

Company announcement

No. 12/2023

Orphazyme A/S

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DK-2200 Copenhagen N

CVR No.: 32266355

Interim Report First Half 2023

Copenhagen, Denmark, September 12, 2023 – Orphazyme A/S (ORPHA.CO) (the “Company”), today announces its Interim Report First Half 2023 for the period January 1 – June 30, 2023.

Business updates and Financial highlights First Half 2023:

Unless otherwise stated, comments in this announcement refer to H1 performance from continuing operations. In 2022, the business operations and activities that were part of the Sale of Assets agreement with Zevra Therapeutics Inc. (Previously KemPharm) were reclassified as discontinued operations, but in 2023 all activities and financials are considered related to continuing operations.

- Operating expenses for the six months ended June 30, 2023 totaled DKK 12.8 million compared to DKK 27.3 million for continuing operations for the same period in 2022.
- The total comprehensive profit/loss for the first half 2023 was a net loss of DKK 12.8 million compared to a total comprehensive profit of DKK 62.5 million for the same period in 2022.
- As of June 30, 2023, Orphazyme held cash totaling DKK 30.3 million compared to DKK 42.5 million as of December 31, 2022.

Update about the business:

- In May 2023, Michael Hove was elected Chairman of the Board of Directors and Jakob Have and Jakob Bendtsen were elected to the Board of Directors replacing the former board.
- In May 2023, it was announced that the board of directors and CEO/CFO Anders Fink Vadsholt had entered into a severance agreement pursuant to which Mr. Vadsholt will step down as CEO/CFO of the Company. Regardless, Mr. Vadsholt has remained available for the Company until his replacement is found, but in no event longer than until 30 September 2023.
- In May 2023, Orphazyme agreed with the plaintiffs on the US Security class action case to settle the case by Orphazyme paying a settlement amount. A written settlement document has been filed by the parties to the Court awaiting its approval. When approved there will be a general 100-day objection period, where the consortia behind the class action can object to the settlement amount. We currently expect to receive final approval by the Court in early 2024 and will update the market once the preliminary approval order has been issued by the Court. Our issued guidance on operating loss and cash position at the end of the year includes the expense and payment of the final settlement amount.
- The Group is in process to liquidate its subsidiaries in US and Switzerland and expect the liquidation will be finalized in H1 2024. Following these liquidations, the Group will only consist of the Danish parent company.
- The management and the board are still in the process of handing over the final parts of the remaining activities to Zevra and the process is expected to be finalized before end of 2023.
- The Company is still in the process to optimize the current cost/supplier setup in order to prepare the Company for a new biotech activity/investment.
- Initial conversations at high level regarding a new biotech activity is started, but further steps will await the final outcome of the US Security class action case and the solvent liquidation of the US and Swiss subsidiaries. The board will keep the market updated as soon as there are relevant updates in the process.
- The board is investigating its current capital structure to potentially strengthen the equity and liquidity of the Company. A strengthened equity and liquidity may result in engagement in activities and investments related to biopharmaceutical research and development and/or participate in partnerships or co-operate with other businesses or invest in an asset not related to biotech activity.

Subsequent Events

Management is not aware of any events subsequent to 30 June 2023 which could be expected to have a significant impact on the group's financial position.

Outlook

The financial outlook for the year is unchanged.

For the full-year 2023 we still expect an operating loss in the range of DKK 30 – 35 million. We still expect to end 2023 with DKK 6 - 10 million in cash. There are inherent risks and uncertainties in our Outlook for 2023 including the limited nature of our business activities, the class action lawsuit in the United States and our future prospects.

In our financial guidance of expected operating loss in the range of DKK 30 – 35 million, the expected settlement amount for the US Security class action case is included in these guidance numbers. Our guidance of expected cash position of DKK 6 – 10 million by the end of the year does also include the expected settlement amount from the US Security class action case.

The settlement and finalization of the US Security Class action case is depending on a lot of factors outside the control of the board, but having this in mind the board is working with a timeline that all matters and processes described above are settled and finalized during H1 2024 so all efforts in H2 2024 can be concentrated in searching for a new biotech activity.

Forward-looking statements, in particular relating to future activities, operating income and expenses as well as other key financials, are subject to risks and uncertainties. Various factors, many of which lie outside of the Company's control, may cause the realized results to differ materially from the expectations presented in this earnings release.

Condensed Consolidated Key Figures

Following the Sale of Assets to Zevra Therapeutics Inc., key figures and ratios are presented for continuing activities unless otherwise stated. Comparative periods have been restated accordingly for the statement of profit or loss and other comprehensive income and the cash flow statements.

DKK (000)	As of and for the six- months ended Jun 30, 2023	As of and for the six-months ended Jun 30, 2022	As of and for the year ended Dec 31, 2022
Statement of profit or loss			
General and administrative expenses	(12,834)	(27,296)	(41,241)
Operating loss	(12,834)	(27,296)	(41,241)
Net financial items	50	56	193
Loss before tax	(12,784)	(27,239)	(41,048)
Income tax benefit	-	2,793	2,736
Loss from continuing operations	(12,784)	(24,446)	(38,312)
Net result from operations held for sale	-	87,429	64,382
Net result for the period	(12,784)	62,983	26,070
Total comprehensive income (loss)	(12,784)	62,531	25,165
Profit / (loss) per share, basic and diluted (DKK)	(0.36)	1.79	0.74
Statement of financial position			
Other non-current assets	-	5,500	-
Cash	30,340	49,532	42,464
Other current assets	5,841	38,557	15,658
Total assets	36,181	93,589	58,122
Share capital	35,312	35,312	35,312
Total equity	28,883	78,205	41,667
Current liabilities	7,298	15,384	16,455
Cash flow statement			
Net cash from operating activities	(12,124)	(116,472)	(117,945)
Net cash from investing activities	-	-	90,347
Net cash from financing activities	-	5,310	(35,078)
Net cash flow from discontinued operations	-	63,577	32,862
Other			
Share price (DKK)	1.67	1.81	0.88
Total outstanding shares	35,312,241	35,312,241	34,952,241
Market capitalization (DKK million)	59.0	64.3	31.1
Equity ratio	80%	84%	72%
Equity per share (DKK)	0.81	2.21	1.18

Management's Review

The first half of 2023 was focusing on handing over the activities to Zevra Therapeutics Inc. executing on the agreement from May 2022 where the Company sold substantially all of our assets and business activities.

At the Annual General Meeting in May 2023, the Board of Directors withdraw their positions and was replaced by Michael Hove (Chairman), Jakob Have and Jakob Bendtsen as board members. The new board will continue to execute on the current strategy handing over the remaining activity to Zevra, finalizing the US court case and optimizing the Company's cost/supplier structure enabling the Company to be engaged in activities and investments related to biopharmaceutical research and development or attract a new activity within the biotech area. Furthermore, the Company may, within its line of business, participate in partnerships or co-operate with other businesses.

We entered H2 2023 with limited ongoing operations and DKK 30,3 million in cash as June 30, 2023.

Risk management

The following significant risks and uncertainties were identified as of June 30, 2023, which could have a significant impact on our outlook and financial prospects:

Securities litigation:

On July 9, 2021, a putative class action lawsuit, captioned Busic v. Orphazyme A/S, et al., No. 21- cv-03640 (N.D. Ill.), was filed against the Company and certain of its current and former directors and officers in the U.S. District Court for the Northern District of Illinois. On September 13, 2021, the Court appointed a lead plaintiff for the putative class. On November 19, 2021, the lead plaintiff filed an amended complaint asserting claims under the U.S. Securities Act of 1933 and the U.S. Securities Exchange Act of 1934 for alleged misrepresentations and/or omissions in the Company's registration statement for its IPO of ADSs in the United States and in subsequent public statements.

The amended complaint seeks an unspecified amount of damages on behalf of a putative class comprised of all persons and entities other than the defendants that purchased or otherwise acquired the ADSs in connection with the IPO in September 2020 and/or between September 29, 2020 and November 4, 2021. On August 11, 2022, the Court granted in part and denied in part defendants' motion to dismiss the amended complaint. The Court dismissed all claims under the Securities Act of 1933 relating to the Company's registration statement for its IPO of ADSs and dismissed as inactionable a number of challenged statements for the lead plaintiff's claims under the Securities Exchange Act of 1934, including all of the challenged statements prior to June 2021. On August 26, 2022, the Court amended its August 11, 2022 order to also dismiss certain claims against certain individual defendants. The Court's dismissal of claims in its August 11 and 26, 2022 orders was without prejudice to the filing of a further amended complaint. On September 8, 2022, the lead plaintiff filed a second amended complaint with new allegations regarding an April 2021 statement by the Company's CEO at the time.

In May 2023, Orphazyme agreed with the plaintiffs on the US Security class action case to settle the case by Orphazyme paying a settlement amount. A written settlement document has been filed by the parties to the Court awaiting its approval. When approved there will be a general 100-day objection period, where the consortia behind the class action can object to the settlement amount. We currently expect to receive final approval by the Court in first half of 2024 and will update the market once the preliminary approval order has been issued by the Court. Our issued guidance on operating loss and cash position at the end of the year includes the expense and payment of the final settlement amount.

In our financial guidance of expected operating loss in the range of DKK 30 – 35 million, the expected settlement amount for the US Security class action case is included in these guidance numbers. Our guidance of expected cash position of DKK 6 – 10 million by the end of the year does also include the expected settlement amount from the US Security class action case.

Financial position and business prospects:

As of June 30, 2023, we had cash of DKK 30 million compared to DKK 42 million end of 2022. We have limited operating activities and prudently manage our expenses. We plan to explore ways to realize value from the Company's remaining assets and may engage in activities and investments related to biopharmaceutical research and development, participate in partnerships or co-operate with other businesses.

For more information on risks and uncertainties relating to Orphazyme's business please refer to our Statutory Annual Report 2022. The risks and uncertainties discussed above are those that the Company currently views as material and specific to the Company, but there can be no assurance that these are the only risks and uncertainties that the Company might face.

Additional risks and uncertainties, including risks that are not known to the Company at present or that its management currently deems immaterial or non-specific to the Company, may also arise or become material or specific to the Company in the future, which could, if such risks were to materialize, have a material and adverse effect on the Company's business, financial condition, and/or results of operations.

With the uncertainties listed above, there can be no assurance that the Company will achieve or sustain profitability or positive cash flows from operations. These interim condensed consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties. Based on the mitigating actions described above, Management is of the view that a going concern assumption is appropriate as of June 30, 2023.

Financial Review

Income statement

The operating result for H1 2023 was a loss of DKK 12.8 million compared to a loss of DKK 27.3 million for the same period last year.

The net result for H1 2023 was a loss of DKK 12.8 million compared to a net profit of DKK 62.5 million for the same period in 2022. The difference primarily relates to the net effect of income received from the Sale of Assets to Zevra in 2022.

Statement of financial position

As of June 30, 2023, we had cash of DKK 30 million compared to DKK 42 million end of 2022. As of June 30, 2023, total equity amounted to DKK 29 million compared to DKK 42 million as of December 31, 2022.

Consolidated Statements of Profit or Loss and Other Comprehensive Income

	Six months ended Jun 30, 2023 DKK (000)	Six months ended Jun 30, 2022 DKK (000)	Twelve months ended Dec 31, 2022 DKK (000)
General and administrative expenses	(12,834)	(27,296)	(41,241)
Operating expenses	(12,834)	(27,296)	(41,241)
Financial income	50	56	193
Loss before tax	(12,784)	(27,239)	(41,048)
Income tax benefit	-	2,793	2,736
Loss from continuing operations	(12,784)	(24,446)	(38,312)
Net result from discontinued operations (Note 3)	-	87,429	64,382
Net result for the period	(12,784)	62,983	26,070
Exchange diff. from translation of foreign operations	-	(452)	(905)
Total comprehensive income (loss)	(12,784)	62,531	26,070
Profit/(loss) per share, basic and diluted	(0.36)	1.79	0.74
Continuing operations	(0.36)	(0.69)	(1.08)
Discontinued operations	-	2.48	1.82

Consolidated Statements of Financial position

	Jun 30, 2023	Jun 30, 2022	Dec 31, 2022
	DKK (000)	DKK (000)	DKK (000)
ASSETS			
Current assets			
Corporation tax receivable	5,500	12,888	7,338
Trade receivables	-	23,765	4,103
Prepayments and other receivables	341	7,404	4,217
Cash	30,340	49,532	42,464
Total current assets	36,181	93,589	58,122
TOTAL ASSETS	36,181	93,589	58,122
EQUITY & LIABILITIES			
Equity			
Share capital	35,312	35,312	35,312
Share premium	2,087,436	2,087,436	2,087,436
Other reserves	(493)	2,447	(493)
Accumulated deficit	(2,093,372)	(2,046,990)	(2,080,588)
Total equity	28,883	78,205	41,667
Current liabilities			
Trade payable and accruals	1,788	11,362	10,540
Corporation tax payable	-	334	284
Other liabilities	5,510	3,688	5,631
Total current liabilities	7,298	15,384	16,455
TOTAL EQUITY AND LIABILITIES	36,181	93,589	58,122

Consolidated Statements of Changes in Shareholders' Equity

DKK (000)	Share capital	Share premium	Foreign currency translation	Other	Accumulated deficit	Total
Balance as of December 31, 2021	34,952	2,082,486	412	2,487	(2,110,998)	9,339
Net loss for the period	-	-	-	-	62,983	62,983
Other comprehensive loss for the period	-	-	(452)	-	-	(452)
<i>Total other comprehensive loss</i>	-	-	(452)	-	62,983	62,531
<i>Transactions with owners</i>						
Capital increase	360	4,950	-	-	-	5,310
Share-based payment costs	-	-	-	-	1,025	1,025
<i>Total transactions with owners</i>	360	4,950	-	-	1,025	6,335
Balance as of June 30, 2022	35,312	2,087,436	(40)	2,487	(2,046,990)	78,205
Balance as of December 31, 2022	35,312	2,087,436	(493)	-	(2,080,588)	41,667
Net loss for the period	-	-	-	-	(12,784)	(12,784)
Balance as of June 30, 2022	35,312	2,087,436	(493)	-	(2,093,372)	28,883

Consolidated Statements of Cash Flow

	Six months ended Jun 30, 2023 DKK (000)	Six months ended Jun 30, 2022 DKK (000)
Operating activities		
Operating loss	(12,834)	(27,296)
Change in trade receivables, prepayments, deposits and other receivables	8,078	19,255
Change in provisions, trade payables, accruals and other liabilities	(8,972)	(108,288)
Interest received / (paid), net	50	(143)
Tax refund	1,554	-
Net cash (used in) provided by operating activities	(12,124)	(116,472)
Financing activities		
Proceeds from issuance of shares	-	5,310
Net cash provided by (used in) financing activities	-	5,310
Changes in cash and cash equivalents from continuing operations	(12,124)	(111,162)
Net cash flow from operations held for sale (Note 2)	-	63,577
Net change in cash	(12,124)	(47,585)
Cash balance at beginning of period	42,464	102,255
Effect of changes in exchange rates	-	(5,138)
Cash balance at end of period	30,340	49,532

Notes to the Interim Consolidated Financial Statement

NOTE 1 – CORPORATE INFORMATION

Orphazyme is headquartered in Copenhagen, Denmark and is publicly traded on Nasdaq Copenhagen.

In April 2018, a wholly owned subsidiary of Orphazyme, Orphazyme U.S., Inc., was incorporated in Delaware, USA and in March 2020, another wholly owned subsidiary, Orphazyme Schweiz GmbH, was incorporated in Zug, Switzerland (together with Orphazyme A/S, "Orphazyme" or "the Group" as applicable). The Company is in the process of winding down these subsidiaries.

These interim consolidated financial statements were approved and authorized for issuance by the Board of Directors on September 12, 2023.

There were no material related party transactions during the first half of 2023 other than remuneration to the Executive Management and the Board of Directors.

As of the date of publication of this interim report, the Company has limited ongoing operational business activities and only one employee.

Basis of preparation

The interim condensed consolidated financial statements for the six months ended June 30, 2023 have been prepared in accordance with IAS 34 Interim Financial Reporting as issued by the International Accounting Standards Board (IASB) and as adopted by the EU, and additional Danish disclosure requirements for interim reports of companies listed on the Nasdaq Copenhagen.

The interim condensed consolidated financial statements do not include all the information and disclosures required in annual financial statements and should be read in conjunction with the Company's latest consolidated annual financial statements as of December 31, 2022. These interim condensed consolidated financial statements have been prepared in accordance with the going concern assumption.

As of June 30, 2023 and as of the date of publication of the interim report, there is no material impact directly related to COVID-19 on the Group's consolidated financial statements, including the judgements and estimates applied.

Updates to the Group's accounting policies

The accounting policies used in the preparation of the interim condensed consolidated financial statements are consistent with those used in the preparation of Orphazyme's annual consolidated financial statements for the year ended December 31, 2022.

The interim financial report has not been reviewed or audited by the Company's independent auditors.

Significant accounting estimates and judgements

The significant accounting estimates and judgements disclosed in note 1.4 of the consolidated financial statements for the year ended December 31, 2022 are still applicable.

NOTE 2 – GOING CONCERN

The expected net result for the year and the limited ongoing operational business activities makes us comfortable with preparing the interim consolidated financial statements on a going concern basis.

NOTE 3 – DISCONTINUED OPERATIONS AND DISPOSAL GROUP HELD FOR SALE

In May 2022, Orphazyme announced that it had signed an agreement to sell substantially all of the Company's assets and business activities, including those relating to the development and approval of arimoclomol and the full claw back liability related to the French early access program, to Zevra Therapeutics Inc.

In 2022, the business operations and activities that were part of the Sale of Assets agreement have been reclassified as discontinued operations. The net result related to the above-mentioned operations held for sale are therefore presented separately in the income statement and the statement of cash flows.

In 2023 there are no discontinuing activities. Net result and net cash flow from operations held for sale and assets and liabilities in disposal group held for sale are specified below:

	Six months ended Jun 30, 2022 DKK (000)
Net revenue	22,324
Research and development expenses	(29,988)
General and administrative expenses	(39,833)
Operating expenses	(69,822)
Financial income	-
Financial expenses	(10,893)
Loss before tax	(58,391)
Income tax benefit	-
Net result for the period	(58,391)
Gain from disposal of assets and liabilities held for sale	145,820
Net result from discontinued operations	87,429
Cash flow from operating activities	102,505
Cash flow from investing activities	1,460
Cash flow from financing activities	(40,388)
Net cash flow from operations held for sale	63,577

NOTE 4 – DEFERRED TAX ASSETS

The Company's tax losses can be carried forward infinitely subject to the general rules on limited deductibility due to ownership changes. In Denmark, the Company's ability to use tax loss carry forwards in any one year is limited to 100% of the first DKK 9.1 million of taxable income plus 60% of taxable income above DKK 9.1 million.

For the period ended June 30, 2023, the Company has unrecognized net tax loss carry-forwards in the Danish entity in the amount of DKK 2,198 million which is equal to a deferred tax asset of DKK 484 million as of June 30, 2023.

Statement by the Board of Directors and the Executive Management

The Board of Directors and the Executive Management have today reviewed and approved the interim financial report of Orphazyme A/S for the period January 1 - June 30, 2023. The interim financial report has not been reviewed or audited by the Company's independent auditors.

The interim financial report for the period January 1 - June 30, 2023 has been prepared in accordance with IAS 34 Interim Financial Reporting. The accounting policies used in the interim financial report are consistent with those accounting policies used in Orphazyme's 2022 Annual Report with the additions described and additional Danish disclosure requirements for interim reports of listed companies.

In our opinion, the interim condensed consolidated financial statements give a true and fair view of Orphazyme's assets, liabilities, and financial position at June 30, 2023 and of the results of its operations and cash flows for the period January 1 - June 30, 2023.

We furthermore consider that the management's review gives a true and fair view of the development in the Group's activities and financial affairs, the profit for the period and the Group's financial position as a whole, as well as a description of the most significant risks and uncertainties to which the Group is subject.

Copenhagen, September 12, 2023.

Board of Directors

Michael Hove

Chairman of the Board

Jakob Have

Jakob Færch Bendtsen

Executive Management

Anders Vadsholt

Chief Executive Officer and Chief Financial Officer