

OpGen

Q123 update

Optimistic start to kick off a promising year

Pharma and biotech

17 May 2023

Price **US\$0.70**
Market cap **US\$4m**

Pro-forma net cash (\$m) at 31 March 2023 (including May 2023 equity raise) 0.2

Shares in issue 6.1m

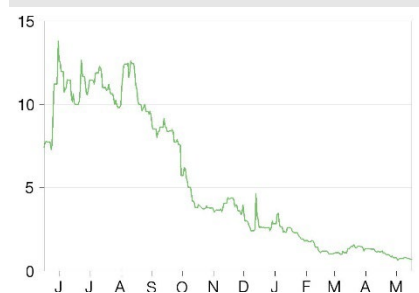
Free float 92.5%

Code OPGN

Primary exchange Nasdaq

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (38.6) (39.6) (89.4)

Rel (local) (38.2) (39.9) (89.7)

52-week high/low \$13.8 \$0.68

Business description

OpGen is primarily a lab diagnostic manufacturer focused on identifying and treating 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 the AMR Gene Panel and Unyvero, the company can provide diagnostic results in hours instead of days under legacy technologies.

Next events

Q223 results August 2023

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OpGen has reported a productive quarter marked by advancements across the board. Operating loss improved to \$5.1m during the quarter (from \$5.8m in Q122), driven by 94% y-o-y top-line growth (to \$0.9m) and stronger cost controls (total expenses of \$6.0m vs \$6.3m in Q122). Looking ahead, we anticipate tailwinds from the post-period signing of the Unyvero distribution partnership with Fisher Healthcare and the *de novo* FDA submission for its UTI panel in April. While Unyvero and ARES will be the key focus areas for FY23, we expect advancement of the FIND collaboration to be another important catalyst. With \$11m in gross proceeds raised to date in FY23, with offsets from upcoming debt repayments, we anticipate OpGen will need to raise another \$7.5m to fund operations for the second half of FY23. Our updated estimates reflect the recent newsflow, including the Fisher Healthcare distribution agreement. Our overall valuation increases to \$71.5m (from \$66.7m) but our per-share valuation decreases to \$11.7/share (\$12.2/share previously) with the higher post-raise share count.

Year end	Revenue (\$m)	EBITDA* (\$m)	PBT* (\$m)	EPS* (\$)	P/revenue (x)	Net debt/ (cash) (\$m)
12/21	4.3	(20.4)	(35.7)	(19.5)	0.93	(14.4)
12/22	2.6	(20.6)	(25.3)	(10.4)	1.53	4.4
12/23e	4.8	(17.9)	(20.8)	(3.4)	0.83	13.7
12/24e	7.1	(17.0)	(20.8)	(2.1)	0.56	34.5

Note: *Figures are normalized, excluding amortization of acquired intangibles, exceptional items and share-based payments. EPS adjusted for 1:20 share consolidation in Jan 2023.

An improved quarter operationally

OpGen reported Q123 revenue of \$0.9m, a 94% increase from \$0.5m in Q122, primarily driven by the higher collaboration revenue from the FIND agreement (\$400k recognized in milestones payments in the quarter; a further \$180k payment expected in Q223). Tighter cost controls by management led to a decline in total expenses to \$6.0 in Q123 from \$6.3m in Q122, improving EDITDA loss to \$4.7m (vs \$5.3m in Q122). Management has maintained its full-year guidance of \$4–5m in total revenue, which we view as achievable provided momentum is sustained through the rest of FY23.

Fisher deal expands Unyvero's commercial footprint

In light of the current challenging market conditions around healthcare funding, we see OpGen's decision to co-commercialize Unyvero in the United States as sound, given Fisher's strong market presence (20x larger salesforce vs OpGen) and existing relationships with several relevant target accounts, which can potentially expedite discussions and shorten sales cycles. We understand that the initial deal is for 30 Unyvero systems, which we assume will be purchased over three years (2023–25) at transfer prices similar to those with European distributor Menarini.

Valuation: \$71.5m or \$11.7 per share

We update our valuation of OpGen to reflect Q123 performance, the Fisher deal and the pro-forma net cash figure following the \$3.5m equity raise in May 2023. Our revised valuation increases to \$71.5m (\$66.7m previously) but our per-share valuation re-adjusts lower to \$11.7/share (from \$12.2/share) with the higher share count (6.1m as at 11 May 2023 vs 5.5m previously). Assuming all 3.9m pre-funded warrants are converted, our fully diluted per-share valuation will reset to \$7.1/share.

Unyvero in focus

Unyvero remains the primary focus in FY23 and we see further uptake in installed Unyvero systems as the key driver for FY23 sales. Several developments were observed post-period, which bodes well for sales uplift, notably the signing of the [co-commercialization/distribution deal with Fisher Healthcare in the United States](#) and the [de novo application filing](#) for the Unyvero urinary tract infection (UTI) test panel during the post-reporting period, to promote Unyvero across various platforms/partnerships. We also see incremental upside from the FIND collaboration for the Unyvero A30 systems, should the deal progress beyond the feasibility stage and into the clinical and beyond.

Distribution agreement with Fisher Healthcare

In April 2023, OpGen entered into a non-exclusive distribution agreement with Fisher Healthcare to market and distribute its Unyvero A50 platform and in vitro diagnostic tests for bacterial pneumonia (Unyvero LRT and LRT BAL) and its research-use only test for UTI (Unyvero UTI). Fisher Healthcare is part of Thermo Fisher Scientific, and we expect OpGen to leverage Fisher's established footprint and relationships with hospitals and diagnostic labs to expand commercial coverage of its Unyvero suite of products in the United States. Management states that Fisher already has several target accounts as part of its network, which might accelerate the current sales cycle of six to 12 months and might generate broader opportunities for hospital network access.

Although a variation to its purely self-commercialization strategy, we see merits in this decision as it allows OpGen to scale market coverage while easing financial demands related to salesforce expansion. Although not explicitly stated, we infer from the [latest S1A filing](#) that the initial order from Fisher is for 30 Unyvero units, which we expect could increase as market traction is achieved. For reference, OpGen currently has 35 Unyvero systems installed in the United States versus 165 systems in Europe, highlighting the scope for expansion in the country. We also note that OpGen will continue direct sales to a list of specifically identified target accounts under the Fisher contract.

OpGen has been exclusively working with distribution partners across different geographies (including with Menarini for Europe) but had previously opted to self-commercialize in the United States, prior to the agreement with Fisher.

FIND collaboration extended

[In April 2023](#), OpGen announced the expansion of its initial R&D agreement (signed in September 2022) with FIND (a global non-profit alliance for diagnostics) with an increase in potential revenue to \$913k, or €830k, roughly €130k higher than the initial €700k deal. Under the expanded scope, OpGen will work on three more deliverables as part of the ongoing feasibility stage for the Unyvero A30 RQ platform, in addition to initially laid out objectives. The company is required to develop an Antimicrobial Stewardship module, which can guide users to choose the best treatment, supported by rule-based information and on the basis of drug availability in a hospital. Additionally, it will develop a 'Data everywhere' concept, which will assess the available hardware and software options for remote connectivity in low- and middle-income countries (LMICs), along with next-generation sequencing (NGS) strain analysis using isolates from sub-Saharan African countries to investigate any sequence differences.

In an important development, OpGen [announced](#) that Curetis (its German subsidiary) has successfully met all the key milestones for Unyvero A30 RQ under the initial R&D collaboration with FIND, which triggered a c \$0.4m milestone payment in Q123 to OpGen. While OpGen is working on the next set of deliverables under the expanded scope of the R&D agreement, the successful

completion of the feasibility phase indicates Unyvero's potential adaptability for LMICs. We note that OpGen will receive up to \$180k in pending payment from the FIND collaboration in Q223.

As a next step, OpGen is in discussion with FIND for the follow-up project and potential new contract for the development of an antimicrobial resistance (AMR) test suitable for LMICs. We see the possibility of the agreement expanding to the next phase of development (including clinical studies, followed by regulatory filings and eventual commercialization) with a significantly higher investment from FIND, which could support the top-line growth.

***De novo* application filed for the UTI test panel in the US**

In [April 2023](#), OpGen announced the filing of the *de novo* application for its Unyvero UTI panel, following encouraging data reported from the recently concluded clinical trials. We highlight that the Unyvero UTI panel has been designed to test for a broad range of bacterial and fungal pathogens as well as AMR markers (25 pathogens and 15 resistance genes) directly from native urine specimens (without the need for culturing), resulting in much quicker turnaround times (four to five hours versus days in the case of culture-based tests). OpGen had reported encouraging final data from its clinical studies (assessing >1,800 patient samples), reporting an overall weighted average sensitivity of 96.8% and specificity of 97.4%. If approved, we anticipate OpGen to launch the UTI panel in the United States in 2024, adding another revenue stream for the business. We also expect OpGen's deal with Fisher Healthcare to expand to include commercial sales of the UTI panel. Note that Fisher's parent company, Thermo Fisher, has significant experience and exposure in UTI diagnostics with an in-house UTI franchise (open PCR platform and standard PCR kits), which should be useful when marketing OpGen's UTI test panel.

Q123 financial performance: An improved quarter

OpGen reported Q123 revenues of \$913k, up 94% year-on-year and a 26.6% quarter-on-quarter improvement over Q422 (\$722k). The growth was primarily driven by the c \$400k in milestones payments recognized under the FIND collaboration, revenues from the Acuitas commercial contracts signed in 2022 and Unyvero product sales. In terms of regions, the domestic US market accounted for 12.6% of the revenue, with the rest attributed to international markets, primarily Europe.

Product sales, accounting for 45% of total revenue (\$411k), were up 12.3% y-o-y (+47% q-o-q) due to incremental cartridge and master mix sales. We also believe that the uplift was supported by commencement of revenue inflows from the two signed Acuitas contracts towards the end of 2022. Collaboration revenue was reported at \$481k, almost entirely driven by the over \$400k in milestone payments received under the FIND collaboration (\$61k in Q122). We remind that OpGen had earlier received \$300k in milestone payment from FIND in Q422. Performance for the Lab services business, on the other hand, was comparatively subdued (a decline of 50% y-o-y to \$22k) due to a decrease in COVID-19 testing services performed by subsidiary Curetis. Gross margins were 10pp lower than Q122 (21.1% vs 31.3%), although this difference can be attributed to increases of over \$250k during the quarter in inventory reserves for obsolescence, expirations and slow-moving inventory, which we believe is attributed to delays in clinical and launch-related activities in China.

Total operating loss was reported at \$5.1m in Q123, lower than \$5.8m in FY21, due to lower expenses as management implemented tight cost controls to manage costs and extend the cash runway. R&D expenses declined 21.7% y-o-y to \$1.8m, driven by the conclusion of the Unyvero UTI clinical trial in Q322 as well as lower payroll-related costs. G&A expenses declined by 7.7% year-on-year to \$2.4m, while sales and marketing expenses remained broadly stable at \$1m. The revenue growth and opex savings percolated down to the bottom line, with the reported net loss improving to \$5.7m, from \$6.8m in Q122.

Estimates revision

We make a number of revisions to our estimates to reflect the Q123 results, near-term operational visibility and the post-period co-commercialization deal with Fisher Healthcare. Although not explicitly stated, based on [public disclosures](#) by OpGen, we understand that the initial deal with Fisher Healthcare is for 30 Unyvero systems. While the effective time period for these orders has not been disclosed, for the purpose of our model we assume the initial deal terms to be for three years (typical for a distribution agreement in this space), with 10 Unyvero systems purchased each year between 2023–25. We estimate a transfer price of \$110/cartridge (similar to the deal dynamics OpGen has with Menarini in Europe). We assume another 10 Unyvero systems being placed directly by OpGen during the year, while lowering the anticipated pace for ramp-up in self-commercialization for OpGen in FY24, assuming the company will instead leverage the Fisher Healthcare infrastructure to expand its market reach. Our estimated growth in Unyvero sales following the Fisher deal (\$3.2m in FY23 and \$5.8m in FY24 vs \$3.1m and \$5.6m previously) is, however, offset by our now lower estimates for new Acuitas AMR systems placed during FY23 and FY24 (six and 12 systems, respectively, vs 12 and 22 systems previously) to reflect traction to date. Overall, our FY23 and FY24 estimates for product sales stand slightly lower (\$3.6m and \$6.7m vs \$3.9m and \$7.2m, respectively). For FY23, the lower product sales have been counterbalanced by an increase in our estimate for FIND-driven collaboration revenue (\$0.9m vs \$0.6m previously). Overall, our FY23 revenue estimates remain broadly unchanged at \$4.8m (\$4.7m previously) and within management's guidance of \$4.0–5.0m. Our revised FY24 revenue estimate is \$7.1m, lower than our previous estimate of \$7.9m. We make only minor adjustments to our estimates for operating expenses, keeping R&D expenses broadly unchanged, lowering sales and marketing expenses slightly and increasing G&A marginally. Overall, our operating loss estimates for FY23 and FY24 now stand at \$19.0m and \$18.0m, respectively (vs \$18.8m and \$16.4m previously).

We estimate the FY23 cash burn to be \$18.1m, in line with management's guidance of \$4.5–5.0m in quarterly cash burn during the year. The end-Q123 net debt balance was \$3.3m (gross cash balance of \$7.0m), with the cash position supported by the \$3.5m in gross proceeds raised in the May 2023 equity issue (pro-forma net cash of \$0.2m). Management expects gross cash at hand to be sufficient to fund operations into July 2023 and has [communicated](#) that it would need another \$7.5m in funding to support operations to the end of the year. Note that OpGen has an upcoming debt repayment of €3.0m (\$3.3m) plus accumulated deferred interest due in June 2023 (tranche 2 of the European Investment Bank, EIB, loan). OpGen has indicated that it is in dialog with the EIB to restructure the second debt tranche as well, which we anticipate would take a similar form of monthly payouts, if negotiations are successful.

We estimate that OpGen will need to raise \$25m in FY24 and another \$40m over FY25–27, before turning EBITDA-positive in FY27. We reflect the capital raise as illustrative debt in our model, as per Edison policy. Management has indicated that it will prioritize non-dilutive sources of funding. We note that OpGen has around 10.9m common warrants outstanding (excluding pre-funded warrants), exercisable at \$0.7785/share (vs the current share price of \$0.7), which if converted would net the company \$8.5m in additional proceeds. However, this would be dilutive to existing shareholders.

Valuation

We update our valuation for OpGen to reflect the Q123 performance, the recently signed co-commercialization deal with Fisher Healthcare and our assessment of the business outlook for the company. For Unyvero (ex-China), we increase our probability of the UTI test panel approval to 90% (80% previously) following the recent *de novo* application filed by the company with the US

FDA. We also incorporate the initial deal with Fisher Healthcare, which we believe is for 30 Unyvero systems. While we don't see this as having a major impact on our peak sales projections (\$120.7m vs \$118.3m previously) given that OpGen will likely scale back its own future sales and marketing plans in the United States, the rNPV (\$103m vs \$93m previously) benefits from the lower sales and marketing expenses we now incorporate. For the Acuitas AMR panel, we revise our estimate for peak sales and rNPV to \$10.2m and \$5m, respectively (\$17.3m and \$9m, previously). We keep our projections for China unchanged for now and continue to estimate a 2026 launch, with an 80% probability of success. For Ares Genetics, we update the valuation for the latest carrying value on the company's books. As we gain more clarity and visibility on sales development and traction, we will update our model to reflect the valuation potential. We also highlight that OpGen has fully impaired its carrying value for Unyvero A30 (a portable sample-to-answer benchtop system, designed to test up to 33 diagnostic targets as compared to the currently marketed and more comprehensive Unyvero A50 system with ability to test up to 50 targets) in its latest filings, and we have therefore removed Unyvero A30 from our valuation as of now. We note that the company has generated over \$900k in sales (including \$180k in Q223) from the FIND preclinical collaboration for the A30 systems and recognize the potential upside, provided the collaboration progresses to the clinic.

Our revised valuation stands at \$71.5m (\$66.7m previously) and incorporates the latest pro-forma net cash figure of \$0.2m (\$2.4m in our last update). Our per-share valuation, however, re-adjusts lower to \$11.7/share (from \$12.2/shares) due to the higher number of shares outstanding (6.1m as at 11 May 2023 vs 5.5m previously) following the May 2023 equity raise. Note that the share count does not incorporate the 3.9m pre-funded warrants issued as part of the raise (very likely to eventually be converted to common stock given the \$0.01 exercise price). Incorporating the likely full exercise of these, our fully diluted per-share valuation will reset to \$7.1/share (based on 10.1m shares outstanding). We also note that if our estimated capital requirement to profitability (\$72.5m through FY23–27) were to be funded through equity issuance, this would require OpGen to issue an additional 104m shares (at the current share price of \$0.70/share), which would dilute our per-share valuation to \$0.63/share. This excludes potential conversion and cash inflow from the 10.9m of common warrants outstanding as of date.

Exhibit 1: OpGen's 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	120.7	2040	103.1
	UTI (US)	Clinical	90%	2024			
	IJI (US)	Pre-clinical	50%	2025			
Unyvero - China	HPN	Registration	80%	2026	36.0	2040	18.9
Acuitas AMR Panel	AMR	Market	100%	2022	10.2	2040	5.0
Aresdb (book value)	Bioinformatics	Market					4.1
Others	IJI	Preclinical					1.7
Unallocated R&D costs							(18.3)
G&A costs							(43.2)
Pro-forma net cash (end-March 2023+May 2023 gross equity raise)							0.2
Total firm value							71.5
Total shares outstanding (m)*							6.1
Value per share (\$)							11.7

Source: Edison Investment Research. Note: *Shares outstanding as of 11 May 2023.

Exhibit 2: Financial summary

	\$'000s	2021	2022	2023e	2024e
Year end 31 December		GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS					
Revenue		4,306	2,607	4,771	7,069
Cost of Sales		(2,848)	(3,424)	(2,684)	(4,167)
Gross Profit		1,458	(817)	2,087	2,902
Sales, General and Administrative Expenses		(13,649)	(13,229)	(13,299)	(13,565)
Research and Development Expense		(10,911)	(8,173)	(7,765)	(7,377)
EBITDA		(20,388)	(20,576)	(17,870)	(16,966)
Operating profit (before amort. and excepts.)		(23,102)	(22,219)	(18,976)	(18,039)
Intangible Amortisation		0	0	0	0
Other		0	0	0	0
Exceptionals		(171)	(12,348)	0	0
Operating Profit		(23,273)	(34,567)	(18,976)	(18,039)
Net Interest		(4,754)	(3,209)	(1,777)	(2,751)
Other		(6,735)	493	0	0
Profit Before Tax (norm)		(35,742)	(25,315)	(20,753)	(20,789)
Profit Before Tax (reported)		(34,762)	(37,283)	(20,753)	(20,789)
Tax		(44)	0	0	0
Deferred tax		0	0	0	0
Profit After Tax (norm)		(35,786)	(25,315)	(20,753)	(20,789)
Profit After Tax (reported)		(34,806)	(37,283)	(20,753)	(20,789)
Average Number of Shares Outstanding (m)		1.8	2.4	6.1	10.0
EPS - normalised (\$)		(19.47)	(10.37)	(3.39)	(2.08)
EPS - Reported (\$)		(22.89)	(15.27)	(3.39)	(2.08)
Dividend per share (c)		0.0	0.0	0.0	0.0
Gross Margin (%)		34	-31	44	41
EBITDA Margin (%)		-473	-789	-375	-240
Operating Margin (before GW and except.) (%)		-537	-852	-398	-255
BALANCE SHEET					
Fixed Assets		31,924	15,158	14,665	14,232
Intangible Assets		21,983	7,441	7,025	6,633
Tangible Assets		5,917	4,920	4,844	4,803
Other		4,024	2,796	2,796	2,796
Current Assets		39,743	10,655	3,582	4,855
Stocks		1,239	1,345	1,011	1,592
Debtors		1,172	514	941	1,395
Cash		36,080	7,440	274	512
Other		1,250	1,356	1,356	1,356
Current Liabilities		19,874	10,588	9,100	3,725
Creditors		1,307	421	402	425
Short term borrowings		14,519	7,024	5,300	0
Current lease liabilities		460	378	632	534
Others		3,588	2,766	2,766	2,766
Long Term Liabilities		10,533	7,646	10,890	36,924
Long term borrowings		7,176	4,851	8,637	35,012
Non-current lease liabilities		2,981	2,566	2,024	1,682
Other long term liabilities		375	229	229	229
Net Assets		41,260	7,579	(1,743)	(21,562)
CASH FLOW					
Operating Cash Flow		(21,479)	(20,450)	(18,087)	(18,382)
Net Interest		0	0	0	0
Tax		0	0	0	0
Capex		(1,984)	(591)	(614)	(639)
Acquisitions/disposals		0	0	0	0
Equity Financing		48,159	4,072	10,474	0
Dividends		0	0	0	0
Other		(266)	0	0	0
Net Cash Flow		24,430	(16,968)	(8,227)	(19,021)
Opening net debt/(cash)		6,717	(14,385)	4,435	13,663
HP finance leases initiated		0	0	0	0
Exchange rate movements		(5)	(13)	(4)	6
Other		-3,322	-1,838	-998	-1,821
Closing net debt/(cash)		(14,385)	4,435	13,663	34,500

Source: Company reports, Edison Investment Research

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