UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2023

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-35813

ORAMED PHARMACEUTICALS INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**98-0376008**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1185 Avenue of the Americas, Third Floor, New York, NY	**10036**
(Address of Principal Executive Offices)	(Zip Code)

844-967-2633
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.012	ORMP	The Nasdaq Capital Market, Tel Aviv Stock Exchange

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of May 11, 2023, there were 40,027,396 shares of the issuer's common stock, $0.012 par value per share, outstanding.

ORAMED PHARMACEUTICALS INC.
FORM 10-Q

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As used in this Quarterly Report on Form 10-Q, the terms "we," "us," "our" and the "Company" mean Oramed Pharmaceuticals Inc. and our wholly-owned subsidiaries, unless otherwise indicated. All dollar amounts refer to U.S. Dollars unless otherwise indicated.

On March 31, 2023, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.615 to $1.00. Unless indicated otherwise by the context, statements in this Quarterly Report on Form 10-Q that provide the dollar equivalent of NIS amounts or provide the NIS equivalent of dollar amounts are based on such exchange rate.

Cautionary Statement Regarding Forward-Looking Statements

The statements contained in this Quarterly Report on Form 10-Q that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws and the Israeli securities law. Words such as "expects," "anticipates," "intends," "plans," "planned expenditures," "believes," "seeks," "estimates," "considers" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Quarterly Report on Form 10-Q. Additionally, statements concerning future matters are forward-looking statements. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity, or our achievements, or industry results, to be materially different from any future results, performance, levels of activity, or our achievements, or industry results, expressed or implied by such forward-looking statements. Such forward-looking statements include, among other statements, statements regarding the following:

- our comprehensive analysis of data from our ORA-D-013-1 Phase 3 trial to understand if there is a path forward for our oral insulin candidate;
- our plan to evaluate potential strategic opportunities;
- our ability to enhance value for our stockholders;
- the expected development and potential benefits from our products;
- the prospects of entering into additional license agreements, or other partnerships or forms of cooperation with other companies or medical institutions;
- future milestones, conditions and royalties under our license agreements;
- expected timing of a clinical study for the potential Oravax Medical Inc., or Oravax, vaccine and its potential to protect against the coronavirus, or COVID-19, pandemic;
- our research and development plans, including pre-clinical and clinical trials plans and the timing of enrollment, obtaining results and conclusion of trials;
- our belief that our technology has the potential to deliver medications and vaccines orally that today can only be delivered via injection;
- the competitive ability of our technology based on product efficacy, safety, patient convenience, reliability, value and patent position;
- the potential market demand for our products;
- our ability to obtain patent protection for our intellectual property;
- our expectation that our research and development expenses will continue to be our major expenditure;
- our expectations regarding our short- and long-term capital requirements;
- our outlook for the coming months and future periods, including but not limited to our expectations regarding future revenue and expenses; and
- information with respect to any other plans and strategies for our business.

Although forward-looking statements in this Quarterly Report on Form 10-Q reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, or our Annual Report, as filed with the Securities and Exchange Commission, or the SEC, on March 6, 2023, as well as those discussed elsewhere in our Annual Report and expressed from time to time in our other filings with the SEC. In addition, historic results of scientific research, clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not suggest different conclusions. Also, historic results referred to in this Quarterly Report on Form 10-Q could be interpreted differently in light of additional research, clinical and preclinical trials results. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. Except as required by law, we undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Quarterly Report on Form 10-Q. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this Quarterly Report on Form 10-Q which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

PART I – FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

ORAMED PHARMACEUTICALS INC.

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF MARCH 31, 2023

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ORAMED PHARMACEUTICALS INC.
INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. Dollars in thousands (except share and per share data)
(UNAUDITED)

	March 31, 2023	December 31, 2022
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 24,104	$ 40,464
Short-term deposits	127,363	111,513
Marketable securities	2,267	3,743
Prepaid expenses and other current assets	1,423	1,389
Total current assets	155,157	157,109
LONG-TERM ASSETS:		
Long-term deposits	7	7
Long-term investments	2,700	2,700
Amounts funded in respect of employee rights upon retirement	24	24
Property and equipment, net	977	815
Operating lease right-of-use assets	915	987
Total long-term assets	4,623	4,533
Total assets	$ 159,780	$ 161,642
Liabilities and stockholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 4,055	$ 4,158
Deferred revenues	674	1,340
Payable to related parties	1	1
Operating lease liabilities	242	247
Total current liabilities	4,972	5,746
LONG-TERM LIABILITIES:		
Long-term deferred revenues	4,000	4,000
Employee rights upon retirement	26	21
Provision for uncertain tax position	11	11
Operating lease liabilities	564	647
Other liabilities	59	61
Total long-term liabilities	4,660	4,740
COMMITMENTS (note 3)		
Equity		
EQUITY ATTRIBUTABLE TO COMPANY'S STOCKHOLDERS:		
Common stock, $0.012 par value (60,000,000 authorized shares; 39,969,979 and 39,563,888 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively)	481	476
Additional paid-in capital	316,965	314,417
Accumulated deficit	(166,476)	(163,081)
Total stockholders' equity	150,970	151,812
Non-controlling interests	(822)	(656)
Total equity	150,148	151,156
Total liabilities and equity	$ 159,780	$ 161,642

The accompanying notes are an integral part of the condensed consolidated financial statements.

ORAMED PHARMACEUTICALS INC.

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

U.S. Dollars in thousands (except share and per share data)

(UNAUDITED)

	Three months ended March 31,	
	2023	**2022**
REVENUES	$ 666	666
RESEARCH AND DEVELOPMENT EXPENSES	4,427	5,836
SALES AND MARKETING EXPENSES	184	590
GENERAL AND ADMINISTRATIVE EXPENSES	1,263	5,492
OPERATING LOSS	5,208	11,252
FINANCIAL INCOME, NET	1,597	544
NET LOSS	$ 3,611	10,708
NET LOSS ATTRIBUTABLE TO NON-CONTROLLING INTERESTS	216	283
NET LOSS ATTRIBUTABLE TO STOCKHOLDERS	3,395	10,425
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	$ 0.08	$ 0.27
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	40,041,258	38,679,622

The accompanying notes are an integral part of the condensed consolidated financial statements.

ORAMED PHARMACEUTICALS INC.

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

U.S. Dollars in thousands

(UNAUDITED)

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity	Non-controlling interests	Total equity
	Shares	$					
	In thousands						
BALANCE AS OF DECEMBER 31, 2022	39,564	$ 476	$ 314,417	$ (163,081)	$ 151,812	$ (656)	$ 151,156
CHANGES DURING THE THREE MONTH PERIOD ENDED MARCH 31, 2023:							
ISSUANCE OF COMMON STOCK, NET	193	2	2,428	-	2,430	-	2,430
STOCK-BASED COMPENSATION	213	3	120	-	123	-	123
STOCK-BASED COMPENSATION OF SUBSIDIARY						50	50
NET LOSS	-	-	-	(3,395)	(3,395)	(216)	(3,611)
BALANCE AS OF MARCH 31, 2023	39,970	$ 481	$ 316,965	$ (166,476)	$ 150, 970	$ (822)	$ 150,148

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity	Non-controlling interests	Total equity
	Shares	$					
	In thousands						
BALANCE AS OF DECEMBER 31, 2021	38,158	$ 459	$ 292,514	$ (126,520)	$ 166,453	$ 157	$ 166,610
CHANGES DURING THE THREE MONTH PERIOD ENDED MARCH 31, 2022:							
ISSUANCE OF COMMON STOCK, NET	277	3	2,966	-	2,969	-	2,969
EXERCISE OF WARRANTS AND OPTIONS	4	(*)	-	-	-	-	-
STOCK-BASED COMPENSATION	125	1	4,028	-	4,029	-	4,029
TAX WITHHOLDINGS RELATED TO STOCK-BASED COMPENSATION SETTLEMENTS	-	-	(677)	-	(677)	-	(677)
NET LOSS	-	-	-	(10,425)	(10,425)	(283)	(10,708)
BALANCE AS OF MARCH 31, 2022	38,564	$ 463	$ 298,831	$ (136,945)	$ 162,349	$ (126)	$ 162,223

(*) Represents an amount of less than $1.

The accompanying notes are an integral part of the condensed consolidated financial statements.

ORAMED PHARMACEUTICALS INC.
INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars in thousands
(UNAUDITED)

	Three months ended March 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,611)	$ (10,708)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	37	11
Exchange differences and interest on deposits and held to maturity bonds	(1,267)	(235)
Changes in fair value of investments	(65)	(110)
Stock-based compensation	173	4,029
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(34)	(295)
Accounts payable, accrued expenses and related parties	(103)	(1,151)
Net changes in operating lease	(16)	-
Deferred revenues	(666)	(666)
Liability for employee rights upon retirement	5	-
Other liabilities	(2)	-
Total net cash used in operating activities	(5,549)	(9,125)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of short-term deposits	(19,000)	-
Proceeds from short-term deposits	4,500	5,000
Proceeds from maturity of held to maturity securities	1,496	2,406
Purchase of property and equipment	(199)	(47)
Total net cash provided by (used in) investing activities	(13,203)	7,359
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	2,430	2,969
Tax withholdings related to stock-based compensation settlements	-	(677)
Total net cash provided by financing activities	2,430	2,292
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(38)	(15)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(16,360)	511
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	40,464	27,456
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 24,104	$ 27,967
(A) SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -		
Interest received	$ 308	$ 122
(B) SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -		
Recognition of operating lease right-of-use assets and liabilities	$ -	$ 647

The accompanying notes are an integral part of the condensed consolidated financial statements.

NOTE 1 - GENERAL:

a. Incorporation and Operations

Oramed Pharmaceuticals Inc. (collectively with its subsidiaries, the "Company", unless the context indicates otherwise), a Delaware corporation, was incorporated on April 12, 2002.

On February 17, 2006, the Company entered into an agreement with Hadasit Medical Services and Development Ltd. to acquire the provisional patent related to an orally ingestible insulin capsule to be used for the treatment of individuals with diabetes.

On May 14, 2007, the Company incorporated a wholly-owned subsidiary in Israel, Oramed Ltd. (the "Subsidiary"), which is engaged in research and development.

On July 30, 2019, the Subsidiary incorporated a wholly-owned subsidiary in Hong Kong, Oramed HK Limited (the "Hong Kong Subsidiary"). As of March 31, 2023, the Hong Kong Subsidiary has no operations.

On March 18, 2021, the Company entered into a license agreement (the "Oravax License Agreement") with Oravax Medical Inc. ("Oravax") and into a stockholders agreement (the "Stockholders Agreement") with Akers Biosciences Inc. ("Akers"), Premas Biotech Pvt. Ltd. ("Premas"), Cutter Mill Capital LLC ("Cutter Mill") and Run Ridge LLC ("Run Ridge"). According to the Stockholders Agreement, Oravax issued 1,890,000 shares of its capital stock to the Company, representing 63% of the issued and outstanding share capital of Oravax, on a fully diluted basis, as of the date of issuance. Consequently, Oramed consolidates Oravax in its consolidated financial statements since that time.

On November 23, 2021, Oravax incorporated a wholly-owned subsidiary in Israel, Oravax Medical Ltd., which is engaged in research and development. Effective January 1, 2022, Oravax transferred its rights and obligations under the Oravax License Agreement to Oravax Medical Ltd.

On January 11, 2023, the Company announced that the ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints. As a result, the Company terminated this trial and a parallel Phase 3, ORA-D-013-2 clinical trial. The Company has also initiated a comprehensive analysis of the data to understand if there is a path forward for its oral insulin candidate. Concurrently, the Company is examining its existing pipeline and has commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for the Company's stockholders. As these results are considered a triggering event, the Company evaluated all of its long lived assets which include fixed assets and operating lease right-of-use assets in the first quarter of 2023 and concluded that no impairment is required.

b. Development and Liquidity Risks

The Company is engaged in research and development in the biotechnology field for innovative pharmaceutical solutions, including an orally ingestible insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules for delivery of other polypeptides, and has not generated significant revenues from its operations. Based on the Company's current cash resources and commitments, the Company believes it will be able to maintain its current planned development activities and the corresponding level of expenditures for at least the next 12 months, although no assurance can be given that the Company will not need additional funds prior to such time. If there are unexpected increases in its operating expenses, the Company may need to seek additional financing during the next 12 months. Successful completion of the Company's development programs and its transition to normal operations is dependent upon obtaining necessary regulatory approvals from the U.S. Food and Drug Administration prior to selling its products within the United States, obtaining foreign regulatory approvals to sell its products internationally, or entering into licensing agreements with third parties. There can be no assurance that the Company will receive regulatory approval of any of its product candidates, and a substantial amount of time may pass before the Company achieves a level of revenues adequate to support its operations, if at all. The Company also expects to incur substantial expenditures in connection with the regulatory approval process for each of its product candidates during their respective developmental periods. Obtaining marketing approval will be directly dependent on the Company's ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries. The Company may also need additional funds to realize the decisions made as part of its strategic review process. The Company cannot predict the outcome of these activities.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:

a. Condensed consolidated financial statements preparation

The condensed consolidated financial statements included herein have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and, on the same basis as the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (the "2022 Form 10-K"). These condensed consolidated financial statements reflect all adjustments that are of a normal recurring nature and that are considered necessary for a fair statement of the results of the periods presented. Certain information and disclosures normally included in annual consolidated financial statements have been omitted in this interim period report pursuant to the rules and regulations of the Securities and Exchange Commission. Because the condensed consolidated interim financial statements do not include all of the information and disclosures required by U.S. GAAP for annual financial statements, they should be read in conjunction with the audited consolidated financial statements and notes included in the 2022 Form 10-K. The results for interim periods are not necessarily indicative of a full fiscal year's results.

b. Loss per common share

Basic and diluted net loss per share of common stock are computed by dividing the net loss attributable to stockholders for the period by the weighted average number of shares of common stock outstanding for each period, including vested restricted stock units ("RSUs"). Outstanding stock options, warrants and unvested RSUs have been excluded from the calculation of the diluted loss per share because all such securities are anti-dilutive for all periods presented. The weighted average number of common stock options, warrants and RSUs excluded from the calculation of diluted net loss was 3,357,911 and 3,463,525 for the three month periods ended March 31, 2023 and March 31, 2022, respectively.

c. Revenue recognition

HTIT

On November 30, 2015, the Company entered into a Technology License Agreement (the "TLA"), with Hefei Tianhui Incubator of Technologies Co. Ltd. ("HTIT") and on December 21, 2015, the parties entered into an Amended and Restated Technology License Agreement that was further amended by the parties on June 3, 2016 and July 24, 2016 (the "HTIT License Agreement"). The HTIT License Agreement and a Stock Purchase Agreement, dated November 30, 2015, between the Company and HTIT (the "SPA") were considered a single arrangement with multiple deliverables. The Company allocated the total consideration of $49,500 between the HTIT License Agreement and the SPA according to their fair value, as follows: $10,617 was allocated to the issuance of common stock (less issuance expenses of $23), based on the quoted price of the Company's shares on the closing date of the SPA on December 28, 2015, and $38,883 was allocated to the HTIT License Agreement.

Under Accounting Standard Codification, ("ASC") 606, the Company identified a single performance obligation in the agreement and determined that the license and services are not distinct as the license and services are highly dependent on each other. In other words, HTIT cannot benefit from the license without the related services, and vice versa.

Since the customer benefits from the services as the entity performs, revenue is recognized over time through the expected product submission date in June 2023, using the input method. The Company used the input method to measure the process for the purpose of recognizing revenue, which approximates the straight line attribution. The Company used significant judgment when it determined the product submission date.

Under ASC 606, the consideration that the Company would be entitled to upon the achievement of contractual milestones, which are contingent upon the occurrence of future events, are a form of variable consideration. When assessing the portion, if any, of such milestones-related consideration to be included in the transaction price, the Company first assesses the most likely outcome for each milestone and excludes the consideration related to milestones of which the occurrence is not considered the most likely outcome.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

The Company then evaluates if any of the variable consideration determined in the first step is constrained by including in the transaction price variable consideration to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company used significant judgment when it determined the first step of variable consideration.

The potential future royalty consideration is also considered a form of variable consideration under ASC 606 as it is based on a percentage of potential future sales of the Company's products. However, the Company applies the sales-based royalty exception and accordingly will recognize the sales-based royalty amounts when the related sale has occurred. To date, the Company has not recognized any royalty-related revenue.

As of March 31, 2023, an aggregate amount of $22,382 was allocated to the HTIT License Agreement, all of which were received through the balance sheet date. Through March 31, 2023, the Company recognized revenue associated with this agreement in the aggregate amount of $19,708, of which $666 was recognized in the quarter ended March 31, 2023, and deferred the remaining amount of $2,674, which is presented as a contract liability on the condensed consolidated balance sheet.

Medicox

On November 13, 2022, the Company entered into a distribution license agreement ("Medicox License Agreement") with Medicox Co., Ltd. ("Medicox"). The Medicox License Agreement grants Medicox an exclusive license to apply for regulatory approval and distribute ORMD-0801 in the Republic of Korea. For further details, see note 3c.

Under ASC 606, the Company identified Medicox as a customer and the Medicox License Agreement as a contract with a customer.

The Company identified a performance obligation in the Medicox License Agreement to stand-ready and provide Medicox with support in its commercialization efforts in the Republic of Korea. This performance obligation includes a non-distinct distribution license for ORMD-0801, which the Company views a predominant item in the combined performance obligation. The Company concluded that the license is not distinct, as no party other than the Company is capable of providing related services to Medicox, and both the license and related services are necessary for the customer to obtain a regulatory approval in the Republic of Korea. In addition, the agreement covers the terms of future manufacturing services, that are contingent on the completion and success of the commercialization efforts.

The Medicox License Agreement contains a fixed consideration of $2,000, which was received by the Company in fiscal year 2022 and is presented under long-term deferred revenues as of March 31, 2023. It also contains variable consideration of contractual milestone payments and sales-based royalties.

The Company's obligation to stand-ready and support Medicox will be recognized on a straight-line basis over the period the Company expects to provide support to Medicox. As of March 31, 2023, this support has not commenced, and no revenue was recognized from the Medicox License Agreement.

If Medicox proceeds with the regulatory approval process in the Republic of Korea, the Company expects most of the revenue to be recognized in 2024, going forward. The Company notes that its Phase 3 trial did not meet its primary and secondary endpoints. If Medicox chooses to terminate the agreement as a result of the outcome of the applicable Phase 3 trials, the Company expects to accelerate revenue recognition and recognize it at such time.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

d. Recently adopted accounting pronouncements

Financial instruments – credit losses

In June 2016, the Financial Accounting Standards Board issued Accounting Standards Update 2016-13 "Financial Instruments—Credit Losses—Measurement of Credit Losses on Financial Instruments." This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance became effective for the fiscal year beginning after December 15, 2022, including interim periods within that year. The Company adopted the provisions of this update as of January 1, 2023, with no material impact on its consolidated financial statements.

e. Fair value

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

As of March 31, 2023, the assets measured at fair value are comprised of equity securities (Level 1). The fair value of held to maturity bonds as presented in note 4 was based on a Level 2 measurement.

As of March 31, 2023, the carrying amounts of cash equivalents, short-term deposits and accounts payable approximate their fair values due to the short-term maturities of these instruments.
The amounts funded in respect of employee rights are stated at cash surrender value which approximates its fair value.

NOTE 3 - COMMITMENTS:

a. On September 2, 2020 (effective as of January 15, 2020), the Subsidiary entered into a CRO Services Agreement with a third party to retain it as a clinical research organization ("CRO") for the Subsidiary's phase 3 clinical trial for its oral insulin. The CRO Services Agreement was amended effective May 26, 2022 and as consideration for its services, the Subsidiary will pay the CRO a total amended amount up to $22,684 during the term of the engagement and based on achievement of certain milestones, of which $16,600 was recognized in research and development expenses through March 31, 2023.

On January 11, 2023, the Company announced that the ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints. As a result, the Company terminated this trial.

b. On September 16, 2020 (effective as of January 15, 2020), the Subsidiary entered into a CRO Services Agreement with a third party to retain it as a CRO for the Subsidiary's phase 3 clinical trial for its oral insulin. The CRO Services Agreement was amended effective May 26, 2022 and as consideration for its services, the Subsidiary will pay the CRO a total amended amount up to $15,796 during the term of the engagement and based on achievement of certain milestones, of which $7,972 was recognized in research and development expenses through March 31, 2023.

On January 11, 2023, the Company announced that the ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints. As a result, the Company terminated this trial and a parallel Phase 3, ORA-D-013-2 clinical trial.

c. On November 13, 2022, the Company entered the Medicox License Agreement with Medicox.

The Medicox License Agreement grants Medicox an exclusive license to apply for regulatory approval and distribute ORMD-0801 in the Republic of Korea. The Medicox License Agreement is for ten years, but the parties have the right to terminate it upon 180 days' notice.

Medicox will comply with agreed distribution targets and will purchase ORMD-0801 at an agreed upon transfer price per capsule. In addition, Medicox will pay the Company up to $15,000 in developmental milestones, $2,000 of which have already been received by the Company, and up to 15% royalties on gross sales. Medicox will also be responsible for obtaining a regulatory approval in the Republic of Korea.

The Company is currently evaluating with Medicox a path forward to continue its collaboration, following the results of the ORA-D-013-1 Phase 3 trial.

For the Company's revenue recognition policy, see note 2c.

d. Grants from the Israel Innovation Authority ("IIA")

Under the terms of the Company's funding from the IIA, royalties of 3% are payable on sales of products developed from a project so funded, up to a maximum amount equaling 100%-150% of the grants received (dollar linked) with the addition of interest at an annual rate based on LIBOR.

At the time the grants were received, successful development of the related projects was not assured. The total amount received through March 31, 2023 was $2,208 ($2,542 including interest).

As of March 31, 2023, the liability to the IIA was $96.

The royalty expenses which are related to the funded project were recognized in cost of revenues in the relevant periods.

U.S. Dollars in thousands (except share and per share data)

NOTE 4 - MARKETABLE SECURITIES:

The Company's marketable securities include investments in equity securities of DNA GROUP (T.R.) Ltd. (formerly D.N.A Biomedical Solutions Ltd.) ("DNA"), Entera Bio Ltd. ("Entera") and in held to maturity securities.

a. Composition:

	March 31, 2023	December 31, 2022
Short-term:		
DNA (see b below)	$ 366	$ 352
Entera (see c below)	136	85
Held to maturity securities (see d below)	1,765	3,306
	$ 2,267	$ 3,743

b. DNA

The DNA ordinary shares are traded on the Tel Aviv Stock Exchange. The fair value of those securities is measured at the quoted prices of the securities on the measurement date.

During the three month period ended March 31, 2023, the Company did not sell any of DNA's ordinary shares. As of March 31, 2023, the Company owns approximately 1.4% of DNA's outstanding ordinary shares.

The cost of the securities as of both March 31, 2023 and December 31, 2022 was $595.

U.S. Dollars in thousands (except share and per share data)

NOTE 4 - MARKETABLE SECURITIES (continued):

c. Entera

Entera ordinary shares have been traded on The Nasdaq Capital Market since June 28, 2018. The Company measures the investment at fair value from such date, since it has a readily determinable fair value (prior to such date the investment was accounted for as a cost method investment (amounting to $1)).

d. Held to maturity securities

The amortized cost and estimated fair value of held to maturity securities as of March 31, 2023, were as follows:

	March 31, 2023			
	Amortized cost	Gross unrealized gains (losses)	Estimated fair value	Average yield to maturity rate
Short-term:				
Commercial bonds	$ 1,738	$ (40)	$ 1,698	0.84%
Accrued interest	27	-	27	
	$ 1,765	$ (40)	$ 1,725	

The amortized cost and estimated fair value of held to maturity securities as of December 31, 2022, were as follows:

	December 31, 2022			
	Amortized cost	Gross unrealized gains (losses)	Estimated fair value	Average yield to maturity rate
Short-term:				
Commercial bonds	$ 3,258	$ (82)	$ 3,176	1.07%
Accrued interest	48	-	48	
	$ 3,306	$ (82)	$ 3,224	

Held to maturity securities which will mature during the 12 months from the balance sheet date are included in short-term marketable securities.

U.S. Dollars in thousands (except share and per share data)

NOTE 5 - STOCKHOLDERS' EQUITY:

On September 1, 2021, the Company entered into a controlled equity offering agreement (the "Cantor Equity Distribution Agreement") with Cantor Fitzgerald & Co., as agent, pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $100,000, through a sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to the Company's effective shelf registration statement on Form S-3 including a prospectus dated July 26, 2021 and prospectus supplement dated September 1, 2021. The Company paid the sales agent a cash commission of 3.0% of the gross proceeds of the sale of any shares sold through the sales agent under the Cantor Equity Distribution Agreement. As of March 31, 2023 and May 11, 2023, 1,971,447 shares were issued under the Cantor Equity Distribution Agreement for aggregate net proceeds of $26,253.

NOTE 6 - LEASES:

The Company has various operating leases for office space and vehicles that expire through 2027. Below is a summary of the Company's operating right-of-use assets and operating lease liabilities as of March 31, 2023 and December 31, 2022:

	March 31, 2023	December 31, 2022
Operating right-of-use assets	$ 915	$ 987
Operating lease liabilities, current	242	247
Operating lease liabilities long-term	564	647
Total operating lease liabilities	$ 806	$ 894

Lease payments for the Company's right-of-use assets over the remaining lease periods as of March 31, 2023 and December 31, 2022 are as follows:

	March 31, 2023	December 31, 2022
2023	212	291
2024	283	291
2025	222	228
2026	120	124
2027	10	10
Total undiscounted lease payments	847	944
Less: Interest*	(41)	(50)
Present value of lease liabilities	$ 806	$ 894

* Future lease payments were discounted by 3%-5.75% interest rate.

NOTE 7 - RELATED PARTY TRANSACTIONS:

On July 1, 2008, the Subsidiary entered into two consulting agreements with KNRY Ltd. ("KNRY"), an Israeli company owned by the Chief Scientific Officer, whereby the President and Chief Executive Officer and the Chief Scientific Officer, through KNRY, provide services to the Company (the "Consulting Agreements"). The Consulting Agreements are both terminable by either party upon 140 days prior written notice. The Consulting Agreements, as amended, provide that KNRY will be reimbursed for reasonable expenses incurred in connection with the performance of the Consulting Agreements and that the monthly consulting fee paid to the President and Chief Executive Officer and the Chief Scientific Officer is NIS 146,705 ($41) and NIS 106,400 ($29), respectively.

In addition to the Consulting Agreements, based on a relocation cost analysis, the Company paid for certain direct costs, related taxes and expenses incurred in connection with the relocation of the President and Chief Executive Officer to the U.S. During the three months ended March 31, 2023, there were no such relocation expenses, compared to $143 for the three months ended March 31, 2022.

Following the relocation of the President and Chief Executive Officer to the State of Israel, the Company entered into two agreements with the President and Chief Executive Officer, replacing his above-mentioned consulting agreement through KNRY, substantially on the same terms, in order to allocate his time and services between the Company and the Subsidiary.

Effective November 1, 2022, the Company entered into a consulting agreement with Shnida Ltd., whereby the President and Chief Executive Officer, through Shnida Ltd., provides services as President and Chief Executive Officer of the Company. The agreement is terminable by either party upon 140 days prior written notice. The agreement provides that Shnida Ltd. will be reimbursed for reasonable expenses incurred in connection with performance of the agreement and that the President and Chief Executive Officer will receive a monthly consulting fee of NIS 88,023 ($24), plus value added tax. Pursuant to the agreement, Shnida Ltd. and the President and Chief Executive Officer each agree that during the term of the agreement and for a 12-month period thereafter, none of them will compete with the Company nor solicit employees of the Company.

In addition, the Company, through the Subsidiary, has entered into an employment agreement with the President and Chief Executive Officer, effective as of November 1, 2022, pursuant to which the President and Chief Executive Officer receives gross monthly salary of NIS 46,901 ($13) in consideration for his services as President and Chief Executive Officer of the Subsidiary. In addition, the President and Chief Executive Officer is provided with a cellular phone and a company car pursuant to the terms of his agreement.

NOTE 8 - SUBSEQUENT EVENTS:

1. On April 17, 2023, the Company granted an aggregate of 868,500 RSUs representing a right to receive shares of the Company's common stock to executive officers and board members of the Company. The RSUs will vest in twelve equal quarterly installments starting May 1, 2023. The total fair value of these RSUs on the date of grant was $1,980, using the quoted closing market share price of $2.28 on the Nasdaq Capital Market on the date of grant.

2. On April 17, 2023, the Company granted an aggregate of 245,500 performance based RSUs ("PSUs") representing a right to receive shares of the Company's common stock to executive officers of the Company. The PSUs will vest upon the Company's common stock achieving and maintaining a specified price per share. The total fair value of these PSUs on the date of grant was $550, using the Monte-Carlo model.

3. On May 1, 2023, the Company granted an aggregate of 20,000 RSUs representing a right to receive shares of the Company's common stock to a board member. The RSUs will vest in twelve quarterly installments starting May 1, 2023. The total fair value of these RSUs on the date of grant was $49, using the quoted closing market share price of $2.45 on the Nasdaq Capital Market on the date of grant.

ITEM 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the related notes included elsewhere herein and in our consolidated financial statements, accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report.

Overview of Operations

We are currently a pharmaceutical company engaged in the research and development of innovative pharmaceutical solutions with a technology platform that allows for the oral delivery of therapeutic proteins.

We have developed an oral dosage form intended to withstand the harsh environment of the stomach and effectively deliver active biological insulin or other proteins. The excipients in the formulation are not intended to modify the proteins chemically or biologically, and the dosage form is designed to be safe to ingest.

On January 11, 2023, we announced that the ORA-D-013-1 Phase 3 trial did not meet its primary or secondary endpoints. As a result, we terminated this trial and a parallel Phase 3, ORA-D-013-2 clinical trial. We have also initiated a comprehensive analysis of the data of both of these trials, to understand if there is a path forward for our oral insulin candidate. Concurrently, we are examining our existing pipeline and have commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for our stockholders.

Oral Insulin

Type 2 Diabetes: We conducted the ORA-D-013-1 Phase 3 trial on patients with type 2 diabetes, or T2D, with inadequate glycaemic control who were on two or three oral glucose-lowering agents. The primary endpoint of the trial was to evaluate the efficacy of our oral insulin capsule, ORMD-0801, compared to placebo in improving glycaemic control as assessed by HbA1c, with a secondary efficacy endpoint of assessing the change from baseline in fasting plasma glucose at 26 weeks. On January 11, 2023, we announced that the ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints. Following the results of the ORA-D-013-1 Phase 3 trial, we also terminated the ORA-D-013-2 Phase 3 trial, a second Phase 3 trial that included T2D patients with inadequate glycaemic control who were attempting to manage their condition with either diet alone or with diet and metformin.

NASH: In December 2020, we initiated a double blind, placebo controlled clinical trial of ORMD-0801 for the treatment of non-alcoholic steatohepatitis, or NASH, in T2D. On September 13, 2022, we reported positive top line results from this trial, demonstrating that ORMD-0801 was safe and well tolerated at 8 mg twice daily dosing, meeting the primary endpoint of no difference in adverse events for ORMD-0801 compared to placebo. The trial also evaluated the effectiveness of ORMD-0801 in reducing liver fat content over the 12-week treatment period by observing several independent measures. All the measurements showed a consistent clinically meaningful trend in favor of ORMD-0801. We are currently evaluating our path forward for ORMD-0801 for NASH.

Oral Vaccine

On March 18, 2021, we formed Oravax, a 63% owned joint venture to commercialize oral vaccines for COVID-19 and other novel coronaviruses based on Premas Biotech Pvt. Ltd.'s proprietary vaccine technology involving a triple antigen virus like particle. Effective January 1, 2022, Oravax transferred its rights and obligations to its wholly-owned subsidiary, Oravax Medical Ltd. For further details, see note 12 to the audited consolidated financial statements included in our Annual Report.

In December 2021, Oravax commenced a Phase 1 clinical trial, which was divided into two cohorts each comprised of 12 participants. In October 2022, Oravax reported positive preliminary Phase 1 data for Cohort A of this trial, meeting primary and secondary endpoints of safety and immunogenicity. These results included significant antibody response (2-6 fold over baseline) as measured by multiple markers of immune response to VLP vaccine antigens observed in the majority of the patients dosed, and no safety issues were observed, including mild symptoms. Cohort B completed dosing on January 5, 2023 and data is expected in the first half of 2023.

Results of Operations

Comparison of three month period ended March 31, 2023 and March 31, 2022

The following table summarizes certain statements of operations data of the Company for the three month periods ended March 31, 2023 and March 31, 2022 (in thousands of dollars except share and per share data):

	Three months ended	
	March 31, 2023	**March 31, 2022**
Revenues	$ 666	$ 666
Cost of revenues	-	-
Research and development expenses	4,427	5,836
Sales and marketing expenses	184	590
General and administrative expenses	1,263	5,492
Financial income, net	1,597	544
Net loss for the period	$ 3,611	$ 10,708
Basic and diluted loss per share of common stock	$ 0.08	$ 0.27
Weighted average shares of common stock outstanding used in computing basic and diluted loss per share of common stock	40,041,258	38,679,622

Revenues

Revenues consist of proceeds related to the HTIT License Agreement that are recognized on a cumulative basis when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur, through the expected product submission date by HTIT of June 2023, using the input method.

Revenues were $666,000 for each of the three month periods ended March 31, 2023 and March 31, 2022.

Cost of Revenues

Cost of revenues consists of royalties related to the HTIT License Agreement that will be paid over the term of the HTIT License Agreement in accordance with revenue recognition accounting and the Israeli Law for the Encouragement of Industrial Research, Development and Technological Innovation, 1984, as amended, including any regulations or investment tracks promulgated thereunder.

There was no cost of revenues for the three month periods ended March 31, 2023 and March 31, 2022.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, employee benefits, costs of materials, supplies, the cost of services provided by outside contractors, including services related to our clinical trials, clinical trial expenses, the full cost of manufacturing drugs for use in research and preclinical development. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as CROs, independent clinical investigators and other third-party service providers to assist us with the execution of our clinical trials.

Clinical activities, which relate principally to clinical sites and other administrative functions to manage our clinical trials, are performed primarily by CROs. CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-trial visits, training and program management.

Clinical trial and pre-clinical trial expenses include regulatory and scientific consultants' compensation and fees, research expenses, purchase of materials, cost of manufacturing of the oral insulin and exenatide capsules, payments for patient recruitment and treatment, as well as salaries and related expenses of research and development staff.

Research and development expenses for the three month period ended March 31, 2023 decreased by 24% to $4,427,000, compared to $5,836,000 for the three month period ended March 31, 2022. The decrease was mainly due to lower expenses related to the Phase 3 trials that were terminated. Stock-based compensation expenses for the three month period ended March 31, 2023 were $17,000, compared to $562,000 during the three month period ended March 31, 2022. This decrease was mainly due to performance equity awards that did not meet their performance conditions during the period ended March 31, 2023.

Following the results of the ORA-D-013-1 Phase 3 trial, which did not meet its primary and secondary endpoints, we terminated both ORA-D-013-1 and ORA-D-013-2 Phase 3 clinical trials. In parallel, we have initiated a comprehensive analysis of the data to understand if there is a path forward for our oral insulin candidate. We are examining our existing pipeline and have commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for our stockholders.

Government grants

In the three month periods ended March 31, 2023 and March 31, 2022, we did not recognize any research and development grants. As of March 31, 2023, we had incurred liabilities to pay royalties to the Israel Innovation Authority of the Israeli Ministry of Economy and Industry of $96,000.

Sales and Marketing Expenses

Sales and marketing expenses include the salaries and related expenses of our commercial functions, consulting costs and other general costs.

Sales and marketing expenses for the three month period ended March 31, 2023 decreased by 69% to $184,000, compared to $590,000 for the three month period ended March 31, 2022. The decrease was primarily due to lower stock-based compensation expenses and consulting expenses. Stock-based compensation costs for the three month period ended March 31, 2023 were $88,000, compared to $364,000 for the three month period ended March 31, 2022. This decrease was mainly due to performance equity awards that did not meet their performance conditions during the period ended March 31, 2023.

General and Administrative Expenses

General and administrative expenses include the salaries and related expenses of our management, consulting costs, legal and professional fees, travel expenses, business development costs, insurance expenses and other general costs.

General and administrative expenses for the three month period ended March 31, 2023 decreased by 77% to $1,263,000 compared to $5,492,000 for the three month period ended March 31, 2022. The decrease was mainly due to lower stock-based compensation expenses and legal expenses. Stock-based compensation costs for the three month period ended March 31, 2023 were $67,000, compared to $3,103,000 for the three month period ended March 31, 2022. This decrease was mainly due to equity awards that were granted and vested in the first quarter of 2022 and to performance equity awards that did not meet their performance conditions during the period ended March 31, 2023.

Financial Income, net

Net financial income increased by 194% to $1,597,000 for the three month period ended March 31, 2023, compared to $544,000 for the three month period ended March 31, 2022. The increase was mainly due to interest from short-term bank deposits.

Basic and Diluted Loss Per Share of Common Stock

Basic and diluted loss per share of common stock for the three month period ended March 31, 2023 decreased by 70% to $0.08, compared to $0.27 for the three month period ended March 31, 2022. The decrease in loss per share was mainly due to lower net loss resulting from the changes set forth above in the three month period ended March 31, 2023 compared to the three month period ended March 31, 2022.

Weighted Average Shares of Common Stock Outstanding

Weighted average shares of common stock outstanding for the three month period ended March 31, 2023 were 40,041,258, compared to 38,679,622 for the three month period ended March 31, 2022. The increase was mainly due to shares issued in connection with our controlled equity offering.

Liquidity and Capital Resources

From inception through March 31, 2023, we have incurred losses in an aggregate amount of $166,476,000. During that period and through March 31, 2023, we have financed our operations through several private placements of our common stock, as well as public offerings of our common stock, raising a total of $255,376,000, net of transaction costs. During that period, we also received cash consideration of $28,001,000 from the exercise of warrants and options. We expect to seek additional financing through similar sources in the future, as needed. As of March 31, 2023, we had $24,104,000 of available cash, $127,363,000 of short-term bank deposits and $2,267,000 of marketable securities.

From inception through March 31, 2023, we have not generated significant revenues from our operations. Management continues to evaluate various financing alternatives for funding new strategic activities, future research and development activities and general and administrative expenses through fundraising in the public or private equity markets. Although there is no assurance that we will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of future third party investments. Based on our current cash resources and commitments, we believe we will be able to maintain our current planned development activities and the corresponding level of expenditures for at least the next 12 months, although no assurance can be given that we will not need additional funds prior to such time.

If there are unexpected increases in our operating expenses, we may need to seek additional financing during the next 12 months. Successful completion of our development programs and our transition to normal operations is dependent upon obtaining necessary regulatory approvals from the FDA prior to selling our products within the United States, obtaining foreign regulatory approvals to sell our products internationally, or entering into licensing agreements with third parties. There can be no assurance that we will receive regulatory approval of any of our product candidates, and a substantial amount of time may pass before we achieve a level of revenues adequate to support our operations, if at all. We also expect to incur substantial expenditures in connection with the regulatory approval process for each of our product candidates during their respective developmental periods. Obtaining marketing approval will be directly dependent on our ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries. We may also need additional funds to realize the decisions made as part of our strategic review process. We cannot predict the outcome of these activities.

As of March 31, 2023, our total current assets were $155,157,000 and our total current liabilities were $4,972,000. On March 31, 2023, we had a working capital surplus of $150,185,000 and an accumulated loss of $166,476,000. As of December 31, 2022, our total current assets were $157,109,000 and our total current liabilities were $5,746,000. On December 31, 2022, we had a working capital surplus of $151,363,000 and an accumulated loss of $163,081,000. The decrease in working capital from December 31, 2022 to March 31, 2023 was mainly due to a decrease in marketable securities, partially offset by a decrease in accounts payable and accrued expenses.

During the three month period ended March 31, 2023, cash and cash equivalents decreased to $24,104,000, from $40,464,000 as of December 31, 2022. The decrease was mainly due to the reasons described below.

Operating activities used cash of $5,549,000 in the three month period ended March 31, 2023, compared to $9,125,000 used in the three month period ended March 31, 2022. Cash used in operating activities primarily consisted of research and development, sales and marketing and general and administrative expenses and changes in stock-based compensation expenses, interest on deposits, prepaid expenses and account payables and accrued expenses.

Investing activities used cash of $13,203,000 in the three month period ended March 31, 2023, compared to cash provided by investing activities of $7,359,000 in the three month period ended March 31, 2022. Cash used by investing activities in the three month period ended March 31, 2023 consisted primarily of the purchase of short-term deposits partially offset by proceeds from held to maturity securities. Cash provided by investing activities in the three month period ended March 31, 2022 consisted primarily of the proceeds of short-term deposits and held to maturity securities.

Financing activities provided cash of $2,430,000 in the three month period ended March 31, 2023, compared to $2,292,000 provided in the three month period ended March 31, 2022. Cash provided by financing activities consisted primarily of proceeds from the issuance of our common stock.

On September 1, 2021, we entered into a controlled equity offering agreement, or the Cantor Equity Distribution Agreement, with Cantor Fitzgerald & Co., as agent, pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $100,000,000, through a sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to our effective shelf registration statement on Form S-3 including a prospectus dated July 26, 2021 and prospectus supplement dated September 1, 2021. We paid the sales agent a cash commission of 3.0% of the gross proceeds of the sale of any shares sold through the sales agent under the Cantor Equity Sales Agreement. As of March 31, 2023, 1,971,447 shares were issued under the Cantor Equity Distribution Agreement for aggregate net proceeds of $26,253,000.

Critical accounting policies and estimates

Our critical accounting policies are described in *"Management's Discussion and Analysis of Financial Condition and Results of Operations"* contained in our Annual Report.

Planned Expenditures

We invest heavily in research and development, and we expect that in the upcoming years our research and development expenses will continue to be our major operating expense.

Following the results of the Phase 3 trials for our oral insulin capsule candidate, ORMD-0801 and the current strategic review initiated by the Company, our obligations may change significantly.

ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There has been no significant change in our exposure to market risk during the quarter ended March 31, 2023. For a discussion of our exposure to market risk, refer to Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," contained in our Annual Report.

ITEM 4 - CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2023. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 6 – EXHIBITS

Number	Exhibit
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15(d)-14(a) under the Securities Exchange Act of 1934, as amended.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101.1*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 formatted in XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Comprehensive Loss, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows and (v) the Notes to Condensed Consolidated Financial Statements.
104.1*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith

** Furnished herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ORAMED PHARMACEUTICALS INC.

Date: May 11, 2023

By: /s/ Nadav Kidron
Nadav Kidron
President and Chief Executive Officer

Date: May 11, 2023

By: /s/ David Silberman
David Silberman
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a)

UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Nadav Kidron, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Oramed Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant 's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2023

By: /s/ Nadav Kidron
Nadav Kidron
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a)

UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, David Silberman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Oramed Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant 's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2023

By: /s/ David Silberman
David Silberman
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the quarterly report of Oramed Pharmaceuticals Inc., or the Company, on Form 10-Q for the period ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Nadav Kidron, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 11, 2023

By: /s/ Nadav Kidron
Nadav Kidron
President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION

PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the quarterly report of Oramed Pharmaceuticals Inc., or the Company, on Form 10-Q for the period ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, David Silberman, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 11, 2023

By: /s/ David Silberman
David Silberman
Chief Financial Officer