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 September 30, 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 November 9, 2023, there were 40,338,979 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 September 30, 2023, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.824 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 recover the proceeds and/or collateral under the Note (as defined herein) and related agreements;
- the fluctuating market price and liquidity and the common stock of Scilex Holding Company, or Scilex, underlying the warrants;
- the possibility that the anticipated benefits of the Transaction (as defined herein) are not realized when expected or at all, including as a result of the impact of, or problems arising from, the ability of Scilex to repay the Note and the ability of the Company to realize the value of the warrants;
- our exposure to potential litigation;
- 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;
- the ability of Oramed and Hefei Tianhui Incubator of Technologies Co. Ltd. to reach agreement on a definitive joint venture agreement and the transactions contemplated by the term sheet;
- future milestones, conditions and royalties under our license agreements;
- the potential of the Oravax Medical Inc., or Oravax, vaccine to protect against the coronavirus, or COVID-19 pandemic;
- our research and development plans, including preclinical 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 this Quarterly Report on Form 10-Q and 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 SEPTEMBER 30, 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)

	September 30, 2023	December 31, 2022
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,468	$ 40,464
Short-term deposits	120,158	111,513
Marketable securities	-	3,743
Investments at fair value	49,413	-
Prepaid expenses and other current assets	666	1,389
Total current assets	175,705	157,109
LONG-TERM ASSETS:		
Long-term deposits	6	7
Investments at fair value	47,406	-
Marketable securities	2,535	-
Other non-marketable equity securities	3,524	2,700
Amounts funded in respect of employee rights upon retirement	26	24
Property and equipment, net	923	815
Operating lease right-of-use assets	768	987
Total long-term assets	55,188	4,533
Total assets	$ 230,893	$ 161,642
Liabilities and stockholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 2,561	$ 4,158
Short-term borrowings	75,363	-
Deferred revenues	-	1,340
Payable to related parties	-	1
Operating lease liabilities	251	247
Total current liabilities	78,175	5,746
LONG-TERM LIABILITIES:		
Long-term deferred revenues	4,000	4,000
Employee rights upon retirement	27	21
Provision for uncertain tax position	11	11
Operating lease liabilities	389	647
Other liabilities	61	61
Total long-term liabilities	4,488	4,740
COMMITMENTS (note 3)		
Equity		
EQUITY ATTRIBUTABLE TO COMPANY'S STOCKHOLDERS:		
Common stock, $0.012 par value (60,000,000 authorized shares; 40,282,688 and 39,563,888 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively)	484	476
Additional paid-in capital	319,540	314,417
Accumulated deficit	(170,892)	(163,081)
Total stockholders' equity	149,132	151,812
Non-controlling interests	(902)	(656)
Total equity	148,230	151,156
Total liabilities and equity	$ 230,893	$ 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)

	Nine months ended		Three months ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
REVENUES	$ 1,340	$ 2,022	$ -	$ 682
RESEARCH AND DEVELOPMENT EXPENSES	7,205	20,362	957	5,347
SALES AND MARKETING EXPENSES	(287)	1,433	(663)	463
GENERAL AND ADMINISTRATIVE EXPENSES	6,314	11,085	2,599	3,061
OPERATING LOSS	11,892	30,858	2,893	8,189
INTEREST EXPENSES	826	-	826	-
FINANCIAL INCOME, NET	4,510	1,930	435	1,036
LOSS BEFORE TAX EXPENSES	8,208	28,928	3,284	7,153
TAX EXPENSES	-	100	-	100
NET LOSS	$ 8,208	$ 29,028	$ 3,284	$ 7,253
NET LOSS ATTRIBUTABLE TO NON-CONTROLLING INTERESTS	397	1,010	62	193
NET LOSS ATTRIBUTABLE TO STOCKHOLDERS	$ 7,811	$ 28,018	$ 3,222	$ 7,060
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	$ 0.19	$ 0.72	$ 0.08	$ 0.18
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	40,246,515	38,856,514	40,445,896	39,100,231

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 NINE MONTH PERIOD ENDED SEPTEMBER 30, 2023:							
ISSUANCE OF COMMON STOCK, NET	193	2	2,426	-	2,428	-	2,428
SHARES ISSUED FOR SERVICES	3	(*)	9	-	9	-	9
STOCK-BASED COMPENSATION	523	6	2,688	-	2,694	-	2,694
STOCK-BASED COMPENSATION OF SUBSIDIARY	-	-	-	-	-	151	151
NET LOSS	-	-	-	(7,811)	(7,811)	(397)	(8,208)
BALANCE AS OF SEPTEMBER 30, 2023	40,283	$ 484	$ 319,540	$ (170,892)	$ 149,132	$ (902)	$ 148,230

	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 NINE MONTH PERIOD ENDED SEPTEMBER 30, 2022:							
ISSUANCE OF COMMON STOCK, NET	770	9	7,336	-	7,345	-	7,345
EXERCISE OF WARRANTS AND OPTIONS	34	(*)	42	-	42	-	42
STOCK-BASED COMPENSATION	151	2	8,767	-	8,769	-	8,769
STOCK-BASED COMPENSATION OF SUBSIDIARY						192	192
TAX WITHHOLDINGS RELATED TO STOCK-BASED COMPENSATION SETTLEMENTS	-	-	(783)	-	(783)	-	(783)
NET LOSS	-	-	-	(28,018)	(28,018)	(1,010)	(29,028)
BALANCE AS OF SEPTEMBER 30, 2022	39,113	$ 470	$ 307,876	$ (154,538)	$ 153,808	$ (661)	$ 153,147

(*) 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 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 JUNE 30, 2023	40,219	$ 484	$ 318,732	$ (167,670)	$ 151,546	$ (891)	$ 150,655
CHANGES DURING THE THREE MONTH PERIOD ENDED SEPTEMBER 30, 2023:							
SHARES ISSUED FOR SERVICES	3	(*)	7	-	7	-	7
STOCK-BASED COMPENSATION	61	(*)	801	-	801	-	801
STOCK-BASED COMPENSATION OF SUBSIDIARY	-	-	-	-	-	51	51
NET LOSS	-	-	-	(3,222)	(3,222)	(62)	(3,284)
BALANCE AS OF SEPTEMBER 30, 2023	40,283	$ 484	$ 319,540	$ (170,892)	$ 149,132	$ (902)	$ 148,230

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity	Non-controlling interests	Total equity
	Shares	$					
	In thousands						
BALANCE AS OF JUNE 30, 2022	38,564	$ 463	$ 300,712	$ (147,478)	$ 153,697	$ (660)	$ 153,037
CHANGES DURING THE THREE MONTH PERIOD ENDED SEPTEMBER 30, 2022:							
ISSUANCE OF COMMON STOCK, NET	493	6	4,371	-	4,377	-	4,377
EXERCISE OF WARRANTS AND OPTIONS	30	(*)	42	-	42	-	42
STOCK-BASED COMPENSATION	26	1	2,857	-	2,858	-	2,858
STOCK-BASED COMPENSATION OF SUBSIDIARY	-		-	-	-	192	192
TAX WITHHOLDINGS RELATED TO STOCK-BASED COMPENSATION SETTLEMENTS	-	-	(106)	-	(106)	-	(106)
NET LOSS	-	-	-	(7,060)	(7,060)	(193)	(7,253)
BALANCE AS OF SEPTEMBER 30, 2022	39,113	$ 470	$ 307,876	$ (154,538)	$ 153,808	$ (661)	$ 153,147

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)

	Nine months ended September 30,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (8,208)	$ (29,028)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	143	41
Exchange differences and interest on deposits and held to maturity bonds	(2,042)	(933)
Changes in fair value of investments	(191)	494
Stock-based compensation	2,845	8,961
Shares issued for services	9	-
Gain on amounts funded in respect of employee rights upon retirement	(2)	-
Accrued interest on short-term borrowings to maturity	813	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	726	1,034
Accounts payable, accrued expenses and related parties	(1,601)	(330)
Net changes in operating lease	(35)	(105)
Deferred revenues	(1,340)	(21)
Liability for employee rights upon retirement	6	(1)
Other liabilities	-	32
Total net cash used in operating activities	(8,877)	(19,856)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of short-term deposits	(91,369)	(111,500)
Proceeds from short-term deposits	84,760	128,000
Proceeds from maturity of held to maturity securities	3,375	5,336
Long-term investments	(99,550)	(2,700)
Funds in respect of employee rights upon retirement	-	3
Purchase of property and equipment	(251)	(188)
Total net cash provided by (used in) investing activities	(103,035)	18,951
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	2,428	7,345
Loans received	99,550	-
Loans paid	(25,000)	-
Proceeds from exercise of warrants and options	-	42
Tax withholdings related to stock-based compensation settlements	-	(783)
Total net cash provided by financing activities	76,978	6,604
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(62)	41
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(34,996)	5,740
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	40,464	27,456
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 5,468	$ 33,196
(A) SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -		
Interest received	$ 3,393	$ 906
Interest paid	$ (14)	$ -
(B) SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -		
Recognition of operating lease right-of-use assets and liabilities	$ -	$ 678

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 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 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. 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 was required. The Company recently completed an analysis of the data from the ORA-D-013-1 Phase 3 trial and found that subpopulations of patients with pooled specific parameters, such as body mass index (BMI), baseline HbA1c, age, gender and body weight, responded well to oral insulin. These subsets exhibited an over 1% placebo adjusted, statistically significant, reduction in HbA1c. The Company is currently considering if there is a path forward for its oral insulin candidate, based on this analysis. 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.

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. Following the termination of the ORA-D-013-1 and ORA-D-013-2 Phase 3 trials, the Company's research and development activities have been significantly reduced while it conducts a strategic review process. As a result, the Company is currently incurring lower research and development and sales and marketing expenses.

NOTE 1 - GENERAL (continued):

Based on the Company's current cash resources and commitments, the Company believes it will be able to maintain its current planned 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. 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.

On August 7, 2023, the Company entered into a Stock Purchase Agreement, as subsequently amended on August 9, 2023 and August 21, 2023, (the "Sorrento SPA"), with Sorrento Therapeutics, Inc. ("Sorrento"), to acquire certain equity securities of Scilex Holding Company ("Scilex"), owned by Sorrento (the "Purchased Securities"), for a purchase price of $105,000. Sorrento and its affiliated debtor, Scintilla Pharmaceuticals, Inc. ("Scintilla" and together with Sorrento, the "Debtors") are in Chapter 11 bankruptcy proceedings.

On August 9, 2023, the Company entered into a Senior Secured, Super-Priority Debtor-in-Possession Loan and Security Agreement (the "Senior DIP Loan Agreement") with the Debtors in the principal amount of $100,000, which included a non-refundable closing fee of $450 paid in full out of the proceeds. This amount was subsequently drawn in full by the Debtors and was intended to be used by the Company as a credit for the consideration for the Purchased Securities, with an additional $5,000 in cash to be paid by the Company at closing. Thereafter, the Company and Sorrento continued discussions and negotiations relating to the sale contemplated under the Sorrento SPA.

On September 21, 2023, the Company entered into and consummated the transactions contemplated by a Securities Purchase Agreement (the "Scilex SPA") with Scilex and Acquiom Agency Services LLC. Pursuant to the Scilex SPA, in exchange for Scilex assuming outstanding obligations of Sorrento under the Senior DIP Loan Agreement (the "DIP Assumption") and for the ability to credit the amounts assumed under the DIP Assumption in exchange for certain equity securities of Scilex owned by Sorrento, Scilex (i) issued to the Company (A) a Senior Secured Promissory Note due 18 months from the date of issuance in the principal amount of $101,875 (the "Note"), which includes accrued and unpaid interest of $875 under the Senior DIP Loan Agreement and $1,000 of fees added to the principal amount of the Note, (B) the Closing Penny Warrant (as defined herein), and (C) the Subsequent Penny Warrants (as defined herein), and (ii) caused the Transferred Warrants (as defined herein) to be transferred to the Company. For further details, see note 7.

On August 8, 2023, the Company borrowed an aggregate of $99,550 pursuant to loan agreements from Israel Discount Bank Ltd. For further details, see note 6.

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 3,745,590 and 3,557,200 for the nine month periods ended September 30, 2023 and September 30, 2022, respectively, and 3,845,271 and 3,715,540 for the three month periods ended September 30, 2023 and September 30, 2022, respectively.

c. Revenue recognition

HTIT

On November 30, 2015, the Company entered into a Technology License Agreement, 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").

As of September 30, 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 September 30, 2023, the Company recognized revenue associated with this agreement in the aggregate amount of $20,382, of which $1,340 was recognized in the nine month period ended September 30, 2023, and deferred the remaining amount of $2,000, which is presented as long-term deferred revenues on the condensed consolidated balance sheet.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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 3a.

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 September 30, 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 September 30, 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 at a later stage. 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 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 September 30, 2023, the fair value of marketable equity securities as presented in note 4 and of the Transferred Warrants included in the Scilex SPA as presented in note 7 were based on a Level 1 measurement. The fair value of held to maturity bonds as presented in note 4 and of the Closing Penny Warrant as presented in note 7 were based on a Level 2 measurement. The fair value of the investment in non-marketable equity securities as presented in note 5, of the Subsequent Penny Warrants as presented in note 7 and of the Note as presented in note 7 were based on a Level 3 measurement.

As of September 30, 2023, the carrying amounts of cash equivalents, short-term deposits, Short-Term Borrowings 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. Medicox License Agreement

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.

b. 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 September 30, 2023 was $2,208 ($2,553 including interest).

As of September 30, 2023, the liability to the IIA was $59.

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 the Transferred Warrants (as defined herein; for further details, see note 7). As of December 31, 2022, marketable securities also included held to maturity securities.

a. Composition

	September 30, 2023	December 31, 2022
Short-term:		
DNA (see b below)	$ -	$ 352
Entera (see c below)	-	85
Held to maturity securities (see d below)	-	3,306
	$ -	$ 3,743
Long-term:		
DNA (see b below)	$ 450	$ -
Entera (see c below)	85	-
Transferred Warrants (see note 7)	2,000	-
	$ 2,535	$ -

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 nine month period ended September 30, 2023, the Company did not sell any of DNA's ordinary shares. As of September 30, 2023, the Company owns approximately 1.4% of DNA's outstanding ordinary shares.

The cost of the securities as of both September 30, 2023 and December 31, 2022 was $595.

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 Company did not have any held to maturity securities as of September 30, 2023.

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	

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

NOTE 5 – NON-MARKETABLE EQUITY SECURITIES:

On August 26, 2022, the Company entered into a stock purchase agreement with Diasome Pharmaceuticals, Inc. ("Diasome"), a privately-held company, pursuant to which the Company purchased shares of Series B preferred stock of Diasome for an aggregate purchase price of approximately $2,700. Following the purchase, the Company holds less than 5% of the issued and outstanding stock of Diasome. The stock purchase agreement provides the Company with the option to purchase additional preferred shares of stock on a pro rata basis at similar terms to the terms and conditions of the current round contingent upon Diasome achieving certain milestones.

The Company accounts for the investment under the measurement alternative in ASC 321 "Investments – Equity Securities," whereby the equity investment is recorded at cost, less impairment. The carrying amount is subsequently remeasured to its fair value in accordance with the provisions of ASC 820 "Fair Value Measurement" when observable price changes occur as of the date the transaction occurred, or it is impaired. Any adjustments to the carrying amount are recorded in the statements of comprehensive loss.

The Company's non-marketable equity securities are an investment in a company without a readily determinable fair value. As of September 30, 2023, the Company recorded an $824 increase in value due to the closing in June 2023 of a Series C investment round in Diasome. The change was recorded using the transaction price of similar securities issued by Diasome, adjusted for contractual rights and obligations of the securities held by the Company.

NOTE 6 - FINANCING:

On August 8, 2023, the Company borrowed an aggregate of $99,550 pursuant to loan agreements from Israel Discount Bank Ltd. (the "Short-Term Borrowings"). The Short-Term Borrowings mature on dates ranging from August 11, 2023 to May 24, 2024, bear interest ranging from 6.66% to 7.38%, and are secured by certificates of deposits issued by Israel Discount Bank Ltd. having an aggregate face amount of $99,550. The net proceeds of the Short-Term Borrowings were used to fund the Note (for further details, see note 7). The Short-Term Borrowings are paid in one payment of principal and interest at each respective maturity. As of September 30, 2023, $25,000 was repaid under the Short-Term Borrowings.

The aggregate remaining annual principal payments on debt until maturity are as follows:

	Annual Principal Payments
2023	$ 25,000
2024	49,550
Total	**$** 74,550

NOTE 7 - INVESTMENTS, AT FAIR VALUE:

Scilex Transaction

On September 21, 2023 (the "Closing Date"), the Company entered into and consummated the transactions (collectively, the "Transaction") contemplated by the Scilex SPA with Scilex and Acquiom Agency Services LLC. Pursuant to the Scilex SPA, in exchange for the DIP Assumption and for the ability to credit the amounts assumed under the DIP Assumption in exchange for certain equity securities of Scilex owned by Sorrento, Scilex (i) issued to the Company (A) the Note, (B) a warrant to purchase up to an aggregate of 4,500,000 shares of common stock of Scilex, par value $0.0001 per share ("Scilex Common Stock"), with an exercise price of $0.01 per share and containing certain restrictions on exercisability (the "Closing Penny Warrant"), and (C) warrants to purchase up to an aggregate of 8,500,000 shares of Scilex Common Stock (the "Subsequent Penny Warrants" and together with the Closing Penny Warrant, the "Penny Warrants"), each with an exercise price of $0.01 per share and each with certain restrictions on exercisability, and (ii) caused certain outstanding warrants to purchase up to an aggregate of 4,000,000 shares of Scilex Common Stock with an exercise price of $11.50 per share to be transferred to the Company (the "Transferred Warrants" and together with the Penny Warrants, the "Warrants"). In addition, on the Closing Date, Scilex reimbursed $1,910 of the Company's Transaction expenses pursuant to the Scilex SPA.

Pursuant to the terms of the Scilex SPA, Scilex agreed to certain restrictions on additional issuances of equity securities. In connection with the Transaction, the Company and Sorrento mutually agreed to terminate the Sorrento SPA and to release all claims the Company and Sorrento may have against one another, and Scilex completed the acquisition of the Purchased Securities.

Note

The principal of the Note issued on September 21, 2023 is $101,875, which includes accrued and unpaid interest of $875 under the Senior DIP Loan Agreement and $1,000 of fees added to the principal amount of the Note. The Note matures on March 21, 2025 or upon an uncured event of default, subject to certain mandatory prepayments, and bears interest at a rate per annum equal to Term SOFR (as defined in the Note) plus 8.5% (subject to a Term SOFR floor of 4.0%), to be paid in-kind, by being capitalized and added to the principal amount of the Note on a monthly basis. The Scilex SPA provides for principal payments of (i) $5,000 on December 21, 2023, (ii) $15,000 on March 21, 2024, and (iii) $20,000 on each of June 21, 2024, September 21, 2024, and December 21, 2024, and for the entire remaining principal balance of the Note to be paid on March 21, 2025. If the Note is not repaid in full on or prior to March 21, 2024, an exit fee equal to approximately $3,056 shall be payable upon repayment of the Note in full.

The Note constitutes senior secured indebtedness of Scilex and is guaranteed by all existing or future formed, direct and indirect, domestic subsidiaries of Scilex and is secured by a first priority security interest in and liens on all of the assets of Scilex, subject to customary and mutually agreed permitted liens and except for certain specified exemptions.

Mandatory prepayments under the Note are required following the earlier of (a) April 1, 2024 and (b) the date upon which certain of Scilex's outstanding indebtedness are repaid in full. Mandatory prepayments may be triggered by certain future equity and debt issuances by Scilex. Voluntary prepayments may be made at Scilex's discretion; provided that, if made prior to the one-year anniversary of the Closing Date, Scilex will also be required to pay a 50% interest make-whole on the portion of the Note so prepaid.

The Note includes customary events of default, upon which the Note will bear interest at a default rate of Term SOFR plus 15.0%, which shall be payable in-kind, by being capitalized and added to the principal amount of the Note on a monthly basis. If the Note is accelerated upon an event of default, Scilex is required to repay the principal amount of the Note at a mandatory default rate of 125% of such principal amount (together with 100% of accrued and unpaid interest thereon and all other amounts due in respect of the Note).

Until the obligations under the Note are repaid in full, the Company has the right to designate one non-voting observer to attend meetings of the board of directors and committees of Scilex and its subsidiaries.

NOTE 7 - INVESTMENTS, AT FAIR VALUE (continued):

Closing Penny Warrant

The Closing Penny Warrant will be exercisable upon the earliest of (i) March 14, 2025, (ii) the date on which the Senior Secured Note has been repaid in full and (iii) the Management Sale Trigger Date (as defined therein), if any, and will expire on the date that is the fifth anniversary of the issuance date (i.e., September 21, 2028). For purposes of the Penny Warrants, the Management Sale Trigger Date is generally the first date that either Dr. Henry Ji, Scilex's Executive Chairperson, or Mr. Jaisim Shah, Scilex's Chief Executive Officer and President and a member of Scilex's Board of Directors, engages in certain sales or other similar transfers of shares of Common Stock or other of the Issuer's or any of its subsidiaries' securities, subject to certain exceptions in connection with financings or similar transactions. The exercise price of the Closing Penny Warrant is $0.01 per share, subject to adjustment.

Subsequent Penny Warrants

Scilex issued four Subsequent Penny Warrants to the Company, each for 2,125,000 shares of Scilex Common Stock, one of which shall vest and become exercisable on the date that is the later of (i) each of March 19, 2024, June 17, 2024, September 15, 2024 or December 14, 2024 (the "Subsequent Penny Warrant Vesting Date") and (ii) the earliest of (A) March 14, 2025, (B) the date on which the Senior Secured Note has been repaid in full and (C) the Management Sale Trigger Date (as defined therein), if any. Each Subsequent Penny Warrant will expire on the date that is the fifth anniversary of the issuance date; provided that, if the Senior Secured Note is repaid in full prior to the Subsequent Penny Warrant Vesting Date applicable to such Subsequent Penny Warrant, such Subsequent Penny Warrant will expire on the date the Senior Secured Note is repaid in full. The Company may exercise the Penny Warrants by means of a "cashless exercise."

The Penny Warrants may not be exercised if the Company, together with its affiliates, would beneficially own in excess of 9.9% of the number of shares of Scilex Common Stock outstanding immediately after giving effect to such exercise; provided, that the Company may increase or decrease such limitation upon 61 days' prior notice to Scilex.

Transferred Warrants

The Transferred Warrants are listed on the Nasdaq Capital Market, have an exercise price of $11.50 per share, are fully exercisable and expire on November 10, 2027.

The Company accounted for the Transferred Warrants as derivatives measured at fair value.

The Company elected the fair value option for the Note and the Penny Warrants in order to reduce operational complexity of bifurcating embedded derivatives. Changes in value are recorded under financial income, net and include interest income on the Note.

The valuation was performed based on several scenarios which some of them took into account a partial or full early repayment of the Note. Each scenario took into consideration the present value of the Note's cash flows (including the exit fee and the prepayment premium) and the Warrants' value. The total value of the Transaction (and of each of its components) was valued on a weighted average of the different scenarios.

The discount rate of the Note was based on the B- rating Zero curve in addition to a risk premium which takes into account the credit risk of Scilex and ranged between 54.80% to 55.25%.

The fair value of the Transferred Warrants was based on their closing price on the Nasdaq Capital Market.

The fair value of the Penny Warrants was calculated based on the closing price of the Scilex stock on the Nasdaq Capital Market, taking into account several scenarios which assume a partial or full early repayment of the Note, when applicable.

On the Closing Date, the fair value of the Transaction was $101,875. As of September 30, 2023, the fair value of the Transaction was $98,819, split between the Note ($80,404, of which $49,413 is presented under short-term investments at fair value and $30,991 is presented under long-term investments at fair value), the Closing Penny Warrant ($6,300), the Subsequent Penny Warrants ($10,115), both presented under long-term investments at fair value and the Transferred Warrants ($2,000) presented under long-term marketable securities. This resulted in a loss of $3,056, attributed mainly to the change in fair value of the Warrants. The difference between the Note's fair value and aggregate unpaid principal balance (which includes interest payable on maturity) is $21,826.

NOTE 8 - STOCKHOLDERS' EQUITY:

1. 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 September 30, 2023 and November 9, 2023, 1,971,447 shares were issued under the Cantor Equity Distribution Agreement for aggregate net proceeds of $26,253.

2. 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.

3. 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 vested on May 26, 2023, 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.

4. 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.

5. During the third quarter of 2023, 86,500 stock options and 110,917 unvested RSUs were forfeited, due to termination of the employment of an executive officer, resulting in a reversal of $663 in sales and marketing expenses.

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

NOTE 9 - 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 September 30, 2023 and December 31, 2022:

	September 30, 2023	December 31, 2022
Operating right-of-use assets	$ 768	$ 987
Operating lease liabilities, current	251	247
Operating lease liabilities long-term	389	647
Total operating lease liabilities	$ 640	$ 894

Lease payments for the Company's right-of-use assets over the remaining lease periods as of September 30, 2023 and December 31, 2022 are as follows:

	September 30, 2023	December 31, 2022
2023	67	291
2024	267	291
2025	210	228
2026	114	124
2027	9	10
Total undiscounted lease payments	667	944
Less: Interest*	(27)	(50)
Present value of lease liabilities	$ 640	$ 894

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

NOTE 10 - RELATED PARTY TRANSACTIONS:

On July 1, 2008, the Company's wholly-owned subsidiary, Oramed Ltd. (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 ($38) and NIS 106,400 ($28), 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 nine months ended September 30, 2023, there were no such relocation expenses, compared to $201 for the nine months ended September 30, 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 ($23), 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 ($12) 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.

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 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 recently completed an analysis of the data from the ORA-D-013-1 Phase 3 trial and found that subpopulations of patients with pooled specific parameters, such as body mass index (BMI), baseline HbA1c, age, gender and body weight, responded well to oral insulin. We are currently considering if there is a path forward for our oral insulin candidate, based on this analysis. We are additionally examining our existing pipeline and have commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for our stockholders.

Scilex Transaction

On August 7, 2023, we entered into a Stock Purchase Agreement, as subsequently amended on August 9, 2023 and August 21, 2023, or the Sorrento SPA, with Sorrento Therapeutics, Inc., or Sorrento, to acquire certain equity securities of Scilex Holding Company, or Scilex, owned by Sorrento, or the Purchased Securities, for a purchase price of $105 million. Sorrento and its affiliated debtor, Scintilla Pharmaceuticals, Inc. or Scintilla and together with Sorrento, the Debtors, are in Chapter 11 bankruptcy proceedings.

On August 9, 2023, we entered into a Senior Secured, Super-Priority Debtor-in-Possession Loan and Security Agreement, or the Senior DIP Loan Agreement, with the Debtors in the principal amount of $100 million, which included a non-refundable closing fee of $450,000 paid in full out of the proceeds. This amount was subsequently drawn in full by the Debtors and was intended to be used by us as a credit for the consideration for the Purchased Securities, with an additional $5 million in cash to be paid by us at closing. Thereafter, we and Sorrento continued discussions and negotiations relating to the sale contemplated under the Sorrento SPA.

Securities Purchase Agreement

On September 21, 2023, or the Closing Date, we entered into and consummated the transactions, or, collectively, the Transaction, contemplated by a Securities Purchase Agreement, or the Scilex SPA, with Scilex and Acquiom Agency Services LLC. Pursuant to the Scilex SPA, in exchange for Scilex assuming Sorrento's outstanding obligations under the Senior DIP Loan Agreement, or the DIP Assumption, and for the ability to credit the amounts assumed under the DIP Assumption in exchange for certain equity securities of Scilex owned by Sorrento, Scilex (i) issued to us (A) a Senior Secured Promissory Note due 18 months from the date of issuance in the principal amount of $101,875,000, or the Note, which includes accrued and unpaid interest of $875,000 under the Senior DIP Loan Agreement and $1,000,000 of fees added to the principal amount of the Note, (B) a warrant to purchase up to an aggregate of 4,500,000 shares of common stock of Scilex, par value $0.0001 per share, or the Scilex Common Stock and containing certain restrictions on exercisability or the Closing Penny Warrant, and (C) warrants to purchase up to an aggregate of 8,500,000 shares of Scilex Common Stock, or the Subsequent Penny Warrants, and, together with the Closing Penny Warrant, the Penny Warrants, each with an exercise price of $0.01 per share and each with certain restrictions on exercisability, and (ii) caused certain outstanding warrants to purchase up to an aggregate of 4,000,000 shares of Scilex Common Stock with an exercise price of $11.50 per share to be transferred to us, or the Transferred Warrants and together with the Penny Warrants, the Warrants. In addition, on the Closing Date, Scilex reimbursed $1,910,000 of the Company's Transaction expenses pursuant to the Scilex SPA.

Pursuant to the terms of the Scilex SPA, Scilex agreed to certain restrictions on additional issuances of equity securities. In connection with the Transaction, we and Sorrento mutually agreed to terminate the Sorrento SPA and to release all claims we and Sorrento may have against one another, and Scilex completed the acquisition of the Purchased Securities.

Senior Secured Promissory Note

The Note matures on March 21, 2025 or upon an uncured event of default, subject to certain mandatory prepayments, and bears interest at a rate per annum equal to Term SOFR (as defined in the Note) plus 8.5% (subject to a Term SOFR floor of 4.0%), to be paid in-kind, by being capitalized and added to the principal amount of the Note on a monthly basis. The Scilex SPA provides for principal payments of (i) $5 million on December 21, 2023, (ii) $15 million on March 21, 2024, and (iii) $20 million on each of June 21, 2024, September 21, 2024, and December 21, 2024, and for the entire remaining principal balance of the Note to be paid on March 21, 2025. If the Note is not repaid in full on or prior to March 21, 2024, an exit fee equal to $3,056,250 shall be payable upon repayment of the Note in full.

The Note constitutes senior secured indebtedness of Scilex and is guaranteed by all existing or future formed, direct and indirect, domestic subsidiaries of Scilex and is secured by a first priority security interest in and liens on all of the assets of Scilex, subject to customary and mutually agreed permitted liens and except for certain specified exemptions.

Mandatory prepayments under the Note are required following the earlier of (a) April 1, 2024 and (b) the date upon which certain of Scilex's outstanding indebtedness is repaid in full). Voluntary prepayments may be made at Scilex's discretion; provided that, if made prior to the one-year anniversary of the Closing Date, Scilex will also be required to pay a customary 50% interest make-whole on the portion of the Note so prepaid.

The Note includes customary events of default, upon which the Note will bear interest at a default rate of Term SOFR plus 15.0%, which shall be payable in-kind, by being capitalized and added to the principal amount of the Note on a monthly basis. If the Note is accelerated upon an event of default, Scilex is required to repay the principal amount of the Note at a mandatory default rate of 125% of such principal amount (together with 100% of accrued and unpaid interest thereon and all other amounts due in respect of the Note).

Until the obligations under the Note are repaid in full, we have the right to designate one non-voting observer, to attend meetings of the board of directors and committees of Scilex and its subsidiaries.

Warrants

The Closing Penny Warrant will be exercisable upon the earliest of (i) March 14, 2025, (ii) the date on which the Note has been repaid in full and (iii) the Management Sale Trigger Date (as defined therein), if any, and will expire on the date that is the fifth anniversary of the issuance date. For purposes of the Penny Warrants, the Management Sale Trigger Date is generally the first date that either Dr. Henry Ji, Scilex's Executive Chairperson, or Mr. Jaisim Shah, Scilex's Chief Executive Officer and President and a member of Scilex's Board of Directors, engages in certain sales or other similar transfers of shares of Scilex Common Stock or other of Scilex's or any of its subsidiaries' securities, subject to certain exceptions as are customary for lock-up agreements executed by directors and officers in connection with financings or similar transactions. The exercise price of the Closing Penny Warrant is $0.01 per share, subject to adjustment.

We were issued four Subsequent Penny Warrants, each for 2,125,000 shares of Scilex Common Stock, which shall vest and become exercisable on the date that is the later of (i) March 19, 2024, June 17, 2024, September 15, 2024 or December 14, 2024, respectively, or the Subsequent Penny Warrant Vesting Date, and (ii) the earliest of (A) March 14, 2025, (B) the date on which the Note has been repaid in full and (C) the Management Sale Trigger Date (as defined therein), if any. Each Subsequent Penny Warrant will expire on the date that is the fifth anniversary of the issuance date; provided that, if the Note is repaid in full prior to the Subsequent Penny Warrant Vesting Date applicable to such Subsequent Penny Warrant, such Subsequent Penny Warrant will expire on the date the Note is repaid in full. We may exercise the Penny Warrants by means of a "cashless exercise."

The Penny Warrants may not be exercised if we, together with our affiliates, would beneficially own in excess of 9.9% of the number of shares of Scilex Common Stock outstanding immediately after giving effect to such exercise; provided, that we may increase or decrease such limitation upon 61 days' prior notice to Scilex.

The Transferred Warrants are listed on the Nasdaq Capital Market, or Nasdaq, have an exercise price of $11.50 per share, are fully exercisable, and expire on November 10, 2027.

Registration Rights Agreement

In connection with the Scilex SPA, on September 21, 2023, we entered into a registration rights agreement with Scilex, pursuant to which Scilex granted the Company certain registration rights applicable to the resale of the shares underlying the Warrants and agreed to pay liquidated damages equal to the product of 2.0% multiplied by the sum of (x) the aggregate principal amount outstanding under the Note and (y) the aggregate Exercise Price (as defined in the Closing Warrant) of the Closing (capped at 12%) of the aggregate subscription amount.

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. We recently completed an analysis of the data from the ORA-D-013-1 Phase 3 trial and found that subpopulations of patients with pooled specific parameters, such as body mass index (BMI), baseline HbA1c, age, gender and body weight, responded well to oral insulin. These subsets exhibited an over 1% placebo adjusted, statistically significant, reduction in HbA1c. We are currently considering if there is a path forward for our oral insulin candidate, based on this analysis.

On August 2, 2023, Oramed signed a non-binding term sheet with Hefei Tianhui Incubator of Technologies Co. Ltd., or HTIT, to establish a joint venture, or the JV, based on Oramed's oral drug delivery technology. The proposed JV would focus on the development and worldwide commercialization of innovative products based on Oramed's oral insulin and POD™ (Protein Oral Delivery) pipeline and HTIT's manufacturing capabilities and technologies. The JV is subject to the execution of a binding definitive agreement.

The JV would be responsible for developing, marketing and commercializing drug products globally, focusing on Oramed's oral insulin and POD™ technology, as well as other assets in the Oramed pipeline. The parties intend for the JV to initiate a Phase 3 oral insulin trial in the United States.

Oramed and HTIT would initially hold equal shares in the JV, with each owning 50% of the equity. The Board of Directors would initially consist of equal representation from HTIT and Oramed, ensuring that both parties have an equal say in decision-making. As part of the JV, HTIT will make an initial investment of $60 million, while Oramed will invest $10 million.

NASH: On September 13, 2022, we reported positive top line results from a double blind, placebo controlled clinical trial of ORMD-0801 for the treatment of non-alcoholic steatohepatitis, or NASH, in T2D, 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 Medical Inc., or 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.

In October 2022, Oravax reported positive preliminary Phase 1 data for Cohort A of a Phase 1 clinical 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 in January 2023. Cohort B measured Immunoglobulin G, or IGG against the spike (S) protein, showing positive IGG in approximately 55% of the patients dosed. We are currently evaluating our path forward for Oravax's oral vaccines for COVID-19.

Impact of Current Events

On October 7, 2023, the State of Israel was attacked by and subsequently declared war on Hamas. As of November 9, 2023, we believe that there is no immediate risk to our business operations related to these events.

Results of Operations

Comparison of nine and three month periods ended September 30, 2023 and September 30, 2022

The following table summarizes certain statements of operations data of the Company for the nine and three month periods ended September 30, 2023 and September 30, 2022 (in thousands of dollars except share and per share data):

	Nine months ended		Three months ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenues	$ 1,340	$ 2,022	$ -	$ 682
Cost of revenues	-	-	-	-
Research and development expenses	7,205	20,362	957	5,347
Sales and marketing expenses	(287)	1,433	(663)	463
General and administrative expenses	6,314	11,085	2,599	3,061
Interest expenses	826	-	826	-
Financial income, net	4,510	1,930	435	1,036
Taxes on income	-	100	-	100
Net loss for the period	$ 8,208	$ 29,028	$ 3,284	$ 7,253
Basic and diluted loss per share of common stock	$ 0.19	$ 0.72	$ 0.08	$ 0.18
Weighted average shares of common stock outstanding used in computing basic and diluted loss per share of common stock	40,246,515	38,856,514	40,445,896	39,100,231

Revenues

Revenues consist of proceeds related to the Amended and Restated Technology License Agreement, dated December 21, 2015, between the Company and HTIT, or as further amended by the parties on June 3, 2016 and July 24, 2016 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 for the nine month period ended September 30, 2023 decreased by 34% to $1,340,000, compared to $2,022,000 for the nine month period ended September 30, 2022. The decrease was mainly due to recognition of revenues until the product submission date by HTIT of June 2023.

There were no revenues for the three month period ended September 30, 2023 while revenues were $682,000 for the three month period ended September 30, 2022. The decrease was mainly due to recognition of revenues until the product submission date by HTIT of June 2023.

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 and nine month periods ended September 30, 2023 and September 30, 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 preclinical 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 nine month period ended September 30, 2023 decreased by 65% to $7,205,000, compared to $20,362,000 for the nine month period ended September 30, 2022. The decrease was mainly due to lower expenses related to the Phase 3 trials that were terminated and to performance equity awards that expired because they did not meet their performance conditions during the period ended September 30, 2023. Stock-based compensation expenses for the nine month period ended September 30, 2023 were $805,000, compared to $1,907,000 during the nine month period ended September 30, 2022. This decrease was mainly due to performance equity awards that expired because they did not meet their performance conditions during the period ended September 30, 2023.

Research and development expenses for the three month period ended September 30, 2023 decreased by 82% to $957,000, compared to $5,347,000 for the three month period ended September 30, 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 September 30, 2023 were $390,000, compared to $771,000 during the three month period ended September 30, 2022. This decrease was mainly due to performance equity awards that expired because they did not meet their performance conditions during the period ended September 30, 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. We recently completed an analysis of the data from the ORA-D-013-1 Phase 3 trial and found that subpopulations of patients with pooled specific parameters responded well to oral insulin. We are currently considering if there is a path forward for our oral insulin candidate, based on this analysis. We are also 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 nine month periods ended September 30, 2023 and September 30, 2022, we did not recognize any research and development grants. As of September 30, 2023, we had incurred liabilities to pay royalties to the Israel Innovation Authority of the Israeli Ministry of Economy and Industry of $59,000.

Sales and Marketing Expenses

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

We recorded sales and marketing income of $287,000 for the nine month period ended September 30, 2023, compared to expenses of $1,433,000 for the nine month period ended September 30, 2022. This was primarily due to termination of the employment of an executive officer, which led to the forfeiture of his unvested options and RSUs, resulting in a reversal of the previously recorded expense. We recorded stock-based compensation income of $440,000 for the nine month period ended September 30, 2023, compared to expenses of $887,000 for the nine month period ended September 30, 2022. This was mainly due to termination of the employment of an executive officer, which led to the forfeiture of his unvested options and RSUs.

We recorded sales and marketing income of $663,000 for the three month period ended September 30, 2023 compared to expenses of $463,000 for the three month period ended September 30, 2022. This was primarily due to termination of the employment of an executive officer, which led to the forfeiture of his unvested options and RSUs, resulting in a reversal of the previously recorded expense. We recorded stock-based compensation income of $663,000 for the three month period ended September 30, 2023, compared to expenses of $463,000 for the three month period ended September 30, 2022. This was primarily due to termination of the employment of an executive officer, which led to the forfeiture of his unvested options and RSUs.

General and Administrative Expenses

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

General and administrative expenses for the nine month period ended September 30, 2023 decreased by 43% to $6,314,000 compared to $11,085,000 for the nine month period ended September 30, 2022. The decrease was mainly due to lower stock-based compensation expenses, lower legal, insurance and public relations and investor relations expenses. Stock-based compensation expenses for the nine month period ended September 30, 2023 were $2,480,000, compared to $6,167,000 for the nine month period ended September 30, 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 expired because they did not meet their performance conditions during the period ended September 30, 2023.

General and administrative expenses for the three month period ended September 30, 2023 decreased by 15% to $2,599,000 compared to $3,061,000 for the three month period ended September 30, 2022. The decrease was mainly due to lower stock-based compensation expenses, partially offset by higher legal and consulting expenses. Stock-based compensation expenses for the three month period ended September 30, 2023 were $1,125,000, compared to $1,977,000 for the three month period ended September 30, 2022. This decrease was mainly due to equity awards granted to directors and officers in the third quarter of 2022.

Interest Expenses

Interest expenses were $826,000 for the three and nine month periods ended September 30, 2023, while there were no interest expenses for the three and nine month periods ended September 30, 2022. The increase was mainly due to interest on the Short-Term Borrowings.

Financial Income, Net

Net financial income increased by 134% to $4,510,000 for the nine month period ended September 30, 2023, compared to $1,930,000 for the nine month period ended September 30, 2022. The increase was mainly due to interest from short-term bank deposits and revaluation of non-marketable equity securities, partially offset by fees incurred as part of the Transaction and revaluation of the Transaction (mainly from the change in fair value of the Warrants).

Net financial income decreased by 58% to $435,000 for the three month period ended September 30, 2023, compared to net financial income of $1,036,000 for the three month period ended September 30, 2022. The decrease was mainly due to fees incurred as part of the Transaction and revaluation of the Transaction (mainly from the change in fair value of the Warrants), partially offset by 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 nine month period ended September 30, 2023 decreased by 74% to $0.19, compared to $0.72 for the nine month period ended September 30, 2022. The decrease in loss per share was mainly due to lower net loss resulting from the changes set forth above in the nine month period ended September 30, 2023 compared to the nine month period ended September 30, 2022.

Basic and diluted loss per share of common stock for the three month period ended September 30, 2023 decreased by 56% to $0.08, compared to $0.18 for the three month period ended September 30, 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 September 30, 2023 compared to the three month period ended September 30, 2022.

Weighted Average Shares of Common Stock Outstanding

Weighted average shares of common stock outstanding for the nine month period ended September 30, 2023 were 40,246,515, compared to 38,856,514 for the nine month period ended September 30, 2022. The increase was mainly due to shares issued in connection with our controlled equity offering.

Weighted average shares of common stock outstanding for the three month period ended September 30, 2023 were 40,445,896, compared to 39,100,231 for the three month period ended September 30, 2022. The increase was mainly due to shares issued in connection with our controlled equity offering during the fourth quarter of 2022 and the first quarter of 2023.

Liquidity and Capital Resources

From inception through September 30, 2023, we have incurred losses in an aggregate amount of $170,892,000. During that period and through September 30, 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 $255,375,000, 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 September 30, 2023, we had $5,468,000 of available cash and $120,158,000 of short-term bank deposits.

From inception through September 30, 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. Following the termination of the ORA-D-013-1 and ORA-D-013-2 Phase 3 trials, the Company's research and development activities have been significantly reduced while it conducts a strategic review process. As a result, the Company is currently incurring lower research and development and sales and marketing expenses.

Based on our current cash resources and commitments, we believe we will be able to maintain our current planned 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. 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.

On August 9, 2023, we entered into the Senior DIP Loan Agreement with the Debtors in the principal amount of $100,000,000.

On the Closing Date, we entered into and consummated the Transaction. Pursuant to the Scilex SPA, in exchange for the DIP Assumption and for the ability to credit the amounts assumed under the DIP Assumption in exchange for certain equity securities of Scilex owned by Sorrento, Scilex (i) issued to us (A) the Note, (B) the Closing Penny Warrant, and (C) the Subsequent Penny Warrants, and (ii) caused the Transferred Warrants to be transferred to us. In addition, on the Closing Date, Scilex reimbursed $1,910,000 of the Company's Transaction expenses pursuant to the Scilex SPA.

Pursuant to the terms of the Scilex SPA, Scilex agreed to certain restrictions on additional issuances of equity securities. In connection with the Transaction, we and Sorrento mutually agreed to terminate the Sorrento SPA and to release all claims the Company and Sorrento may have against one another, and Scilex completed the acquisition of the Purchased Securities.

On August 8, 2023, we borrowed an aggregate of $99,550,000 pursuant to loan agreements from Israel Discount Bank Ltd., or the Short-Term Borrowings. The Short-Term Borrowings mature on dates ranging from August 11, 2023 to May 24, 2024, bear interest ranging from 6.66% to 7.38%, are secured by certificates of deposits issued by Israel Discount Bank Ltd. having an aggregate face amount of $99,550,000. The net proceeds of the Short-Term Borrowings were used to fund the Note. The Short-Term Borrowings are paid in one payment of principal and interest at each respective maturity. As of September 30, 2023, $25,000,000 was repaid under the Short-Term Borrowings.

As of September 30, 2023, our total current assets were $175,705,000 and our total current liabilities were $78,175,000. On September 30, 2023, we had a working capital surplus of $97,530,000 and an accumulated loss of $170,892,000. 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 September 30, 2023 was mainly due to a decrease in cash and cash equivalents, marketable securities, partially offset by an increase in short term deposits and accounts payable and accrued expenses.

During the nine month period ended September 30, 2023, cash and cash equivalents decreased to $5,468,000, from $40,464,000 as of December 31, 2022. The decrease was mainly due to the reasons described below.

Operating activities used cash of $8,877,000 in the nine month period ended September 30, 2023, compared to $19,856,000 used in the nine month period ended September 30, 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, interest paid on Short-Term Borrowings, accounts payable and accrued expenses.

Investing activities used cash of $103,035,000 in the nine month period ended September 30, 2023, compared to cash provided by investing activities of $18,951,000 in the nine month period ended September 30, 2022. Cash used by investing activities in the nine month period ended September 30, 2023 consisted primarily of our investment in the Transaction and the purchase of short-term deposits, partially offset by proceeds from short term investing activities.

Financing activities provided cash of $76,978,000 in the nine month period ended September 30, 2023, compared to $6,604,000 provided in the nine month period ended September 30, 2023. Cash provided by financing activities consisted primarily of proceeds from the Short-Term Borrowings.

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 September 30, 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, except as mentioned below.

Our investment in the Transferred Warrants is accounted for as derivatives measured at fair value.

We elected the fair value option for the Note and Penny Warrants in order to reduce operational complexity of bifurcating embedded derivatives. Changes in value are recorded in financial income, net and include interest income on the Note.

The fair value of the Note and the Penny Warrants is impacted by our assumptions regarding the possibility of an early repayment of the Note, in accordance with the terms of the Note.

Planned Expenditures

We have invested 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 September 30, 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 September 30, 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 September 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1A - RISK FACTORS

An investment in our securities involves a high degree of risk. You should consider carefully the following information about these risks, together with the other risks contained under the heading "Item 1A. Risk Factors" in our Annual Report before making an investment decision. Our business, prospects, financial condition and results of operations may be materially and adversely affected as a result of any of the following risks. The value of our securities could decline as a result of any of these risks. You could lose all or part of your investment in our securities. Some of the statements in "Item 1A. Risk Factors" are forward-looking statements. The following risk factors are not the only risk factors facing the Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Related to Our Business

If we fail to establish a joint venture with HTIT, if such joint venture is not successful or if we fail to realize the benefits we anticipate from such joint venture, we may not be able to capitalize on the full market potential of our drug products and technology.

On August 2, 2023, we signed a non-binding term sheet with HTIT to establish a joint venture, or the JV, based on Oramed's oral drug delivery technology. The JV is subject to the execution of a binding definitive agreement and there can be no assurances, that we will enter into the binding and definitive agreements with HTIT in a particular time period, or at all, or on terms similar to those set forth in the non-binding term sheet, or that if such definitive agreements are entered into, that the JV will receive the necessary regulatory approvals for the Phase 3 oral insulin trial in the United States or that our drug products and our technology will be developed and commercialized successfully. In addition, the JV will subject us to a number of risks including risks relating to the lack of full control of the JV, potential disagreements with HTIT about how to manage the JV that may result in the delay or termination of the commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources, conflicting interests of the JV, and the JV and its business not being profitable.

While we believe that our board representation, voting rights and other contractual rights with respect to the JV will serve to mitigate some of these risks, we may have disagreements with the other directors and HTIT that could impair our ability to influence the JV to act in a manner that we believe is in the best interests of our Company.

We have lent a substantial amount of funds to Scilex. In the event that Scilex is unable to service its obligations under and defaults on the Note, it could have a material adverse effect on our business.

On September 21, 2023, we were issued the Note in an aggregate principal amount of $101,875,000 by Scilex pursuant to the Scilex SPA. The Note matures on March 21, 2025 and is payable in six principal installments, with the first installment payable on December 21, 2023. Interest under the Note accrues at a fluctuating per annum interest rate equal to the sum of (1) the greater of (x) four percent (4%) and (y) Term SOFR (as defined in the Note) and (2) eight and one half percent (8.5%), payable in-kind on a monthly basis.

There is no guarantee that Scilex will be able to service its repayment obligations under the Note. Although the Note is secured by a first priority security interest in and liens on all of the assets of Scilex and its subsidiaries, no assurance can be made that Scilex will be able to repay the Note when due. In such an event, we could lose all or a substantial portion of our loan investment. Additionally, Scilex has disclosed in its periodic reports filed with the SEC that there is substantial doubt about its ability to continue as a going concern. If Scilex is unable to continue as a going concern or defaults on the Note, we may be unable to recover some or all of the principal amount of the Note, which could have a material adverse affect on our business, financial condition and results of operations.

We may have difficulty realizing the full value of the Warrants.

The Closing Penny Warrant will be exercisable upon the earliest of (i) March 14, 2025, (ii) the date on which the Note has been repaid in full, and (iii) the Management Sale Trigger Date (as defined therein), if any, and will expire on the date that is the fifth anniversary of the issuance date. For purposes of the Penny Warrants, the Management Sale Trigger Date is generally the first date that certain members of Scilex management engage in certain sales or other similar transfers of shares of Scilex Common Stock or other of Scilex's or any of its subsidiaries' securities, subject to certain exceptions as are customary for lock-up agreements executed by directors and officers in connection with financings or similar transactions.

The Subsequent Penny Warrants will vest and become exercisable on the date that is the later of (i) Subsequent Penny Warrant Vesting Date, and (ii) the earliest of (A) March 14, 2025, (B) the date on which the Note has been repaid in full and (C) the Management Sale Trigger Date, if any. Each Subsequent Penny Warrant will expire on the date that is the fifth anniversary of the issuance date; provided that, if the Note is repaid in full prior to the Subsequent Penny Warrant Vesting Date applicable to such Subsequent Penny Warrant, such Subsequent Penny Warrant will expire on the date the Note is repaid in full.

The Transferred Warrants are listed on Nasdaq, have an exercise price of $11.50 per share, are fully exercisable, and expire on November 10, 2027.

Because of the foregoing restrictions on exercisability of the Closing Penny Warrant and the Subsequent Penny Warrants, and exercise price of the Transferred Warrants, we may not be able to exercise the Warrants for shares of Scilex Common Stock at a time when it would be financially beneficial for us to do so. Accordingly, there is no guarantee that we will be able to realize the full or any value of the Warrants.

ITEM 2 - UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On September 15, 2023, we issued 3,000 shares of our common stock to Corporate Profile, LLC, or Corporate Profile, in payment of a portion of the consulting fee for investor relations services owed to Corporate Profile pursuant to a Letter Agreement, dated August 3, 2023, between us and Corporate Profile.

We issued these shares pursuant to an exemption from registration contained in Section 4(a)(2) of the Securities Act of 1933, as amended.

ITEM 6 – EXHIBITS

Number	Exhibit
10.1+	Securities Purchase Agreement, dated September 21, 2023 by and between Scilex Holding Company and Oramed Pharmaceuticals Inc. (incorporated by reference from our current report on Form 8-K filed September 26, 2023).
10.2	Senior Secured Promissory Note, dated September 21, 2023 issued to Oramed Pharmaceuticals Inc. by Scilex Holding Company (incorporated by reference from our current report on Form 8-K filed September 26, 2023).
10.3	Warrant No. ORMP CS-1 to Purchase Common Stock of Scilex Holding Company (incorporated by reference from our current report on Form 8-K filed September 26, 2023).
10.4	Warrant No. ORMP CS-2 to Purchase Common Stock of Scilex Holding Company (incorporated by reference from our current report on Form 8-K filed September 26, 2023).
10.5	Warrant No. ORMP CS-3 to Purchase Common Stock of Scilex Holding Company (incorporated by reference from our current report on Form 8-K filed September 26, 2023).
10.6	Warrant No. ORMP CS-4 to Purchase Common Stock of Scilex Holding Company (incorporated by reference from our current report on Form 8-K filed September 26, 2023).
10.7	Warrant No. ORMP CS-5 to Purchase Common Stock of Scilex Holding Company (incorporated by reference from our current report on Form 8-K filed September 26, 2023).
10.8	Scilex Holding Company Specimen Warrant Certificate (incorporated by reference from our current report on Form 8-K filed September 26, 2023).
10.9	Registration Rights Agreement, dated September 21, 2023, by and between Oramed Pharmaceuticals Inc. and Scilex Holding Company (incorporated by reference from our current report on Form 8-K filed September 26, 2023).
10.10+	Subsidiary Guarantee, dated September 21, 2023, by and among Oramed Pharmaceuticals, Acquiom Agency Services LLC, Scilex Holding Company, and certain subsidiaries of Scilex Holding Company party thereto (incorporated by reference from our current report on Form 8-K filed September 26, 2023).
10.11	Security Agreement, dated September 21, 2023, by and among Oramed Pharmaceuticals, Acquiom Agency Services LLC, Scilex Holding Company, and certain subsidiaries of Scilex Holding Company party thereto (incorporated by reference from our current report on Form 8-K filed September 26, 2023).
10.12	Mutual Termination and Release Agreement, dated September 21, 2023, by and between Sorrento Therapeutics, Inc. and Oramed Pharmaceuticals, Inc. (incorporated by reference from our current report on Form 8-K filed September 26, 2023).
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 September 30, 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

\+ Certain exhibits and similar attachments to this agreement have been omitted in accordance with Item 601(a)(5) of Regulation S-K. A copy of any omitted exhibit or other attachment will be furnished supplementally to the SEC upon request.

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: November 9, 2023

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

Date: November 9, 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: November 9, 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: November 9, 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 September 30, 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: November 9, 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 September 30, 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: November 9, 2023

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