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

# FORM 10-Q

 $oxdituil \mathbf{QUARTERLY}$  REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2023

 $\Box$  Transition report pursuant to Section 13 or 15(d) of the Securities exchange act of 1934

Commission file number: 001-35813

# ORAMED PHARMACEUTICALS INC.

	(Exac	et Name of Registrant as Specified in Its Charter)	
	Delaware		98-0376008
(State	or Other Jurisdiction of		(I.R.S. Employer
Incorp	oration or Organization)		Identification No.)
1185 Avenue of the A	americas, Third Floor, Nev	w York, NY	10036
(Address of	Principal Executive Office	es)	(Zip Code)
		844-967-2633	
	(Regis	strant'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 v	ralue \$0.012	ORMP	The Nasdaq Capital Market, Tel Aviv Stock Exchange
	hs (or for such shorter perio	led all reports required to be filed by Section 13 o od that the registrant was required to file such rep	
		Yes ⊠ No □	
	O	tted electronically every Interactive Data File req ceding 12 months (or for such shorter period that	*
		Yes ⊠ No □	
	ee the definitions of "large	accelerated filer, an accelerated filer, a non-accele accelerated filer," "accelerated filer," "smaller re	
Large accelerated filer		Accelerated filer	
Non-accelerated filer	$\boxtimes$	Smaller reporting company Emerging growth company	
		if the registrant has elected not to use the extender and to Section 13(a) of the Exchange Act. $\Box$	ed transition period for complying with any new
Indicate by check mark wheth	ner the registrant is a shell c	company (as defined in Rule 12b-2 of the Exchan	ge Act).
		Yes □ No ⊠	
As of August 10, 2023, there	were 40,275,688 shares of	the issuer's common stock, \$0.012 par value per	share, outstanding.

# ORAMED PHARMACEUTICALS INC. FORM 10-Q

# TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION	1
<u>ITEM 1 - FINANCIAL STATEMENTS</u>	1
ITEM 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	18
ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	24
<u>ITEM 4 - CONTROLS AND PROCEDURES</u>	24
PART II - OTHER INFORMATION	25
<u>ITEM 1A. – RISK FACTORS</u>	25
ITEM 6 - EXHIBITS	26

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

On June 30, 2023, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.70 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," "plans," "plans," "planned expenditures," "believes," "seeks," "estimates," "considers" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Quarterly Report on Form 10-Q. Additionally, statements concerning future matters are forward-looking statements. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity, or our achievements, or industry results, to be materially different from any future results, performance, levels of activity, or our achievements, or industry results, expressed or implied by such forward-looking statements. Such forward-looking statements include, among other statements, statements regarding the following:

- our comprehensive analysis of data from our ORA-D-013-1 Phase 3 trial to understand if there is a path forward for our oral insulin candidate;
- our plan to evaluate potential strategic opportunities;
- our ability to close the Stock Purchase Agreement (as defined herein) with Sorrento Therapeutics, Inc., or Sorrento, in a timely manner or at all;
- our and Sorrento's ability to satisfy the conditions to completion of the Transaction (as defined herein), including receipt of required regulatory and other approvals or any other reason;
- the possibility that Sorrento may receive higher or otherwise better offers from competing bidders at an auction in a supervised process in the Bankruptcy Court (as defined herein);
- the occurrence of any event, change or other circumstances that could give rise to the termination of the Stock Purchase Agreement by either the Company or Sorrento;
- the outcome and timing of Sorrento's Chapter 11 process and approval of the Transaction by the Bankruptcy Court;
- the possibility that the anticipated benefits of the Transaction are not realized when expected or at all, including as a result of the impact of, or problems arising from, the Company's purchase of the Purchased Securities (as defined herein);
- the possibility that the Transaction may be more expensive to complete than anticipated;
- our ability to recover the proceeds and/or collateral under the DIP Loan Agreement (as defined herein);
- our exposure to potential litigation;
- our ability to enhance value for our stockholders;
- the expected development and potential benefits from our products;
- the prospects of entering into additional license agreements, or other partnerships or forms of cooperation with other companies or medical institutions;
- the ability of Oramed and Hefei Tianhui Incubator of Technologies Co. Ltd. to reach agreement on a definitive joint venture agreement and the transactions contemplated by the term sheet;
- future milestones, conditions and royalties under our license agreements;
- expected timing of a clinical study for the potential Oravax Medical Inc., or Oravax, vaccine and its potential to protect against the coronavirus, or COVID-19, pandemic;
- our research and development plans, including pre-clinical and clinical trials plans and the timing of enrollment, obtaining results and conclusion of trials;

- our belief that our technology has the potential to deliver medications and vaccines orally that today can only be delivered via injection;
- the competitive ability of our technology based on product efficacy, safety, patient convenience, reliability, value and patent position;
- the potential market demand for our products;
- our ability to obtain patent protection for our intellectual property;
- our expectation that our research and development expenses will continue to be our major expenditure;
- our expectations regarding our short- and long-term capital requirements;
- our outlook for the coming months and future periods, including but not limited to our expectations regarding future revenue and expenses;
- information with respect to any other plans and strategies for our business.

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

# PART I – FINANCIAL INFORMATION

# ITEM 1 - FINANCIAL STATEMENTS

# ORAMED PHARMACEUTICALS INC.

# INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF JUNE 30, 2023

# TABLE OF CONTENTS

	Page
CONDENSED CONSOLIDATED FINANCIAL STATEMENTS:	
Balance sheets	2
Statements of comprehensive loss	3
Statements of changes in stockholders' equity	4
Statements of cash flows	6
Notes to financial statements	7-17
Notes to Intalicial statements	, 1,

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

	June 30, 2023		December 31, 2022		
Assets					
CURRENT ASSETS:	ф	C ECE	ф	40.464	
Cash and cash equivalents	\$	6,767	\$	40,464	
Short-term deposits		142,491		111,513	
Marketable securities		943		3,743	
Prepaid expenses and other current assets		769	_	1,389	
Total current assets		150,970		157,109	
LONG-TERM ASSETS:					
Long-term deposits		7		7	
Non-marketable equity securities		3,524		2,700	
Amounts funded in respect of employee rights upon retirement		26		24	
Property and equipment, net		945		815	
Operating lease right-of-use assets		842		987	
Total long-term assets		5,344		4,533	
Total assets	\$	156,314	\$	161,642	
	Ψ	150,514	Ψ	101,042	
Liabilities and stockholders' equity					
CURDENCE LABOR REPO					
CURRENT LIABILITIES:	ф	000	ф	4.450	
Accounts payable and accrued expenses	\$	828	\$	4,158	
Deferred revenues		-		1,340	
Payable to related parties		3		1	
Operating lease liabilities	_	236		247	
Total current liabilities		1,067		5,746	
LONG-TERM LIABILITIES:					
Long-term deferred revenues		4,000		4,000	
Employee rights upon retirement		27		21	
Provision for uncertain tax position		11		11	
Operating lease liabilities		488		647	
Other liabilities		66		61	
Total long-term liabilities		4,592		4,740	
COMMITMENTS (note 3)					
Equity					
EQUITY ATTRIBUTABLE TO COMPANY'S STOCKHOLDERS:					
Common stock, \$0.012 par value (60,000,000 authorized shares; 40,219,396 and 39,563,888 shares issued and					
outstanding as of June 30, 2023 and December 31, 2022, respectively)		484		476	
Additional paid-in capital		318,732		314,417	
Accumulated deficit		(167,670)		(163,081)	
Total stockholders' equity		151,546		151,812	
Non-controlling interests		(891)		(656)	
Total equity		150,655		151,156	
Total liabilities and equity	\$	156,314	\$	161,642	

# INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS U.S. Dollars in thousands (except share and per share data) (UNAUDITED)

	Six months ended				Three months ended																																																															
		June 30, 2023	J	June 30, 2022		June 30, 2023		•		•		•		,		,		•		•		•		•		•		•		•		,		•		•		,		•		,		•		•		,		,		,		•		•		•		•		•		,		•		June 30, 2022
REVENUES	\$	1,340		1,340	\$	674		674																																																												
RESEARCH AND DEVELOPMENT EXPENSES		6,248		15,015		1,821		9,179																																																												
SALES AND MARKETING EXPENSES		376		970		192		380																																																												
GENERAL AND ADMINISTRATIVE EXPENSES		3,715		8,024		2,452		2,532																																																												
OPERATING LOSS		8,999		22,669		3,791		11,417																																																												
FINANCIAL INCOME, NET		4,075		894		2,478		350																																																												
NET LOSS	\$	4,924		21,775	\$	1,313		11,067																																																												
NET LOSS ATTRIBUTABLE TO NON-CONTROLLING INTERESTS		335		817		119		534																																																												
NET LOSS ATTRIBUTABLE TO STOCKHOLDERS		4,589		20,958		1,194		10,533																																																												
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	\$	0.11	\$	0.54	\$	0.03	\$	0.27																																																												
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF					_																																																															
COMMON STOCK		40,144,725		38,732,636		40,225,594		38,795,318																																																												

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY U.S. Dollars in thousands (UNAUDITED)

	Commo Shares In thousands	on Stock	Additional paid-in capital	Accumulated deficit	Total stockholders' equity	Non- controlling interests	Total equity
BALANCE AS OF DECEMBER 31, 2022 CHANGES DURING THE SIX MONTH PERIOD ENDED	39,564	\$ 476	\$ 314,417	\$ (163,081)	\$ 151,812	\$ (656)	\$ 151,156
JUNE 30, 2023: ISSUANCE OF COMMON STOCK, NET STOCK-BASED	193	2	2,428	-	2,430	-	2,430
COMPENSATION STOCK-BASED COMPENSATION OF ORAVAX	462	6	1,887	-	1,893	100	1,893
NET LOSS	_	_	_	(4,589)	(4,589)	(335)	(4,924)
BALANCE AS OF JUNE 30, 2023	40,219	\$ 484	\$ 318,732			\$ (891)	\$ 150,655
	Commo	on Stock	Additional paid-in	Accumulated	Total stockholders'	Non- controlling	Total
	Shares In thousands	\$	capital	deficit	equity	interests	equity
BALANCE AS OF DECEMBER 31, 2021 CHANGES DURING THE SIX MONTH PERIOD ENDED JUNE 30, 2022:	Shares In thousands 38,158	\$ \$ 459		<b>deficit</b> \$ (126,520)		\$ 157	* 166,610
DECEMBER 31, 2021 CHANGES DURING THE SIX MONTH PERIOD ENDED JUNE 30, 2022: ISSUANCE OF COMMON STOCK, NET	In thousands	<u> </u>					
DECEMBER 31, 2021 CHANGES DURING THE SIX MONTH PERIOD ENDED JUNE 30, 2022: ISSUANCE OF COMMON STOCK, NET EXERCISE OF WARRANTS AND OPTIONS	In thousands 38,158	\$ 459	\$ 292,514		\$ 166,453		\$ 166,610
DECEMBER 31, 2021 CHANGES DURING THE SIX MONTH PERIOD ENDED JUNE 30, 2022: ISSUANCE OF COMMON STOCK, NET EXERCISE OF WARRANTS AND OPTIONS STOCK-BASED COMPENSATION	In thousands 38,158	\$ 459	\$ 292,514		\$ 166,453 2,968		\$ 166,610
DECEMBER 31, 2021 CHANGES DURING THE SIX MONTH PERIOD ENDED JUNE 30, 2022: ISSUANCE OF COMMON STOCK, NET EXERCISE OF WARRANTS AND OPTIONS STOCK-BASED COMPENSATION TAX WITHHOLDINGS RELATED TO STOCK-BASED COMPENSATION SETTLEMENTS	In thousands 38,158 277	\$ 459 3 (*)	\$ 292,514 2,965 - 5,910	\$ (126,520) - - -	\$ 166,453 2,968 (*) 5,911	\$ 157 - -	\$ 166,610 2,968 (*) 5,911
DECEMBER 31, 2021 CHANGES DURING THE SIX MONTH PERIOD ENDED JUNE 30, 2022: ISSUANCE OF COMMON STOCK, NET EXERCISE OF WARRANTS AND OPTIONS STOCK-BASED COMPENSATION TAX WITHHOLDINGS RELATED TO STOCK-BASED COMPENSATION	In thousands 38,158 277	\$ 459 3 (*)	\$ 292,514 2,965 - 5,910		\$ 166,453 2,968 (*) 5,911		\$ 166,610 2,968 (*) 5,911

<sup>(\*)</sup> Represents an amount of less than \$1.

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY U.S. Dollars in thousands (UNAUDITED)

	Commo	on Stock \$	Additional paid-in capital	Accumulated deficit	Total stockholders' equity	Non- controlling interests	Total equity
	In thousands	Ψ	cupitui	uciicit	equity	interests	equity
BALANCE AS OF MARCH 31, 2023	39,970	\$ 481	\$ 316,965	\$ (166,476)	\$ 150,970	\$ (822)	\$ 150,148
CHANGES DURING THE THREE MONTH PERIOD ENDED JUNE 30, 2023:							
STOCK-BASED COMPENSATION	249	3	1,767	-	1,770	-	1,770
STOCK-BASED COMPENSATION OF ORAVAX	_	_	_	_	_	50	50
NET LOSS	_	-	-	(1,194)	(1,194)	(119)	(1,313)
BALANCE AS OF							
JUNE 30, 2023	40,219	\$ 484	\$ 318,732	\$ (167,670)	\$ 151,546	\$ (891)	\$ 150,655
	Commo		Additional paid-in	Accumulated	Total stockholders'	Non- controlling	Total
	Shares	on Stock \$		Accumulated deficit		-	Total equity
BALANCE AS OF	Shares In thousands	\$	paid-in capital	deficit	stockholders' equity	controlling interests	equity
MARCH 31, 2022	Shares		paid-in		stockholders' equity	controlling	equity
	Shares In thousands	\$	paid-in capital	deficit	stockholders' equity	controlling interests	equity
MARCH 31, 2022 CHANGES DURING THE THREE MONTH PERIOD ENDED JUNE 30, 2022: ISSUANCE OF	Shares In thousands	\$	paid-in capital	deficit	stockholders' equity	controlling interests	equity
MARCH 31, 2022 CHANGES DURING THE THREE MONTH PERIOD ENDED JUNE 30, 2022: ISSUANCE OF COMMON STOCK, NET	Shares In thousands	\$	paid-in capital	deficit	stockholders' equity	controlling interests	equity
MARCH 31, 2022 CHANGES DURING THE THREE MONTH PERIOD ENDED JUNE 30, 2022: ISSUANCE OF COMMON STOCK, NET STOCK-BASED	Shares In thousands	\$	paid-in capital  \$ 298,831	deficit	stockholders' equity  \$ 162,349	controlling interests	equity  \$ 162,223
MARCH 31, 2022 CHANGES DURING THE THREE MONTH PERIOD ENDED JUNE 30, 2022: ISSUANCE OF COMMON STOCK, NET	Shares In thousands	\$	paid-in capital  \$ 298,831	deficit	stockholders' equity  \$ 162,349	controlling interests	* 162,223
MARCH 31, 2022 CHANGES DURING THE THREE MONTH PERIOD ENDED JUNE 30, 2022: ISSUANCE OF COMMON STOCK, NET STOCK-BASED COMPENSATION	Shares In thousands	\$	paid-in capital  \$ 298,831  (1) 1,882	deficit	\$ 162,349  \$ 162,349	s (126)	equity  \$ 162,223  (1) 1,882

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

		Six months ended June 30,				
		2023		2022		
CASH FLOWS FROM OPERATING ACTIVITIES:						
Net loss	\$	(4,924)	\$	(21,775)		
Adjustments required to reconcile net loss to net cash used in operating activities:						
Depreciation		89		26		
Exchange differences and interest on deposits and held to maturity bonds		(457)		(319)		
Changes in fair value of investments		(820)		375		
Stock-based compensation		1,993		5,911		
Gain on amounts funded in respect of employee rights upon retirement		(2)		-		
Changes in operating assets and liabilities:				500		
Prepaid expenses and other current assets		620		699		
Accounts payable, accrued expenses and related parties		(3,328)		(1,054)		
Net changes in operating lease		(25)		(99)		
Deferred revenues		(1,340)		(1,340)		
Liability for employee rights upon retirement		6		(1)		
Other liabilities		5		(38)		
Total net cash used in operating activities		(8,183)		(17,615)		
CASH FLOWS FROM INVESTING ACTIVITIES:						
Purchase of short-term deposits		(89,919)		(107,000)		
Proceeds from short-term deposits		59,500		121,000		
Proceeds from maturity of held to maturity securities		2,725		3,786		
Funds in respect of employee rights upon retirement		-		3		
Purchase of property and equipment		(219)		(67)		
Total net cash provided by (used in) investing activities		(27,913)		17,722		
CASH FLOWS FROM FINANCING ACTIVITIES:						
Proceeds from issuance of common stock, net of issuance costs		2,430		2,968		
Tax withholdings related to stock-based compensation settlements		-		(677)		
Total net cash provided by financing activities		2,430		2,291		
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS		(31)		38		
		(81)	_			
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		(33,697)		2,436		
		(33,037)		<b>_</b> , .50		
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD		40,464		27,456		
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$	6,767	\$	29,892		
·	<u>Ψ</u>	0,707	Ψ	23,032		
(A) SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -						
Interest received	\$	2,866	\$	739		
(B) SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -		_,	_	. 50		
Recognition of operating lease right-of-use assets and liabilities	\$		\$	678		
recognition of operating tease right-or-use assets due natifices	Ф	-	Ψ	0/0		

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS U.S. Dollars in thousands (except share and per share data) (UNAUDITED)

#### **NOTE 1 - GENERAL:**

#### a. Incorporation and Operations

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

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

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

On January 11, 2023, the Company announced that the ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints. As a result, the Company terminated this trial and a parallel Phase 3, ORA-D-013-2 clinical trial. As these results are considered a triggering event, the Company evaluated all of its long lived assets which include fixed assets and operating lease right-of-use assets in the first quarter of 2023 and concluded that no impairment was required. The Company recently completed an analysis of the data from the ORA-D-013-1 Phase 3 trial and found that subpopulations of patients with pooled specific parameters, such as body mass index (BMI), baseline HbA1c, age, gender and body weight, responded well to oral insulin. These subsets exhibited an over 1% placebo adjusted, statistically significant, reduction in HbA1c. The Company is currently considering if there is a path forward for its oral insulin candidate, based on this analysis. Concurrently, the Company is examining its existing pipeline and has commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for the Company's stockholders.

#### b. Development and Liquidity Risks

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

On August 9, 2023, the Company entered into the DIP Loan Agreement (as defined herein) with the Debtors (as defined herein) in the principal amount of \$100,000. This amount will be used by the Company as a credit bid for the consideration for the Purchased Securities (as defined herein), with an additional \$5,000 in cash to be paid by the Company at closing. This transaction will significantly reduce the Company's cash position. However, the Company believes it will be able to maintain its current planned development activities and the corresponding level of expenditures for at least the next 12 months, although no assurance can be given that the Company will not need additional funds prior to such time. See note 9 for additional information regarding the DIP Loan Agreement.

On August 8, 2023, the Company borrowed an aggregate of \$99,550 pursuant to loan agreements from the Israel Discount Bank, LTD (the "Short-Term Borrowings"). The Short-Term Borrowings mature on dates ranging from August 11, 2023 to May 24, 2024, bear interest ranging from 6.66% to 7.38%, are secured by certificates of deposits issued by the Israel Discount Bank, LTD having an aggregate face amount of \$99,550. The net proceeds of the Short-Term Borrowings were used to fund the DIP Loan Agreement.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS U.S. Dollars in thousands (except share and per share data) (UNAUDITED)

#### **NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:**

#### a. Condensed consolidated financial statements preparation

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

#### b. Loss per common share

Basic and diluted net loss per share of common stock are computed by dividing the net loss attributable to stockholders for the period by the weighted average number of shares of common stock outstanding for each period, including vested restricted stock units ("RSUs"). Outstanding stock options, warrants and unvested RSUs have been excluded from the calculation of the diluted loss per share because all such securities are anti-dilutive for all periods presented. The weighted average number of common stock options, warrants and RSUs excluded from the calculation of diluted net loss was 3,694,057 and 3,470,361 for the six month periods ended June 30, 2023 and June 30, 2022, respectively, and 4,026,508 and 3,477,121 for the three month periods ended June 30, 2023 and June 30, 2022, respectively.

#### c. Revenue recognition

#### HTIT

On November 30, 2015, the Company entered into a Technology License Agreement (the "TLA"), with Hefei Tianhui Incubator of Technologies Co. Ltd. ("HTIT") and on December 21, 2015, the parties entered into an Amended and Restated Technology License Agreement that was further amended by the parties on June 3, 2016 and July 24, 2016 (the "HTIT License Agreement").

As of June 30, 2023, an aggregate amount of \$22,382 was allocated to the HTIT License Agreement, all of which were received through the balance sheet date. Through June 30, 2023, the Company recognized revenue associated with this agreement in the aggregate amount of \$20,382, of which \$1,340 was recognized in the six month period ended June 30, 2023, and deferred the remaining amount of \$2,000, which is presented as long-term deferred revenues on the condensed consolidated balance sheet.

# Medicox

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

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

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

The Medicox License Agreement contains a fixed consideration of \$2,000, which was received by the Company in fiscal year 2022 and is presented under long-term deferred revenues as of June 30, 2023. It also contains variable consideration of contractual milestone payments and sales-based royalties.

The Company's obligation to stand-ready and support Medicox will be recognized on a straight-line basis over the period the Company expects to provide support to Medicox. As of June 30, 2023, this support has not commenced, and no revenue was recognized from the Medicox License Agreement.

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

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS U.S. Dollars in thousands (except share and per share data) (UNAUDITED)

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

#### d. Recently adopted accounting pronouncements

Financial instruments - credit losses

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

#### e. Fair value

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

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2: Observable prices that are based on inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

As of June 30, 2023, the fair value of marketable equity securities as presented in note 4 was based on a Level 1 measurement. The fair value of held to maturity bonds as presented in note 4 was based on a Level 2 measurement. The fair value of the investment in non-marketable equity securities as presented in note 5 was based on a Level 3 measurement.

As of June 30, 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.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS U.S. Dollars in thousands (except share and per share data) (UNAUDITED)

#### **NOTE 3 - COMMITMENTS:**

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

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

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

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

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

#### b. Grants from the Israel Innovation Authority ("IIA")

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

At the time the grants were received, successful development of the related projects was not assured. The total amount received through June 30, 2023 was \$2,208 (\$2,548 including interest).

As of June 30, 2023, the liability to the IIA was \$96.

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

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
U.S. Dollars in thousands (except share and per share data)
(UNAUDITED)

# **NOTE 4 - MARKETABLE SECURITIES:**

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

# a. Composition:

Short-term:	ne 30, 023	mber 31, 2022
DNA (see b below)	\$ 334	\$ 352
Entera (see c below)	99	85
Held to maturity securities (see d below)	 510	3,306
	\$ 943	\$ 3,743

# b. DNA

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

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

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

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS U.S. Dollars in thousands (except share and per share data) (UNAUDITED)

# NOTE 4 - MARKETABLE SECURITIES (continued):

#### c. Entera

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

# d. Held to maturity securities

The amortized cost and estimated fair value of held to maturity securities as of June 30, 2023, were as follows:

			June 30	, 2023		
	ortized cost	Gross unrealized gains (losses)		Estimated fair value		Average yield to maturity rate
Short-term:						
Commercial bonds	\$ 501	\$	(10)	\$	491	0.8%
Accrued interest	9		-		9	
	\$ 510	\$	(10)	\$	500	

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

				December	31, 20	022	
Short-term:		Amortized cost		Gross unrealized gains (losses)		timated ir value	Average yield to maturity rate
Commercial bonds	\$	3,258	\$	(82)	\$	3,176	1.07%
Accrued interest	•	48	•	-	,	48	
	\$	3,306	\$	(82)	\$	3,224	

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

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS U.S. Dollars in thousands (except share and per share data) (UNAUDITED)

#### NOTE 5 - NON-MARKETABLE EQUITY SECURITIES:

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

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

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

#### **NOTE 6 - STOCKHOLDERS' EQUITY:**

- 1. On September 1, 2021, the Company entered into a controlled equity offering agreement (the "Cantor Equity Distribution Agreement") with Cantor Fitzgerald & Co., as agent, pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to \$100,000, through a sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to the Company's effective shelf registration statement on Form S-3 including a prospectus dated July 26, 2021 and prospectus supplement dated September 1, 2021. The Company paid the sales agent a cash commission of 3.0% of the gross proceeds of the sale of any shares sold through the sales agent under the Cantor Equity Distribution Agreement. As of June 30, 2023 and August 10, 2023, 1,971,447 shares were issued under the Cantor Equity Distribution Agreement for aggregate net proceeds of \$26,253.
- 2. On April 17, 2023, the Company granted an aggregate of 868,500 RSUs representing a right to receive shares of the Company's common stock to executive officers and board members of the Company. The RSUs will vest in twelve equal quarterly installments starting May 1, 2023. The total fair value of these RSUs on the date of grant was \$1,980, using the quoted closing market share price of \$2.28 on the Nasdaq Capital Market on the date of grant.
- 3. On April 17, 2023, the Company granted an aggregate of 245,500 performance based RSUs ("PSUs") representing a right to receive shares of the Company's common stock to executive officers of the Company. The PSUs vested on May 26, 2023, upon the Company's common stock achieving and maintaining a specified price per share. The total fair value of these PSUs on the date of grant was \$550, using the Monte-Carlo model.
- 4. On May 1, 2023, the Company granted an aggregate of 20,000 RSUs representing a right to receive shares of the Company's common stock to a board member. The RSUs will vest in twelve quarterly installments starting May 1, 2023. The total fair value of these RSUs on the date of grant was \$49, using the quoted closing market share price of \$2.45 on the Nasdaq Capital Market on the date of grant.

# NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS U.S. Dollars in thousands (except share and per share data) (UNAUDITED)

# **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 as of June 30, 2023 and December 31, 2022:

	June 30, 2023		mber 31, 2022
Operating right-of-use assets	\$	842	\$ 987
Operating lease liabilities, current		236	247
Operating lease liabilities long-term		488	647
Total operating lease liabilities	\$	724	\$ 894

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

	June 30, 2023	December 31, 2022
2023	138	291
2024	276	291
2025	217	228
2026	118	124
2027	10	10
Total undiscounted lease payments	759	944
Less: Interest*	(35)	(50)
Present value of lease liabilities	\$ 724	\$ 894

<sup>\*</sup> Future lease payments were discounted by 3%-5.75% interest rate.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS U.S. Dollars in thousands (except share and per share data) (UNAUDITED)

#### **NOTE 8 - RELATED PARTY TRANSACTIONS:**

On July 1, 2008, the Company's wholly-owned subsidiary, Oramed Ltd. (the "Subsidiary"), entered into two consulting agreements with KNRY Ltd. ("KNRY"), an Israeli company owned by the Chief Scientific Officer, whereby the President and Chief Executive Officer and the Chief Scientific Officer, through KNRY, provide services to the Company (the "Consulting Agreements"). The Consulting Agreements are both terminable by either party upon 140 days prior written notice. The Consulting Agreements, as amended, provide that KNRY will be reimbursed for reasonable expenses incurred in connection with the performance of the Consulting Agreements and that the monthly consulting fee paid to the President and Chief Executive Officer and the Chief Scientific Officer is NIS 146,705 (\$40) and NIS 106,400 (\$29), respectively.

In addition to the Consulting Agreements, based on a relocation cost analysis, the Company paid for certain direct costs, related taxes and expenses incurred in connection with the relocation of the President and Chief Executive Officer to the U.S. During the six months ended June 30, 2023, there were no such relocation expenses, compared to \$190 for the six months ended June 30, 2022.

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

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

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

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS U.S. Dollars in thousands (except share and per share data) (UNAUDITED)

#### **NOTE 9 - SUBSEQUENT EVENTS:**

#### **Stock Purchase Agreement**

On August 7, 2023, the Company entered into a Stock Purchase Agreement, as amended by a First Amendment to Stock Purchase Agreement, dated as of August 9, 2023 (together, the "Stock Purchase Agreement"), with Sorrento Therapeutics, Inc. ("Sorrento"), to acquire certain securities of Scilex Holding Company ("Scilex") owned by Sorrento, including (A) 59,726,737 shares of common stock of Scilex; provided, that the Company will have an option to purchase up to 2,259,058 additional shares of common stock of Scilex, which Sorrento is holding in abeyance on behalf of certain warrant holders of Sorrento (the "Option Shares"), at an exercise price of \$1.13 per Option Share; (B) 29,057,096 shares of Series A preferred stock of Scilex; and (C) public warrants exercisable for 1,386,617 shares of common stock of Scilex, and private placement warrants exercisable for 3,104,000 shares of common stock of Scilex, (collectively, the "Purchased Securities") (such acquisition of the Purchased Securities, the "Transaction") for a total purchase price of \$105,000. The consideration for the Transaction consists of a credit bid by the Company on a dollar-for-dollar basis of the full amount of outstanding obligations as of the closing date under the DIP Facility (as defined below), with the remaining balance of the purchase price to be paid in cash at closing. Sorrento and its wholly-owned subsidiary (collectively, the "Debtors") are debtors in Chapter 11 bankruptcy proceedings pending before the United States Bankruptcy Court for the Southern District of Texas (the "Bankruptcy Court") which commenced on February 13, 2023. The Transaction is being conducted through a Bankruptcy Court-supervised process and is subject to the receipt of higher or otherwise better offers from competing bidders at an auction and approval of the sale by the Bankruptcy Court. Scilex is a company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain.

Completion of the Transaction is subject to the satisfaction or waiver of customary and certain other closing conditions, including governmental and bankruptcy court approvals, the approval of an amendment to Scilex's governance documents, the grant of an irrevocable proxy and call option (with an exercise price of \$1 (not in thousands)) with respect to the remaining share of Scilex Series A preferred stock retained by Sorrento, no trigger event in Scilex's governance documents having occurred and the Purchased Securities shall represent at least a majority in voting power of Scilex, entry by the Company and Scilex into a new registration rights agreement, and no event of default under the DIP Facility. Sorrento has also agreed to provide certain transition services for a period of 90 days following the closing. The Company may also terminate the Stock Purchase Agreement (a) if the auction has not commenced on or before August 14, 2023 or if the sale order has not been entered by the Bankruptcy Court by August 21, 2023, (b) if Sorrento's bankruptcy case is converted to chapter 7, or (c) if Sorrento materially breaches the DIP Facility or the Company is unable to credit bid in payment of the DIP Facility.

The Stock Purchase Agreement provides for certain termination rights including, but not limited to, by mutual written consent of the parties, and by either party in the event that the Transaction is not consummated by September 30, 2023, or pursuant to any legal prohibition or injunction. The Stock Purchase Agreement provides for payment to the Company by Sorrento of a termination fee of \$3,413 and expense reimbursement of up to \$1,000 for outside counsel upon termination of the Stock Purchase Agreement under certain circumstances, including if Sorrento enters into a transaction involving the disposition of any portion of the Purchased Securities to a person other than the Company.

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS U.S. Dollars in thousands (except share and per share data) (UNAUDITED)

#### NOTE 9 - SUBSEQUENT EVENTS (continued):

#### **DIP Loan Agreement**

On August 9, 2023, the Company entered into a Senior Secured, Super-Priority Debtor-in-Possession Loan and Security Agreement by and among the Debtors, the Company and the guarantors from time to time party thereto (the "DIP Loan Agreement"), pursuant to which the Company will provide to the Debtors a non-amortizing super-priority senior secured debtor-in-possession term loan financing facility in an aggregate principal amount of \$100,000 (the "DIP Facility"). The DIP Facility proceeds will be used (i) to refinance and pay in full the approximately \$82,000 of obligations outstanding under the Debtors' current DIP facility (the "Existing DIP Facility"), (ii) for working capital and other general corporate purposes of the Debtors (subject to an agreed budget), and (iii) the payment of certain statutory fees and bankruptcy-related expenses and fees.

The DIP Facility is provided on substantially the same terms and conditions as those of the Existing DIP Facility, subject to, among other things, (a) mutually agreed-upon permitted asset sales of collateral, the proceeds of such asset sales are included in the DIP Facility collateral package; (b) agreed-upon "stalking horse" bidder protections; (c) agreed-upon milestones and other deadlines for, among other things, the auction, the sale hearing and the outside date for consummation of the Transaction; (d) an agreed budget, or the DIP budget; and (e) the Bankruptcy Court order. On August 7, 2023, the Bankruptcy Court entered an order, approving the Debtors' entry into the DIP Loan Agreement and the "stalking horse" bidder protections, among other things.

The DIP Facility bears interest at a per annum rate equal to 15%, payable in cash (and a default interest rate that shall accrue at an additional per annum rate of 3% plus the non-default interest) and other fees and charges. The DIP Facility is secured by first-priority liens on substantially all of the Debtors' assets, subject to certain enumerated exceptions.

The DIP Facility matures on the earliest of: (i) October 15, 2023; (ii) the effective date of a plan of reorganization in the Debtors' Chapter 11 case; (iii) the sale or other disposition of all or substantially all of the collateral; (iv) the date of the acceleration of the obligations in accordance with the DIP Loan Agreement; (v) the dismissal of the Chapter 11 cases or conversion into Chapter 7 cases; (vi) the date of termination of the Stock Purchase Agreement or other related definitive documentation as a result of a material breach by the Debtors; and (vii) the date on which a trigger event in Scilex's governance documents has occurred.

The DIP Loan Agreement includes the following milestones:

By no later than:	Event
August 14, 2023	The auction for the sale of the Purchased Securities shall have commenced.
August 18, 2023	The Bankruptcy Court shall commence a hearing to consider approval of the sale of the Purchased Securities.
August 21, 2023	The Bankruptcy Court shall have entered an order approving the sale of the Purchased Securities in form and substance acceptable to the Company.
September 30, 2023	The closing of the sale of the Purchased Securities shall have occurred.

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

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

#### **Overview of Operations**

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

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

On January 11, 2023, we announced that the ORA-D-013-1 Phase 3 trial did not meet its primary or secondary endpoints. As a result, we terminated this trial and a parallel Phase 3, ORA-D-013-2 clinical trial. We recently completed an analysis of the data from the ORA-D-013-1 Phase 3 trial and found that subpopulations of patients with pooled specific parameters, such as body mass index (BMI), baseline HbA1c, age, gender and body weight, responded well to oral insulin. We are currently considering if there is a path forward for our oral insulin candidate, based on this analysis. We are additionally examining our existing pipeline and have commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for our stockholders.

#### **Stock Purchase Agreement**

On August 7, 2023, the Company entered into a Stock Purchase Agreement, as amended by a First Amendment to Stock Purchase Agreement, dated as of August 9, 2023 (together, the Stock Purchase Agreement), with Sorrento, to acquire certain securities, or the Transaction, of Scilex Holding Company, or Scilex owned by Sorrento, including (A) 59,726,737 shares of common stock of Scilex; including an option to purchase up to 2,259,058 additional shares; (B) 29,057,096 shares of Series A preferred stock of Scilex; and (C) public warrants exercisable for 1,386,617 shares of common stock of Scilex, and private placement warrants exercisable for 3,104,000 shares of common stock of Scilex, or collectively, the Purchased Securities, for a total purchase price of \$105,000,000. The consideration for the Transaction consists of a credit bid by the Company on a dollar-for-dollar basis of the full amount of outstanding obligations as of the closing date under the DIP Facility (as defined below), with the remaining balance of the purchase price to be paid in cash at closing. Sorrento and its wholly-owned subsidiary or collectively, the Debtors, are debtors in Chapter 11 bankruptcy proceedings pending before the United States Bankruptcy Court for the Southern District of Texas or the Bankruptcy Court, which commenced on February 13, 2023. Scilex is a company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain.

The Transaction is being conducted through a Bankruptcy Court-supervised process and is subject to the receipt of higher or otherwise better offers from competing bidders at an auction, approval of the sale by the Bankruptcy Court, and the satisfaction of certain closing conditions. Accordingly, the Company can give no assurances of the outcome of the Transaction and whether the Company will be successful in acquiring the Purchased Securities. See note 9 – Subsequent Events for additional information regarding the Transaction.

# **DIP Loan Agreement**

On August 9, 2023, the Company entered into the Senior Secured, Super-Priority Debtor-in-Possession Loan and Security Agreement by and among the Debtors, the Company and the guarantors from time to time party thereto, or the DIP Loan Agreement, pursuant to which the Company will provide to the Debtors a non-amortizing super-priority senior secured debtor-in-possession term loan financing facility in an aggregate principal amount of \$100,000,000, the DIP Facility. The DIP Facility proceeds will be used (i) to refinance and pay in full the approximately \$82,000,000 of obligations outstanding under the Debtors' current DIP facility, the Existing DIP Facility, (ii) for working capital and other general corporate purposes of the Debtors (subject to an agreed budget), and (iii) the payment of certain statutory fees and bankruptcy-related expenses and fees.

The DIP Facility bears interest at a per annum rate equal to 15%, payable in cash (and a default interest rate that shall accrue at an additional per annum rate of 3% plus the non-default interest) and other fees and charges. The DIP Facility is secured by first-priority liens on substantially all of the Debtors' assets, subject to certain enumerated exceptions.

The DIP Facility matures on the earliest of: (i) October 15, 2023; (ii) the effective date of a plan of reorganization in the Debtors Chapter 11 case; (iii) the sale or other disposition of all or substantially all of the collateral; (iv) the date of the acceleration of the obligations in accordance with the DIP Loan Agreement; (v) the dismissal of the Chapter 11 cases or conversion into Chapter 7 cases; (vi) the date of termination of the Stock Purchase Agreement or other related definitive documentation as a result of a material breach by the Debtors; and (vii) the date on which a trigger event in Scilex's governance documents has occurred. See Note 9 – Subsequent Events for additional information regarding the DIP Loan Agreement.

#### **Oral Insulin**

Type 2 Diabetes: We conducted the ORA-D-013-1 Phase 3 trial on patients with type 2 diabetes, or T2D, with inadequate glycaemic control who were on two or three oral glucose-lowering agents. The primary endpoint of the trial was to evaluate the efficacy of our oral insulin capsule, ORMD-0801, compared to placebo in improving glycaemic control as assessed by HbA1c, with a secondary efficacy endpoint of assessing the change from baseline in fasting plasma glucose at 26 weeks. On January 11, 2023, we announced that the ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints. Following the results of the ORA-D-013-1 Phase 3 trial, we also terminated the ORA-D-013-2 Phase 3 trial, a second Phase 3 trial that included T2D patients with inadequate glycaemic control who were attempting to manage their condition with either diet alone or with diet and metformin. We recently completed an analysis of the data from the ORA-D-013-1 Phase 3 trial and found that subpopulations of patients with pooled specific parameters, such as body mass index (BMI), baseline HbA1c, age, gender and body weight, responded well to oral insulin. These subsets exhibited an over 1% placebo adjusted, statistically significant, reduction in HbA1c. We are currently considering if there is a path forward for our oral insulin candidate, based on this analysis.

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

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

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

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

#### **Oral Vaccine**

On March 18, 2021, we formed Oravax, a 63% owned joint venture to commercialize oral vaccines for COVID-19 and other novel coronaviruses based on Premas Biotech Pvt. Ltd.'s proprietary vaccine technology involving a triple antigen virus like particle.

In December 2021, Oravax commenced a Phase 1 clinical trial, which was divided into two cohorts each comprised of 12 participants. In October 2022, Oravax reported positive preliminary Phase 1 data for Cohort A of this trial, meeting primary and secondary endpoints of safety and immunogenicity. These results included significant antibody response (2-6 fold over baseline) as measured by multiple markers of immune response to VLP vaccine antigens observed in the majority of the patients dosed, and no safety issues were observed, including mild symptoms. Cohort B completed dosing on January 5, 2023. Cohort B measured Immunoglobulin G, or IGG against the spike (S) protein, showing positive IGG in approximately 55% of the patients dosed.

#### **Results of Operations**

# Comparison of six and three month periods ended June 30, 2023 and June 30, 2022

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

	Six months ended			Three months ended				
	June 30, 2023		June 30, 2022		June 30, 2023		June 30, 2022	
Revenues	\$	1,340	\$	1,340	\$	674	\$	674
Cost of revenues		-		-		-		-
Research and development expenses		6,248		15,015		1,821		9,179
Sales and marketing expenses		376		970		192		380
General and administrative expenses		3,715		8,024		2,452		2,532
Financial income, net		4,075		894		2,478		350
Net loss for the period	\$	4,924	\$	21,775	\$	1,313	\$	11,067
Basic and diluted loss per share of common stock	\$	0.11	\$	0.54	\$	0.03	\$	0.27
Weighted average shares of common stock outstanding used in computing basic								
and diluted loss per share of common stock		40,144,725		38,732,636		40,225,594		38,795,318

#### Revenues

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

Revenues were \$1,340,000 for each of the six month periods ended June 30, 2023 and June 30, 2022.

Revenues were \$674,000 for each of the three month periods ended June 30, 2023 and June 30, 2022.

# Cost of Revenues

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

There was no cost of revenues for the three and six month periods ended June 30, 2023 and June 30, 2022.

#### **Research and Development Expenses**

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

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

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

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

Research and development expenses for the six month period ended June 30, 2023 decreased by 58% to \$6,248,000, compared to \$15,015,000 for the six month period ended June 30, 2022. The decrease was mainly due to lower expenses related to the Phase 3 trials that were terminated. Stock-based compensation expenses for the six month period ended June 30, 2023 were \$415,000, compared to \$1,136,000 during the six month period ended June 30, 2022. This decrease was mainly due to performance equity awards that expired because they did not meet their performance conditions during the period ended June 30, 2023.

Research and development expenses for the three month period ended June 30, 2023 decreased by 80% to \$1,821,000, compared to \$9,179,000 for the three month period ended June 30, 2022. The decrease was mainly due to lower expenses related to the Phase 3 trials that were terminated. Stock-based compensation expenses for the three month period ended June 30, 2023 were \$398,000, compared to \$574,000 during the three month period ended June 30, 2022. This decrease was mainly due to equity awards that vested in the second half of 2022.

Following the results of the ORA-D-013-1 Phase 3 trial, which did not meet its primary and secondary endpoints, we terminated both ORA-D-013-1 and ORA-D-013-2 Phase 3 clinical trials. We recently completed an analysis of the data from the ORA-D-013-1 Phase 3 trial and found that subpopulations of patients with pooled specific parameters responded well to oral insulin. We are currently considering if there is a path forward for our oral insulin candidate, based on this analysis. We are also examining our existing pipeline and have commenced an evaluation process of potential strategic opportunities, with the goal of enhancing value for our stockholders.

#### Government grants

In the six month periods ended June 30, 2023 and June 30, 2022, we did not recognize any research and development grants. As of June 30, 2023, we had incurred liabilities to pay royalties to the Israel Innovation Authority of the Israeli Ministry of Economy and Industry of \$96,000.

#### Sales and Marketing Expenses

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

Sales and marketing expenses for the six month period ended June 30, 2023 decreased by 61% to \$376,000, compared to \$970,000 for the six month period ended June 30, 2022. The decrease was primarily due to lower stock-based compensation expenses and consulting expenses. Stock-based compensation expenses for the six month period ended June 30, 2023 were \$223,000, compared to \$584,000 for the six month period ended June 30, 2022. This decrease was mainly due to performance equity awards that expired because they did not meet their performance conditions during the period ended June 30, 2023.

Sales and marketing expenses for the three month period ended June 30, 2023 decreased by 49% to \$192,000, compared to \$380,000 for the three month period ended June 30, 2022. The decrease was primarily due to lower stock-based compensation expenses. Stock-based compensation expenses for the three month period ended June 30, 2023 were \$136,000, compared to \$220,000 for the three month period ended June 30, 2022. This decrease was mainly due to performance equity awards that expired because they did not meet their performance conditions during the period ended June 30, 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 six month period ended June 30, 2023 decreased by 54% to \$3,715,000 compared to \$8,024,000 for the six month period ended June 30, 2022. This decrease was mainly due to lower stock-based compensation expenses and legal expenses. Stock-based compensation expenses for the six month period ended June 30, 2023 were \$1,355,000, compared to \$4,190,000 for the six month period ended June 30, 2022. This decrease was mainly due to equity awards that were granted and vested in the first quarter of 2022 and to performance equity awards that expired because they did not meet their performance conditions during the period ended June 30, 2023.

General and administrative expenses for the three month period ended June 30, 2023 decreased by 3% to \$2,452,000 compared to \$2,532,000 for the three month period ended June 30, 2022. This decrease was mainly due to decreases in legal expenses, public relations and investor relations expenses and insurance expenses partially offset by increases in stock-based compensation expenses and consulting expenses. Stock-based compensation expenses for the three month period ended June 30, 2023 were \$1,285,000, compared to \$1,087,000 for the three month period ended June 30, 2022. This increase was mainly due to equity awards granted to directors and officers in the second quarter of 2023.

#### Financial Income, net

Net financial income increased by 356% to \$4,075,000 for the six month period ended June 30, 2023, compared to \$894,000 for the six month period ended June 30, 2022. The increase was mainly due to interest from short-term bank deposits and revaluation of non-marketable equity securities.

Net financial income increased by 608% to \$2,478,000 for the three month period ended June 30, 2023, compared to \$350,000 for the three month period ended June 30, 2022. The increase was mainly due to interest from short-term bank deposits and revaluation of non-marketable equity securities.

#### Basic and Diluted Loss Per Share of Common Stock

Basic and diluted loss per share of common stock for the six month period ended June 30, 2023 decreased by 80% to \$0.11, compared to \$0.54 for the six month period ended June 30, 2022. The decrease in loss per share was mainly due to lower net loss resulting from the changes set forth above in the six month period ended June 30, 2023 compared to the six month period ended June 30, 2022.

Basic and diluted loss per share of common stock for the three month period ended June 30, 2023 decreased by 89% to \$0.03, compared to \$0.27 for the three month period ended June 30, 2022. The decrease in loss per share was mainly due to lower net loss resulting from the changes set forth above in the three month period ended June 30, 2023 compared to the three month period ended June 30, 2022.

#### Weighted Average Shares of Common Stock Outstanding

Weighted average shares of common stock outstanding for the six month period ended June 30, 2023 were 40,144,725, compared to 38,732,636 for the six month period ended June 30, 2022. The increase was mainly due to shares issued in connection with our controlled equity offering.

Weighted average shares of common stock outstanding for the three month period ended June 30, 2023 were 40,225,594, compared to 38,795,318 for the three month period ended June 30, 2022. The increase was mainly due to shares issued in connection with our controlled equity offering.

#### **Liquidity and Capital Resources**

From inception through June 30, 2023, we have incurred losses in an aggregate amount of \$167,670,000. During that period and through June 30, 2023, we have financed our operations through several private placements of our common stock, as well as public offerings of our common stock, raising a total of \$255,376,000, net of transaction costs. During that period, we also received cash consideration of \$28,001,000 from the exercise of warrants and options. We expect to seek additional financing through similar sources in the future, as needed. As of June 30, 2023, we had \$6,767,000 of available cash, \$142,491,000 of short-term bank deposits and \$943,000 of marketable securities.

From inception through June 30, 2023, we have not generated significant revenues from our operations. Management continues to evaluate various financing alternatives for funding new strategic activities, future research and development activities and general and administrative expenses through fundraising in the public or private equity markets. Although there is no assurance that we will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of future third party investments. Based on our current cash resources and commitments, we believe we will be able to maintain our current planned development activities and the corresponding level of expenditures for at least the next 12 months, although no assurance can be given that we will not need additional funds prior to such time.

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

On August 9, 2023, we entered into the DIP Loan Agreement with the Debtors in the principal amount of \$100,000,000. This amount will be used by the Company as a credit bid for the consideration for the Purchased Securities, with an additional \$5,000,000 in cash to be paid by the Company at closing. This transaction will significantly reduce our cash position. However, we believe we will be able to maintain our current planned development activities and the corresponding level of expenditures for at least the next 12 months, although no assurance can be given that we will not need additional funds prior to such time. See Note 9 – Subsequent Events for additional information regarding the DIP Loan Agreement.

On August 8, 2023, we borrowed an aggregate of \$99,550,000 pursuant to loan agreements from the Israel Discount Bank, LTD (the "Short-Term Borrowings"). The Short-Term Borrowings mature on dates ranging from August 11, 2023 to May 24, 2024, bear interest ranging from 6.66% to 7.38%, are secured by certificates of deposits issued by the 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 DIP Loan Agreement.

As of June 30, 2023, our total current assets were \$150,970,000 and our total current liabilities were \$1,067,000. On June 30, 2023, we had a working capital surplus of \$149,903,000 and an accumulated loss of \$167,670,000. As of December 31, 2022, our total current assets were \$157,109,000 and our total current liabilities were \$5,746,000. On December 31, 2022, we had a working capital surplus of \$151,363,000 and an accumulated loss of \$163,081,000. The decrease in working capital from December 31, 2022 to June 30, 2023 was mainly due to a decrease in cash and cash equivalents, marketable securities, partially offset by an increase in short term deposits and accounts payable and accrued expenses.

During the six month period ended June 30, 2023, cash and cash equivalents decreased to \$6,767,000, from \$40,464,000 as of December 31, 2022. The decrease was mainly due to the reasons described below.

Operating activities used cash of \$8,183,000 in the six month period ended June 30, 2023, compared to \$17,615,000 used in the six month period ended June 30, 2022. Cash used in operating activities primarily consisted of research and development, sales and marketing and general and administrative expenses and changes in stock-based compensation expenses, interest on deposits, account payables and accrued expenses.

Investing activities used cash of \$27,913,000 in the six month period ended June 30, 2023, compared to cash provided by investing activities of \$17,222,000 in the six month period ended June 30, 2022. Cash used by investing activities in the six month period ended June 30, 2023 consisted primarily of the purchase of short-term deposits, partially offset by proceeds from short term investing activities.

Financing activities provided cash of \$2,430,000 in the six month period ended June 30, 2023, compared to \$2,291,000 provided in the six month period ended June 30, 2023. Cash provided by financing activities consisted primarily of proceeds from the issuance of our common stock.

On September 1, 2021, we entered into a controlled equity offering agreement, or the Cantor Equity Distribution Agreement, with Cantor Fitzgerald & Co., as agent, pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to \$100,000,000, through a sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to our effective shelf registration statement on Form S-3 including a prospectus dated July 26, 2021 and prospectus supplement dated September 1, 2021. We paid the sales agent a cash commission of 3.0% of the gross proceeds of the sale of any shares sold through the sales agent under the Cantor Equity Sales Agreement. As of June 30, 2023, 1,971,447 shares were issued under the Cantor Equity Distribution Agreement for aggregate net proceeds of \$26,253,000.

#### Critical accounting policies and estimates

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

#### **Planned Expenditures**

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

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

#### ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There has been no significant change in our exposure to market risk during the quarter ended June 30, 2023. For a discussion of our exposure to market risk, refer to Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," contained in our Annual Report.

#### ITEM 4 - CONTROLS AND PROCEDURES

#### **Disclosure Controls and Procedures**

Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2023. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II - OTHER INFORMATION

# ITEM 1A. RISK FACTORS.

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

#### **Risks Related to Our Business**

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

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

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

We may not be able to close the Stock Purchase Agreement with Sorrento and complete the Transaction, realize the anticipated benefits of the Transaction, or recover the proceeds and/or collateral under the DIP Loan Agreement, which may impact our operations and financial condition.

On August 7, 2023, we entered into the Stock Purchase Agreement with Sorrento to acquire the Purchased Securities for a total purchase price of \$105,000,000. In addition, on August 9, 2023, we entered into the DIP Loan Agreement, pursuant to which the Company will provide to Sorrento and its wholly-owned subsidiary a non-amortizing super-priority senior secured debtor-in-possession term loan financing facility in an aggregate principal amount of \$100,000,000. Sorrento and its wholly-owned subsidiary are debtors in Chapter 11 bankruptcy proceedings pending before the Bankruptcy Court and the Transaction is being conducted through a Bankruptcy Court-supervised process and is subject to the receipt of higher or otherwise better offers from competing bidders at an auction and the approval of the sale by the Bankruptcy Court. The Stock Purchase Agreement includes certain other closing conditions, including the receipt of governmental approvals, the approval of an amendment to Scilex's governance documents, the grant of an irrevocable proxy and call option with respect to the remaining share of Scilex Series A preferred stock retained by Sorrento, no occurrence of a trigger event in Scilex's governance documents having occurred, entry by the Company and Scilex into a new registration rights agreement, and no occurrence of an event of default under the DIP Facility. The Stock Purchase Agreement also provides for certain termination rights including, but not limited to, by mutual written consent of the parties, and by either party in the event that the Transaction is not consummated by September 30, 2023, or pursuant to any legal prohibition or injunction.

There can be no assurances that Sorrento won't receive higher or otherwise better offers from competing bidders, that the Bankruptcy Court will approve the Transaction, that the Company and Sorrento will be able to satisfy the other closing conditions in a timely matter or at all and acquire the Purchased Securities, or regarding the occurrence of any event, change or other circumstances that could give rise to the termination of the Stock Purchase Agreement by either the Company or Sorrento. There can be also no assurances, even if the Transaction is consummated, that we will be able to realize the anticipated benefits of the Transaction when expected or at all, and to recover the proceeds and/or collateral under the DIP Loan Agreement. The Transaction may also be more expensive to complete than anticipated by us and may subject us to potential litigation. This, in turn, may adversely affect our operations and financial condition.

# ITEM 6 – EXHIBITS

Number	Exhibit					
2.1+	Stock Purchase Agreement dated August 7, 2023, by and between Oramed Pharmaceuticals Inc. and Sorrento Therapeutics, Inc.					
	(incorporated by reference from our current report on Form 8-K filed August 9, 2023).					
2.2*	<u>First Amendment to Stock Purchase Agreement dated August 9, 2023, by and between Oramed Pharmaceuticals Inc. and Sorrento Therapeutics, Inc.</u>					
10.1*	Representative Form of Indemnification Agreements between Oramed Pharmaceuticals Inc. and each of our directors and officers.					
10.0						
10.2+	Senior Secured, Super-Priority Debtor-In-Possession Loan and Security Agreement dated August 9, 2023, by and between Oramed Pharmaceuticals Inc., Sorrento Therapeutics, Inc. and Scintilla Pharmaceuticals, Inc. (incorporated by reference from our current report on Form 8-K filed August 9, 2023).					
	<u>Form 6-K filed August 5, 2025).</u>					
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.					
20.011						
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 June 30, 2023 formatted in					
101.1"	XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Comprehensive Loss, (iii) Condensed					
	Consolidated Statement of Changes in Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows and (v) the Notes to					
	Condensed Consolidated Financial Statements.					
104.1*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).					

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

# **SIGNATURES**

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

# ORAMED PHARMACEUTICALS INC.

Date: August 10, 2023 By: /s/ Nadav Kidron

Date: August 10, 2023

Nadav Kidron

President and Chief Executive Officer

By: /s/ David Silberman

David Silberman Chief Financial Officer

(Principal Financial and Accounting Officer)

# FIRST AMENDMENT TO STOCK PURCHASE AGREEMENT

THIS FIRST AMENDMENT TO STOCK PURCHASE AGREEMENT (this "**Amendment**") is made as of August 9, 2023, by and between Sorrento Therapeutics, Inc., a Delaware corporation (the "**Seller**"), and Oramed Pharmaceuticals Inc., a Delaware corporation (the "**Purchaser**"). Capitalized terms used herein without definition shall have the meaning ascribed to such terms in the Stock Purchase Agreement.

WHEREAS, the Seller and the Purchaser are parties to that certain Stock Purchase Agreement, dated as of August 7, 2023 (the "Stock Purchase Agreement").

WHEREAS, the Parties desire to amend the Stock Purchase Agreement as set forth herein to extend the time period after which the Stock Purchase Agreement may be terminated in the absence of the entry of a Sale Order.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is acknowledged by each of the parties, the parties hereby agree as follows:

#### 1. AMENDMENT TO STOCK PURCHASE AGREEMENT

Subsection 7(e) of the Stock Purchase Agreement is hereby amended to delete the words "by August 17, 2023" in such section and to replace them with the words "by August 21, 2023."

The definition of "Replacement DIP Facility" in the Stock Purchase Agreement is hereby amended to delete the words "August 8, 2023" in such definition and to replace them with the words "August 9, 2023."

#### 2. GENERAL

A. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and to be performed entirely within such State. All actions and proceedings arising out of or relating to this Amendment and the transactions contemplated hereby shall be heard and determined exclusively in the United States Bankruptcy Court for the Southern District of Texas, and the Parties hereby irrevocably submit to the exclusive jurisdiction of such court in any such action or proceeding and irrevocably waive the defense of an inconvenient forum to the maintenance of any such action or proceeding; provided, however, that, if the Bankruptcy Case is closed, any action, claim, suit or proceeding arising out of, based upon, or relating to this Agreement or the transactions contemplated herby shall be heard and determined exclusively in any state or federal court located in New York County, New York. Each Party agrees that a final, non-appealable judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY THAT MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES, AND THEREFORE IT HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

B. <u>Ratification</u>. Except as expressly modified and amended by the provisions of this Amendment, all provisions of the Stock Purchase Agreement shall remain in full force and effect in accordance with their terms; provided, that in the event of any conflict between the terms of the Amendment and the terms of the Stock Purchase Agreement the terms of this Amendment shall control. References to the Stock Purchase Agreement in other documents and agreements will be deemed to be references to the Stock Purchase Agreement, as amended by this Amendment, regardless of whether such documents and agreements refer to any amendments of the Stock Purchase Agreement.

C. <u>Miscellaneous Provisions</u>. The provisions of Sections 10(e) (*Notices*), 10(i) (*Entire Agreement; Waiver and Amendment*) and 10(j) (*Counterparts*) of the Stock Purchase Agreement shall each apply to this Amendment *mutatis mutandis*.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties have executed this First American	ndment to Stock Purchase Agreement as of the date first written above.
	SELLER:
	SORRENTO THERAPEUTICS, INC.
	By: Name: Mohsin Y. Meghji Title: Chief Restructuring Officer
	PURCHASER:
	ORAMED PHARMACEUTICALS INC.
	By: Name: Nadav Kidron Title: Chief Executive Officer

#### INDEMNIFICATION AGREEMENT

THIS INDEMNIFICATION AGREEMENT (the "Agreement") is made and entered into as of	between <b>Oramed</b>
Pharmaceuticals Inc., a Delaware corporation (the "Company"), and("Indemnitee").	

WHEREAS, highly competent persons have become more reluctant to serve corporations as directors or officers unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the By-laws and/or the Certificate of Incorporation of the Company require indemnification of the officers and directors of the Company. Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware ("DGCL"). The By-laws and/or Certificate of Incorporation and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the Board of Directors of the Company (the "Board") officers and other persons with respect to indemnification;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company's stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the By-laws and/or Certificate of Incorporation of the Company and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder; and

NOW, THEREFORE, in consideration of Indemnitee's agreement to serve as an officer and director from and after the date hereof, the parties hereto agree as follows:

- 1. <u>Indemnity of Indemnitee</u>. The Company hereby agrees to hold harmless and indemnify Indemnitee to the fullest extent permitted by law, as such may be amended from time to time. In furtherance of the foregoing indemnification, and without limiting the generality thereof:
- (a) <u>Proceedings Other Than Proceedings by or in the Right of the Company</u>. Indemnitee shall be entitled to the rights of indemnification provided in this <u>Section I(a)</u> if, by reason of his Corporate Status (as hereinafter defined), the Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding (as hereinafter defined) other than a Proceeding by or in the right of the Company. Pursuant to this <u>Section 1(a)</u>, Indemnitee shall be indemnified against all Expenses (as hereinafter defined), judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by him, or on his behalf, in connection with such Proceeding or any claim, issue or matter therein, if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and with respect to any criminal Proceeding, had no reasonable cause to believe the Indemnitee's conduct was unlawful.

(b) <u>Proceedings by or in the Right of the Company.</u> Indemnitee shall be entitled to the rights of indemnification provided in this <u>Section 1(b)</u> if, by reason of his Corporate Status, the Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding brought by or in the right of the Company. Pursuant to this <u>Section 1(b)</u>, Indemnitee shall be indemnified against all Expenses, judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by the Indemnitee, or on the Indemnitee's behalf, in connection with such Proceeding if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company; provided, however, if applicable law so provides, no indemnification against such Expenses shall be made in respect of any claim, issue or matter in such Proceeding as to which Indemnitee shall have been adjudged to be liable to the Company unless and to the extent that the Court of Chancery of the State of Delaware shall determine that such indemnification may be made.

(c) <u>Indemnification for Expenses of a Party Who is Wholly or Partly Successful</u>. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of his Corporate Status, a party to and is successful, on the merits or otherwise, in any Proceeding, he shall be indemnified to the maximum extent permitted by law, as such may be amended from time to time, against all Expenses, judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by him or on his behalf in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him or on his behalf in connection with each successfully resolved claim, issue or matter. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

2. Additional Indemnity. In addition to, and without regard to any limitations on, the indemnification provided for in Section 1 of this Agreement, the Company shall and hereby does indemnify and hold harmless Indemnitee against all Expenses, judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by him or on his behalf if, by reason of his Corporate Status, he is, or is threatened to be made, a party to or participant in any Proceeding (including a Proceeding by or in the right of the Company), including, without limitation, all liability arising out of the negligence or active or passive wrongdoing of Indemnitee. The only limitation that shall exist upon the Company's obligations pursuant to this Agreement shall be that the Company shall not be obligated to make any payment to Indemnitee that is finally determined (under the procedures, and subject to the presumptions, set forth in Sections 5 and 6 hereof) to be unlawful.

#### 3. Contribution.

(a) Whether or not the indemnification provided in Sections 1 and 2 hereof is available in respect of any threatened, pending or completed Proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), the Company shall pay, in the first instance, the entire amount of any judgment or settlement of such Proceeding without requiring Indemnitee to contribute to such payment and the Company hereby waives and relinquishes any right of contribution it may have against Indemnitee. The Company shall not enter into any settlement of any Proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such Proceeding) unless such settlement provides for a full and final release of all claims asserted against Indemnitee.

(b) Without diminishing or impairing the obligations of the Company set forth in the preceding subparagraph, if, for any reason, Indemnitee shall elect or be required by law to pay all or any portion of any judgment or settlement in any threatened, pending or completed Proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such Proceeding), the Company shall contribute to the amount of Expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred and paid or payable by Indemnitee in proportion to the relative benefits received by the Company and all officers, directors or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, from the transaction or events from which such Proceeding arose; provided, however, that the proportion determined on the basis of relative benefit may, to the extent necessary to conform to law, be further adjusted by reference to the relative fault of the Company and all officers, directors or employees of the Company other than Indemnitee who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, in connection with the transaction or events that resulted in such Expenses, judgments, fines or settlement amounts, as well as any other equitable considerations which applicable law may require to be considered. The relative fault of the Company and all officers, directors or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, shall be determined by reference to, among other things, the degree to which their actions were motivated by intent to gain personal profit or advantage, the degree to which their liability is primary or secondary and the degree to which their conduct is active or passive.

(c) The Company hereby agrees to fully indemnify and hold Indemnitee harmless from any claims of contribution which may be brought by officers, directors or employees of the Company, other than Indemnitee, who may be jointly liable with Indemnitee.

(d) To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

- 3. <u>Indemnification for Expenses of a Witness</u>. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of his Corporate Status, a witness, or is made (or asked) to respond to discovery requests, in any Proceeding to which Indemnitee is not a party, he shall be indemnified against all Expenses actually and reasonably incurred by him or on his behalf in connection therewith.
- 4. Advancement of Expenses. Notwithstanding any other provision of this Agreement, the Company shall advance all Expenses incurred by or on behalf of Indemnitee in connection with any Proceeding by reason of Indemnitee's Corporate Status within thirty (30) days after the receipt by the Company of a statement or statements from Indemnitee requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements shall reasonably evidence the Expenses incurred by Indemnitee and shall include or be preceded or accompanied by a written undertaking by or on behalf of Indemnitee to repay any Expenses advanced if it shall ultimately be determined by a final judicial determination (as to which all rights of appeal therefrom have been exhausted or lapsed) that Indemnitee is not entitled to be indemnified against such Expenses. Any advances and undertakings to repay pursuant to this Section 4 shall be unsecured and interest free.
- 5. <u>Procedures and Presumptions for Determination of Entitlement to Indemnification</u>. It is the intent of this Agreement to secure for Indemnitee rights of indemnity that are as favorable as may be permitted under the DGCL and public policy of the State of Delaware. Accordingly, the parties agree that the following procedures and presumptions shall apply in the event of any question as to whether Indemnitee is entitled to indemnification under this Agreement:
- (a) To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification, provided that Indemnitee shall not be required to provide any documentation or information which is privileged or otherwise protected from disclosure. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification. Notwithstanding the foregoing, any failure of Indemnitee to provide such a request to the Company, or to provide such a request in a timely fashion, shall not relieve the Company of any liability that it may have to Indemnitee unless, and to the extent that, such failure actually and materially prejudices the interests of the Company.
- (b) Upon written request by Indemnitee for indemnification pursuant to the first sentence of Section 5(a) hereof, a determination with respect to Indemnitee's entitlement thereto shall be made in the specific case by one of the following four methods, which shall be at the election of Indemnitee, in his sole discretion: (1) by a majority vote of the disinterested directors, even though less than a quorum, (2) by a majority vote of a committee of disinterested directors designated by a majority vote of the disinterested directors, even though less than a quorum, (3) if there are no disinterested directors or if a Change of Control shall have occurred after the date hereof, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to the Indemnitee, or (4) by a simple majority of the stockholders of the Company voting on the matter. For purposes hereof, disinterested directors are those members of the Board who are not parties to the Proceeding in respect of which indemnification is sought by Indemnitee.

"Change of Control" shall mean the occurrence of any of the following:

(a) any "person," as such term is currently used in Section 13(d) of the Securities Exchange Act of 1934, as amended (the "1934 Act") (a "person"), becomes a "beneficial owner" (as such term is currently used in Rule 13d-3 promulgated under the 1934 Act (a "Beneficial Owner") of 30% or more of the Voting Stock (as defined below) of the Company;

- (b) the Board of Directors of the Company adopts any plan of liquidation providing for the distribution of all or substantially all of the Company's assets;
- (c) all or substantially all of the assets or business of the Company are disposed of in any one or more transactions pursuant to a sale, merger, consolidation or other transaction (unless the shareholders of the Company immediately prior to such sale, merger, consolidation or other transaction beneficially own, directly or indirectly, in substantially the same proportion as they owned the Voting Stock of the Company, more than fifty percent (50%) of the Voting Stock or other ownership interests of the entity or entities, if any, that succeed to the business of the Company);
- (d) the Company combines with another company and is the surviving corporation but, immediately after the combination, the shareholders of the Company immediately prior to the combination hold, directly or indirectly, fifty percent (50%) or less of the Voting Stock of the combined company; or
- (e) Continuing Directors cease to constitute at least a majority of the Board of Directors of the Company.
- "Voting Stock" of any entity shall mean the issued and outstanding share capital or other securities of any class or classes having general voting power under ordinary circumstances, in the absence of contingencies, to elect the members of the board of directors (or members of a similar managerial body if such entity has no board of directors) of such entity.
- "Continuing Director" means a director who either was a director of the Company on the Commencement Date or who became a director of the Company subsequent thereto and whose election, or nomination for election by the Company's shareholders, was approved by a majority of the Continuing Directors then on the Board of Directors of the Company.
- (c) If the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 5(b) hereof, the Independent Counsel shall be selected as provided in this Section 5(c). The Independent Counsel shall be selected by the Board. Indemnitee may, within 10 days after such written notice of selection shall have been given, deliver to the Company a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in this Agreement, and the objection shall set forth with reasonable particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If a written objection is made and substantiated, the Independent Counsel selected may not serve as Independent Counsel unless and until such objection is withdrawn or a court has determined that such objection is without merit. If, within 20 days after submission by Indemnitee of a written request for indemnification pursuant to Section 5(a) hereof, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Court of Chancery of the State of Delaware or other court of competent jurisdiction for resolution of any objection which shall have been made by the Indemnitee to the Company's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by the court or by such other person as the court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 5(b) hereof. The Company shall pay any and all reasonable fees and expenses of Independent Counsel incurred by such Independent Counsel in connection with acting pursuant to Section 5(b) hereof, and the Company shall pay all reasonable fees and expenses (including those

(d) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall presume that Indemnitee is entitled to indemnification under this Agreement. Anyone seeking to overcome this presumption shall have the burden of proof and the burden of persuasion by clear and convincing evidence. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(e) Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise (as hereinafter defined), including financial statements, or on information supplied to Indemnitee by the officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected by the Enterprise. In addition, the knowledge and/or actions, or failure to act, of any director, officer, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement. Whether or not the foregoing provisions of this Section 5(e) are satisfied, it shall in any event be presumed that Indemnitee has at all times acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his conduct was unlawful. Anyone seeking to overcome this presumption shall have the burden of proof and the burden of persuasion by clear and convincing evidence.

(f) If the person, persons or entity empowered or selected under Section 5 to determine whether Indemnitee is entitled to indemnification shall not have made a determination within thirty (30) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall be deemed to have been made and Indemnitee shall be entitled to such indemnification absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 30-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making such determination with respect to entitlement to indemnification in good faith requires such additional time to obtain or evaluate documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 5(f) shall not apply if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 5(b) of this Agreement and if (A) within fifteen (15) days after receipt by the Company of the request for such determination, the Board or the Disinterested Directors, if appropriate, resolve to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within sixty (60) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within forty (40) days after having been so called and such determination is made thereat.

(g) Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any Independent Counsel, member of the Board or stockholder of the Company shall act reasonably and in good faith in making a determination regarding the Indemnitee's entitlement to indemnification under this Agreement. Any costs or expenses (including attorneys' fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom.

(h) The Company acknowledges that a settlement or other disposition short of final judgment may be successful if it permits a party to avoid expense, delay, distraction, disruption and uncertainty. In the event that any Proceeding to which Indemnitee is a party is resolved in any manner other than by adverse judgment against Indemnitee (including, without limitation, settlement of such Proceeding with or without payment of money or other consideration) it shall be presumed that Indemnitee has been successful on the merits or otherwise in such Proceeding. Anyone seeking to overcome this presumption shall have the burden of proof and the burden of persuasion by clear and convincing evidence.

(i) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his conduct was unlawful.

## 6. Remedies of Indemnitee.

- (a) In the event that (i) a determination is made pursuant to <u>Section 5</u> of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to <u>Section 4</u> of this Agreement, (iii) no determination of entitlement to indemnification is made pursuant to <u>Section 5(b)</u> of this Agreement within 30 days after receipt by the Company of the request for indemnification (subject to extension, as provided in <u>Section 5(f)</u>), (iv) payment of indemnification is not made pursuant to this Agreement within ten (10) days after receipt by the Company of a written request therefor or (v) payment of indemnification is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification or such determination is deemed to have been made pursuant to <u>Section 5</u> of this Agreement, Indemnitee shall be entitled to an adjudication in an appropriate court of the State of Delaware, or in any other court of competent jurisdiction, of Indemnitee's entitlement to such indemnification. Indemnitee shall commence such proceeding seeking an adjudication within 180 days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this <u>Section 6(a)</u>. The Company shall not oppose Indemnitee's right to seek any such adjudication.
- (b) In the event that a determination shall have been made pursuant to <u>Section 5(b)</u> of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding commenced pursuant to this <u>Section 6</u> shall be conducted in all respects as a de novo trial on the merits, and Indemnitee shall not be prejudiced by reason of the adverse determination under <u>Section 5(b)</u>.
- (c) If a determination shall have been made pursuant to <u>Section 5(b)</u> of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding commenced pursuant to this <u>Section 6</u>, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's misstatement not materially misleading in connection with the application for indemnification, or (ii) a prohibition of such indemnification under applicable law.
- (d) In the event that Indemnitee, pursuant to this <u>Section 6</u>, seeks a judicial adjudication of his rights under, or to recover damages for breach of, this Agreement, or to recover under any directors' and officers' liability insurance policies maintained by the Company, the Company shall pay on his behalf, in advance within ten (10) days after the receipt by the Company of a statement from Indemnitee requesting such payment, any and all expenses (of the types described in the definition of Expenses in this Agreement) actually and reasonably incurred by him in such judicial adjudication, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of expenses or insurance recovery.
- (e) The Company shall be precluded from asserting in any judicial proceeding commenced pursuant to this Section 6 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court that the Company is bound by all the provisions of this Agreement. The Company shall indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefore) advance, to the extent not prohibited by law, such expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advance of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of Expenses or insurance recovery, as the case may be.
- (f) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.
  - 7. Non-Exclusivity; Survival of Rights; Insurance; Primacy of Indemnification; Subrogation.
- (a) The rights of indemnification as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the By-laws, any agreement, a vote of stockholders, a resolution of directors of the Company, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in his Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in the DGCL, whether by statute or judicial decision, permits greater indemnification than would be afforded currently under the Certificate of Incorporation, By-laws and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers
employees, or agents or fiduciaries of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise
that such person serves at the request of the Company, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the
maximum extent of the coverage available for any director, officer, employee, agent or fiduciary under such policy or policies. If, at the time of the receipt
of a notice of a claim pursuant to the terms hereof, the Company has directors' and officers' liability insurance in effect, the Company shall give prompt
notice of the commencement of such proceeding to the insurers in accordance with the procedures set forth in the respective policies. The Company shall
thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such
proceeding in accordance with the terms of such policies.

- (c) In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee (other than against the Outside Indemnitors), who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.
- (d) The Company hereby acknowledges that the Indemnitee may have other sources of indemnification or insurance, whether currently in force or established in the future (collectively, the "Outside Indemnitors"). The Company hereby agrees: (i) that it is the indemnitor of first resort (i.e., its obligations to the Indemnitee are primary and any obligation of the Outside Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by the Indemnitee are secondary); (ii) that it shall be required to advance the full amount of Expenses incurred by the Indemnitee and shall be liable in full for all indemnifiable amounts to the extent legally permitted and as required by the Company's Certificate of Incorporation and Bylaws or any agreement between the Company and the Indemnitee, without regard to any rights the Indemnitee may have against the Outside Indemnitors and (iii) that it irrevocably waives, relinquishes and releases the Outside Indemnitors from any and all claims against the Outside Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Outside Indemnitors on behalf of the Indemnitee with respect to any claim for which the Indemnitee have sought indemnification from the Company shall affect the foregoing and the Outside Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of the Indemnitee against the Company. The Company and the Indemnitee agree that the Outside Indemnitors are express third party beneficiaries of the terms hereof.
- (e) The Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, employee or agent of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise.
- 8. Exception to Right of Indemnification. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnity in connection with any claim made against Indemnitee:
- (a) for an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Securities Exchange Act of 1934, as amended, or similar provisions of state statutory law or common law; or
- (b) in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation, (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law or (iii) such Proceeding is brought by Indemnitee to assert, interpret or enforce his rights under this Agreement.

- 9. <u>Duration of Agreement</u>. All agreements and obligations of the Company contained herein shall continue during the period Indemnitee is an officer or director of the Company (or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise) and shall continue thereafter so long as Indemnitee shall be subject to any Proceeding (or any proceeding commenced under <u>Section 6</u> hereof) by reason of his Corporate Status, whether or not he is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Agreement. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the parties hereto and their respective successors (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), assigns, spouses, heirs, executors and personal and legal representatives.
- 10. <u>Security</u>. To the extent requested by Indemnitee and approved by the Board, the Company may at any time and from time to time provide security to Indemnitee for the Company's obligations hereunder through an irrevocable bank line of credit, funded trust or other collateral. Any such security, once provided to Indemnitee, may not be revoked or released without the prior written consent of the Indemnitee.

## 11. Enforcement.

- (a) The Company expressly confirms and agrees that it has entered into this Agreement and assumes the obligations imposed on it hereby in order to induce Indemnitee to serve as an officer or director of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as an officer or director of the Company.
- (b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof.
- (c) The Company shall not seek from a court, or agree to, a "bar order" which would have the effect of prohibiting or limiting the Indemnitee's rights to receive advancement of expenses under this Agreement.

# 12. <u>Definitions</u>. For purposes of this Agreement:

- (a) "Corporate Status" describes the status of a person who is or was a director, officer, employee, agent or fiduciary of the Company or any subsidiary thereof or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that such person is or was serving at the express written request of the Company.
- (b) "**Disinterested Director**" means a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee and who is not subject to any other relationship that may reasonably prejudice such director's determination as to the Indemnitee's entitlement to indemnification hereunder.
- (c) "**Enterprise**" shall mean the Company and any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that Indemnitee is or was serving at the express written request of the Company as a director, officer, employee, agent or fiduciary.
- (d) "Expenses" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, participating, or being or preparing to be a witness in a Proceeding, or responding to, or objecting to, a request to provide discovery in any Proceeding. Expenses also shall include Expenses incurred in connection with any appeal resulting from any Proceeding and any federal, state, local or foreign taxes imposed on the Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, including without limitation the premium, security for, and other costs relating to any cost bond, supersede as bond, or other appeal bond or its equivalent.

(e) "Independent Counsel" means a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

- (f) "**Proceeding**" includes any threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought by or in the right of the Company or otherwise and whether civil, criminal, administrative or investigative, in which Indemnitee was, is or will be involved as a party or otherwise, by reason of his or his Corporate Status, by reason of any action taken by him or of any inaction on his part while acting in his Corporate Status; in each case whether or not he is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Agreement; including one pending on or before the date of this Agreement, but excluding one initiated by an Indemnitee pursuant to Section 6 of this Agreement to enforce his rights under this Agreement.
- 13. <u>Severability</u>. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision. Without limiting the generality of the foregoing, this Agreement is intended to confer upon Indemnitee indemnification rights to the fullest extent permitted by applicable laws. In the event any provision hereof conflicts with any applicable law, such provision shall be deemed modified, consistent with the aforementioned intent, to the extent necessary to resolve such conflict.
- 14. <u>Modification and Waiver</u>. No supplement, modification, termination or amendment of this Agreement shall be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions hereof (whether or not similar) nor shall such waiver constitute a continuing waiver.
- 15. <u>Notice By Indemnitee</u>. Indemnitee agrees promptly to notify the Company in writing upon being served with or otherwise receiving any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification covered hereunder. The failure to so notify the Company shall not relieve the Company of any obligation which it may have to Indemnitee under this Agreement or otherwise unless and only to the extent that such failure or delay materially prejudices the Company.
- 16. Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed electronic mail or facsimile if sent during normal business hours of the recipient, and if not so confirmed, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to Indemnitee at the address set forth below Indemnitee signature hereto, and to the Company, at its principal executive offices to the attention of the President, or to such other address as may have been furnished to Indemnitee by the Company or to the Company by Indemnitee, as the case may be.
- 17. <u>Counterparts</u>. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same Agreement. This Agreement may also be executed and delivered by facsimile signature and in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 18. <u>Headings</u>. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.
- 19. Governing Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties with respect to the subject matter of this Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. The Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Chancery Court of the State of Delaware (the "Delaware Court"), and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (iv) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

SIGNATURE PAGE TO FOLLOW

written.	IN WITNESS WHEREOF, the parties hereto have executed this Indemnification Agreement on and as of the day and year first above	
		COMPANY ORAMED PHARMACEUTICALS INC.
		By: Name: Title:
		INDEMNITEE
		Name: Address:
	10	

## **Schedule to Exhibit 10.1**

The following executive officers and directors are each party to an Indemnification Agreement or Amended and Restated Indemnification Agreement with the Company, each of which is substantially identical in all material respects to the representative Indemnification Agreement filed herewith and is dated as of the respective date listed below.

Name of Signatory	Date
Nadav Kidron President, Chief Executive Officer and Chairman	March 26, 2017
Miriam Kidron Chief Scientific Officer and Director	March 26, 2017
Dr. Arie Mayer, Ph.D. Director	December 5, 2019
Yadin Rozov Director	April 5, 2022
Leonard Sank Director	January 26, 2017
Benjamin Shapiro Director	April 30. 2023
Joshua Hexter Chief Operating & Business Officer	September 8, 2019
David Silberman Chief Financial Officer	July 4, 2021
Netanel Derovan Chief Legal Officer	December 7, 2021
Michael Rabinowitz Chief Commercial Officer	July 25, 2021
	11

### 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.;
- 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: August 10, 2023 By: /s/ Nadav Kidron

Nadav Kidron

President and Chief Executive Officer

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

### UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

- I, David Silberman, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Oramed Pharmaceuticals Inc.;
- 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: August 10, 2023 By: /s/ David Silberman

David Silberman Chief Financial Officer

### **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 June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Nadav Kidron, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

- 1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 10, 2023 By: /s/ Nadav Kidron

Nadav Kidron

President and Chief Executive Officer

### **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 June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, David Silberman, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

- 1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 10, 2023 By: /s/ David Silberman

David Silberman Chief Financial Officer