

OpGen

US momentum offset by one-time items

Earnings update

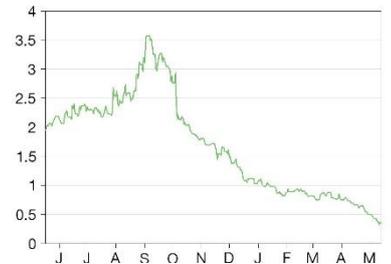
Pharma & biotech

16 May 2022

Price **US\$0.32**
Market cap **US\$16.6m**

Net cash (\$m) at 31 March 2022	8.3
Shares in issue	46.6
Free float	92.5%
Code	OPGN
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(50.3)	(62.7)	(82.6)
Rel (local)	(45.1)	(59.1)	(82.3)
52-week high/low	US\$3.6	US\$0.3	

Business description

OpGen is primarily a lab diagnostic manufacturer focused on the identification and treatment of bacterial infections. With the acquisition of Curetis in H120, management has the technology necessary to detect pathogens and predict resistance. Through the dual platform offering of AMR Gene Panel and Unyvero, the company has the ability to provide diagnostic results in hours instead of days under legacy technologies.

Next events

Unyvero UTI panel read out data and FDA submission	H222
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OpGen reported Q122 revenues of \$470k, compared to \$830k in the prior year period. The decline was largely attributable to the discontinuation of the FISH business, the conclusion of the NY Department of Health collaboration and softness in Unyvero international. In contrast, US Unyvero sales increased 76% from the prior year. In light of the current performance and anticipated slower ramp-up in China, we have trimmed our FY22–24 revenue estimates and pushed profitability to FY26 (versus FY24 previously).

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (\$)	DPS (\$)	P/E (x)	Yield (%)
12/20	4.2	(24.7)	(1.57)	0.0	N/A	N/A
12/21	4.3	(35.7)	(1.17)	0.0	N/A	N/A
12/22e	5.0	(22.8)	(0.49)	0.0	N/A	N/A
12/23e	8.1	(19.0)	(0.41)	0.0	N/A	N/A

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

Unyvero performance – a mixed bag

Despite the bright spots in the US with the continued build-up of the domestic salesforce, there were several one-time offsets and softness in the international business. Management continues to build international Unyvero sales through its distributor arrangements, the latest being with AnnarDx in Colombia (and potentially other markets in South America). There was no material update to the anticipated supplementary clinical study in China (covering ~600 patients across three sites) required for the approval of the Unyvero hospitalized pneumonia (HPN) test/cartridge from the Chinese authorities (National Medical Products Administration, NMPA). These unanticipated delays are primarily driven by the stringent COVID-19 restrictions. Management anticipates US sales growth to outpace sales abroad driven by continued investments in its US salesforce. We expect this improving mix to have a positive impact on margins.

Acuitas commercialization efforts at full steam

Following FDA clearance in October 2021, OpGen's legacy Acuitas AMR Gene Panel (Acuitas) has now been launched in the US. Sales efforts remain strong, and the company continues to market to over 400 institutions and 1,000 key stakeholders. Based on the six- to 12-month anticipated sales cycle, we are likely to see the first agreements signed in the next few weeks.

Valuation: \$91m or \$2.0 per share

Based on the quarterly update and lower cash position, we have adjusted our valuation to \$91m or \$2.0 per share, from \$98m or \$2.1 per share, previously. Following advancement in the commercialisation of OpGen's product portfolio, we have now segregated our NPV valuation into separate products to better reflect their individual contributions to the group valuation. We estimate the \$30.7m gross cash at end-Q122 provides an operating runway into 2023, but we project the need to raise a total of \$55m before reaching profitability in FY26.

Financials

OpGen reported Q122 revenue of \$470k, a 43% y-o-y decline over \$830k in the prior year. Lower revenues are attributed to the exit from the fluorescence in situ hybridization (FISH) business at the end of Q121 (\$170k in sales in Q121), culmination of the collaboration agreement with the New York State (NYS) Department of Health in September 2021 (\$108k in sales in Q121) and lower international sales from the Unyvero business. These declines were offset by stronger than expected US sales (up 76% y-o-y to \$154k in Q122).

Overall product sales of \$366k declined 40% from the prior year, while laboratory services of \$43k declined 56% from the prior year. Softness in laboratory services was attributable to lower requirements for COVID-19 testing. Collaboration revenues of \$61k declined 49% from the prior year, mainly due to the conclusion of the NYS Department of Health project.

The company reported operating losses of \$5.8m, down slightly from \$6.3m in the prior year. Overall operating expenses increased as a percentage of sales with the softness in international sales. As expected, R&D expenses declined 18% to \$2.3m following the completion of the Acuitas AMR clinical trials in H221 and lower associated payroll related expenses. G&A expenses were mostly in line with Q121, while S&M expenses increased 17% with the continued investment in the US salesforce to drive commercialization of both Unyvero and Acuitas systems and related consumables. The normalized loss before tax during the quarter stood at \$6.8m, broadly in line with the Q121 figure of \$7.1m (excluding the \$7.8m warrant inducement expense during Q121).

Management previously guided for a 25–50% revenue growth in the Products and Services segment in FY22 (including over 50% growth from the US). Our current estimates assume a slower ramp-up in international sales (including a slower roll out in China with COVID lockdown induced delays). For China, while we maintain our total sales potential expectations (€180m over eight years), we now assume delayed commercialization (mid-2023) and have assumed an 80% probability of approval to factor in the uncertainty. We expect the momentum in volumes/sales to start improving from FY24 with a steady growth thereafter with the continued investments in a dedicated salesforce, which also have an impact on our bottom-line projections. We expect the company to reach profitability in 2026, versus 2024 previously.

OpGen's subsidiary Curetis and the European Investment Bank (EIB) propose to restructure the first tranche (approximately €13.35m) of debt that matured on 22 April, subject to the finalization of legal agreements. Curetis repaid €5m in cash in April 2022 and the remaining c €8.35m (\$9m) is to be paid in equal instalments over the following 12-month period (monthly cash instalments of around €0.7m). The second and third tranches of EIB debt amount to €3.0m (\$3.2m) and €5.0m (\$5.3m) plus accumulated deferred interest, respectively, and continue to be due for repayment in June 2023 and June 2024.

At the end Q122, OpGen had \$30.7m in gross cash and \$22.4m in debt. With \$11.3m of debt due in FY22 and an estimated upcoming quarterly operating cash burn of c \$5m (consistent with the Q122 rate), we estimate the need to raise c \$20m in incremental funds in FY23 (incorporated as illustrative debt in our model) excluding expected repayment of EIB debt components. We also project the need to raise another \$35m in FY24–25 before reaching the scale to fund operations from internally generated cash flows. This is higher than our previous estimate of \$45m and is driven by our more conservative assumptions for the sales ramp-up. These estimates will be revisited as the developmental pipeline and commercialization efforts progress.

Valuation

We have slightly adjusted our valuation from \$98m or \$2.10 per share to \$91m or \$2.0 per share. While the implied enterprise value of OpGen's products/platforms increases to \$82.9m from \$78.2m, the decline in the overall valuation has been driven by a lower net cash position at the end of Q122. Given that a significant proportion of OpGen's development pipeline has progressed towards commercialization (including the legacy AMR Gene Panel following the FDA approval in H221), we have now segregated our valuation to reflect contributions from each of these products/segments to the group NPV. Unyvero, as expected, comprises the bulk of our valuation as we now factor in the potential contributions from the complicated urinary tract infection (cUTI) and invasive joint infection (IJI) cartridges, adjusted for their respective probabilities of approval (80% and 50% respectively). This contribution has been tempered by the uncertainty we have now built in for the Chinese market (80% probability of success). Progression on the aforementioned products will create upside opportunities for the company. While OpGen is actively seeking monetization opportunities for its AresDB dataset, accurately valuing the asset given the limited information available currently has proven challenging. We have therefore used the carrying value of the asset in our valuation as the next best alternative. We will update this figure as more information becomes available. Our per share valuation remains largely unchanged at \$2.0.

Exhibit 1: OpGen valuation

Product	Main indication	Status	Probability of successful commercialization	Launch year	Peak sales (\$m)	Patent protection	rNPV (\$m)
Unyvero excluding China	Lower respiratory	Market	100%	2020	130.9	2040	103.4
	UTI (US)	Clinical	80%	2024			
	IJI (US)	Preclinical	50%	2025			
Unyvero - China	HPN	Registration	80%	2023	42.2	2040	26.2
Acuitas AMR Panel	AMR	Market	100%	2022	22.2	2040	16.7
AresDB (book value)	Bioinformatics	Market					4.8
Unyvero A30 (book value) and others	IJI	Preclinical					11.0
Unallocated R&D costs							(25.9)
G&A costs							(53.3)
Net cash (as of March 2022)							8.3
Total firm value							91.2
Total shares outstanding (m)							46.6
Value per share (\$)							2.0

Source: Edison Investment Research

Exhibit 2: Financial summary

	\$'000s	2019	2020	2021	2022e	2023e
Year end 31 December		GAAP	GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS						
Revenue		3,499	4,214	4,306	5,013	8,113
Cost of Sales		(1,632)	(3,848)	(2,848)	(2,616)	(4,515)
Gross Profit		1,867	366	1,458	2,397	3,598
Sales, General and Administrative Expenses		(8,496)	(12,367)	(13,649)	(12,542)	(10,843)
Research and Development Expense		(5,121)	(9,965)	(10,911)	(9,820)	(8,896)
EBITDA		(10,829)	(19,631)	(20,388)	(17,363)	(13,925)
Operating Profit (before amort. and excepts.)		(11,750)	(21,966)	(23,102)	(19,965)	(16,141)
Intangible Amortisation		0	0	0	0	0
Other		0	0	0	0	0
Exceptionals		(522)	(752)	(171)	0	0
Operating Profit		(12,272)	(22,718)	(23,273)	(19,965)	(16,141)
Net Interest		(178)	(3,294)	(4,754)	(2,857)	(2,889)
Other		2	(66)	(6,735)	0	0
Profit Before Tax (norm)		(11,928)	(24,742)	(35,742)	(22,823)	(19,031)
Profit Before Tax (reported)		(12,447)	(26,078)	(34,762)	(22,823)	(19,031)
Tax		0	(132)	(44)	0	0
Deferred tax		0	0	0	0	0
Profit After Tax (norm)		(11,928)	(24,875)	(35,786)	(22,823)	(19,031)
Profit After Tax (reported)		(12,447)	(26,211)	(34,806)	(22,823)	(19,031)
Average Number of Shares Outstanding (m)		1.6	15.8	36.7	46.6	46.6
EPS - normalised (\$)		(7.38)	(1.57)	(1.17)	(0.49)	(0.41)
EPS - Reported (\$)		(7.70)	(1.66)	(1.14)	(0.49)	(0.41)
Dividend per share (c)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets		3,755	32,863	31,924	29,719	27,915
Intangible Assets		1,418	24,606	21,983	20,956	20,001
Tangible Assets		2,133	5,791	5,917	4,738	3,890
Other		203	2,466	4,024	4,024	4,024
Current Assets		6,667	16,888	39,743	9,487	6,437
Stocks		473	1,486	1,239	1,075	1,856
Debtors		568	653	1,172	961	1,556
Cash		2,708	13,360	36,080	6,200	1,775
Other		2,918	1,388	1,250	1,250	1,250
Current Liabilities		4,939	7,372	19,917	15,831	14,743
Creditors		4,565	6,673	5,398	6,431	6,224
Short term borrowings		374	699	14,519	9,399	8,519
Long Term Liabilities		1,190	21,188	10,533	4,067	18,382
Long term borrowings		329	19,379	7,176	996	15,696
Other long term liabilities		860	1,809	3,356	3,070	2,685
Net Assets		4,293	21,191	41,217	19,308	1,228
CASH FLOW						
Operating Cash Flow		(11,506)	(23,397)	(21,479)	(18,185)	(17,299)
Net Interest		0	0	0	0	0
Tax		0	0	0	0	0
Capex		(32)	(130)	(1,984)	(397)	(413)
Acquisitions/disposals		0	1,267	0	0	0
Equity Financing		13,062	33,793	48,159	0	0
Dividends		0	0	0	0	0
Other		0	0	(266)	0	0
Net Cash Flow		1,524	11,533	24,430	(18,582)	(17,711)
Opening net debt/(cash)		(3,514)	(2,005)	6,717	(14,385)	4,195
HP finance leases initiated		0	0	0	0	0
Exchange rate movements		(19)	(2)	(5)	(13)	(4)
Other		(3013)	(20,254)	(3,322)	15	(529)
Closing net debt/(cash)		(2,005)	6,717	(14,385)	4,195	22,440

Source: OpGen, Edison Investment Research

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