

8 September 2022

Open Orphan plc ("Open Orphan" or the "Group")

Interim results and Trading Update

Continued profitability and double-digit EBITDA margin achieved

Open Orphan plc (AIM: ORPH), (to be renamed hVIVO plc (AIM: HVO) effective 26 October 2022), a rapidly growing specialist contract research organisation (CRO) and the world leader in testing infectious and respiratory disease vaccines and antivirals using human challenge clinical trials, announces its unaudited interim results for the six months ended 30 June 2022.

Financial highlights

- Revenue of £18.9m (H1 2021: £23.2m), with a strong order book for delivery in H2 2022
 - Management reiterates full year revenue guidance of c. £50m, underpinned by robust trading in July and August and record contracted order book increased nearly threefold to c. £70m as at 30 June 2022 (H1 2021: £25m)
- EBITDA growth of c.10% to £2.3m (H1 2021: £2.1m) with significantly increased EBITDA margins of 12.1% (H1 2021: 8.9%)
- Cash generative with cash equivalents of £15.9m (H1 2021: £14.9m) as at 30 June 2022

Operational highlights

- Agreement with Vaxart Inc. to develop an Omicron COVID-19 human challenge model with the intent to conduct a subsequent Omicron human challenge study in 2023
- Commenced first full-service influenza challenge model programme for a top five global pharmaceutical client (£14.7m contract)
- Other significant contract wins include £7.3m influenza challenge trial signed with a European biotech, £7.2m respiratory syncytial virus ("RSV") human challenge study with top five global pharma company and £5m RSV challenge trial signed with a European Biotech
- Modest investment in hVIVO's facilities enabled the Group to significantly expand screening capacity:
 - Doubled volunteer screening capacity to 1,000 per week
 - Opened a new primary FluCamp volunteer recruitment facility in Whitechapel, increasing bed capacity by 44% from 43 beds to 62 beds
 - o Opened a new Manchester volunteer recruitment and screening centre
 - hVIVO's primary lab at QMB expanded and new satellite lab facilities were added in the new screening sites in Whitechapel (East London) and Manchester
- Broadened the scope of the business to offer Phase II / III field based studies
 - First contract awarded by existing Big Pharma client to act as a vaccination site for a Phase II field study
- Launched a new Malaria human challenge model to offer anti-parasite challenge models
- Yamin 'Mo' Khan appointed Chief Executive Officer in February 2022, strengthening Executive Management
 Team and bringing significant CRO experience
- Martin Gouldstone appointed Independent Non-Executive Director, adding strong corporate development experience in the CRO, healthcare and pharmaceutical sectors

Post-period end highlights

- £10.4m contract for a new full-service challenge model development programme with an existing top 5 global pharmaceutical client
- £6.2m Influenza human challenge study contract with US biotechnology company Cocrystal Pharma Inc.
- hVIVO's laboratory received College of American Pathologists ("CAP") accreditation increasing its marketability to provide third party laboratory services
- Revenue for July and August of c.£9m with cash balance of c. £20m as at 1 September 2022

As announced this morning, the Group intends to change its name to hVIVO plc, which it expects to take
effect on the AIM market of the London Stock Exchange and the Euronext Growth Exchange on 26 October
2022

Current trading and outlook

As at 1 September 2022, Open Orphan's order book of signed contracts has increased further to c. £80m, which is expected to be recognised across 2022, 2023 and 2024, and remains well capitalised with a cash balance of c.£20m.

Over the period, Open Orphan has further grown its pipeline of new opportunities, with a number of advanced negotiations ongoing with new and existing clients across the Group's world leading portfolio of human challenge models. This growth is being driven by the Group's competitive position as market leader coupled with the increasing demand for human challenge services in the rapidly expanding infectious and respiratory disease clinical trials market.

Management is committed to the long-term growth of the Group and is focused on strengthening its position as a partner of choice to the global biopharma industry, to which it counts four of the top 10 global biopharma companies as regular repeat clients. To further drive future growth, the Group has expanded and diversified its offering, and is currently adding new challenge models to its portfolio such as Omicron and a new influenza strain. In addition, hVIVO has expanded its screening facilities, adding new lab and clinical services. Furthermore, Venn has expanded its service offering into new areas including Advanced Therapy Medicinal Products services (ATMP) as it continues to deliver its services to a wider range of clients.

These developments, in addition to an exceptionally strong start to H2 2022, reaffirm the Board's confidence of meeting current expectations for FY2022. The Group remains well positioned and well capitalised to deliver sustainable long-term profitability targeting double digit EBITDA profit margins of between 13–15%.

Yamin 'Mo' Khan, Chief Executive Officer of Open Orphan, said: "I am pleased to report that the Group has leveraged the strong foundations laid in 2021, continuing its profitable momentum into 2022. Importantly, the Group achieved double digit EBITDA profit margins for the first time, a key goal for the business following the first full year of EBITDA profitability last year. In the second half, we expect revenues to grow considerably and profit margins to increase further as a number of significant contracts signed earlier in the year enter the clinic.

"Going forward, I am highly encouraged by the Group's market-leading position, expanding addressable markets, and very substantial order book. With an order book of signed contracts worth c. £80m as at 1 September 2022, we have excellent forward visibility into H2 2022 and 2023, which gives us confidence in our ability to sustain our considerable organic growth over the long term. The Board expects to deliver full year revenues in line with guidance, and we look forward to the rest of 2022 and beyond with confidence."

Investor presentation

Yamin 'Mo' Khan, Chief Executive Officer, and Leo Toole, Chief Financial Officer, will provide a live presentation relating to the interim results via the Investor Meet Company platform on 8 September 2022 at 18:00 BST.

The presentation is open to all existing and potential shareholders. Investors can sign up to Investor Meet Company for free and add to meet Open Orphan here.

Interested in becoming a volunteer?

hVIVO recruits many of its volunteers for its challenge study clinical trials through its dedicated volunteer recruitment website, www.flucamp.com. By volunteering to take part in one of our studies in a safe, controlled, clinical environment under expertly supervised conditions you are playing your part to further medical research and help increase the understanding of respiratory illnesses.

For further information please contact:

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Notes to Editors

Open Orphan plc

Open Orphan plc (London and Euronext: ORPH) is changing its name to hVIVO plc (AIM and Euronext: HVO), which is expected to take effect on the AIM market of the London Stock Exchange and the Euronext Growth Exchange market on 26 October 2022.

hVIVO is a rapidly growing contract research company that is a world leader in testing infectious and respiratory disease products using human challenge clinical trials. The Company provides services to Big Pharma, biotech, and government/public health organisations.

The Company has a leading portfolio of human challenge study models for infectious and respiratory diseases, including the recently established COVID-19 model, and is developing a number of new models, such as Malaria, to address the dramatic growth of the global infectious disease market. The Paris and Breda offices have over 25 years of experience providing drug development services such as biometry, data management, statistics CMC, PK and medical writing to third party clients as well as supporting the London-based challenge studies.

hVIVO runs challenge studies in London from its Whitechapel quarantine clinic, its state-of-the-art QMB clinic with its highly specialised on-site virology and immunology laboratory, and its newly opened clinic in Plumbers Row. To recruit volunteers / patients for its studies, the Company leverages its unique clinical trial recruitment capacity via its FluCamp volunteer screening facilities in London and Manchester. The newly opened facilities have expanded the scope of the business to enable the offering of Phase I and Phase II vaccine field trials, PK studies, bridging studies, and patient trials as part of large international multi-centre studies.

CEO Statement

Introduction

I am delighted with the progress the Group has made since my appointment as CEO earlier this year. During the period, we have made significant strides, building on the strong foundations laid in 2021, enabling the delivery of long term revenue growth and sustainable profitability.

Sustainable growth in profitability

The Group has continued its momentum following our first full year of profitability in 2021. Increased operational productivity and efficiency has contributed to an improved EBITDA margin of 12.1% (2021: 8.9%) during the first half of 2021. In H2, we expect to see further utilisation and productivity gains, with the Group targeting double digit EBITDA margin of between 13-15% for the full year.

The Group delivered £18.9m of revenue in H1 (2021: £23.2m). We remain very confident of achieving our target of c. £50m revenue for FY 2022, supported by our record contracted order book of c. £80m as at 1 September 2022 and our increased operational capacity.

The Group is very well capitalised with £15.9m cash as at 30 June 2022 (2021: £14.9m) and net cash post period end of c. £20m as at 1 September 2022. As a result, the Group is well positioned to deliver future growth.

Customer delivery

The Group is a trusted partner to the global biopharma industry, with world-class capabilities in challenge agent manufacture, a unique portfolio of human challenge models, and specialist drug development and clinical consultancy services. The Group has an extensive range of Big Pharma and biotech clients, many of which are repeat, multi-year customers.

hVIVO signed five significant contracts in the period, across RSV, influenza, and COVID-19, with the revenues from these contracts set to be recognised across H2 2022 and FY 2023, further contributing to our robust contracted order book, which stands at c. £80m as at 1 September 2022.

Biopharma companies are increasingly seeing the significant benefits of the early human efficacy data that can be generated from human challenge studies. In H1 2022, two of our clients obtained Breakthrough Therapy designation from the US Food and Drug Administration ("FDA") because of the successful clinical data achieved from hVIVO challenge trials.

In March, we expanded our hVIVO facilities, including doubling our FluCamp volunteer screening capacity and increasing our number of beds. This allowed us to expand the scope of the business to offer additional services including clinical field trial services. The increased volunteer recruitment capacity enables the Group to recruit larger cohorts more quickly, cementing our position as a leader in volunteer recruitment. We now also have the potential to utilise volunteers who are not suitable for challenge trials into non-challenge trials.

Our primary hVIVO lab at QMB has been expanded and new satellite lab facilities have been added in our new screening sites in Plumbers Row (East London) and Manchester. In addition, we received College of American Pathologists ("CAP") accreditation, increasing hLAB's marketability to provide third party laboratory services including virology, immunology biomarker and molecular testing. This is the first step towards expanding our standalone lab services business, under the hLAB brand and will be an additional revenue driver for the Group.

Outlook

We look forward to building on the excellent progress that we have made during H1, as we deliver on our core business for our clients whilst also leveraging our newly diversified offering.

Increased revenues and profit margins

Increased recruitment capacity and new revenues streams in conjunction with our record order book of future contracted revenue underpin our confidence in achieving our current expectations for FY2022, with continued growth in FY 2023. This is further demonstrated by strong trading performance with revenues of c. £9m across July and August 2022.

The investment in our facilities expansion has further enhanced and diversified our revenue potential. We signed our first contract under our expanded services in May 2022, acting as a vaccination site for a Phase II field study for an existing Big Pharma client's RSV vaccine candidate. The work associated with our expanded offering can be performed by utilising our existing staff and infrastructure. For future contracts that may involve the sourcing of volunteers, we will also be able to leverage our FluCamp database of volunteers that were previously found to be unsuitable for challenge studies, generating additional high-margin revenue streams for the Group.

Challenge models

We expect our influenza and RSV challenge models to continue to be the key revenue drivers for the core business. However, we are seeing increased interest across the entire spectrum of infectious and respiratory disease, driving our pipeline to record levels.

We signed our largest commercial challenge programme contract with an existing top five global pharmaceutical client earlier this year, worth £14.7m. This includes the manufacture of an influenza subvariant challenge agent, and a subsequent characterisation study and challenge trial. Furthermore, we recently signed a £10.4m contract with another repeat top 5 global pharmaceutical client to manufacture a new influenza challenge virus, leveraging an existing in-house generated challenge model. The Group will subsequently conduct a human challenge trial to test the client's antiviral product. These full-service contracts are significant growth drivers for the Group.

In June 2022, we announced the development of the world's first Omicron human challenge model and we remain on track to complete the challenge agent manufacture. Following manufacture, we intend to conduct a characterisation study followed by Omicron human challenge studies in 2023.

We continue to see significant interest in our HRV-asthma model as we look to increase our penetration in the respiratory market. Furthermore, the launch of our malaria model is attracting substantial interest and we are in line to conduct our first anti-parasitic study in the near future.

Venn Life Sciences

Our Venn Life Sciences teams in Paris and Breda continue to deliver exceptional drug development consultancy services enabling its clients to bring their products to the market quickly and efficiently. Venn is a trusted partner to an extensive range of clients, and our highly skilled scientific team have helped nurture several long-term client relationships.

Venn's offering is highly synergistic with hVIVO, with preclinical work leading to follow-on clinical programmes providing an end-to-end early clinical development service. This was illustrated by the £5m RSV human challenge study contract signed in March 2022 with a European biotech, resulting from pre-clinical work completed by the Venn Breda team.

Order book and pipeline

Our contracted order book has increased to record size, growing threefold to c. £70m at 30 June 2022 (H1 2021: £25m), and growing further to c. £80m as at 1 September 2022. This gives us clear visibility over our revenues until the end of FY 2023 and beyond. I have been delighted with our ability to secure these contracts showcasing the value that our Big Pharma and biotech clients attribute to conducting a challenge trial.

Name Change

The Group has announced its intention to change its name to hVIVO plc, which is expected to take effect on the AIM market of the London Stock Exchange and the Euronext market on 26 October 2022. The Board believes that the name change better reflects the Group's core human challenge and early clinical services business, where the hVIVO name has strong brand recognition, as well as aligning the Group more closely with its long and established heritage.

Summary

We are committed to the long-term growth of the Group and are focused on strengthening our position as the partner of choice to the global biopharma industry. I am delighted with the progress that we have made in H1 2022. The team has made great strides in winning significant new contracts, realising efficiencies to improve profitability, and expanding our facilities to address the increased demand for our services. Our newly diversified offering and upgraded operational infrastructure, coupled with the surging interest in human challenge trials and the wider growth of the infectious disease clinical trial market, means we are well placed to deliver on and continue to grow our order book and leverage new opportunities. I am excited by what the future holds for the Group and our ability to deliver long term sustainable growth.

Yamin 'Mo' Khan Chief Executive Officer

8 September 2022

Consolidated Statement of Comprehensive Income For the six months ended 30 June 2022

		6 Months	6 Months	Year
		ended	ended	ended
		30 June 2022	30 June 2021	31 Dec
		Unaudited	Unaudited	2021
				Audited
	Note	£'000	£'000	£'000
Operations				
Revenue, from contracts with customers		18,010	21,946	36,864
Other operating income		861	1,220	2,141
Direct project and administrative costs		(16,581)	(21,093)	(36,117)
EBITDA before exceptional items		2,290	2,073	2,888
Depreciation and amortisation		(1,436)	(1,409)	(2,565)
Exceptional items		(186)	965	267
Operating Profit		668	1,629	590
Finance		(172)	(111)	
expense				(215)
Share based payment charge	7	(18)	-	(27)
Share of loss of associate using equity method	5	(25)	(64)	(71)
Profit before income tax		453	1,454	277
Income tax (charge)		(176)	(187)	(351)
Profit/(Loss) for the period		277	1,267	(74)
Profit/(Loss) for the year is attributable				
to:				
Owners of the		277	1,267	
parent				(74)
Other comprehensive income				
Currency translation differences		(173)	(336)	(111)
Total comprehensive profit/(loss) for the period		104	931	(185)

Earnings per share from operations attributable to the owners of the parent during the period

Basic and diluted Profit/(loss) per Note ordinary share

From operations	3	0.04p	0.19p	(0.01p)
For the period		0.04p	0.19p	(0.01p)

Consolidated Statement of Financial Position

As at 30 June 2022

		6 months ended 30 June 2022 Unaudited	6 months ended 30 June 2021 Unaudited	Year ended 31 Dec 2021 Audited
	Note	£'000	£'000	£'000
Assets				
Non-current assets		6 200	C 101	6 240
Intangible assets		6,200	6,194 1,077	6,219 927
Property, plant and equipment Investment in associates	6	1,496 6,980	7,012	7,005
Right-of-use leased assets	0	2,178	2,358	2,788
Total non-current assets		16,854	16,641	16,939
Total Hon-current assets		10,834	10,041	10,939
Current assets				
Inventories		687	729	659
Trade and other receivables		13,371	8,977	8,944
Current tax recoverable		-	28	38
Cash and cash equivalents		15,932	14,910	15,694
Total current assets		29,990	24,644	25,335
Total assets		46,844	41,285	42,274
Equity attributable to owners	_	674	674	674
Share capital	4	671	671	671
Share premium account	4	(6.056)	- (C 05C)	(6.056)
Merger reserve		(6,856)	(6,856)	(6,856)
Foreign currency reserves		1,158	1,106	1,331
Share option and warrant reserve	4	345	493	327
Retained earnings	4	25,483	26,353	25,206
Total equity		20,802	21,767	20,680
Liabilities				
Non-current liabilities				
Trade and other payables		-	-	-
Lease liabilities		752	520	863
Leasehold provision		40	20	40
Total non-current liabilities		792	540	903
Current liabilities		22.720	46.004	40.300
Trade and other payables		23,729	16,934	18,396
Deferred taxation		- 1 42E	25 1.606	1 001
Lease liabilities		1,425	1,696	1,991
Leasehold provision Borrowings		10 86	323	10 294
Total current liabilities		25,250	18,978	20,691
Total liabilities		26,042	19,518	21,594
Total equity and liabilities		46,844	41,285	42,274
Total equity and habilities		70,077	71,203	72,214

Consolidated Statement of Changes in Shareholders' Equity

	Share capital £'000	Share premium £'000	Merger reserves £'000	Share Option & Warrant reserve £'000	Foreign Currency reserve £'000	Retained earnings	Total £'000
At 1 January 2021	731	44,480	(6,856)	493	1,442	(17,993)	22,297
Changes in equity for 6 months ended 30 June 2021							
Total profit for the period	-	-	-	-	-	1,267	1,267
Currency translation differences	-	-	-	-	(336)	-	(336)
Total comprehensive profit for the period	-	-	-	-	(336)	1,267	931
Transactions with the owners							
Shares issued	3	36	-	-	-	-	39
Capital reduction	(63)	(44,516)	-	-	-	44,579	-
Distribution in specie	-	-	-	-	-	(1,500)	(1,500)
At 30 June 2021	671	-	(6,856)	493	1,106	26,353	21,767
Changes in equity for 6 months ended 31 December 2021							
Total loss for the period	-	-	-	-	-	(1,341)	(1,341)
Currency translation differences	-	-	-	-	225	-	225
Total comprehensive loss for the period	-	-	-	-	225	(1,341)	(1,116)
Transactions with the owners Shares issued	-	1	_	-	_	-	1
Share based payment exercised	-	-	-	(193)	-	193	-
Share based payment charge	-	-	-	27	-	-	27
At 31 December 2021	671	1	(6,856)	327	1,331	25,206	20,680
Changes in equity for 6 months ended 30 June 2022							
Total profit for the period	-	-	-	-	-	277	277
Currency translation differences	-	-	-	-	(173)	-	(173)
Total comprehensive profit for the period	-	-	-	-	(173)	277	104
Transactions with the owner							
Shares issued	-	-	-	-	-	-	-
Share based payment charge	-	-	-	18	-	-	18
At 30 June 2022	671	1	(6,856)	345	1,158	25,483	20,802

Consolidated Statement of Cash Flows

For the 6 months ended 30 June 2022

Cash used in operations Profit before income tax Adjustments for: - Depreciation & amortisation - Exceptional items - Net (gain)/loss on disposals of fixed assets & leases - Finance expense - Share based payment charge - R & D Credit Incl. in other income - Share of Imutex loss Changes in working capital: - Lease payments - (Increase)/Decrease Trade and other receivables - (Increase)/Decrease Inventories - Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	Months ended in 2022 audited £'000 453 1,436 186 (19) 172 18 (724) 25 (1,163) (4,389) (28) 5,333 1,300	6 Months ended 30 Jun 2021 Unaudited £'000 1,454 1,409 (965) - 111 - (1,067) 64 (1,176) 881 224 (4,464)	Year ended 31 Dec 2021 Audited £'000 277 2,565 (267) 189 215 27 (1,842) 71 (2,329) 904 294 (2,972)
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- Depreciation & amortisation - Exceptional items - Net (gain)/loss on disposals of fixed assets & leases - Finance expense - Share based payment charge - R & D Credit Incl. in other income - Share of Imutex loss Changes in working capital: - Lease payments - (Increase)/Decrease Trade and other receivables - (Increase)/Decrease Inventories - Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	186 (19) 172 18 (724) 25 (1,163) (4,389) (28) 5,333	(965) - 111 - (1,067) 64 (1,176) 881 224 (4,464)	(267) 189 215 27 (1,842) 71 (2,329) 904 294 (2,972)
- Exceptional items - Net (gain)/loss on disposals of fixed assets & leases - Finance expense - Share based payment charge - R & D Credit Incl. in other income - Share of Imutex loss Changes in working capital: - Lease payments - (Increase)/Decrease Trade and other receivables - (Increase)/Decrease Inventories - Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	186 (19) 172 18 (724) 25 (1,163) (4,389) (28) 5,333	(965) - 111 - (1,067) 64 (1,176) 881 224 (4,464)	(267) 189 215 27 (1,842) 71 (2,329) 904 294 (2,972)
- Net (gain)/loss on disposals of fixed assets & leases - Finance expense - Share based payment charge - R & D Credit Incl. in other income - Share of Imutex loss Changes in working capital: - Lease payments - (Increase)/Decrease Trade and other receivables - (Increase)/Decrease Inventories - Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	(19) 172 18 (724) 25 (1,163) (4,389) (28) 5,333	111 - (1,067) 64 (1,176) 881 224 (4,464)	189 215 27 (1,842) 71 (2,329) 904 294 (2,972)
- Finance expense - Share based payment charge - R & D Credit Incl. in other income - Share of Imutex loss Changes in working capital: - Lease payments - (Increase)/Decrease Trade and other receivables - (Increase)/Decrease Inventories - Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	172 18 (724) 25 (1,163) (4,389) (28) 5,333	(1,067) 64 (1,176) 881 224 (4,464)	215 27 (1,842) 71 (2,329) 904 294 (2,972)
- Share based payment charge - R & D Credit Incl. in other income - Share of Imutex loss Changes in working capital: - Lease payments - (Increase)/Decrease Trade and other receivables - (Increase)/Decrease Inventories - Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	18 (724) 25 (1,163) (4,389) (28) 5,333	(1,067) 64 (1,176) 881 224 (4,464)	27 (1,842) 71 (2,329) 904 294 (2,972)
- R & D Credit Incl. in other income - Share of Imutex loss Changes in working capital: - Lease payments - (Increase)/Decrease Trade and other receivables - (Increase)/Decrease Inventories - Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	(724) 25 (1,163) (4,389) (28) 5,333	(1,176) 881 224 (4,464)	(1,842) 71 (2,329) 904 294 (2,972)
- Share of Imutex loss Changes in working capital: - Lease payments - (Increase)/Decrease Trade and other receivables - (Increase)/Decrease Inventories - Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	25 (1,163) (4,389) (28) 5,333	(1,176) 881 224 (4,464)	71 (2,329) 904 294 (2,972)
Changes in working capital: - Lease payments - (Increase)/Decrease Trade and other receivables - (Increase)/Decrease Inventories - Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	(1,163) (4,389) (28) 5,333	(1,176) 881 224 (4,464)	(2,329) 904 294 (2,972)
- Lease payments - (Increase)/Decrease Trade and other receivables - (Increase)/Decrease Inventories - Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	(4,389) (28) 5,333	881 224 (4,464)	904 294 (2,972)
- (Increase)/Decrease Trade and other receivables - (Increase)/Decrease Inventories - Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	(4,389) (28) 5,333	881 224 (4,464)	904 294 (2,972)
- (Increase)/Decrease Inventories - Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	(28) 5,333	224 (4,464)	294 (2,972)
- Increase/(Decrease) Trade and other payables Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	5,333	(4,464)	(2,972)
Net cash generated/(used) in operations Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities			
Income tax (R & D Credit) received Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	1,300	(2.520)	(2.060)
Net cash generated/(used) in operating activities Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities		(3,529)	(2,868)
Cash flow from investing activities Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	-	-	1,304
Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities	1,300	(3,529)	(1,564)
Purchase of property, plant and equipment Purchase of intangible assets Net cash used in investing activities			
Purchase of intangible assets Net cash used in investing activities	(858)	(259)	(329)
Net cash used in investing activities	(79)	(132)	(410)
	(937)	(391)	(739)
Cash flow from financing activities			
Proceeds from issuance of ordinary shares & options	_	21	40
Exceptional items (paid)	(85)	(472)	(1,169)
Net Interest (paid)	(6)	(5)	(21)
Loan Note redemptions	(208)	(45)	(45)
Net cash used in financing activities	(299)	(501)	(1,195)
The cash asea in maneing activities	(233)	(301)	(1,155)
Net increase/(decrease) in cash and cash equivalents		(4,421)	(3,498)
Cash and cash equivalents at beginning of period	64	19,205	19,205
FX translation	64 15,694	19,205	(12)
Cash and cash equivalents at end of period		19,205	(13)

NOTES FORMING PART OF THE INTERIM FINANCIAL STATEMENTS

1. General information

Open Orphan Plc is a company incorporated in England and Wales. The Company is a public limited company, limited by shares, listed on the AIM market of the London Stock Exchange and on Euronext Growth in Dublin. The address of the registered office is Queen Mary Bio Enterprises, Innovation Centre, 42 New Road, London, E1 2AX, UK.

The principal activity of the Group is that of a rapidly growing specialist CRO pharmaceutical services company which is the world leader in the testing of vaccines and antivirals using human challenge clinical trials. The Group has a presence in the UK, Ireland, France and Netherlands.

The financial statements are presented in GBP£'000 (except where indicated otherwise), the currency of the primary economic environment in which the Group's trading companies operate. The Group comprises Open Orphan Plc and its subsidiary companies.

The registered number of the Company is 07514939.

2. Basis of preparation and accounting policies

The consolidated financial statements of Open Orphan Plc have been prepared in accordance with UK adopted international accounting standards (IFRSs), IFRIC interpretations and the Companies Act 2006 applicable to companies reporting under IFRS.

The consolidated financial statements have been prepared under the historical cost convention.

The accounting policies applied by the Group in this financial information are the same as those applied by the Group in its financial statements for the year ended 31 December 2021 and which will form the basis of the 2022 financial statements.

The financial information presented herein does not constitute full statutory accounts under Section 434 of the Companies Act 2006 and was not subject to a formal review by the auditors. The financial information in respect of the year ended 31 December 2021 has been extracted from the statutory accounts which have been delivered to the Registrar of Companies. The Group's Independent Auditor's report on those accounts was unqualified, did not include references to any matters to which the auditor drew attention by way of emphasis without qualifying their report and did not contain a statement under section 498(2) or 498(3) of the Companies Act 2006. The financial information for the half years ended 30 June 2022 and 30 June 2021 is unaudited and the twelve months to 31 December 2021 is audited.

There are no material events to report after the end of the reporting period.

The Interim Financial Statements were approved by the Board of Directors on 07 September 2022.

3. Earnings per share

(a) Basic

Basic earnings per share is calculated by dividing the profit/ (loss) attributable to equity holders of the Company by the weighted average number of ordinary shares in issue during the period.

	6 Months ended 30 Jun 2022 Unaudited £'000	6 Months ended 30 Jun 2021 Unaudited £'000	Year ended 31 Dec 2021 Audited £'000
Profit/(Loss) from continuing operations attributable to equity holders of the Company	277	1,267	(74)
Total	277	1,267	(74)
Weighted-average Ordinary Shares in issue	670,929,314	669,501,577	670,187,313
Earnings per Share (£ pence)	0.04	0.19	(0.01)

(b) Diluted

Due to the profitable result in the period the effect of the share options and warrants noted below maybe considered to be dilutive. In prior periods due to losses, they were considered anti-dilutive.

Total	10,657,640	10,731,952	10,657,640
Warrants	2,264,427	2,264,427	2,264,427
Options	8,393,213	8,467,525	8,393,213
Potential dilutive ordinary shares:			
	Unaudited	Unaudited	Audited
	30 Jun 2022	30 Jun 2021	31 Dec 2021
	ended	ended	ended
	6 Months	6 Months	Year

4. Prior year Capital Reduction and Distribution-in-Specie

On 19 May 2021, Open Orphan PLC received Court approval for reduction in its capital. Consequently, the deferred share capital balance of £62,833 was bought back by the Company and the balance in the Share Premium account of £44,516,591 of the Company was transferred to retained earnings.

On 18 June 2021, Open Orphan Plc made a distribution in specie to all shareholders on the share register at close of business on 17 June 2021. Shareholders received shares in Poolbeg Pharma Ltd. These shares were held in trust by Croft Nominees Limited for a period of 9 months following Poolbeg Pharma Ltd.'s admission to the AIM market of the London Stock Exchange. Poolbeg Pharma Ltd changed its name to Poolbeg Pharma Plc on 23 June 2021. Following a successful period of fund-raising, Poolbeg Pharma Plc was admitted to the AIM Market on 14 July 2021.

5. Share of loss of associates and joint ventures

hVIVO Limited holds equity investments in development stage bio-pharmaceutical companies. As the invested companies are incurring research and development expenditure to develop products, no revenue will be generated, and losses will be presented, until the products are successfully commercialised.

At 30 June 2022, the Group held an investment in one associate, PrEP Biopharm Limited, and one joint venture, Imutex Limited (see Note 6).

The carrying amount of PrEP Biopharm Limited was fully impaired to £nil as at 31 December 2018 due to consideration of the then economic performance of this asset. This impairment was not an indication or an opinion on the utility of PrEP-001 but recognised that further development would need additional investment, and this was no longer part of hVIVO's re-focussed business model at that time.

The carrying amount of the investment in Imutex Limited is considered to be fully recoverable.

The Group's share of after- tax losses of its joint venture is set out below:

	6 Months ended 30 Jun 2022 Unaudited £'000	6 Months ended 30 Jun 2021 Unaudited £'000	Year ended 31 Dec 2021 Audited £'000
Share of loss of joint venture	(25)	(64)	(71)
Share of total comprehensive loss	(25)	(64)	(71)

6. Investment in associates and joint ventures

A reconciliation of the carrying value of the Group's investments in joint ventures and associates is as follows:

	6 Months ended	6 Months ended	Year ended
	30 Jun 2022	30 Jun 2021	31 Dec 2021
	Unaudited	Unaudited	Audited
At start of period	£'000	£'000	£'000
	7,005	7,076	7,076
Share of loss of associate using equity method	(25)	(64)	(71)
At end of period	6,980	7,012	7,005

7. Share based payments

There was a share-based payment charge in the period of £18,000 (H1 2021: Nil).

8. Press

A copy of this announcement is available from the Company's website, being www.openorphan.com. If you would like to receive a hard copy of the interim report, please contact the Open Orphan Plc offices on +353 1 644 0007 to request a copy.