EDISON

OpGen

Financial update

FDA clearance a step forward

Pharma & biotech

With the recent 510(k) clearance of the Acuitas AMR Gene Panel in bacterial isolates, OpGen has reached the next stage of its corporate evolution. As a reminder, the panel detects 28 genetic antimicrobial resistance (AMR) markers in isolated bacterial colonies from 26 different pathogens and provides genomic profile data much quicker than traditional methods (2.5 hours versus one to four days).

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	3.8	(30.9)	(0.85)	0.0	N/A	N/A
12/22e	8.3	(25.5)	(0.63)	0.0	N/A	N/A

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

Chinese NMPA approval expected in 2022

OpGen previously announced that the Chinese National Medical Products Administration (NMPA) requested additional clinical data (to be generated in China) prior to approval for the Unyvero A50 pneumonia cartridge. The company believes the study should only take approximately six months to conduct, though the exact start date would depend on the approval of the clinical study design by both the NMPA and OpGen's partner Beijing Clear Biotech (BCB). Approval and launch are currently expected in 2022.

Registration received in Colombia

OpGen's partner Annar Health Technologies has gained preliminary registration for the Unyvero A50 system in Colombia. As a reminder, Annar has agreed to purchase a minimum of 10 Unyvero systems over the three-year term following approval. OpGen sold the first Unyvero A50 system and kits to Annar in October.

Unyvero UTI trial interim data in Q122

OpGen has initiated a clinical trial for the Unyvero Urinary Tract Infection (UTI) Panel. The trial is expected to enroll more than 1,500 prospective patient samples. The company plans an interim data analysis after the first few hundred samples are tested prior to proceeding with full enrolment. The interim analysis is expected to be conducted in Q122 with the full trial expected to be completed in 2022.

Valuation: $98m or $2.10 per share

We have adjusted our valuation from $91m or $2.38 per share to $98m or $2.10 per share. The drivers to the change in total valuation include an increase in the probability of success from 40% to 50%. Additionally, there was an increase in net cash following a preferred stock and warrant offering in October that raised $13.9m in net proceeds. This was partially offset by more conservative near-term revenue assumptions as we believe initial orders from BCB may slip into 2023. The per share value fell due to a greater number of shares outstanding (assuming the convertible preferred stock is converted into common).

17 November 2021

Price	**US$1.7**
Market cap	**US$66m**

Net cash ($m) at 30 September 2021 + offerings	19.6
Common shares in issue	39.0m
Free float	92.5%
Code	OPGN
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(18.7)	(36.3)	(17.1)
Rel (local)	(22.7)	(39.3)	(36.0)

52-week high/low	US$3.58	US$1.65

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

Unyvero UTI panel interim analysis	Q122

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Edison profile page

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Q321 update

In October, OpGen received 510(k) clearance from the FDA for the Acuitas AMR Gene Panel in bacterial isolates. The panel detects 28 genetic AMR markers in isolated bacterial colonies from 26 different pathogens and provides genomic profile data much quicker than traditional methods (2.5 hours versus one to four days). The company believes the Acuitas AMR Gene Panel is the first FDA cleared molecular diagnostic panel that detects such a broad panel of AMR markers from isolates. The commercial launch is underway. The company is targeting over 400 institutions and well over 1,000 individual key stakeholders at these institutions directly.

The next FDA submission is expected to be for the Unyvero UTI Panel. OpGen has initiated a clinical trial that is expected to include more than 1,500 prospective patient samples. On its earnings call, the company announced plans for an interim data analysis after the first few hundred samples are tested prior to proceeding with full enrolment. The interim analysis is expected to be conducted in Q122 with the full trial expected to be completed in 2022, after which the company will seek clearance from the FDA.

With regards to the planned Unyvero Invasive Joint Infection (IJI) trial, the company has designed the trial and identified study sites but is awaiting feedback from the FDA, which is unlikely prior to 2022 due to the volume of COVID-19 related submissions to the agency.

OpGen previously announced that the Chinese NMPA requested additional clinical data (to be generated in China) prior to approval for the Unyvero A50 pneumonia cartridge. The company believes the study should only take approximately six months to conduct though the exact start date would depend on the approval of the clinical study design by both the NMPA and OpGen's partner BCB. Approval and launch are currently expected in 2022. As a reminder, BCB 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).

In Colombia, OpGen's partner Annar Health Technologies has gained preliminary registration for the Unyvero A50 system in Colombia. Annar has agreed to purchase a minimum of 10 Unyvero systems over the three-year term following approval. OpGen sold the first Unyvero A50 system and kits to Annar in October.

Valuation

We have adjusted our valuation from $91m or $2.38 per share to $98m or $2.10 per share. The drivers to the change in total valuation include an increase in the probability of success from 40% to 50%. Additionally, there was an increase in net cash following a preferred stock and warrant offering in October that raised $13.9m in net proceeds. This was offset with more conservative near-term revenue assumptions as we believe initial orders from BCB may slip into 2023 due to NMPA approval potentially coming in late 2022. The per share value fell due to a greater number of shares outstanding. Note that as we assume all the preferred stock will convert into common shares, we have included them in our valuation per share calculation (see additional details in the Financials section of this report).

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	50%	2020	183	2039	100.0%	78.2
Total								78.2
Pro forma net cash (Q321 + subsequent offerings)								19.6
Total firm value								**97.8**
Total shares (assuming full preferred stock conversion, m)								46.5
Value per share ($)								**2.10**
Options (m)								18.2
Total number of shares (m)								64.7
Diluted value per share ($)								1.51

Source: Edison Investment Research

Financials

OpGen reported Q321 revenue of $1.2m, up 17% compared to the prior year. Product sales increased 7% to almost $644,000 due to an increase in Unyvero sales, though this was offset by OpGen's exit from the fluorescence in situ hybridization (FISH) business at the end of Q121. Laboratory Services increased 71% to almost $193,000 due to an increase in Ares Genetics' laboratory services as well as due to COVID-19 testing services. Collaboration revenue increased 18% due to an increase in Ares Genetics collaboration revenue.

R&D expenses were down 2% to $2.4m due to reduced expenses related to Acuitas AMR clinical trials. SG&A expenses were $3.1m, down 6% compared to the same period a year ago due to a decrease in payroll expenses. OpGen's net loss for the quarter was $6.1m, an improvement from the $7.7m loss seen in Q320.

Following these results, we have increased our FY21 revenue expectations by $0.5m due to the strong quarter. However, we have reduced our FY22 revenue estimates by $8.3m as some of the initial orders from BCB may slip into 2023 as NMPA approval may not happen until 2023 (it is a six-month study but it still needs to have the clinical trial design signed off by both BCB and the NMPA and it will also take some time to have everything in place for its initiation). We have also lowered our R&D and SG&A expense estimates for FY21 by $0.6m apiece. We have left our FY22 R&D estimate the same but lowered our forecast SG&A by $4.7m as we no longer expect a significant expense ramp compared to FY21. The company has stated on its earnings call that it will be in a better position to provide guidance on FY22 revenue and expenses on its annual results conference call in March 2022.

The company had $25.4m in gross cash (and $21.2m in debt) at the end of Q321. Subsequent to the end of the quarter, the company sold 680,000 shares for net proceeds of $1.5m in an at-the-market (ATM) offering. Additionally, the company conducted a preferred stock and warrant offering that raised $13.9m in net proceeds ($15m gross). As part of the transaction, a single healthcare institutional investor was issued 150,000 shares of convertible preferred stock and warrants to purchase up to 7.5m shares of common stock. The preferred shares convert into 7.5m common shares at a conversion price of $2.00 per share at any time after the company has received stockholder approval to increase the number of authorized shares of common stock. The warrants have an exercise price of $2.05 per share and will become exercisable either on the date of stockholder approval or six months following the date of issuance, whichever is later. They expire five years following the initial exercise date. There will be a special meeting of stockholders on 8 December 2021 to approve the proposed increase of the number of authorized shares of common stock from 50m to 100m.

We forecast that OpGen will need to raise approximately $45m in additional capital prior to reaching profitability (up from $30m due to more conservative revenue estimates in the near term), which we now expect to occur in 2024 (previously 2023). The precise amount raised will depend on the timing of Chinese and FDA approvals, and whether it uses cash on hand to repay the $25.4m (nominal value) 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 in nominal value than the carrying value on the balance sheet due to an unamortized debt discount.

Exhibit 2: Financial summary

$'000s	2019	2020	2021e	2022e
Year end 31 December	GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS				
Revenue	3,499	4,214	3,807	8,300
Cost of Sales	(1,632)	(3,848)	(5,511)	(5,810)
Gross Profit	1,867	366	(1,704)	2,490
Sales, General and Administrative Expenses	(8,496)	(12,367)	(13,550)	(14,096)
Research and Development Expense	(5,121)	(9,965)	(10,914)	(11,569)
EBITDA	(11,741)	(21,966)	(26,169)	(23,174)
Operating Profit (before amort. and except.)	(11,741)	(21,966)	(26,169)	(23,174)
Intangible Amortisation	0	0	0	0
Other	10	0	0	0
Exceptionals	(521)	(752)	(171)	0
Operating Profit	(12,261)	(22,718)	(26,340)	(23,174)
Net Interest	(188)	(3,294)	(4,711)	(2,296)
Other	2	(66)	(6,963)	0
Profit Before Tax (norm)	(11,928)	(25,260)	(30,880)	(25,471)
Profit Before Tax (reported)	(12,446)	(26,078)	(38,014)	(25,471)
Tax	0	(132)	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(11,928)	(25,392)	(30,880)	(25,471)
Profit After Tax (reported)	(12,446)	(26,211)	(38,014)	(25,471)
Average Number of Shares Outstanding (m)	1.6	15.8	36.3	40.6
EPS - normalised ($)	(7.38)	(1.57)	(0.85)	(0.63)
EPS - Reported ($)	(7.70)	(1.66)	(1.05)	(0.63)
Dividend per share ($)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	3,755	32,863	34,617	38,251
Intangible Assets	1,418	24,606	24,781	26,576
Tangible Assets	2,133	5,791	6,300	8,140
Other	203	2,466	3,536	3,536
Current Assets	6,667	16,888	34,456	22,833
Stocks	473	1,486	1,357	1,357
Debtors	568	653	751	830
Cash	2,708	13,360	30,028	18,326
Other	2,918	1,388	2,320	2,320
Current Liabilities	(4,939)	(7,372)	(19,166)	(8,148)
Creditors	(4,565)	(6,673)	(4,498)	(4,498)
Short term borrowings	(374)	(699)	(14,668)	(3,650)
Long Term Liabilities	(1,190)	(21,188)	(9,824)	(36,485)
Long term borrowings	(329)	(19,379)	(6,484)	(32,834)
Other long term liabilities	(860)	(1,809)	(3,339)	(3,651)
Net Assets	4,293	21,191	40,083	16,450
CASH FLOW				
Operating Cash Flow	(11,505)	(23,397)	(26,676)	(21,625)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(32)	(130)	(1,825)	(1,898)
Acquisitions/disposals	0	1,267	0	0
Financing	13,062	33,793	48,224	0
Dividends	0	0	0	0
Other	(3,836)	0	0	0
Net Cash Flow	(2,310)	11,533	19,723	(23,523)
Opening net debt/(cash)	(3,514)	(2,005)	6,717	(8,876)
HP finance leases initiated	0	0	0	0
Exchange rate movements	4	(1,587)	727	0
Other	798	(18,669)	(4,857)	(3,511)
Closing net debt/(cash)	(2,005)	6,717	(8,876)	18,159

Source: company reports, Edison Investment Research

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