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

FORM 10-Q

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

For the quarterly period ended _____

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

For the transition period from September 1, 2021 to December 31, 2021

Commission file number: 001-35813

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

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

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

Former Fiscal Year: August 31
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

Yes ☒ No ☐

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

Yes ☒ No ☐

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

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

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

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

Yes ☐ No ☒

As of March 30, 2022, there were 38,564,016 shares of the issuer's common stock, $0.012 par value per share, outstanding.

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On February 28, 2022, the Board of Directors approved a change of the Company's fiscal year from the period beginning on September 1 and ending on August 31 to the period beginning on January 1 and ending on December 31. As a result, this report on Form 10-Q is a transition report and includes financial information for the transition period from September 1, 2021 through December 31, 2021, or the Transition Period. Subsequent to this report, the Company's fiscal year will begin on January 1 and end on December 31.

As used in this Transition 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 December 31, 2021, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.11 to $1.00. Unless indicated otherwise by the context, statements in this Transition 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.

Forward-Looking Statements

The statements contained in this Transition 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. Words such as "expects," "anticipates," "intends," "plans," "planned expenditures," "believes," "seeks," "estimates," "considers" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Transition 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:

- the expected development and potential benefits from our products in treating diabetes;
- the prospects of entering into additional license agreements, or other partnerships or forms of cooperation with other companies or medical institutions;
- future milestones, conditions and royalties under the license agreement with Hefei Tianhui Incubator of Technologies Co., Ltd., or HTIT, as well as our disagreements with HTIT;
- expected timing of a clinical trial for the potential Oravax vaccine and its potential to protect against the coronavirus, or COVID-19, pandemic;
- our consideration of ways in which our shareholders could benefit more directly from Oravax, including the potential issuance of some of our shares in Oravax to our shareholders as a dividend;
- our research and development plans, including pre-clinical and clinical trials plans and the timing of enrollment, obtaining results and conclusion of trials, and our expectation to file a Biologics License Application, or BLA thereafter;
- 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 product efficacy, safety, patient convenience, reliability, value and patent position;
- the potential market demand for our products;
- our expectation that in upcoming years our research and development expenses, net, 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; and
- our expectations regarding the impact of COVID-19, including on our clinical trials and operations.

Although forward-looking statements in this Transition Report on Form 10-Q reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended August 31, 2021, or our Annual Report, as filed with the Securities and Exchange Commission, or the SEC, on November 24, 2021, 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 Transition 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 Transition 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 Transition Report on Form 10-Q. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this Transition 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 DECEMBER 31, 2021

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

	December 31, 2021	August 31, 2021
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 27,456	$ 77,245
Short-term deposits	111,077	11,044
Marketable securities	7,747	5,851
Prepaid expenses and other current assets	1,657	1,197
Total current assets	147,937	95,337
LONG-TERM ASSETS:		
Long-term deposits	25,094	25,016
Marketable securities	3,875	6,692
Amounts funded in respect of employee rights upon retirement	26	24
Property and equipment, net	388	397
Operating lease right-of-use assets	500	533
Total long-term assets	29,883	32,662
Total assets	$ 177,820	$ 127,999
Liabilities and stockholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 4,535	$ 3,792
Deferred revenues	2,703	2,703
Payable to related parties	-	54
Operating lease liabilities	130	130
Total current liabilities	7,368	6,679
LONG-TERM LIABILITIES:		
Long-term deferred revenues	3,340	4,244
Employee rights upon retirement	22	21
Provision for uncertain tax position	11	11
Operating lease liabilities	370	403
Other liabilities	99	124
Total long-term liabilities	3,842	4,803
COMMITMENTS (note 2)		
Equity		
EQUITY ATTRIBUTABLE TO COMPANY'S STOCKHOLDERS:		
Common stock, $0.012 par value (60,000,000 authorized shares; 38,158,792 and 35,293,889 shares issued and outstanding as of December 31, 2021 and August 31, 2021, respectively)	459	424
Additional paid-in capital	292,514	230,201
Accumulated deficit	(126,520)	(114,852)
Total stockholders' equity	166,453	115,773
Non-controlling interests	157	744
Total equity	166,610	116,517
Total liabilities and equity	$ 177,820	$ 127,999

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

ORAMED PHARMACEUTICALS INC.

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

(UNAUDITED)

	Four months ended December 31,	
	2021	**2020**
REVENUES	$ 904	904
RESEARCH AND DEVELOPMENT EXPENSES	9,037	6,889
SALES AND MARKETING EXPENSES	898	-
GENERAL AND ADMINISTRATIVE EXPENSES	3,295	1,576
OPERATING LOSS	12,326	7,561
FINANCIAL INCOME	(158)	(260)
FINANCIAL EXPENSES	87	23
NET LOSS FOR THE PERIOD	$ 12,255	7,324
NET LOSS ATTRIBUTABLE TO NON-CONTROLLING INTERESTS	587	-
NET LOSS ATTRIBUTABLE TO STOCKHOLDERS	11,668	7,324
LOSS PER SHARE		
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	$ 0.31	$ 0.30
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	37,113,137	24,394,010

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

ORAMED PHARMACEUTICALS INC.

INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

U.S. Dollars in thousands

(UNAUDITED)

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity	Non-controlling interests	Total equity
	Shares	$					
	In thousands						
BALANCE AS OF AUGUST 31, 2021	35,293	$ 424	$ 230,201	$ (114,852)	$ 115,773	744	$ 116,517
CHANGES DURING THE FOUR MONTH PERIOD ENDED DECEMBER 31, 2021:							
ISSUANCE OF COMMON STOCK, NET	2,631	32	59,901	-	59,933	-	59,933
EXERCISE OF WARRANTS AND OPTIONS	92	1	638	-	639	-	639
STOCK-BASED COMPENSATION	142	2	1,774	-	1,776	-	1,776
NET LOSS	-	-	-	(11,668)	(11,668)	(587)	(12,255)
BALANCE AS OF DECEMBER 31, 2021	38,158	$ 459	$ 292,514	$ (126,520)	$ 166,453	157	$ 166,610

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	$			
	In thousands				
BALANCE AS OF AUGUST 31, 2020	23,675	$ 284	$ 125,209	$ (92,614)	$ 32,879
CHANGES DURING THE FOUR MONTH PERIOD ENDED DECEMBER 31, 2020:					
ISSUANCE OF COMMON STOCK, NET	2,985	36	12,965	-	13,001
STOCK-BASED COMPENSATION	-	-	413	-	413
NET LOSS	-	-	-	(7,324)	(7,324)
BALANCE AS OF DECEMBER 31, 2020	26,660	$ 320	$ 138,587	$ (99,938)	$ 38,969

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

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

	Four months ended December 31,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (12,255)	$ (7,324)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	18	7
Exchange differences and interest on deposits and held to maturity bonds	(34)	(13)
Changes in fair value of investments	72	(123)
Stock-based compensation	1,776	413
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(460)	(448)
Accounts payable, accrued expenses and related parties	689	150
Deferred revenues	(904)	(904)
Liability for employee rights upon retirement	1	2
Other liabilities	(25)	(23)
Total net cash used in operating activities	(11,122)	(8,263)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Investment in short-term deposits	(100,000)	(12,460)
Purchase of held to maturity securities	-	(678)
Purchase of corporate bonds designated as fair value	-	(1,091)
Proceeds from sale of short-term deposits	-	8,960
Proceeds from maturity of held to maturity securities	761	2,410
Proceeds from sale of mutual funds	-	775
Funds in respect of employee rights upon retirement	-	(1)
Purchase of property and equipment	(9)	(320)
Total net cash provided by (used in) investing activities	(99,248)	(2,405)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	59,933	13,001
Proceeds from exercise of options	639	-
Total net cash provided by financing activities	60,572	13,001
EFFECT OF EXCHANGE RATE CHANGES ON CASH	9	1
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(49,789)	2,334
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	77,245	19,296
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 27,456	$ 21,630
(A) SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -		
Interest received	$ 128	$ 152
(B) SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES:		
Recognition of operating lease right of use assets and liabilities	$ -	$ 582

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:

a. General:

1) Incorporation and operations

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

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

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

On July 30, 2019, the Subsidiary incorporated a wholly-owned subsidiary in Hong Kong, Oramed HK Limited (the "Hong Kong Subsidiary"). As of December 31, 2021, the Hong Kong Subsidiary has no operations.

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

2) Change in Fiscal Year

On February 28, 2022, the Board of Directors approved a change of the Company's fiscal year from the period beginning on September 1 and ending on August 31 to the period beginning on January 1 and ending on December 31. As a result, this report on Form 10-Q is a transition report and includes financial information for the transition period from September 1, 2021 through December 31, 2021, or the Transition Period. Subsequent to this report, the Company's fiscal year will begin on January 1 and end on December 31.

3) 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 cannot predict the outcome of these activities.

In addition to the foregoing, based on the Company's current assessment, the Company does not expect any material impact on its development timeline and its liquidity due to the worldwide spread of the COVID-19 virus. However, the Company has experienced delays in clinical trials due to slow-downs of recruitment for trials generally. The Company may experience further delays if the pandemic continues for an extended period of time and it is continuing to assess the effect on its operations by monitoring the spread of COVID-19 and the actions implemented by governments to combat the virus throughout the world.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

b. Loss per common share

Basic and diluted net loss per common share are computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding for each period. Outstanding stock options, warrants and restricted stock units ("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 3,894,588 and 5,268,347 for the four month periods ended December 31, 2021 and December 31, 2020, respectively.

c. Revenue recognition

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

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

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

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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

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

As of December 31, 2021, an aggregate amount of $22,382 was allocated to the HTIT License Agreement, all of which were received through the balance sheet date. Through December 31, 2021, the Company has recognized revenue associated with this agreement in the aggregate amount of $16,339, of which $904 was recognized in the transition period between September 1, 2021 and December 31, 2021, and deferred the remaining amount of $6,043 which is presented as deferred revenues on the condensed consolidated balance sheet.

d. 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 August 31, 2021 (the "2021 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 2021 Form 10-K. The results for interim periods are not necessarily indicative of a full fiscal year's results.

e. Recently issued accounting pronouncements, not yet adopted

In June 2016, the Financial Accounting Standards Board issued Accounting Standards Update 2016-13 "Financial Instruments—Credit Losses—Measurement of Credit Losses on Financial Instruments." This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance will be effective for the fiscal year beginning after December 15, 2022, including interim periods within that year. The adoption of this guidance is not expected to have a significant impact on the Company's consolidated financial statements.

NOTE 2 - COMMITMENTS:

a. In March 2011, the Subsidiary sold shares of its investee company, Entera Bio Ltd. ("Entera") to D.N.A Biomedical Solutions Ltd. ("D.N.A"), retaining 117,000 ordinary shares (after giving effect to a stock split by Entera in July 2018). In consideration for the shares sold to D.N.A, the Company received, among other payments, ordinary shares of D.N.A (see also note 4).

As part of this agreement, the Subsidiary entered into a patent transfer agreement according to which the Subsidiary assigned to Entera all of its rights to a patent application related to the oral administration of proteins that it has licensed to Entera since August 2010, in return for royalties of 3% of Entera's net revenues and a license back of that patent application for use in respect of diabetes and influenza. As of December 31, 2021, Entera had not paid any royalties to the Subsidiary. On December 11, 2018, Entera announced that it had entered into a research collaboration and license agreement with Amgen, Inc. ("Amgen"). To the extent the Amgen license results in net revenues as defined in the patent transfer agreement, the Subsidiary will be entitled to the aforementioned royalties. As part of a consulting agreement with a third party dated February 15, 2011, the Subsidiary is obliged to pay this third party royalties of 8% of the net royalties received in respect of the patent that was sold to Entera in March 2011.

NOTE 2 - COMMITMENTS (continued):

b. According to the HTIT License Agreement, the Company granted HTIT an exclusive commercialization license in the territory of the People's Republic of China, Macau and Hong Kong (the "Territory"), related to the Company's oral insulin capsule, ORMD-0801 (the "Product"). Pursuant to the HTIT License Agreement, HTIT will conduct, at its own expense, certain pre-commercialization and regulatory activities with respect to the Subsidiary's technology and ORMD-0801 capsule, and will pay to the Subsidiary (i) royalties of 10% on net sales of the related commercialized products to be sold by HTIT in the Territory ("Royalties"), and (ii) an aggregate of $37,500, of which $3,000 was payable immediately, $8,000 will be paid subject to the Company entering into certain agreements with certain third parties, and $26,500 will be paid upon achievement of certain milestones and conditions. In the event that the Company does not meet certain conditions, the Royalties rate may be reduced to a minimum of 8%. Following the final expiration of the Company's patents covering the technology in the Territory in 2033, the Royalties rate may be reduced, under certain circumstances, to 5%.

The royalty payment obligation shall apply during the period of time beginning upon the first commercial sale of the Product in the Territory, and ending upon the later of (i) the expiration of the last-to-expire licensed patents in the Territory; and (ii) 15 years after the first commercial sale of the Product in the Territory (the "Royalty Term").

The HTIT License Agreement shall remain in effect until the expiration of the Royalty Term. The HTIT License Agreement contains customary termination provisions.

Among others, the Company's involvement through the product submission date will include consultancy for the pre-commercialization activities in the Territory, as well as advisory services to HTIT on an ongoing basis.

As of December 31, 2021, the Company has received milestone payments in an aggregate amount of $20,500 as follows: the initial payment of $3,000 was received in January 2016. Following the achievement of certain milestones, the second and third payments of $6,500 and $4,000, respectively, were received in July 2016, the fourth milestone payment of $4,000 was received in October 2016 and the fifth milestone payment of $3,000 was received in January 2019.

On August 21, 2020, the Company received a letter from HTIT, disputing certain pending payment obligations of HTIT under the TLA. The payment obligation being disputed is $6,000, out of which only an amount of $2,000 has been received and has been included in deferred revenue in each of the consolidated balance sheets as of December 31, 2021 and as of August 31, 2021. The Company wholly disputes the claims made by HTIT and has been engaged in discussions and exchanges with HTIT in an attempt to clarify and resolve disagreements between the parties regarding milestone payments and work plan implementation.

In addition, on November 30, 2015, the Company entered into the SPA with HTIT, according to which, the Company issued 1,155,367 shares of common stock to HTIT for $12,000. The transaction closed on December 28, 2015.

The HTIT License Agreement and the SPA were considered a single arrangement with multiple deliverables. The Company allocated the total consideration of $49,500 between the HTIT License Agreement and the SPA according to their fair value, as follows: $10,617 was allocated to the issuance of common stock (less issuance expenses of $23), based on the quoted price of the Company's shares on the closing date of the SPA on December 28, 2015, and $38,883 was allocated to the HTIT License Agreement. The Company determined that revenues are recognized over time through the expected product submission date in June 2023.

In July 2015, according to the letter of intent signed between the parties or their affiliates, HTIT's affiliate paid the Subsidiary a non-refundable amount of $500 as a no-shop fee. The no-shop fee was deferred and the related revenue is recognized over the estimated term of the HTIT License Agreement.

For the Company's revenue recognition policy see note 1c.

NOTE 2 - COMMITMENTS (continued):

c. On December 18, 2017, the Subsidiary entered into an agreement with a vendor for the process development and production of one of its oral capsule ingredients in the amount of $2,905 that will be paid over the term of the engagement and based on the achievement of certain development milestones, of which $1,592 was recognized in research and development expenses through December 31, 2021.

d. On September 2, 2020 (effective as of January 15, 2020), the Subsidiary entered into a CRO Services Agreement with a third party to retain it as a clinical research organization ("CRO") for the Subsidiary's phase 3 clinical trial for its oral insulin. As consideration for its services, the Subsidiary will pay the CRO a total amount of $21,589 during the term of the engagement and based on achievement of certain milestones, of which $10,235 was recognized in research and development expenses through December 31, 2021.

e. On September 16, 2020 (effective as of January 15, 2020), the Subsidiary entered into a CRO Services Agreement with a third party to retain it as a CRO for the Subsidiary's phase 3 clinical trial for its oral insulin. As consideration for its services, the Subsidiary will pay the CRO a total amount of $12,343 during the term of the engagement and based on achievement of certain milestones, of which $4,926 was recognized in research and development expenses through December 31, 2021.

f. On December 2, 2021, the Subsidiary entered into an addendum (the "Addendum") to the current lease agreement for its facilities in Israel. The Addendum refers to the lease of an additional space of 264 square meters for a period of 60 months commencing February 1, 2022. The Subsidiary has the option to extend the period for another 60 months. The annual lease payment, including management fees, is approximately NIS 435 ($140). As security for its obligation under this lease agreement, the Company provided a bank guarantee in an amount equal to four monthly lease payments. For accounting purposes, the lease commenced on February 1, 2022 as the Subsidiary did not have access to the space until that date.

g. **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 December 31, 2021 was $2,207 ($2,514 including interest).

As of December 31, 2021, the liability to the IIA was $207.

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

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

NOTE 3 - FAIR VALUE:

The Company measures fair value and discloses fair value measurements for financial assets. Fair value is based on the price that would be received to sell an asset 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 December 31, 2021, the assets measured at fair value are comprised of equity securities (Level 1). The fair value of held to maturity bonds as presented in note 4 was based on a Level 2 measurement.

As of December 31, 2021, 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.

As of December 31, 2021, the carrying amounts of long-term deposits approximate their fair values due to the stated interest rates which approximate market rates.

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

There were no Level 3 items for the periods between September 1 through December 31, 2021 or September 1 through December 31, 2020.

NOTE 4 - MARKETABLE SECURITIES:

The Company's marketable securities include investments in equity securities of D.N.A and Entera and in held to maturity bonds.

a. Composition:

	December 31, 2021	August 31, 2021
Short-term:		
D.N.A (see b below)	$ 863	$ 701
Entera (see c below)	337	571
Held to maturity bonds (see d below)	6,547	4,579
	$ 7,747	$ 5,851
Long-term:		
Held to maturity bonds (see d below)	$ 3,875	$ 6,692
	$ 11,622	$ 12,543

b. D.N.A

The D.N.A 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.

As of December 31, 2021, the Company owns approximately 1.7% of D.N.A's outstanding ordinary shares.

The cost of the securities as of December 31, 2021 and August 31, 2021 was $595.

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

NOTE 4 - MARKETABLE SECURITIES (continued):

c. Entera

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

d. Held to maturity securities

The amortized cost and estimated fair value of held to maturity securities as of December 31, 2021, were as follows:

	December 31, 2021			
	Amortized cost	Gross unrealized gains (losses)	Estimated fair value	Average yield to maturity rate
Short-term:				
Commercial bonds	$ 6,432	$ (115)	$ 6,317	1.37%
Accrued interest	115	-	115	
Long-term	3,875	(29)	3,846	1.20%
	$ 10,422	$ (144)	$ 10,278	

The amortized cost and estimated fair value of held to maturity securities as of August 31, 2021, were as follows:

	August 31, 2021			
	Amortized cost	Gross unrealized gains (losses)	Estimated fair value	Average yield to maturity rate
Short-term:				
Commercial bonds	$ 4,463	$ (98)	$ 4,365	1.73%
Accrued interest	116	-	116	
Long-term	6,692	610	7,302	1.08%
	$ 11,271	$ 512	$ 11,783	

Held to maturity securities which will mature during the 12 months from the balance sheet date are included in short-term marketable securities. Held to maturity securities with maturity dates of more than one year are considered long-term marketable securities.

NOTE 5 - 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 our 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 December 31, 2021, 565,120 shares were issued under the Cantor Equity Distribution Agreement for aggregate net proceeds of $12,298. As of March 30, 2022, 841,638 shares were issued under the Cantor Equity Distribution Agreement for aggregate net proceeds of $15,275.

2. On November 3, 2021, the Company entered into a securities purchase agreement with several institutional and accredited investors (the "Purchasers"), pursuant to which the Company agreed to sell, in a registered direct offering (the "Offering"), an aggregate of 2,000,000 shares of the Company's common stock to the Purchasers for an offering price of $25.00 per share. The closing of the sale of the shares occurred on November 5, 2021. The net proceeds to the Company from the Offering, after deducting the placement agent's fees and expenses and the Company's Offering expenses, were approximately $46,375.

3. The following are the significant stock options transactions with employees and board members made during the four months ended December 31, 2021:

    a. On September 1, 2021, the Company granted options to purchase an aggregate of 50,000 shares of common stock of the Company at an exercise price of $20.19 per share (equivalent to the closing price of the Company's common stock on the date of grant) to the Chief Financial Officer. The options shall vest in four equal installments of 12,500 options on each of June 27, 2022, June 27, 2023, June 27, 2024 and June 27, 2025. These options expire on September 1, 2031. The fair value of all these options on the date of grant was $574, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $20.19; dividend yield of 0% for all years; expected volatility of 61.62%; risk-free interest rates of 0.93%; and expected term of 6.16 years.

    b. On September 1, 2021, the Company granted 50,000 RSUs to the Chief Financial Officer that shall vest as follows:

    33,333 if the closing price per share of the Company's common stock will be at least $25.00 for at least 20 days out of any 30-trading day period; and

        1. If the first condition is met any time before June 27, 2022, then the RSUs will vest in three equal installments (on June 27, 2022, June 27, 2023 and June 27, 2024).

        2. If the first condition is met any time between June 27, 2022 and June 27, 2023, then 1/3 of the RSUs will vest immediately, and the remainder will vest in two equal installments (on June 27, 2023 and June 27, 2024).

        3. If the first condition is met anytime between June 27, 2023 and June 27, 2024, then 2/3 of the RSUs will vest immediately, and the remaining 1/3 will vest on June 27, 2024).

NOTE 5 - STOCKHOLDERS' EQUITY (continued)

4. If the first condition is met any time after June 27, 2024, then the RSUs will vest immediately.

16,667 upon achievement of a certain licensing agreement as specified by the Board of Directors; and

1. If the first condition is met any time before June 27, 2022, then the RSUs will vest in three equal installments (on June 27, 2022, June 27, 2023 and June 27, 2024).

2. If the first condition is met any time between June 27, 2022 and June 27, 2023, then 1/3 of the RSUs will vest immediately, and the remainder will vest in two equal installments (on June 27, 2023 and June 27, 2024).

3. If the first condition is met any time between June 27, 2023 and June 27, 2024, then 2/3 of the RSUs will vest immediately, and the remaining 1/3 will vest on June 27, 2024).

4. If the first condition is met any time after June 27, 2024, then the RSUs will vest immediately.

These RSUs expire on September 1, 2031.

The total value of the RSUs is $662, using the Monte-Carlo model for RSUs with market conditions.

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

NOTE 6 - LEASES

The right-of-use asset and lease liability are initially measured at the present value of the lease payments, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Company's incremental borrowing rate based on the information available at the date of adoption in determining the present value of the lease payments. The Company's incremental borrowing rate is estimated to approximate the interest rate on similar terms and payments and in economic environments where the leased asset is located.

The Company has various operating leases for office space and vehicles that expire through 2025. Below is a summary of our operating right-of-use assets and operating lease liabilities as of December 31, 2021 and August 31, 2021:

	December 31, 2021	August 31, 2021
Operating right-of-use assets	$ 500	$ 533
Operating lease liabilities, current	130	130
Operating lease liabilities long-term	370	403
Total operating lease liabilities	$ 500	$ 533

Minimum lease payments for the Company's right-of-use assets over the remaining lease periods as of December 31, 2021 and August 31, 2021 are as follows:

	December 31, 2021	August 31, 2021
2022	$ 155	$ 156
2023	140	138
2024	140	136
2025	93	136
Total undiscounted lease payments	528	565
Less: Interest*	(28)	(32)
Present value of lease liabilities	$ 500	$ 533

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

NOTE 7 - RELATED PARTY TRANSACTIONS:

On July 1, 2008, the Subsidiary entered into two consulting agreements with KNRY Ltd. ("KNRY"), an Israeli company owned by the Chief Scientific Officer, whereby the President and Chief Executive Officer and the Chief Scientific Officer, through KNRY, provide services to the Company (the "Consulting Agreements"). The Consulting Agreements are both terminable by either party upon 140 days prior written notice. The Consulting Agreements, as amended, provide that KNRY will be reimbursed for reasonable expenses incurred in connection with the performance of the Consulting Agreements and that the monthly consulting fee paid to the President and Chief Executive Officer and the Chief Scientific Officer is NIS 146,705 ($47) and NIS 106,400 ($34), respectively.

In addition to the Consulting Agreements, based on a relocation cost analysis, the Company pays 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 four months ended December 31, 2021, such relocation expenses were $109, compared to $92 for the four months ended December 31, 2020.

NOTE 8 – SUBSEQUENT EVENTS:

a. On January 3, 2022, the Company granted an aggregate of 150,000 shares of the Company's common stock to the Company's President and Chief Executive Officer. The total fair value of these shares on the date of grant was $2,084, using the quoted closing market share price of $13.89 on the Nasdaq Capital Market on the date of grant.

b. On January 3, 2022, the Company granted an aggregate of 207,500 RSUs representing a right to receive shares of the Company's common stock to the Company's employees and board members as follows: 63,000 to the President and Chief Executive Officer; 42,000 to the Chief Scientific Officer; 21,000 to the Chief Operating Officer, 19,000 to the Chief Financial Officer and Treasurer, 19,000 to the Chief Commercial Officer, 18,000 to the Chief Legal Officer and Secretary (effective as of the time his employment with the Company commenced on January 9, 2022), an aggregate of 24,000 to four board members and 1,500 to an employee. The RSUs will vest in four equal annual instalments on each of January 1, 2023, 2024, 2025 and 2026. These RSUs expire on January 3, 2032. The total fair value of these RSUs on the date of grant was $2,882, using the quoted closing market share price of $13.89 on the Nasdaq Capital Market on the date of grant.

c. On January 3, 2022, the Company granted options to purchase an aggregate of 321,500 shares of common stock of the Company to the Company's employees and board members at an exercise price of $13.89 per share (equivalent to the closing price of the Company's common stock on the date of grant) as follows: 107,000 to the President and Chief Executive Officer; 72,000 to the Chief Scientific Officer; 36,000 to the Chief Operating Officer, 32,000 to the Chief Financial Officer and Treasurer and 32,000 to the Chief Commercial Officer, an aggregate of 40,000 to four board members and 2,500 to an employee. The options will vest in four equal annual instalments on each of January 1, 2023, 2024, 2025 and 2026. These options expire on January 3, 2032. The fair value of all these options on the date of grant was $2,627, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $13.89; dividend yield of 0% for all years; expected volatility of 62.94%; risk-free interest rates of 1.46%; and expected term of 6.25 years.

d. On January 3, 2022, the Company granted options to purchase an aggregate of 30,000 shares of common stock of the Company to the Company's Chief Legal Officer and Secretary (effective as of the time his employment with the Company commenced on January 9, 2022), at an exercise price of $12.03 per share (equivalent to the closing price of the Company's common stock on January 10, 2022 which represents the first trading date after his employment with the Company commenced). The options will vest in four equal annual instalments on each of January 1, 2023, 2024, 2025 and 2026. These options expire on January 3, 2032. The fair value of all these options on the date of grant was $214, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $12.03; dividend yield of 0% for all years; expected volatility of 63.19%; risk-free interest rates of 1.62%; and expected term of 6.25 years.

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 currently engaged in the research and development of innovative pharmaceutical solutions with a technology platform that delivers protein orally instead of by injection. Our first drug candidate is an oral insulin capsule to be used for the treatment of individuals with uncontrolled diabetes. We utilize clinical research organizations, or CROs, to conduct our clinical trials.

Through our research and development efforts, we have successfully developed an oral dosage form intended to withstand the harsh environment of the stomach and effectively deliver active biological insulin or other proteins, such as Glucagon-like peptide-1, or GLP-1, leptin, and others. 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. We plan to continue to conduct clinical trials to show the effectiveness of our technology.

Oral Insulin

Our proprietary flagship product, an orally ingestible insulin capsule, or ORMD-0801, allows insulin to travel from the gastrointestinal tract via the portal vein to the liver, revolutionizing the manner in which insulin is delivered. This novel mode of delivery enables a closer mirroring of the human body's delivery of insulin.

FDA Guidance: In August 2017, the U.S. Food and Drug Administration, or FDA, instructed us that the regulatory pathway for the submission of ORMD-0801 would be a BLA. If approved, the BLA pathway would grant us 12 years of marketing exclusivity for ORMD-0801, from the approval date, and an additional six months of exclusivity may be granted to us if the product also receives approval for use in pediatric patients.

Phase 2b Trial: In February 2020, we announced positive topline data from the second and final cohort of our Phase 2b trial. Treatment with ORMD-0801 at all doses demonstrated an excellent safety profile, with no serious drug-related adverse events and with no increased frequency of hypoglycemic episodes or weight gain compared to placebo.

Phase 3 Trial: Based on guidance received from the FDA as part of the end-of-Phase 2 meeting for ORMD-0801, we submitted the protocols to the FDA for our pivotal Phase 3 trials. In line with the FDA's expectations and recommendations, we are currently conducting two Phase 3 trials concurrently in patients with type 2 diabetes, or T2D. These trials involve about 1,125 patients to provide evidence of ORMD-0801's safety and efficacy in T2D patients over a treatment period of 6 to 12 months. A geographically diverse patient population is being recruited from multiple sites throughout the United States, Europe, and Israel. Our Phase 3 trial is composed of two protocols:

ORA-D-013-1: This trial is currently being conducted on T2D patients with inadequate glycaemic control who are currently on two or three oral glucose-lowering agents. This U.S. trial is in the process of recruiting 675 patients from over 90 clinical sites located throughout the U.S. Patients will be randomized 1:1:1 in this double-dummy trial into cohorts of: 8 mg ORMD-0801 once-daily at night and placebo 45 minutes before breakfast; 8 mg ORMD-0801 twice-daily, at night and 45 minutes before breakfast; and placebo twice-daily, at night and 45 minutes before breakfast. The primary endpoint of the trial is to evaluate the efficacy of 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. We initiated this trial in December 2020. In November 2021, we announced that 75% of the 675 patients were enrolled and randomized.

ORA-D-013-2: This trial will include T2D patients with inadequate glycaemic control who are attempting to manage their condition with either diet alone or with diet and metformin or SGL2 monotherapy. A total of 450 patients will be recruited through 36 sites in the U.S. and 25 sites in Western Europe and Israel. Patients will be randomized 1:1 into two cohorts dosed with: 8 mg ORMD-0801 at night; and placebo at night. The primary endpoint is to evaluate the efficacy of ORMD-0801 compared to placebo in improving glycaemic control as assessed by HbA1c over a 26-week treatment period, with a secondary efficacy endpoint of assessing the change from baseline in fasting plasma glucose at 26 weeks. We initiated this trial in the U.S. in March 2021. In August 2021, we announced that over 25% of the 450 patients were enrolled and randomized.

We expect to receive the efficacy data from the trials after patients have completed the first 6 months of treatment. Safety will be further monitored as patients will be exposed to the drug over an additional 6 months (total 12 months). The trial's topline results are expected in 2022 and we anticipate filing a BLA with the FDA in 2024. A BLA would grant us 12 years of marketing exclusivity from the date of approval in the U.S.

HTIT License. On November 30, 2015, we, Oramed Ltd. and HTIT entered into a Technology License Agreement, or TLA, and on December 21, 2015, these 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.

On August 21, 2020, we received a letter from HTIT, disputing certain pending payment obligations of HTIT under the TLA. We wholly dispute said claims and we are in discussions with HTIT in an attempt to reach a mutually agreeable solution. For further information, see note 2.b. to our interim condensed consolidated financial statements.

NASH trial: In September 2020, we initiated an open label clinical trial of our oral insulin capsule, ORMD-0801, for the treatment of non-alcoholic steatohepatitis, or NASH, in type 2 diabetes. This 10 patient multi-center trial is comprised of three clinical sites in Belgium. The trial will measure change and percent change in MRI-PDFF from baseline to week 12. Data from this trial is expected in the second half of 2022.

In December 2020, we initiated a double blind, placebo controlled clinical trial of our oral insulin capsule, ORMD-0801, for the treatment of NASH in type 2 diabetes. This 30 patient multi-center trial is comprised of five clinical sites: three in the U.S. and two in Israel. The trial will measure change and percent change in MRI-PDFF from baseline to week 12. In March 2022, we announced the completion of patient enrollment. Data from this trial is expected in the second half of 2022.

Oral Glucagon-Like Peptide-1

Oral GLP-1, is an incretin hormone, which stimulates the secretion of insulin from the pancreas. In addition to our flagship product, the ORMD-0801 insulin capsule, we use our technology for an orally ingestible GLP-1 capsule, or ORMD-0901. Data from this trial is expected in the second half of 2022.

In February 2019, we completed a Phase 1 pharmacokinetic trial to evaluate the safety and pharmacokinetics of ORMD-0901 compared to placebo in healthy volunteers. In June 2021, we initiated a follow-on trial in T2D patients in the U.S. under an Investigational New Drug application.

Oral Vaccine

On March 18, 2021, we entered into a license agreement, or the Oravax License Agreement, with Oravax, Oramed's 63% owned joint venture, pursuant to which we will grant to Oravax an exclusive, worldwide license of our rights in certain patents and related intellectual property relating to our proprietary oral delivery technology to further develop, manufacture and commercialize oral vaccines for COVID-19 and other novel coronaviruses based on Premas Biotech Pvt. Ltd.'s, or Premas's, proprietary vaccine technology involving a triple antigen virus like particle, or the Oravax Product, which was previously owned by Cystron Biotech LLC, or Cystron, and later acquired by Akers Biosciences Inc., or Akers.

In consideration for the grant of the license, the Oravax License Agreement provides that we will receive (i) royalties equal to 7.5% on net sales, as defined in the Oravax License Agreement, of each product commercialized by Oravax, its affiliates and permitted sublicensees related to the license during the term specified in the Oravax License Agreement, (ii) sublicensing fees equal to 15% of any non-sales-based consideration received by Oravax from a permitted sublicensee and (iii) other payments ranging between $25 million to $100 million, based on certain sales milestones being achieved by Oravax. The parties further agreed to establish a development and steering committee, which will consist of three members, of which two members will be appointed by us, that will oversee the ongoing research, development, clinical and regulatory activity with respect to the Oravax Product. In addition, we agreed to buy and Oravax agreed to issue to us 1,890,000 shares of common stock of Oravax, representing 63% of the common stock of Oravax for the aggregate amount of $1.5 million. Akers agreed to contribute to Oravax $1.5 million in cash and substantially all of the assets of Cystron, including a license agreement to Premas's novel vaccine technology. Nadav Kidron, the Company's President and Chief Executive Officer, was one of the former members of Cystron.

On October 29, 2021, we announced Oravax's oral COVID-19 vaccine has received clearance from the South African Health Products Regulatory Authority to initiate a Phase 1 trial and subsequently to commence patient enrollment in a first in human, Phase 1 clinical trial, for its oral COVID-19 vaccine and on December 14, 2021, Oravax screened and enrolled the first participant in a Phase 1 clinical trial of its oral virus-like particle (VLP) COVID-19 vaccine in Johannesburg, South Africa. The trial protocol requires participants who have never been vaccinated for, or infected with, COVID-19. This has caused delays, as many volunteers have failed the screening process due to prior asymptomatic infection. We are exploring ways to increase enrollment, which may include changes to the protocol as well as additional clinical sites.

On December 29, 2021, Oravax signed a cooperation and purchase agreement for an initial pre-purchase of 10 million doses of oral COVID-19 vaccines with Tan Thanh Holdings to commercialize the vaccine in Southeast Asia.

COVID-19 Impact

We do not expect any material impact on our development timeline and our liquidity due to the worldwide spread of the COVID-19 virus. However, we have experienced delays in clinical trials due to slow-downs of recruitment for trials generally. We may experience further delays if the pandemic continues for an extended period of time and we are continuing to assess the effect on our operations by monitoring the spread of COVID-19 and the actions implemented by governments to combat the virus throughout the world.

Results of Operations

Comparison of four month periods ended December 31, 2021 and December 31, 2020

The following table summarizes certain statements of operations data of the Company for the four month periods ended December 31, 2021 and December 31, 2020 (in thousands of dollars except share and per share data):

	Four months ended	
	December 31, 2021	December 31, 2020
Revenues	$ 904	$ 904
Cost of revenues	-	-
Research and development expenses	9,037	6,889
Sales and Marketing expenses	898	-
General and administrative expenses	3,295	1,576
Financial income (expenses), net	71	237
Taxes on income	-	-
Net loss for the period	$ 12,255	$ 7,324
Loss per common share - basic and diluted	$ 0.31	$ 0.30
Weighted average common shares outstanding	37,113,137	24,394,010

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 of June 2023, using the input method.

Revenues were $904,000 for the four month periods ended December 31, 2021 and December 31, 2020.

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 four month periods ended December 31, 2021 and December 31, 2020.

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 capsule manufacturing, payments for patient recruitment and treatment, as well as salaries and related expenses of research and development staff.

Research and development expenses for the four month period ended December 31, 2021 increased by 31% to $9,037,000, from $6,889,000 for the four month period ended December 31, 2020. The increase is primarily due to an increase in expenses related to our Phase 3 and NASH clinical trials in addition to expenses related to the in process research and development costs in Oravax. Stock-based compensation costs for the four month period ended December 31, 2021 were $649,000, compared to $171,000 during the four month period ended December 31, 2020. The increase is mainly attributable to awards granted to a consultant and to new award grants in fiscal year 2021.

Government grants

In the four month periods ended December 31, 2021 and December 31, 2020, we did not recognize any research and development grants. As of December 31, 2021, we incurred liabilities to pay royalties to the Israel Innovation Authority of the Israeli Ministry of Economy and Industry of $207,000.

Sales and Marketing expenses

Sales and marketing expenses include the salaries and related expenses of our commercial functions, consulting costs and other general costs. We anticipate that our commercial activities will increase in the future towards and following potential approval of our planned BLA submission for ORMD-0801.

Sales and marketing expenses for the four month period ended December 31, 2021 were $898,000 while we incurred no expenses for the four month period ended December 31, 2020. The increase in costs related to sales and marketing expenses activities is primarily attributable to stock-based compensation expenses, salary related expenses and consulting expenses. Stock-based compensation costs for the four month period ended December 31, 2021 were $579,000 while there were no stock-based compensation expenses during the four month period ended December 31, 2020. The increase is attributable to awards granted to an employee during fiscal year 2021.

General and Administrative expenses

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

General and administrative expenses for the four month period ended December 31, 2021 increased by 109% to $3,295,000 from $1,576,000 for the four month period ended December 31, 2020. The increase in costs related to general and administrative activities is primarily attributable to an increase in stock-based compensation expenses and professional fees expenses as well as public relations and investor relations expenses. Stock-based compensation costs for the four month period ended December 31, 2021 were $1,034,000, compared to $242,000 during the four month period ended December 31, 2020. The increase is mainly attributable to awards granted to an employee during the four month period ended December 31, 2021 and to new award grants during fiscal year 2021.

Financial income (expense), net

Net financial income decreased to $71,000 for the four month period ended December 31, 2021, compared to $237,000 for the four month period ended December 31, 2020. The decrease is primarily attributable to a decrease in fair value of the ordinary shares of Entera.

Liquidity and capital resources

From inception through December 31, 2021, we have incurred losses in an aggregate amount of $126,520,000. During that period and through March 30, 2022, 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 $244,402,000, net of transaction costs. During that period, we also received cash consideration of $27,938,000 from the exercise of warrants and options. We expect to seek to obtain additional financing through similar sources in the future, as needed. As of December 31, 2021, we had $27,456,000 of available cash, $136,171,000 of short-term and long-term bank deposits and $11,622,000 of marketable securities.

We have not generated significant revenues from our operations. Management continues to evaluate various financing alternatives for funding 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 the Company will not need additional funds prior to such time.

If there are unexpected increases in our operating expenses, the Company 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 U.S. Food and Drug Administration 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 cannot predict the outcome of these activities.

As of December 31, 2021, our total current assets were $147,937,000 and our total current liabilities were $7,368,000. On December 31, 2021, we had a working capital surplus of $140,569,000 and an accumulated loss of $126,520,000. As of August 31, 2021, our total current assets were $95,337,000 and our total current liabilities were $6,679,000. On August 31, 2021, we had a working capital surplus of $88,658,000 and an accumulated loss of $114,852,000. The increase in working capital from August 31, 2021 to December 31, 2021 was primarily due to capital raising.

During the four month period ended December 31, 2021, cash and cash equivalents decreased to $27,456,000 from the $77,245,000 reported as of August 31, 2021, which is due to the reasons described below.

Operating activities used cash of $11,122,000 in the four month period ended December 31, 2021, compared to $8,263,000 used in the four month period ended December 31, 2020. Cash used in operating activities primarily consisted of research and development, sales and marketing and general and administrative expenses, as well as changes in deferred revenue due to the HTIT License Agreement, partially offset by changes in accounts payable and accrued expenses and stock-based compensation.

Investing activities used cash of $99,248,000 in the four month period ended December 31, 2021, compared to cash used in investing activities of $2,405,000 in the four month period ended December 31, 2020. Cash used in investing activities in the four month period ended December 31, 2021 consisted primarily of the purchase of short-term deposits. Cash used in investing activities in the four month period ended December 31, 2020 consisted primarily of the purchase of short-term deposits, offset by the proceeds from bonds held to maturity.

Financing activities provided cash of $60,572,000 in the four month period ended December 31, 2021, compared to $13,001,000 provided in the four month period ended December 31, 2020. Cash provided by financing activities consisted primarily of proceeds from the issuance of our common stock.

On September 1, 2021, we entered into a controlled equity offering agreement, or the Cantor Equity Distribution Agreement, with Cantor Fitzgerald & Co., as agent, pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $100,000,000, through a sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to our effective shelf registration statement on Form S-3 including a prospectus dated July 26, 2021 and prospectus supplement dated September 1, 2021. We paid the sales agent a cash commission of 3.0% of the gross proceeds of the sale of any shares sold through the sales agent under the Cantor Equity Sales Agreement. As of March 30, 2022, 841,638 shares were issued under the Cantor Equity Distribution Agreement for aggregate net proceeds of $15,275,000.

On November 3, 2021, we entered into a securities purchase agreement with several institutional and accredited investors, or the Purchasers, pursuant to which we agreed to sell, in a registered direct offering, or the Offering, an aggregate of 2,000,000 shares of our common stock to the Purchasers for an offering price of $25.00 per share. The closing of the sale of the shares occurred on November 5, 2021. The net proceeds to us from the Offering, after deducting the placement agent’s fees and expenses and the Company’s Offering expenses, were approximately $46,375,000.

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.

ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There has been no significant change in our exposure to market risk during the four month period ended December 31, 2021. 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 December 31, 2021. 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 four month period ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 6 - EXHIBITS

Number	Exhibit
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101.1*	The following financial statements from the Company's Transition Report on Form 10-Q for the four month period ended December 31, 2021 formatted in XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Comprehensive Loss, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows and (v) the Notes to Condensed Consolidated Financial Statements.
104.1*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith

** Furnished herewith

SIGNATURES

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

ORAMED PHARMACEUTICALS INC.

Date: March 30, 2022

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

Date: March 30, 2022

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

Exhibit 31.1

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

UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Nadav Kidron, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 30, 2022

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

Exhibit 31.2

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

UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, David Silberman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 30, 2022

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

Exhibit 32.1

CERTIFICATION

PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the transition report of Oramed Pharmaceuticals Inc., or the Company, on Form 10-Q for the period between September 1, 2021 and December 31, 2021, 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: March 30, 2022

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

Exhibit 32.2

CERTIFICATION

PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the transition report of Oramed Pharmaceuticals Inc., or the Company, on Form 10-Q for the period between September 1, 2021 and December 31, 2021, 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: March 30, 2022

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