)	(171)	0
Operating Profit	(12,261)	(22,718)	(28,013)	(18,767)
Net Interest	(188)	(3,294)	(4,686)	(2,284)
Other	2	(66)	(7,184)	0
Profit Before Tax (norm)	(11,928)	(25,260)	(32,528)	(21,050)
Profit Before Tax (reported)	(12,446)	(26,078)	(39,882)	(21,050)
Tax	0	(132)	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(11,928)	(25,392)	(32,528)	(21,050)
Profit After Tax (reported)	(12,446)	(26,211)	(39,882)	(21,050)
Average Number of Shares Outstanding (m)	1.6	15.8	36.4	40.6
EPS - normalised ($)	(7.38)	(1.57)	(0.90)	(0.52)
EPS - Reported ($)	(7.70)	(1.66)	(1.10)	(0.52)
Dividend per share ($)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	3,755	32,863	35,453	39,014
Intangible Assets	1,418	24,606	25,444	27,268
Tangible Assets	2,133	5,791	6,459	8,195
Other	203	2,466	3,551	3,551
Current Assets	6,667	16,888	17,399	11,354
Stocks	473	1,486	1,334	1,334
Debtors	568	653	473	1,660
Cash	2,708	13,360	13,511	6,279
Other	2,918	1,388	2,082	2,082
Current Liabilities	(4,939)	(7,372)	(20,657)	(8,507)
Creditors	(4,565)	(6,673)	(4,857)	(4,857)
Short term borrowings	(374)	(699)	(15,800)	(3,650)
Long Term Liabilities	(1,190)	(21,188)	(8,169)	(34,827)
Long term borrowings	(329)	(19,379)	(4,871)	(31,221)
Other long-term liabilities	(860)	(1,809)	(3,298)	(3,606)
Net Assets	4,293	21,191	24,025	7,034
CASH FLOW				
Operating Cash Flow	(11,505)	(23,397)	(28,494)	(17,260)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(32)	(130)	(1,723)	(1,792)
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	2,607	(19,052)
Opening net debt/(cash)	(3,514)	(2,005)	6,717	7,160
HP finance leases initiated	0	0	0	0
Exchange rate movements	4	(1,587)	296	0
Other	798	(18,669)	(3,346)	(2,380)
Closing net debt/(cash)	(2,005)	6,717	7,160	28,592

Source: Company reports, Edison Investment Research

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