EDISON

OpGen

Financial update

An increased focus on Unyvero

Pharma & biotech

OpGen Q320 sales were $1.1m, up 63% from Q319, thanks to the merger with Curetis. The company announced that it will be increasing its focus on the Unyvero platform, partly due to its level of automation and ease-of-use and partly due to the desire to improve the company's operating efficiency. In light of this, OpGen has decided to discontinue the legacy FISH products business as of mid-2021 and also to discontinue the Acuitas AMR Gene Panel clinical trial in urine samples for complicated urinary tract infections (cUTI). The company plans to initiate a clinical trial program for cUTI with the Unyvero platform in mid-2021, expanding into invasive joint infections (IJI) in the US later in that year.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/18	2.9	(13.4)	(44.45)	0.0	N/A	N/A
12/19	3.5	(11.9)	(7.38)	0.0	N/A	N/A
12/20e	3.9	(25.7)	(1.62)	0.0	N/A	N/A
12/21e	10.5	(24.7)	(1.21)	0.0	N/A	N/A

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

Leading IVD partner exercises option on ARESdb

In Q320, OpGen completed an R&D and option agreement for ARESdb with an unnamed leading in vitro diagnostic (IVD) corporation. That partner in October exercised its option to negotiate an exclusive license agreement. The size and scope of the agreement are being negotiated but may include an upfront license or technology fee, R&D funding as well as milestone and royalty payments.

Bacterial isolates 510(k) clearance update

OpGen filed for 510(k) clearance of its Acuitas AMR Gene Panel test in bacterial isolates with the FDA in Q219. The process appears to be nearing completion, with the company submitting a formal response to additional FDA information requests in October 2020. The company believes it has addressed all of the FDA's requests for additional information with timing of clearance unknown, as the agency prioritizes emergency use authorizations related to the COVID-19 pandemic for at least the remainder of the year.

Platform consolidation

With the announced platform consolidation to increase the focus on the Unyvero product line, the company expects to realize significant operational synergies from regulatory, quality management, logistic and service standpoints.

Valuation: $59.1m or $2.93 per share

We have decreased our valuation from $68.4m or $3.47 per basic share to $59.1m or $2.93 per share. The decrease is mainly due to higher net debt, the elimination of the legacy FISH business and a higher number of shares outstanding. The company had $10.5m in gross cash at the end of Q320 and added an additional $0.8m through an at-the-market (ATM) offering after the end of the quarter.

19 November 2020

Price	**US$1.97**
Market cap	**US$40m**

Net debt ($m) at 30 September 2020 plus ATM offering	8.1
Shares in issue	20.2m
Free float	96.6%
Code	OPGN
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(16.9)	(4.8)	78.3
Rel (local)	(18.8)	(9.6)	56.0

52-week high/low	US$4.0	US$1.0

Business description

OpGen is a diagnostic company focused on revolutionizing the identification and treatment of bacterial infections. Following the merger 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	2020/21
ARESdb exclusive partnership	2021

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Q320 results

OpGen reported revenue of $1.1m for Q320, up 63% compared to $0.6m reported in the same quarter last year mainly due to the inclusion of Curetis products. Product sales were up 5% to $0.6m while collaboration revenue was up 356% to $0.3m, mainly due to Ares Genetics and its partnership with a global IVD corporation. Laboratory services revenue was $0.1m.

R&D expenses increased from $1.1m in Q319 to $2.4m, while SG&A expenses were up from $2.0m to $3.3m. OpGen's Q320 operating loss was $6.2m (vs $6.5m in Q220 and $3.4m in Q319) and the post-tax loss was $7.7m, up from $3.5m in the same quarter last year.

The company announced in October that it will be increasing its focus on the Unyvero platform. In light of this focus, OpGen has decided to discontinue the legacy FISH products business as of mid-2021 and also to discontinue the Acuitas AMR Gene Panel clinical trial in urine samples for cUTI. The company plans to initiate a clinical trial program for cUTI with the Unyvero platform in mid-2021, expanding into IJI in the US later in that year (the Unyvero system has already received FDA clearance for lower respiratory tract infections/pneumonia in the US). Besides providing users with an improved experience due to Unyvero's level of automation and ease of use, the company expects to realize significant operational synergies from regulatory, quality management, logistic and service standpoints from having fewer platforms.

The 510(k) clearance process for the Acuitas AMR Gene Panel test in bacterial isolates is ongoing. The company submitted a formal response to additional FDA information requests in October 2020. The company believes it has addressed all of the FDA's requests for additional information, with the timing of clearance unknown as the agency prioritizes emergency use authorizations related to the COVID-19 pandemic for at least the remainder of the year. OpGen expects to launch the product very shortly after receiving clearance from the FDA.

With regards to China, where OpGen is partnered with Beijing Clear Biotech, there continues to be progress towards approval for the Unyvero system, which the company currently expects to occur in 2021. The current agreement with Beijing Clear Biotech includes 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 National Medical Products Administration (NMPA). Based upon 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.

Subsidiary Ares Genetics also continues to make progress. OpGen in Q320 completed an R&D and option agreement for ARESdb with an unnamed leading global IVD corporation. That partner in October exercised its option to exclusively negotiate a potential exclusive license agreement for human clinical diagnostic use. The size and scope of the agreement are being negotiated but may include an upfront license or technology fee, R&D funding as well as milestone and royalty payments.

Valuation

We have decreased our valuation from $68.4m or $3.47 per basic share to $59.1m or $2.93 per share. The decrease is mainly due to higher net debt, the elimination of the legacy FISH business and a higher number of shares outstanding.

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%	67.2
Total								67.2
Pro forma net cash/(debt) (Q320 plus ATM)								(8.1)
Total firm value								59.1
Total basic shares (m)								20.2
Value per basic share ($)								2.93
Options (m)								2.2
Total number of shares (m)								22.4
Diluted value per share ($)								2.64

Source: Edison Investment Research

Financials

Our FY20 revenue estimate has decreased from $4.6m to $3.9m, due to a lower run rate in the quarter. Additionally, we have lowered our FY21 revenue estimate from $12.5m to $10.5m primarily due to the elimination of the FISH business in the middle of the year. We have also made changes to our operating expense estimates. We have decreased our SG&A estimate by $0.6m for FY20 and by $2.1m for FY21 due to continued expense controls in this area. We have decreased our R&D estimate by $1.1m for FY20 in part because of the discontinuation of the Acuitas AMR Gene Panel trial in urine, however we have increased our FY21 R&D estimate by $2.0m due to the clinical trial costs associated with Unyvero in cUTI and IJI infections.

The company had $10.5m in gross cash at the end of Q320 and added an additional $0.8m through an ATM offering after the end of the quarter. There is also $18.2m in Q320 debt on the balance sheet and $1.2m in short-term debt. We model an additional financing need of $36.6m ($32.4m previously) in total through to profitability in FY23 (including $6.6m through the end of FY20 and an additional $13.5m in FY21, though we believe the company has enough runway to wait until FY21 to raise additional capital). As per our policy, we assume future financings are to be funded with illustrative debt.

Exhibit 2: Financial summary

$'000s	2018	2019	2020e	2021e
Year end 31 December	GAAP	GAAP	GAAP	GAAP
PROFIT & LOSS				
Revenue	2,946	3,499	3,866	10,497
Cost of Sales	(1,848)	(1,632)	(3,459)	(5,511)
Gross Profit	1,098	1,867	407	4,986
Sales, General and Administrative Expenses	(8,601)	(8,496)	(12,601)	(13,861)
Research and Development Expense	(5,677)	(5,121)	(10,130)	(12,359)
EBITDA	(13,180)	(11,741)	(22,324)	(21,234)
Operating Profit (before amort. and except.)	(13,180)	(11,741)	(22,324)	(21,234)
Intangible Amortisation	0	0	0	0
Other	0	10	0	0
Exceptionals	0	(521)	(751)	0
Operating Profit	(13,180)	(12,261)	(23,074)	(21,234)
Net Interest	(186)	(188)	(3,349)	(3,483)
Other	(2)	2	(247)	0
Profit Before Tax (norm)	(13,366)	(11,928)	(25,673)	(24,717)
Profit Before Tax (FRS 3)	(13,368)	(12,446)	(26,671)	(24,717)
Tax	0	0	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(13,366)	(11,928)	(25,673)	(24,717)
Profit After Tax (FRS 3)	(13,368)	(12,446)	(26,671)	(24,717)
Average Number of Shares Outstanding (m)	0.3	1.6	15.5	20.4
EPS - normalised ($)	(44.45)	(7.38)	(1.62)	(1.21)
EPS - Reported ($)	(44.49)	(7.70)	(1.72)	(1.21)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	3,167	3,755	29,601	31,390
Intangible Assets	1,686	1,418	23,988	25,809
Tangible Assets	1,222	2,133	5,312	5,280
Other	259	203	301	301
Current Assets	5,783	6,667	14,735	4,666
Stocks	544	473	2,975	2,975
Debtors	374	568	423	445
Cash	4,572	2,708	11,337	1,246
Other	293	2,918	0	0
Current Liabilities	(4,381)	(4,939)	(9,415)	(8,258)
Creditors	(3,983)	(4,565)	(8,258)	(8,258)
Short term borrowings	(399)	(374)	(1,157)	0
Long Term Liabilities	(1,260)	(1,190)	(25,648)	(40,234)
Long term borrowings	(660)	(329)	(24,788)	(39,288)
Other long term liabilities	(600)	(860)	(860)	(946)
Net Assets	3,309	4,293	9,274	(12,437)
CASH FLOW				
Operating Cash Flow	(11,074)	(11,505)	(23,277)	(22,115)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(137)	(32)	(13)	(14)
Acquisitions/disposals	0	0	1,267	0
Financing	14,128	13,062	24,421	0
Dividends	0	0	0	0
Other	(293)	(3,836)	0	0
Net Cash Flow	2,624	(2,310)	2,397	(22,129)
Opening net debt/(cash)	(836)	(3,514)	(2,005)	14,608
HP finance leases initiated	0	0	0	0
Exchange rate movements	(13)	4	(1,067)	0
Other	66	798	-17943	-1305
Closing net debt/(cash)	(3,514)	(2,005)	14,608	38,042

Source: Company reports, Edison Investment Research

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