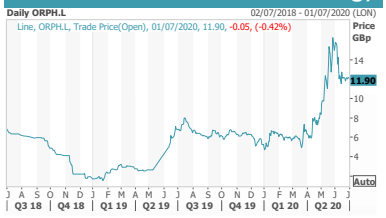
Pharmaceuticals & Biotechnology



Source: Refinitiv

Market data

EPIC/TKR	**ORPH**
Price (p)	**12.0**
12m High (p)	16.0
12m Low (p)	4.6
Shares (m)	663.9
Mkt Cap (£m)	79.7
EV (£m)	17.0
Free Float*	62.7
Market	93%

**As defined by AIM Rule 26*

Description

Open Orphan (ORPH) is a rapidly growing specialist CRO pharmaceutical services company, which is a world leader in the testing of vaccines and anti-virals through the use of human challenge study models. ORPH is comprised of two specialist CRO services businesses; hVIVO and Venn Life Sciences and has offices in London, Dublin, Paris, and the Netherlands.

Company information

Exec. Chairman	Cathal Friel
CEO	-
CFO	Leo Toole

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www.openorphan.com

Key shareholders

Chairman	6.9%
Invesco	7.9%

Diary

Sep'20	Interim results

Analyst

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OPEN ORPHAN

Poised for profitability

ORPH has developed into a specialist pharmaceutical services group through the acquisitions of Venn Life Sciences (Venn LS) and hVIVO, to become a world leader in the testing of vaccines and anti-virals. The original strategy was to build a company generating sales of €40m-€50m within two years, which it looks set to achieve. The enlarged entity has a broad and complementary portfolio of services for its pharmaceutical customers and is on the cusp of reaching profitability. Cost savings and new contract wins should see ORPH turn profitable by the end of fiscal 2020. COVID-19 has brought an unexpected opportunity for the company.

- **Strategy:** ORPH is a contract research organisation (CRO) offering specialist challenge tests to pharmaceutical/biotech companies for the development, among others, of new vaccines and anti-viral drugs. This positions it well for the emerging virus risk management stemming from the COVID-19 pandemic event.

- **Acquisitions:** The past 12 months have seen significant change, with the reverse merger into Venn (June 2019), followed by the acquisition of hVIVO, to create a broad and complementary offering to its enlarged customer base. Its 24-bed quarantine facility is best-in-class for vaccine and virus-related development.

- **Funded to profitability:** Both its challenge study activities and laboratory services divisions are close to covering the fixed and variable costs, i.e. on the cusp of breakeven, which is being accelerated through cost savings and new contracts. The recent funding (€14m) has provided the necessary working capital.

- **Risks:** OPRH is a fast-growing company with an ambitious management team. Despite the significant activities of the past 12 months, the company is likely to take further opportunities should they arise in the fragmented European CRO market. These are likely to require further share issues.

- **Investment summary:** ORPH has made great strides to deliver on its inorganic growth strategy to develop profitable CRO with a broad service offering. Forecasts reflect the expectations for the enlarged entity, but do not include anything for the COVID-19 challenge model opportunity, which could be substantial. Despite this, ORPH is set to report good profits in fiscal 2021.

Financial summary and valuation

Year-end Dec (€m)	ORPH 2019	Venn LS 2019	hVIVO 2019	*Pro forma* 2019	2020E	2021E
Sales	3.84	15.09	8.45	25.66	32.00	45.00
COGS	-	-	-	-21.50	-22.00	-27.00
Operating costs	-9.07	-	-	-13.99	-12.70	-11.50
EBITDA	-4.43	-5.05	-3.79	-10.13	-0.80	8.32
Underlying EBIT	-5.15	-6.47	-5.89	-14.25	-3.00	6.20
Reported EBIT	-6.22	-	-6.87	-16.30	-3.00	6.20
Underlying PBT	-5.55	-	-5.99	-14.47	-3.09	7.10
Statutory PBT	-6.62	-	-6.97	-16.52	-3.09	7.10
Underlying EPS (¢)	-3.31	-	-	-2.72	-0.52	1.07
Statutory EPS (¢)	-3.96	-	-	-3.10	-0.52	1.07
Net cash/(debt)	-2.46	-	-	-0.18	15.91	21.92
Equity issues	5.36	-	-	5.36	20.40	0.00

Source: Hardman & Co Life Sciences Research

Company overview

Background

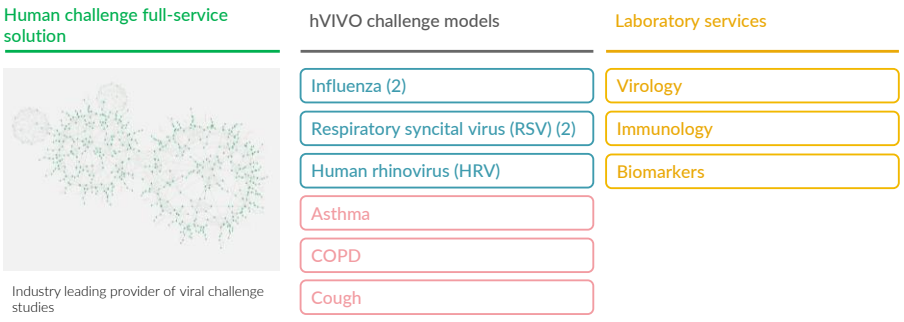
ORPH was incorporated in the Republic of Ireland on 18 July 2017 with a strategy and product offering to develop a market-leading services platform for drug companies seeking to commercialise their products across Europe with a particular focus on drugs to treat rare diseases. It offered data platforms that could match the needs of 500 pharmaceutical/biotech companies worldwide with about 4,000 physicians and key opinion leaders in Europe focused on orphan drugs.

In Europe, the services market for orphan drugs was, and still is, highly fragmented. A large number of small-scale consultancies existed because of a dysfunctional regulatory system in Europe where, despite an EU-wide regulator, reimbursement needs to be negotiated on a country-by-country basis. ORPH's strategy was to build upon its existing capability and expertise to become a full-service consultancy for orphan and other speciality healthcare products through a focused acquisition strategy.

In May 2019, as part of this acquisition strategy, ORPH reversed into Venn Life Sciences, an experienced CRO with established contacts and contracts with several pharmaceutical companies, in a share swap that valued the companies at £4.0m and £5.7m, respectively.

This was followed in January 2020 with the all-share acquisition of hVIVO, a specialist in "challenge" studies to test the efficacy of vaccines and anti-viral drugs. hVIVO possessed a proprietary portfolio of eight challenge study models, which was a complementary and novel addition to ORPH's offering. To put this in perspective, hVIVO had only two competitors worldwide, each with only one challenge model. hVIVO was a spin-out for Queen Mary University of London (QMUL) and the share swap valued the company at £13.0m.

hVIVO services



Source: Open Orphan

In order to fund its organic and inorganic growth strategy, ORPH has undertaken a number of capital increases over and above the shares issued as part of any acquisition.

Recent funding history

Date	Activity	Gross £m	Net £m
19 Jun 2019	Placing of shares @ 5.6p	4.5	3.6
31 Jan 2020	Placing and Subscription of shares @ 6.1p	5.3	5.0
26 May 2020	Placing and Subscription of shares @ 11.0p	12.6	12.0
Total to date		**22.4**	**20.6**

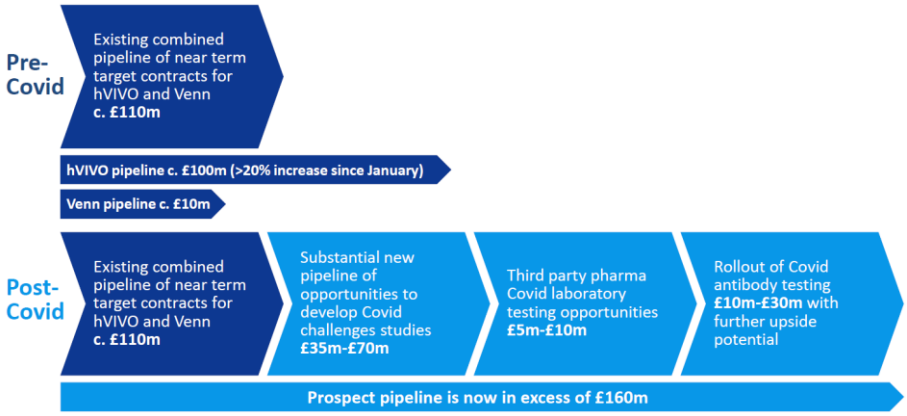
Source: Hardman & Co Life Sciences Research

Opportunity

Following acquisition, management strategy is to integrate the businesses as quickly as possible, reduce the cost base, expand the portfolio of CRO services on offer to customers and to convert the pipeline of prospects into signed contracts. Today, OPRH is a niche, rapid-growth CRO business that is on the cusp of profitability – expected from 3Q'20.

The challenge study models on offer from ORPH can potentially speed up vaccine development and approval by 2-3 years by testing the efficacy on human volunteers over a short period of time in a controlled environment – quarantine clinic. Therefore, the COVID-19 pandemic has provided an incredible opportunity for the group. ORPH is very well positioned to assist with the global need, and level of development activity, with respect to a COVID-19 vaccine. The latest funding round was made to advance the development of the world's first seasonal coronavirus and COVID-19 challenge study models.

Prospect pipeline



Source: Open Orphan

News flow

The benefits of an enlarged group have been clear from a number of recent contract wins, highlighting the cross-selling activities, as illustrated in the following chart taken from a recent investor presentation. In addition to this, the company has formally launched (4 June) its COVID-19 antibody testing service – hVIVO COVID Clear Test – aimed at large employer groups and channel partners, including GP networks, nursing services, health clinics and private hospitals.

Current trading and contract wins

- hVIVO strong pipeline results to build H2 2020 revenue forecast and to build momentum for 2021
- hVIVO recent contract wins: 6th of March £3.2m RSV study, with £7m follow-on study, 4th of May £3.5m RSV study
- Venn trading in line with last year despite Covid risks while managing cost reduction and office closures
- Q1 2020 €2.5m in recent contract wins with tier-1 pharma inc. J&J, Roche, Servier, and Ipsen
- Other contract wins inc. Boehringer Ingelheim, SFA Therapeutics, Carna BioScience etc.

Source: Open Orphan

Financial summary

- ORPH has just published its results for 2019, but this covers the stub of the old Open Orphan DAC and Venn Life Sciences from the merger on 28 June 2019.
- The annual report provides a summary of the 2019 performance for these groups on a standalone basis, together with a summary of hVIVO's results.
- ***Pro forma:*** The group will look very different going forward. Therefore, a *pro forma*, where possible, of the enlarged entity has been provided so that a comparison with forecasts is more meaningful.
- **Net cash/(debt):** On a *pro forma* basis, the combined entity had net debt of -€0.18m, comprised of gross cash of €3.5m, less loans and leases of -€3.68m. This has been boosted by two capital increases, totalling gross new capital of €19.0m.
- **Forecasts:** Based on our assumptions, the company looks set to make a modest loss in fiscal 2020 and then move into profit and become cash-generative in fiscal 2021, as the enlarged group eliminates duplication of costs and benefits from synergies for customers emerging from the complementary service offering.

Financial summary

Year-end Dec (€m)	ORPH 2019	Venn LS 2019	hVIVO 2019	*Pro forma* 2019	2020E	2021E
Profit & Loss						
Sales	3.84	15.09	8.45	25.66	32.00	45.00
COGS	-	-	-	-21.50	-22.00	-27.00
Operating costs	-9.07			-13.99	-12.70	-11.50
Share-based costs	-0.12			-0.30	-0.30	-0.30
EBITDA	-4.43		-3.79	-10.13	0.00	0.00
Other income (grants etc.)	0.20		1.28	1.47	0.00	0.00
Underlying EBIT	**-5.15**		**-5.89**	**-14.25**	**-3.00**	**6.20**
Exceptional items	-1.07		-0.98	-2.05	0.00	0.00
Statutory EBIT	-6.22		-6.87	-16.30	-3.00	6.20
Net financials	-0.40		-0.10	-0.22	-0.09	0.90
Underlying PBT	**-5.55**		**-5.99**	**-14.47**	**-3.09**	**7.10**
Statutory PBT	0.08				0.00	0.00
Tax liability/credit	0.08				0.00	0.00
Underlying net income	-5.47				-3.09	7.10
Underlying basic EPS (¢)	**-3.31**			**-2.72**	**-0.52**	**1.07**
Statutory basic EPS (¢)	-3.96			-3.10	-0.52	1.07
Balance sheet						
Share capital	0.37			0.53	0.66	0.66
Reserves	2.98			13.50	28.58	35.68
Leases	1.68		0.00	1.68		
Loans & borrowings	2.00		0.00	2.00	2.00	2.00
less: Cash & deposits	1.22		2.28	3.50	18.49	24.50
Invested capital	**5.86**			**14.27**	**14.48**	**15.57**
Cashflow						
Underlying EBIT	-5.15				-3.00	6.20
Change in working capital	1.44				-1.00	-1.48
Company op. cashflow	**-2.88**				**-1.50**	**7.13**
Capital expenditure	-0.03				-0.50	-0.50
Equity issues	5.36				19.00	0.00
Change in net debt	**1.95**				**14.99**	**6.01**
Opening net cash	-4.41				-2.46	14.81
Closing net cash	**-2.46**				**14.81**	**20.82**

Source: Hardman & Co Life Sciences Research

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