**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, 2024**

**☐ 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 7, 2024, there were 40,312,069 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," "Oramed" 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, 2024, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.710 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 plan to evaluate potential strategic opportunities;
- our potential repurchases of shares of our common stock;
- our ability to recover the proceeds and/or collateral under the Tranche A Note or the Tranche B Note (each as defined herein), or, collectively, the Notes, and related agreements from Scilex Holding Company, or Scilex;
- the fluctuating market price and liquidity of the common stock of Scilex underlying the warrants we hold;
- the possibility that the anticipated benefits of the 2023 Scilex 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 Notes and the ability of the Company to realize the value of the warrants;
- the ability of Oramed, Hefei Tianhui Biotech Co., Ltd., or HTIT Biotech, and Technowl Limited to reach agreement and enter into additional agreements within a three-month period of the signing of the JV Agreement (as defined herein), and the ability of the parties to succeed in the goals set out for the joint venture;
- 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;
- 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;
- 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, or our Annual Report, as filed with the Securities and Exchange Commission, or the SEC, on March 6, 2024, 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, 2024

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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, 2024 | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | $ 42,104 | $ 9,055 |
| Short-term deposits | 42,741 | 95,279 |
| Investments at fair value | 57,455 | 57,713 |
| Prepaid expenses and other current assets | 474 | 537 |
| Total current assets | 142,774 | 162,584 |
| **LONG-TERM ASSETS:** | | |
| Long-term deposits | 2 | 7 |
| Investments at fair value | 16,901 | 51,035 |
| Marketable securities | 646 | 1,807 |
| Other non-marketable equity securities | 3,524 | 3,524 |
| Amounts funded in respect of employee rights upon retirement | 30 | 27 |
| Property and equipment, net | 718 | 873 |
| Operating lease right-of-use assets | 486 | 694 |
| Total long-term assets | 22,307 | 57,967 |
| Total assets | $ 165,081 | $ 220,551 |
| **Liabilities and stockholders' equity** | | |
| **CURRENT LIABILITIES:** | | |
| Accounts payable and accrued expenses | $ 4,995 | $ 1,609 |
| Short-term borrowings | - | 51,013 |
| Payable to related parties | 35 | 325 |
| Operating lease liabilities | 243 | 267 |
| Total current liabilities | 5,273 | 53,214 |
| **LONG-TERM LIABILITIES:** | | |
| Long-term deferred revenues | 4,000 | 4,000 |
| Employee rights upon retirement | 29 | 28 |
| Provision for uncertain tax position | 11 | 11 |
| Operating lease liabilities | 186 | 342 |
| Other liabilities | 60 | 63 |
| Total long-term liabilities | 4,286 | 4,444 |
| **COMMITMENTS (note 5)** | | |
| **EQUITY ATTRIBUTABLE TO COMPANY'S STOCKHOLDERS:** | | |
| Common stock, $0.012 par value (60,000,000 authorized shares; 40,209,575 and 40,338,979 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively) | 484 | 485 |
| Additional paid-in capital | 322,384 | 320,892 |
| Accumulated deficit | (166,427) | (157,556) |
| Total stockholders' equity | 156,441 | 163,821 |
| Non-controlling interests | (919) | (928) |
| Total equity | 155,522 | 162,893 |
| Total liabilities and equity | $ 165,081 | $ 220,551 |

**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, 2024 | September 30, 2023 | September 30, 2024 | September 30, 2023 |
| **REVENUES** | $ - | 1,340 | $ - | - |
| **RESEARCH AND DEVELOPMENT** | (4,863) | (7,205) | (2,242) | (957) |
| **SALES AND MARKETING** | - | 287 | - | 663 |
| **GENERAL AND ADMINISTRATIVE** | (4,323) | (6,314) | (847) | (2,599) |
| **OPERATING LOSS** | (9,186) | (11,892) | (3,089) | (2,893) |
| | | | | |
| **INTEREST EXPENSES** | (853) | (826) | - | (826) |
| **FINANCIAL INCOME (LOSS), NET** | 3,902 | 4,510 | (15,420) | 435 |
| **LOSS BEFORE TAX EXPENSES** | $ (6,137) | (8,208) | $ (18,509) | (3,284) |
| **TAX EXPENSES** | (2,767) | - | (1,133) | - |
| **NET LOSS** | $ (8,904) | (8,208) | $ (19,642) | (3,284) |
| **NET LOSS ATTRIBUTABLE TO NON-CONTROLLING INTERESTS** | (33) | (397) | (23) | (62) |
| **NET LOSS ATTRIBUTABLE TO STOCKHOLDERS** | (8,871) | (7,811) | (19,619) | (3,222) |
| **BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK** | $ (0.22) | $ (0.19) | $ (0.48) | $ (0.08) |
| **WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK** | 40,882,110 | 40,246,515 | 40,896,845 | 40,445,896 |

**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, 2023** | 40,339 | $ 485 | $ 320,892 | $ (157,556) | $ 163,821 | $ (928) | $ 162,893 |
| **CHANGES DURING THE NINE MONTH PERIOD ENDED SEPTEMBER 30, 2024** | | | | | | | |
| **STOCK-BASED COMPENSATION** | 410 | 5 | 2,777 | - | 2,782 | - | 2,782 |
| **STOCK-BASED COMPENSATION OF SUBSIDIARY** | - | - | - | - | - | 42 | 42 |
| **REPURCHASE AND RETIREMENT OF COMMON STOCK** | (539) | (6) | (1,285) | | (1,291) | | (1,291) |
| **NET LOSS** | - | - | - | (8,871) | (8,871) | (33) | (8,904) |
| **BALANCE AS OF SEPTEMBER 30, 2024** | 40,210 | $ 484 | $ 322,384 | $ (166,427) | $ 156,441 | $ (919) | $ 155,522 |

| | 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 |

* Represents an amount of less than $1.

**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, 2024** | 40,629 | $ 488 | $ 323,385 | $ (146,808) | $ 177,065 | $ (911) | $ 176,154 |
| **CHANGES DURING THE THREE MONTH PERIOD ENDED SEPTEMBER 30, 2024** | | | | | | | |
| **STOCK-BASED COMPENSATION** | 120 | 2 | 284 | - | 286 | - | 286 |
| **STOCK-BASED COMPENSATION OF SUBSIDIARY** | - | - | - | - | - | 15 | 15 |
| **REPURCHASE AND RETIREMENT OF COMMON STOCK** | (539) | (6) | (1,285) | | (1,291) | | (1,291) |
| **NET LOSS** | - | - | - | (19,619) | (19,619) | (23) | (19,642) |
| **BALANCE AS OF SEPTEMBER 30, 2024** | 40,210 | $ 484 | $ 322,384 | $ (166,427) | $ 156,441 | $ (919) | $ 155,522 |

| | 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 |

* Represents an amount of less than $1.

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

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

| | Nine months ended September, | |
|---|---|---|
| | **2024** | **2023** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net loss | $ (8,904) | $ (8,208) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 162 | 143 |
| Exchange differences and interest on deposits and held to maturity bonds | (2,162) | (2,042) |
| Changes in fair value of investments | (140) | (191) |
| Stock-based compensation | 2,824 | 2,845 |
| Shares issued for services | - | 9 |
| Gain on amounts funded in respect of employee rights upon retirement | (3) | (2) |
| Change in accrued interest on short-term borrowings | (1,463) | 813 |
| Prepaid expenses and other current assets | 63 | 726 |
| Accounts payable, accrued expenses and related parties | 3,096 | (1,601) |
| Net changes in operating lease | 28 | (35) |
| Deferred revenues | - | (1,340) |
| Liability for employee rights upon retirement | 1 | 6 |
| Other liabilities | (3) | - |
| Total net cash used in operating activities | (6,501) | (8,877) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Purchase of short-term deposits | (42,450) | (91,369) |
| Proceeds from short-term deposits | 97,152 | 84,760 |
| Proceeds from maturity of held to maturity securities | - | 3,375 |
| Proceeds from long-term deposits | 5 | - |
| Long-term investments | (1,307) | (99,550) |
| Proceeds from long-term investments and marketable securities | 37,000 | - |
| Purchase of property and equipment, net | (7) | (251) |
| Total net cash provided by (used in) investing activities | 90,393 | (103,035) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Proceeds from issuance of common stock, net of issuance costs | - | 2,428 |
| Repurchase and retirement of common stock | (1,291) | - |
| Loans received | - | 99,550 |
| Loans repaid | (49,550) | (25,000) |
| Total net cash provided by (used in) financing activities | (50,841) | 76,978 |
| **EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS** | (2) | (62) |
| | | |
| **INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS** | 33,049 | (34,996) |
| | | |
| **CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD** | 9,055 | 40,464 |
| **CASH AND CASH EQUIVALENTS AT END OF PERIOD** | $ 42,104 | $ 5,468 |
| | | |
| **(A) SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -** | | |
| Interest received | $ 6,873 | $ 3,393 |
| Interest paid | $ (2,316) | $ (14) |
| **(B) SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES -** | | |
| Recognition of operating lease right-of-use assets and liabilities | 58 | - |
| Derecognition of right-of-use asset | (26) | - |
| Derecognition of lease liability | 23 | - |

**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, Oravax Medical Inc. ("Oravax") was established by the Company and others. The Company holds a 63% interest in Oravax. Consequently, the Company consolidates Oravax in its consolidated financial statements since that time.

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 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 (ORMD-0801). These subsets exhibited an over 1% placebo adjusted, statistically significant, reduction in HbA1c. Based on this analysis, the Company submitted a new Phase 3 clinical trial protocol (ORA-D-013-3) to the U.S. Food and Drug Administration (the "FDA").

On January 22, 2024, the Company and its wholly-owned subsidiary, Oramed Ltd., entered into a joint venture agreement (the "JV Agreement"), with Hefei Tianhui Biotech Co., Ltd. ("HTIT Biotech") and Technowl Limited, a wholly-owned indirect subsidiary of HTIT Biotech ("HTIT Sub" and together with HTIT Biotech, "HTIT"), pursuant to which, subject to the terms and conditions set forth in the JV Agreement, the parties will establish a joint venture (the "JV"), based on the Company's oral drug delivery technology.

The JV will focus on the development and worldwide commercialization of innovative products based on the Company's oral insulin and POD™ (Protein Oral Delivery) pipeline and HTIT's manufacturing capabilities and technologies. The JV expects to conduct a Phase 3 oral insulin clinical trial in the United States.

The Company and HTIT will initially hold equal shares in the JV, with each owning 50% of the equity. The board of directors will initially consist of equal representation from HTIT and the Company. HTIT will contribute to the JV cash and credit to purchase materials, while the Company will contribute cash and shares of the Company's common stock (that will be subject to certain registration rights) and will transfer intellectual property related to its oral insulin and POD™ technology, as well as other assets in the Company's pipeline.

The consummation of the JV Agreement is subject to and contingent upon the parties entering into additional agreements pursuant to the JV Agreement. There is no assurance that the parties will complete and sign these additional agreements.

**NOTE 1 - GENERAL** (continued):

**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.

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.

**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, 2023 (the "2023 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 2023 Form 10-K. The results for interim periods are not necessarily indicative of a full fiscal year's results.

**b. Repurchase and retirement of common stock**

The Company debited the common stock account by the par value of the shares retired and allocated the excess of the repurchase price over the par value of the shares to additional paid in capital

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

**c**. **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 4,780,566 and 3,745,590 for the nine month periods ended September 30, 2024 and September 30, 2023, respectively, and 4,703,601 and 3,845,271 for the three month periods ended September 30, 2024 and September 30, 2023, respectively.

**d. Recently issued accounting pronouncements, not yet adopted**

In November 2023, the Financial Accounting Standard Board (the "FASB") issued Accounting Standards Update ("ASU") 2023-07 "Segment Reporting: Improvements to Reportable Segment Disclosures." This guidance expands public entities' segment disclosures primarily by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. Public entities with a single reportable segment are required to provide the new disclosures and all the disclosures required under Accounting Standards Codification 280 "Segment Reporting". The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments are required to be applied retrospectively to all prior periods presented in an entity's financial statements. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements related disclosures.

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

**d. Recently issued accounting pronouncements, not yet adopted** (continued):

In December 2023, the FASB issued ASU 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." This guidance is intended to enhance the transparency and decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the U.S. and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively. Early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

**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.

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

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

**e. Fair value** (continued):

The Company's financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows:

| | September 30, 2024 | | | |
|---|---|---|---|---|
| | **Level 1** | **Level 2** | **Level 3** | **Total** |
| Assets: | | | | |
| Marketable Securities | | | | |
| DNA (as defined below) | 424 | - | - | 424 |
| Entera (as defined below) | 222 | - | - | 222 |
| Closing Penny Warrant (see note 4) | - | 4,161 | - | 4,161 |
| Subsequent Penny Warrants (see note 4) | - | 6,877 | 982 | 7,859 |
| Tranche A Note (see note 4) | - | - | 61,060 | 61,060 |
| Profit Sharing Loan Agreement (see note 4) | | | 1,276 | 1,276 |
| | $ 646 | $ 11,038 | $ 63,318 | $ 75,002 |

| | December 31, 2023 | | | |
|---|---|---|---|---|
| | **Level 1** | **Level 2** | **Level 3** | **Total** |
| Assets: | | | | |
| Marketable Securities | | | | |
| DNA | 297 | - | - | 297 |
| Entera | 70 | - | - | 70 |
| Transferred Warrants (see note 4) | 1,440 | - | - | 1,440 |
| Closing Penny Warrant (see note 4) | - | 9,180 | - | 9,180 |
| Subsequent Penny Warrants (see note 4) | - | - | 6,502 | 6,502 |
| Tranche A Note (see note 4) | - | - | 93,066 | 93,066 |
| | $ 1,807 | $ 9,180 | $ 99,568 | $ 110,555 |

As of September 30, 2024 and December 31, 2023, the carrying amounts of cash equivalents, short-term deposits, and accounts payable approximate their fair values due to the short-term maturities of these instruments.

The amounts funded in respect of employee rights are stated at cash surrender value which approximates its fair value.

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

## NOTE 3 - 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 4).

**Composition**

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| **Long-term:** | | |
| DNA | $ 424 | $ 297 |
| Entera | 222 | 70 |
| Transferred Warrants (see note 4) | - | 1,440 |
| | $ 646 | $ 1,807 |

## NOTE 4 - INVESTMENTS, AT FAIR VALUE:

***2023 Scilex Transaction***

On September 21, 2023, the Company entered into and consummated the transactions (collectively, the "2023 Scilex Transaction") contemplated by a securities purchase agreement with Scilex, pursuant to which Scilex issued to the Company:

a. A senior secured promissory note (the "Tranche A Note"), with a principal amount of $101,875, maturing on March 21, 2025 and bearing interest of SOFR plus 8.5%, payable in-kind. Scheduled principal payments are due on December 21, 2023, March 21, 2024, June 21, 2024, September 21, 2024, and December 21, 2024, with the balance due on March 21, 2025. As per the Tranche A Note terms, if the Tranche A Note is not repaid in full on or prior to March 21, 2024, an exit fee of $3,056 is due. Since the Tranche A Note was not repaid by that date, the Company is entitled to the above-mentioned exit fee at the maturity date of the Tranche A Note. As of September 30, 2024, Scilex has repaid $41,700 of the amount due under the Tranche A Note. See the description of the Extension Agreement (as defined below).

b. Warrants to purchase up to 4,500,000 shares of Scilex common stock with an exercise price of $0.01 per share (the "Closing Penny Warrants") and four additional warrants (the "Subsequent Penny Warrants") each for 2,125,000 shares of Scilex common stock with an exercise price of $0.01 per share. The Closing Penny Warrants were vested on September 21, 2023, and each of the Subsequent Penny Warrants shall vest on each of March 19, 2024, June 17, 2024, September 15, 2024 and December 14, 2024. The Closing Penny Warrants and the Subsequent Penny Warrants shall become exercisable on the earliest of (i) March 14, 2025 and (ii) the date on which the Tranche A Note has been repaid in full.

   As of September 30, 2024, 4,500,000 Closing Penny Warrants were vested according to the terms of Tranche A Note, 6,375,000 Subsequent Penny Warrants were vested according to the terms of the Tranche A Note and additional 1,062,500 Subsequent Penny Warrants were vested as per the Extension Agreement (as defined below).

   As of September 30, 2024, 4,500,000 Closing Penny Warrants and 2,000,000 Subsequent Penny Warrants are exercisable (see below).

**NOTE 4 - INVESTMENTS, AT FAIR VALUE** (continued):

c. Transferred warrants (the "Transferred Warrants") to purchase 4,000,000 shares of Scilex common stock at $11.50 per share, fully exercisable and expiring on November 10, 2027. On September 20, 2024, the Company sold the Transferred Warrants for consideration of $300 (see below). As a result, as of September 30, 2024 the Company does not hold any Transferred Warrants.

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

The Company elected the fair value option for the Tranche A 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 Tranche A Note.

The valuation was performed based on several scenarios. Each scenario took into consideration the present value of the Tranche A Note's cash flows (including the exit fee and the prepayment premium) and the Warrants' value. The total value of the 2023 Scilex Transaction (and of each of its components) was valued on a weighted average of the different scenarios.

The discount rate of the Tranche A 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 53.05% to 53.08%.

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 common stock on the Nasdaq Capital Market, taking into account several scenarios. The difference between the Tranche A Note's fair value and aggregate unpaid principal balance (which includes interest payable on maturity) is $11,849.

On August 30, 2024, Scilex agreed that 4,500,000 Closing Penny Warrants and 937,500 Subsequent Penny Warrants became exercisable as of such date.

On September 20, 2024, the Company and Scilex entered into an extension agreement (the "Extension Agreement") to extend the due date of the September 21, 2024 payment (see note 9). Pursuant to the Extension Agreement, Scilex paid to the Company $2,000 on September 23, 2024, which payment is to be applied as follows: (i) $1,700 to the payment due under the Tranche A Note on March 21, 2025 and (ii) $300 to purchase the Transferred Warrants. In addition, 1,062,500 Subsequent Penny Warrants were accelerated from December 15, 2024 and became exercisable into shares of Scilex common stock at any time after September 20, 2024.

As of December 31, 2023, the fair value of the 2023 Scilex Transaction was $110,188, split between the Tranche A Note ($93,066), the Closing Penny Warrant ($9,180), the Subsequent Penny Warrants ($6,502) and the Transferred Warrants ($1,440).

As of September 30, 2024, the fair value of the 2023 Scilex Transaction was $73,080, split among the Tranche A Note ($61,060), Closing Penny Warrant ($4,161) and Subsequent Penny Warrants ($7,859). As a result of the reevaluation of the Tranche A Note, the Company recorded financial loss of $108 for the nine month period ended September 30, 2024.

Based on anticipated gains from the 2023 Scilex Transaction, the Company anticipates taxable income for the fiscal year ending December 31, 2024. As a result, the Company expects to fully utilize its tax loss carryforward and incur associated tax expenses. During the nine month period ended September 30, 2024, the Company recognized tax expenses of $2,767. Tax provision of $2,767 has been classified to accounts payable and accrued expenses. The provision for income taxes in the interim period is determined using an estimated annual effective tax rate (taking into account utilization of carryforward tax losses of the Company).

**NOTE 4 - INVESTMENTS, AT FAIR VALUE** (continued):

On October 7, 2024, the Company entered into a convertible note agreement with certain institutional investors and Scilex to refinance $25,000 of the Tranche A Note. For more information see note 9.

***Profit Sharing Loan Agreement***

On September 4, 2024, the Company entered into a loan agreement (the "Profit Sharing Loan Agreement") with Rabi Binyamin 4 Tama 38 Ltd. (the "Borrower") to finance a real estate project (the "Project"). According to the terms of the Profit Sharing Loan Agreement, Oramed agreed to loan NIS 5.5 million ($1,523) (the "Loan Principal") to the Borrower. NIS 4.7 million ($1,307) was loaned upon signing the Profit Sharing Loan Agreement and an additional NIS 0.8 million ($216) will be loaned upon certain milestones which are expected to occur in the first half of 2025. Upon completion of the Project, the Company is entitled to receive the Loan Principal and the greater of: (i) 20% annual interest of the Loan Principal and (ii) 40% of the Project profits.

The Company decided to designate the Profit Sharing Loan Agreement as a whole under the Fair-Value option in accordance with Accounting Standards Codification Topic 825 "Financial Instruments".

**NOTE 5 - COMMITMENTS:**

On September 23, 2024, the Company's wholly owned subsidiary, Oramed Ltd. (the "Subsidiary") entered into a Clinical Research Organization Services Agreement with a third party, to retain it as a clinical research organization ("CRO"). The services covered by the agreement include strategic planning, expert consultation, data processing, regulatory, clerical, project management and other research and development services requested by the Company for the Phase 3 clinical trial. As consideration for its services, the Company will pay the CRO a total amount of $11,577 during the term of the engagement and based on achievement of certain milestones, of which $581 recognized in research and development expenses through September 30, 2024.

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

**NOTE 6 - STOCKHOLDERS' EQUITY:**

***Stock -based compensation***

Below is a table summarizing all of the RSUs grants to employees and Directors made during the nine month period ended September 30, 2024.

| | No. of RSUs granted | Exercise price | Vesting period | Fair value at grant* | Expiration period (in years) |
|---|---|---|---|---|---|
| Employees | 1,389,540 | 0 | ** | $ 3,278,782 | 10 |
| Directors | 221,920 | 0 | *** | $ 530,654 | 10 |

* The RSUs' fair value is based on the Company's share price on the Nasdaq Capital Market on the grant dates.

**

**Employees:**

| No. of RSUs granted | Vesting period |
|---|---|
| 950,500 | Vesting in 12 equal quarterly installments starting January 8, 2024. |
| 294,000 | Vesting on April 4, 2025. |
| 93,360 | Vesting on June 18, 2026. |
| 46,680 | Vesting in 4 equal quarterly installments starting September 18, 2026. |
| 5,000 | Vesting in 12 equal quarterly installments starting July 1, 2024. |
| **1,389,540** | **Total RSUs granted to Employees** |

See expected vesting period of 34,000 performance-based RSUs ("PSUs") below.

***

**Directors:**

| No. of RSUs granted | Vesting period |
|---|---|
| 172,500 | Vesting in 3 equal annual installments starting January 1, 2025. |
| 41,360 | Vesting in 4 equal quarterly installments starting April 1, 2024. |
| 7,300 | Vesting in 3 equal annual installments starting July 1, 2024. |
| 760 | Vesting in 2 equal quarterly installments starting October 1, 2024. |
| **221,920** | **Total RSUs granted to Directors** |

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

**NOTE 6 - STOCKHOLDERS' EQUITY** (continued):

***Stock based compensation*** (continued):

Below is a table summarizing all of the PSU grants to the Chief Financial Officer made during the nine month period ended September 30, 2024.

| No. of PSUs granted | Exercise price | Expected vesting period | Fair value at grant | Expiration period (in years) |
|---|---|---|---|---|
| 34,000 | 0 | 2.5 years | $ 73,379 | 10 |

On June 20, 2024, the Company granted 34,000 PSUs representing a right to receive shares of the Company's common stock to the Company's Chief Financial Officer. The total amount of the PSUs shall vest upon the later of (i) June 18, 2026 and (ii) when the closing price per share of Common Stock of the Company on the Nasdaq Capital Market reaches an average of $4.00 over any 10-trading day period. The total fair value of these PSUs on the date of grant was $73, using the Monte-Carlo model, based on the quoted closing market share price of $2.21 on the Nasdaq Capital Market on the date of grant.

***Buyback program***

In June 2024, the Company's board of directors authorized a stock buyback program pursuant to which the Company may, from time to time, repurchase and retire up to $20,000 in maximum value of its common stock. Share repurchases may be executed through various means, including, without limitation, open market transactions, privately negotiated transactions or otherwise in compliance with Rule 10b-18 under the Securities Exchange Act of 1934, as amended. The stock buyback program does not obligate the Company to purchase any shares and expires in 12 months. The authorization for the stock buyback program may be terminated, increased or decreased by the Company's board of directors in its discretion at any time.

During the three months ended September 30, 2024, the Company has repurchased and retired 539,452 shares of its common stock under this program for approximately $1,291 at an average price of $2.40 per share. All repurchases were funded with cash on hand.

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

**NOTE 7 - 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:

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Operating right-of-use assets | $ 486 | $ 694 |
| | | |
| Operating lease liabilities, current | 243 | 267 |
| Operating lease liabilities long-term | 186 | 342 |
| Total operating lease liabilities | $ 429 | $ 609 |

Lease payments for the Company's right-of-use assets over the remaining lease periods are as follows:

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| 2024 | 67 | 282 |
| 2025 | 221 | 222 |
| 2026 | 139 | 120 |
| 2027 | 18 | 10 |
| Total undiscounted lease payments | 445 | 634 |
| Less: Interest* | (16) | (25) |
| Present value of lease liabilities | $ 429 | $ 609 |

* Future lease payments were discounted by 3%-7% interest rate.

**NOTE 8 - RELATED PARTY TRANSACTIONS:**

On July 1, 2008, the Subsidiary entered into a consulting agreement with KNRY Ltd. ("KNRY"), an Israeli company owned by the Chief Scientific Officer, whereby the Chief Scientific Officer, through KNRY, provides services to the Company (the "Consulting Agreement"). The Consulting Agreement is terminable by either party upon 140 days prior written notice. The Consulting Agreement, as amended, provide that KNRY will be reimbursed for reasonable expenses incurred in connection with the performance of the Consulting Agreement and the monthly consulting fee paid to the Chief Scientific Officer is NIS 117,040 ($32).

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, as amended, 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 96,825 ($26), 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, as amended, pursuant to which the President and Chief Executive Officer receives gross monthly salary of NIS 51,591 ($14) in consideration for his services as President and Chief Executive Officer of the Subsidiary. In addition, the President and Chief Executive Officer is provided with a cellular phone and a company car pursuant to the terms of his agreement.

**NOTE 9 - SUBSEQUENT EVENTS:**

***A. Scilex Refinancing and Royalty Transaction***

On October 7, 2024, the Company entered into a securities purchase agreement (the "Convertible Notes SPA") with certain institutional investors (together with the Company, the "Buyers") and Scilex to refinance a portion of the Tranche A Note and pay off certain other indebtedness of Scilex. Pursuant to the Convertible Notes SPA, the Buyers purchased in a registered offering by Scilex (i) a new tranche B of senior secured convertible notes of Scilex in the aggregate principal amount of $50,000 (the "Tranche B Notes") repayable on a quarterly basis for 2 years, which Tranche B Notes are convertible into shares of Scilex common stock and (ii) warrants to purchase up to 7,500,000 shares of Scilex common stock (the "Tranche B warrants"). The Company purchased 50% of Tranche B Note and Tranche B Warrants.

Scilex received from the Company, in consideration for the Tranche B Note and the Tranche B Warrants issued to the Company, an exchange and reduction of the principal outstanding balance under the Tranche A Note of $22,500. As a result, the Company holds an aggregate principal amount of $25,000 under the Tranche B Note and 3,750,000 Tranche B Warrants.

In addition, on October 8, 2024, the Company and certain institutional investors (together with the Company, the "RPA Purchasers") entered into a Purchase and Sale Agreement (the "Royalty Purchase Agreement") with Scilex and Scilex Pharmaceuticals Inc. Pursuant to the Royalty Purchase Agreement, the RPA Purchasers acquired the right to receive, in the aggregate, 8.0% of net sales worldwide for 10 years (the "Purchased Receivables") with respect to ZTlido (lidocaine topical system) 1.8%, SP-103 (lidocaine topical system) 5.4%, and any related, improved, successor, replacement or varying dosage forms of the foregoing.

The Company acquired the right to receive 50% of the Purchased Receivables, as more fully described in the Royalty Purchase Agreement. In consideration for its interest in the Purchased Receivables, the Company exchanged and reduced $2,500 of the principal balance under the Tranche A Note.

Following the refinancing as described above, on October 8, 2024, Scilex used $12,500 of the net proceeds from the proceeds of the Tranche B Note for the repayment and satisfaction of the outstanding balance under the Tranche A Note.

***B.*** On October 24, 2024 and November 5, 2024, the Company received an additional aggregate payment of approximately $1,400 pursuant to the terms of the Tranche A Note, which requires mandatory prepayments of 70% of the net cash proceeds received by Scilex from any debt or equity financings, subject to certain conditions and exceptions.

## 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 gastrointestinal tract and effectively deliver active insulin or other proteins. The formulation is 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 Phase 3 oral insulin trial (ORA-D-013-1) 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. In 2023, we completed an analysis of the ORA-D-013-1 Phase 3 trial data and found that subpopulations of patients with pooled specific parameters, such as body mass index (BMI), baseline HbA1c and age, responded well to oral insulin. Based on this analysis, we have submitted a protocol for a new Phase 3 clinical trial to the FDA. 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.

***2023 Scilex Transaction***

On September 21, 2023, we entered into and consummated the transactions, or, collectively, the 2023 Scilex Transaction, contemplated by a securities purchase agreement, or the Scilex-Oramed SPA, with Scilex Holding Company, or Scilex, pursuant to which Scilex issued to us:

a. A senior secured promissory note, or the Tranche A Note, with a principal amount of $101,875, maturing on March 21, 2025 and bearing interest of SOFR plus 8.5%, payable in-kind. Scheduled principal payments are due on December 21, 2023, March 21, 2024, June 21, 2024, September 21, 2024, and December 21, 2024, with the balance due on March 21, 2025. As per the Tranche A Note terms, if the Tranche A Note is not repaid in full on or prior to March 21, 2024, an exit fee of $3,056 is due. Since the Tranche A Note was not repaid by that date, we entitled to the above-mentioned exit fee at the maturity date of the Tranche A Note. As of September 30, 2024, Scilex has repaid $41,700 of the amount due under the Tranche A Note. See the description of the Extension Agreement (as defined below).

b. Warrants to purchase up to 4,500,000 shares of Scilex common stock with an exercise price of $0.01 per share, or the Closing Penny Warrants, and four additional warrants, or the Subsequent Penny Warrants, each for 2,125,000 shares of Scilex common stock with an exercise price of $0.01 per share. The Closing Penny Warrants were vested on September 21, 2023, and each of the Subsequent Penny Warrants shall vest on each of March 19, 2024, June 17, 2024, September 15, 2024 and December 14, 2024. The Closing Penny Warrants and the Subsequent Penny Warrants shall become exercisable on the earliest of (i) March 14, 2025 and (ii) the date on which the Tranche A Note has been repaid in full.

   As of September 30, 2024, 4,500,000 Closing Penny Warrants were vested according to the terms of Tranche A Note, 6,375,000 Subsequent Penny Warrants were vested according to the terms of the Tranche A Note and additional 1,062,500 Subsequent Penny Warrants were vested as per the Extension Agreement (as defined below).

   As of September 30, 2024, 4,500,000 Closing Penny Warrants and 2,000,000 Subsequent Penny Warrants are exercisable (see below).

c. Transferred warrants, or the Transferred Warrants, to purchase 4,000,000 shares of Scilex common stock at $11.50 per share, fully exercisable and expiring on November 10, 2027. On September 20, 2024, we sold the Transferred Warrants for consideration of $300,000 (see below). As a result, as of September 30, 2024 we do not hold any Transferred Warrants.

On August 30, 2024, Scilex agreed that 4,500,000 Closing Penny Warrants and 937,500 Subsequent Penny Warrants became exercisable as of such date.

On September 20, 2024, we and Scilex entered into an extension agreement, or the Extension Agreement, to extend the due date of the September 21, 2024 payment under the Tranche A Note. Pursuant to the Extension Agreement, Scilex paid us $2,000,000 on September 23, 2024, which payment is to be applied as follows: (i) $1,700,000 to the payment due under the Tranche A Note on March 21, 2025 and (ii) $300,000 to purchase the Transferred Warrants. In addition, 1,062,500 Subsequent Penny Warrants were accelerated from December 15, 2024 and became exercisable into shares of Scilex common stock at any time after September 20, 2024.

***Scilex Refinancing***

On October 7, 2024, we entered into a securities purchase agreement, or the Convertible Notes SPA, with certain institutional investors, or the Investors, and together with us, the Buyers, and Scilex, pursuant to which the Buyers purchased in a registered offering (i) a new tranche B of senior secured convertible notes of Scilex in the aggregate principal amount of $50,000,000, or the Tranche B Notes, which Tranche B Notes are convertible into shares of Scilex common stock and (ii) warrants, or the Tranche B Warrants, to purchase up to 7,500,000 shares of Scilex common stock. In the transaction, Scilex refinanced a portion of the Tranche A Note issued to us and paid off certain other indebtedness of Scilex. The transactions contemplated by the Convertible Notes SPA were consummated on October 8, 2024.

*Senior Convertible Notes*

The aggregate purchase price for the Tranche B Note issued to us and the related Tranche B Warrants was $22,500,000. The Tranche B Note issued to us bears an initial principal balance of $25,000,000 and an original issue discount of 10.0%. As consideration for the Tranche B Note and Tranche B Warrants, we exchanged a portion of the Tranche A Note resulting in a reduction of the principal outstanding balance under the Tranche A Note of $22,500,000. Additionally, Scilex used $12,500,000 of the net proceeds from the offering for the repayment and satisfaction of the outstanding balance under the Tranche A Note.

The Tranche B Notes bear interest at a rate of 5.5% per annum, payable in arrears on the first trading day of each calendar quarter, beginning January 2, 2025, payable, at Scilex's option, either in cash or in shares of Scilex common stock, subject to certain conditions. Unless earlier converted or redeemed, the Tranche B Note will mature on the two-year anniversary of the issuance date, subject to extension at the option of us in certain circumstances as provided in the Tranche B Note. The Tranche B Notes will be Scilex's senior secured obligation (alongside and under certain circumstances subordinate to, the Tranche A Note) and will rank senior to the right to payment of the holders of Scilex's subordinated debt and will be pari passu with all other indebtedness of Scilex.

At any time after issuance, all amounts due under the Tranche B Notes are convertible, in whole or in part, and subject to certain beneficial ownership limitations, at our option, into Scilex common stock at the initial fixed conversion price of $1.09 per share, which is subject to adjustments provided that the conversion price cannot be lower than $1.04 unless Scilex shareholder approval is obtained. The Tranche B Notes may not be converted to the extent such conversion would result in our beneficially owning in excess of 4.99%, or the Maximum Percentage, of shares of the Scilex common stock outstanding immediately after giving effect to such conversion. At our option, the Maximum Percentage may be raised up to 9.99%, except that any increase will only be effective upon 61 days' prior notice to Scilex.

Scilex has the right (assuming no failure of certain specific conditions relating to Scilex's equity) to redeem in cash all, but not less than all, of the amount then outstanding under the Tranche B Notes at a 35% redemption premium to the greater of (i) the amount then outstanding under the Tranche B Notes to be redeemed and (ii) the equity value of the Scilex common stock underlying such Tranche B Notes. Scilex has a mandatory obligation to redeem the Tranche B Notes upon an event of default relating to bankruptcy. The Tranche B Notes are subject to redemption at the election of each holder in certain circumstances, including, a change of control of Scilex, a subsequent placement of certain securities of Scilex, and asset sales by Scilex. The Tranche B Notes contain affirmative and negative covenants binding on Scilex and its subsidiaries and prohibit Scilex from entering into specified fundamental transactions unless the successor entity assumes all of Scilex's obligations under the Tranche B Notes.

The Tranche B Notes contain certain customary events of default, including, without limitation, a cross-default to other specified indebtedness or any other indebtedness involving an obligation of $5,000,000 or more. The interest rate of the Tranche B Notes will automatically increase to 15.0% per annum upon the occurrence and during the continuance of an event of default. Scilex is also required to pay a late charge of 15.0% on any amount of principal or other amounts that are not paid when due (solely to the extent such amounts are not then accruing interest at the default rate of 15.0% per annum).

In connection with any amortization, certain redemptions or other repayment of the Tranche B Notes, Scilex will also pay an amount equal to the amount of additional interest that would accrue under such Tranche B Notes at the interest rate then in effect assuming that the amount so converted, redeemed, amortized or otherwise repaid on such date of determination instead remained outstanding through and including the maturity date of such Tranche B Notes.

Scilex's obligations under the Tranche A Note and Tranche B Notes are secured by a security interest in all or substantially all of the property of Scilex and each of its subsidiaries, respectively, pursuant to an amended and restated security agreement, or the Amended and Restated Security Agreement, with Scilex and its subsidiaries.

*Tranche B Warrants*

The Tranche B Warrants are exercisable for a period of five years from the date of issuance. The Tranche B Warrants issued to us at Closing will initially be exercisable for 3,750,000 shares of Scilex common stock, subject to the Maximum Percentage limitation.

The Tranche B Warrants will initially be exercisable for cash at an exercise price equal to $1.09 per share of Scilex common stock, subject to adjustments upon the occurrence of any stock split, stock dividend, stock combination, recapitalization, similar transactions and/or full-ratchet adjustment in connection with a subsequent offering at a per share price less than the fixed conversion price then in effect subject to a floor price of $1.04 unless shareholder approval is obtained. If at the time of exercise, there is no effective registration statement registering the shares of Scilex common stock underlying the Tranche B Warrants, such warrants may be exercised on a cashless basis pursuant to their terms.

*Amendment to Scilex-Oramed SPA*

In connection with the execution of the Convertible Notes SPA, on October 8, 2024, we, Scilex and the Agent amended the Scilex-Oramed SPA to account for the issuance of the Tranche B Notes and the execution of certain related documents, including the Subordination Agreement (as defined herein) and an agreement, or the Agreement Among Holders, pursuant to which we and the Investors agreed that, subject to certain conditions and exceptions, the payment of the obligations in respect of the Tranche B Notes will be subject to the prior payment in full of all obligations in respect of the Tranche A Note up to the Maximum First Out Amount (as defined in the Agreement Among Holders).

***Royalty Transaction***

On October 8, 2024, we and certain institutional investors, or, collectively, the RPA Purchasers, entered into a Purchase and Sale Agreement, or the Royalty Purchase Agreement, with Scilex and Scilex Pharmaceuticals Inc., or Scilex Pharma. Pursuant to the Royalty Purchase Agreement, the RPA Purchasers acquired the right to receive, in the aggregate, 8.0% of net sales worldwide for 10 years, or the Purchased Receivables, with respect to ZTlido (lidocaine topical system) 1.8%, SP-103 (lidocaine topical system) 5.4%, and any related, improved, successor, replacement or varying dosage forms of the foregoing, or the Covered Products. We have acquired the right to receive 50% of the Purchased Receivables, as more fully described in the Royalty Purchase Agreement.

In full consideration for the sale, transfer, conveyance and granting of the Purchased Receivables, and subject to the terms and conditions set forth in the Royalty Purchase Agreement, the aggregate purchase price paid by the RPA Purchasers for the Purchased Receivables was $5,000,000 (net of expenses of the RPA Purchasers). In consideration for our interest in the Purchased Receivables, we exchanged and reduced $2,500,000 of the principal balance under the Tranche A Note.

The Royalty Purchase Agreement terminates six months following receipt by the RPA Purchasers of all payments of the Purchased Receivables to which each RPA Purchaser is entitled thereunder during the period commencing on the date of closing and expiring on the tenth anniversary of such closing date.

Pursuant to the terms of the Royalty Purchase Agreement, Scilex Pharma entered into a security agreement with the collateral agent (as identified therein) for the benefit of the RPA Purchasers, dated as of October 8, 2024, or the Royalty Security Agreement. Under the Royalty Security Agreement, Scilex's and Scilex Pharma's due performance and payment under the Royalty Purchase Agreement is secured by certain collateral, including a collection account and certain material contracts, intellectual property rights and the regulatory approvals, in each case related to the Covered Products. Scilex Pharma, the collateral agent and the Agent also entered into a subordination agreement, or the Subordination Agreement, whereby the parties agreed that all obligations, liabilities and indebtedness under the Royalty Purchase Agreement will be secured by first priority liens on the collateral under the Royalty Security Agreement, or the Royalty Collateral, and all obligations under the Amended and Restated Security Agreement, including in respect of the Tranche A Note and the Tranche B Notes, will be secured by second priority liens on the Royalty Collateral and first priority liens on all other collateral granted under the Amended and Restated Security Agreement.

***Binding Term Sheet Regarding Rest of World License Agreement***

On October 8, 2024, we, certain other institutional investors and Scilex entered into a binding term sheet, or the ROW License Term Sheet, regarding a license and development agreement, or the Lido License Agreement, with respect to services, compositions, products, dosages and formulations comprising lidocaine, including without limitation, the product and any future product defined as a "Product" under Scilex Pharma's existing (i) Product Development Agreement, dated as of May 11, 2011, with Oishi Koseido Co., Ltd., or Oishi, and Itochu Chemical Frontier Corporation, or Itochu, as amended, and (ii) the associated Commercial Supply Agreement, dated February 16, 2017, between Scilex, Oishi and Itochu, as amended. Subject to determination of a final structure for the transactions contemplated by the ROW License Term Sheet, it is anticipated that we and such institutional investors will hold the Lido License Agreement through a joint venture, Lido Dev Co.

In consideration for the rights to be provided under the proposed Lido License Agreement, as more fully described in the ROW License Term Sheet, (a) Lido Dev Co. will invest (whether through cash consideration or in-kind payment through the provision of services) $200,000 per year toward expanding the Product, (b) Scilex will grant Lido Dev Co. a worldwide, exclusive right, license and interest to all products rights for the development, out-licensing, commercialization of any Product outside of the United States and other territories, other than certain excluded designated territories, or the ROW Territory, and (c) each of Lido Dev Co. and Scilex will receive fifty percent of the net revenue (less expenses) generated from any Product in the ROW Territory.

Scilex is required to use its commercially reasonable efforts to obtain the consent of Oishi and Itochu to the Lido License Agreement. If that consent is not obtained within 30 days of execution of the ROW License Term Sheet, Lido Dev Co. has the right to designate an agent to continue negotiations directly with Oishi and Itochu. Definitive documents for the Lido License Agreement and related matters are subject to ongoing negotiation among the parties thereto.

***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 or 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. In 2023, we 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 BMI, baseline HbA1c and age, responded well to oral insulin. These subsets exhibited an over 1% placebo adjusted, statistically significant, reduction in HbA1c. Based on this analysis, we have submitted a protocol for a new Phase 3 clinical trial to the FDA.

*Joint Venture Agreement*: On January 22, 2024, Oramed and its wholly-owned subsidiary, Oramed Ltd., entered into a joint venture agreement, or the JV Agreement, with HTIT Biotech and Technowl Limited, a wholly-owned indirect subsidiary of HTIT Biotech and together with HTIT Biotech, HTIT, pursuant to which, subject to the terms and conditions set forth in the JV Agreement, the parties will establish a joint venture, or the JV, based on Oramed's oral drug delivery technology.

The JV will 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 expects to conduct a Phase 3 oral insulin clinical trial in the United States.

Oramed and HTIT will initially hold equal shares in the JV, with each owning 50% of the equity. The board of directors will initially consist of equal representation from HTIT and Oramed. HTIT will contribute to the JV cash and credit to purchase materials, while Oramed will contribute cash and shares of Oramed common stock (that will be subject to certain registration rights) and will transfer intellectual property related to its oral insulin and POD™ technology, as well as other assets in the Oramed pipeline.

The consummation of the JV Agreement is subject to and contingent upon the parties entering into additional agreements pursuant to the JV Agreement. There is no assurance that the parties will complete and sign these additional agreements.

***Oral Vaccine***

On March 18, 2021, we entered into a license agreement with 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.

***Impact of Current Events***

On October 7, 2023, the State of Israel was attacked by and subsequently declared war on Hamas. Israel has been in an ongoing state of war with Hamas since that time. Following the attack by Hamas, Hezbollah has also launched attacks against Israel and Israel has been responding to these attacks with targeted air strikes. It is possible that other terrorist organizations, including Palestinian military organizations in the West Bank, as well as other hostile countries, will join the hostilities. As of November 7, 2024, we believe that there is no immediate risk to our business operations related to these events. For further information, see "Item 1A. Risk Factors," under "We are affected by the political, economic and military risks of having operations in Israel" in our Annual Report.

**Results of Operations**

***Comparison of nine and three month periods ended September 30, 2024 and September 30, 2023***

The following table summarizes certain statements of operations data of the Company for the nine and three month periods ended September 30, 2024 and September 30, 2023 (in thousands of dollars except share and per share data):

| | Nine months ended | | Three months ended | |
|---|---|---|---|---|
| | **September 30, 2024** | **September 30, 2023** | **September 30, 2024** | **September 30, 2023** |
| Revenues | $ - | $ 1,340 | $ - | $ - |
| Research and development | (4,863) | (7,205) | (2,242) | (957) |
| Sales and marketing | - | 287 | - | 663 |
| General and administrative | (4,323) | (6,314) | (847) | (2,599) |
| Interest expenses | (853) | (826) | - | (826) |
| Financial income (loss), net | 3,902 | 4,510 | (15,420) | 435 |
| Net loss before tax expenses | $ (6,137) | $ (8,208) | $ (18,509) | $ (3,284) |
| Tax expenses | (2,767) | - | (1,133) | - |
| Net loss | (8,904) | (8,208) | (19,642) | (3,284) |
| Basic and Diluted loss per share of common stock | $ (0.22) | $ (0.19) | $ (0.48) | $ (0.08) |
| Weighted average shares of common stock outstanding used in computing basic and diluted loss per share of common stock | 40,882,110 | 40,246,515 | 40,896,845 | 40,445,896 |

***Revenues***

Revenues consist of proceeds related to the Amended and Restated Technology License Agreement, dated December 21, 2015, between us 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.

There were no revenues for the nine month period ended September 30, 2024 while revenues were $1,340,000 for the nine month period ended September 30, 2023. The decrease was due to recognition of revenues until the product submission date by HTIT of June 2023.

There were no revenues for the three month periods ended September 30, 2024 and 2023.

***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 contract research organizations, or 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, 2024 decreased by 33% to $4,863,000, compared to $7,205,000 for the nine month period ended September 30, 2023. The decrease was mainly due to lower expenses related to the Phase 3 trials that were terminated and was partially offset by higher stock-based compensation expenses.

Research and development expenses for the three month period ended September 30, 2024 increased by 134% to $2,242,000, compared to $957,000 for the three month period ended September 30, 2023. The increase was due to costs related to the new Phase 3 clinical trial preparations.

*Government grants*

In the nine month periods ended September 30, 2024 and September 30, 2023, we did not receive any research and development grants. As of September 30, 2024, 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 did not recognize any sales and marketing expenses for the nine month period ended September 30, 2024, compared to an income of $287,000 for the nine period ended September 30, 2023. The income primarily resulted from the reversal of previously recognized expenses related to forfeited employee stock options, following the termination of an executive officer in fiscal year 2023.

We did not recognize any stock-based compensation expenses for the nine month period ended September 30, 2024, compared to an income of $440,000 for the nine month period ended September 30, 2023. The income primarily resulted from the reversal of previously recognized expenses related to forfeited employee stock options, following the termination of an executive officer in fiscal year 2023.

We did not recognize any sales and marketing expenses for the three month periods ended September 30, 2024, compared to an income of $663,000 for the three month period ended September 30, 2023. The income primarily resulted from the reversal of previously recognized expenses related to forfeited employee stock options, following the termination of an executive officer in fiscal year 2023.

***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, 2024 decreased by 32% to $4,323,000 compared to $6,314,000 for the nine month period ended September 30, 2023. This decrease was mainly due to the reversal of previously recognized expenses following the resignation of certain executive officers.

General and administrative expenses for the three month period ended September 30, 2024 decreased by 67% to $847,000 compared to $2,599,000 for the three month period ended September 30, 2023. This decrease was mainly due to the reversal of previously recognized expenses following the resignation of an executive officer.

***Interest Expenses***

Interest expenses were $853,000 for the nine month period ended September 30, 2024, compared to $826,000 for the nine month period ended September 30, 2023. The increase was mainly due to interest on the Short-Term Borrowings (as defined below).

There were no interest expenses for the three month period ended September 30, 2024, compared to interest expenses of $826,000 for the three month period ended September 30, 2023, since the Short-Term Borrowings (as defined below) received from Discount Bank Ltd. were terminated during the second quarter of 2024 (see below).

***Financial Income (Loss), Net***

Net financial income decreased by 14% to $3,902,000 for the nine month period ended September 30, 2024, compared to $4,510,000 for the nine month period ended September 30, 2023. The decrease was mainly due to the lower interest income on deposits.

Net financial loss was $15,420,000 for the three month period ended September 30, 2024, compared to $435,000 net financial income for the three month period ended September 30, 2023. The change was mainly due to the revaluation of the investments in Scilex.

***Tax expenses***

During the nine and three month periods ended September 30, 2024, we recognized tax expenses totaling $2,767,000 and $1,133,000, respectively. The tax expenses are primarily attributable to the 2023 Scilex Transaction. The provision for income taxes in the interim period is determined using an estimated annual effective tax rate (taking into account utilization of our carryforward tax losses).

During the three and nine month periods ended September 30, 2023, we did not recognize any tax expenses.

***Liquidity and Capital Resources***

From inception through September 30, 2024, we have incurred losses in an aggregate amount of $166,427,000. During that period and through September 30, 2024, 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 $255,384,000, 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, 2024, we had $42,104,000 of available cash and $42,741,000 of short-term bank deposits.

From inception through September 30, 2024, we have not generated significant revenues from our operations. Following the termination of the ORA-D-013-1 and ORA-D-013-2 Phase 3 trials, our research and development activities have been significantly reduced while it conducts a strategic review process. However, in the three month period ended September 30, 2024 we increased the research and development activities that related to the new Phase 3 clinical trial.

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.

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 matured on dates ranging from August 11, 2023 to May 24, 2024, bore interest ranging from 6.66% to 7.38%, were 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 Tranche A Note. The Short-Term Borrowings were paid in one payment of principal and interest at each respective maturity. As of September 30, 2024, we repaid the entire Short-Term Borrowings amount.

As of September 30, 2024, our total current assets were $142,774,000 and our total current liabilities were $5,274,000. On September 30, 2024, we had a working capital surplus of $137,500,000 and an accumulated loss of $166,427,000. As of December 31, 2023, our total current assets were $162,584,000 and our total current liabilities were $53,214,000. On December 31, 2023, we had a working capital surplus of $109,370,000 and an accumulated loss of $157,556,000. The increase in working capital from December 31, 2023 to September 30, 2024 was mainly due to an increase in cash and cash equivalents and in investments at fair value, together with a decrease in short-term borrowings partially offset by a decrease in short-term deposits.

During the nine month period ended September 30, 2024, cash and cash equivalents increased to $42,104,000, from $9,055,000 as of December 31, 2023. The increase was mainly due to the reasons described below.

Operating activities used cash of $6,500,000 in the nine month period ended September 30, 2024, compared to $8,877,000 used in the nine month period ended September 30, 2023. Cash used in operating activities primarily consisted research and development, general and administrative expenses, partially offset by interest received from short-term deposits, an increase in accounts payable and accrued expenses and stock based compensation.

Investing activities provided cash of $90,393,000 in the nine month period ended September 30, 2024, compared to used cash of $103,035,000 in the nine month period ended September 30, 2023. Cash provided by investing activities in the nine month period ended September 30, 2024 consisted primarily of proceeds from short-term deposits and proceeds from long-term investments. Cash used by investing activities in the nine month period ended September 30, 2023 consisted primarily of the purchase of short-term deposits, partially offset by proceeds from short-term investing activities.

Financing activities used cash of $50,842,000 in the nine month period ended September 30, 2024, compared to cash of $76,978,000 provided in the nine month period ended September 30, 2023. Cash used by financing activities in the nine month period ended September 30, 2024, consisted primarily of repayments of the Short-Term Borrowings and repurchases of our shares. Cash provided by financing activities in the nine month period ended September 30, 2023, consisted primarily of proceeds from the issuance of our common stock.

On March 18, 2024, we entered into an at the market offering agreement, or the ATM Agreement, with Rodman & Renshaw LLC and StockBlock Securities LLC, as agents, pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $75,000,000 through a sales agent, subject to certain terms and conditions. The ATM is not currently active since we do not have an effective shelf registration statement covering the shares of common stock issuable thereunder. As of September 30, 2024 and through November 7, 2024, no shares were issued under the ATM Agreement.

On September 4, 2024, we entered into a loan agreement, or the Profit Sharing Loan Agreement, with Rabi Binyamin 4 Tama 38 Ltd., or the Borrower, to finance a real estate project, or the Project. According to the terms of the Profit Sharing Loan Agreement, we agreed to loan NIS 5.5 million ($1,523), or the Loan Principal, to the Borrower. NIS 4.7 million ($1,307) was loaned upon signing the Profit Sharing Loan Agreement and the remaining NIS 0.8 million ($216) will be loaned upon certain milestones which are expected to occur in the first half of 2025. Upon completion of the Project, the we are entitled to receive the Loan Principal and the greater of: (i) 20% annual interest of the Loan Principal and (ii) 40% of the Project profits.

***Critical accounting policies and estimates***

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

**Planned Expenditures**

We 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, and the new Phase 3 clinical trial for our oral insulin capsule candidate, ORMD-0801 and the current strategic review initiated by us, our obligations may change.

## PART II – OTHER INFORMATION

### ITEM 2 – UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In June 2024, the Company's board of directors authorized a stock buyback and retirement program pursuant to which the Company may, from time to time, repurchase up to $20 million in maximum value of its common stock. Share repurchases may be executed through various means, including, without limitation, open market transactions, privately negotiated transactions or otherwise in compliance with Rule 10b-18 under the Securities Exchange Act of 1934, as amended. The stock buyback program does not obligate the Company to purchase any shares and expires in 12 months. The authorization for the stock buyback program may be terminated, increased or decreased by the Company's board of directors in its discretion at any time.

The Company has repurchased and retired 539,452 shares of its common stock under this program for approximately $1,292,000 at an average price of $2.401 per share. All purchases were funded with cash on hand.

The following sets forth information with respect to repurchase and retirement made by the Company of its shares of common stock during the third quarter of 2024:

| Period | Total number of shares purchased | Average price paid per share | Total number of shares purchased as part of publicly announced plans or programs | Approximate dollar value of shares that may yet be purchased under the plans or programs |
|---|---|---|---|---|
| July 1-31, 2024 | 2,542 | $ 2.456 | 2,542 | $ 8,195,680 |
| August 1-31, 2024 | 325,439 | $ 2.386 | 325,439 | $ 8,062,303 |
| September 1-30, 2024 | 211,471 | $ 2.416 | 211,471 | $ 7,975,634 |
| Total | 539,452 | $ 2.401 | 539,452 | 7,975,634 |

### 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, 2024. 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, 2024. 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, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### ITEM 6 - EXHIBITS

| Number | Exhibit |
|---|---|
| 10.1 | Securities Purchase Agreement, dated October 7, 2024, by and between Scilex Holding Company and the investors signatory thereto (incorporated by reference from our current report on Form 8-K filed October 8, 2024). |
| 10.2 | Amendment No. 1 to Scilex-Oramed SPA, dated October 8, 2024, by and between Scilex Holding Company and Oramed Pharmaceuticals Inc (incorporated by reference from our current report on Form 8-K filed October 8, 2024). |
| 10.3 | Tranche B Senior Secured Convertible Note, dated October 8, 2024, issued by Scilex Holding Company to the Company (incorporated by reference from our current report on Form 8-K filed October 8, 2024). |
| 10.4 | Warrant to Purchase Common Stock, dated October 8, 2024, issued by Scilex Holding Company to the Company (incorporated by reference from our current report on Form 8-K filed October 8, 2024). |
| 10.5 | Purchase and Sale Agreement, dated October 8, 2024, by and among Scilex Holding Company, Silex Pharmaceuticals Inc. and the purchasers signatory thereto (incorporated by reference from our current report on Form 8-K filed October 8, 2024). |
| 10.6 | Security Agreement, dated October 8, 2024, by and among Scilex Pharmaceuticals Inc., and the purchasers signatory thereto (incorporated by reference from our current report on Form 8-K filed October 8, 2024). |
| 10.7 | Subordination Agreement, dated October 8, 2024, by and among Scilex Pharmaceuticals Inc., Acquiom Agency Services LLC and other signatories thereto (incorporated by reference from our current report on Form 8-K filed October 8, 2024). |
| 10.8 | Consent and Amendment, dated as of October 8, 2024, by and between Scilex Holding Company and Oramed Pharmaceuticals Inc (incorporated by reference from our current report on Form 8-K filed October 8, 2024). |
| 10.9 | Subsidiary Guarantee Amendment, dated October 8, 2024, made by certain of Scilex Holding Company subsidiaries in favor of the holders of that certain Tranche A Note (incorporated by reference from our current report on Form 8-K filed October 8, 2024). |
| 10.10 | Amended and Restated Security Agreement, dated October 8, 2024, by and among Scilex Holding Company, the Subsidiaries of Scilex Holding Company party thereto, Oramed Pharmaceuticals Inc. and Acquiom Agency Services LLC (incorporated by reference from our current report on Form 8-K filed October 8, 2024). |
| 10.11 | Rest of World License Term Sheet, dated October 8, 2024, between Oramed Pharmaceuticals Inc., Scilex Holding Company and the other parties signatories thereto (incorporated by reference from our current report on Form 8-K filed October 8, 2024). |
| 10.12 | Agreement Among Holders, dated October 8, 2024, by and between Oramed Pharmaceuticals Inc., Acquiom Agency Services LLC and the other signatories thereto (incorporated by reference from our current report on Form 8-K filed October 8, 2024). |
| 10.13 | Master Services Agreement dated September 23, 2024, between Oramed Ltd. and InClin, Inc. (incorporated by reference from our current report on Form 8-K filed September 26, 2024). |
| 10.14 | Letter Agreement, dated as of September 20, 2024, by and between Oramed Pharmaceuticals Inc. and Scilex Holding Company (incorporated by reference from our current report on Form 8-K filed September 23, 2024). |
| 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, 2024 formatted in XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Comprehensive Loss, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows and (v) the Notes to Condensed Consolidated Financial Statements. |
| 104.1* | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101). |

* Filed herewith

** Furnished herewith

**SIGNATURES**

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

**ORAMED PHARMACEUTICALS INC.**

Date: November 7, 2024

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

Date: November 7, 2024

By: /s/ Avraham Gabay
Avraham Gabay
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 7, 2024

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, Avraham Gabay, 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 7, 2024

By: /s/ Avraham Gabay
Avraham Gabay
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, 2024, 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 7, 2024

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, 2024, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Avraham Gabay, 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 7, 2024

By: /s/ Avraham Gabay
Avraham Gabay
Chief Financial Officer