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 November 30, 2020

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

Commission file number: 000-50298

ORAMED PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

Yes ☒ No ☐

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

Yes ☒ No ☐

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

Large accelerated filer ☐
Non-accelerated filer ☒
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 January 14, 2021, there were 26,661,004 shares of the issuer's common stock, $0.012 par value per share, outstanding.

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

On November 30, 2020, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.308 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.

PART I – FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

ORAMED PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF NOVEMBER 30, 2020

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

	November 30, 2020	August 31, 2020
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 14,931	$ 19,296
Short-term deposits	10,592	11,060
Marketable securities	8,825	9,544
Prepaid expenses and other current assets	1,676	611
Total current assets	36,024	40,511
LONG-TERM ASSETS:		
Long-term deposits	2	2
Marketable securities	3,878	3,928
Amounts funded in respect of employee rights upon retirement	18	18
Property and equipment, net	409	99
Operating lease right-of-use assets	640	75
Total long-term assets	4,947	4,122
Total assets	$ 40,971	$ 44,633
Liabilities and stockholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 2,808	$ 1,699
Deferred revenues	2,703	2,703
Payable to related parties	93	90
Operating lease liabilities	138	44
Total current liabilities	5,742	4,536
LONG-TERM LIABILITIES:		
Deferred revenues	6,273	6,947
Employee rights upon retirement	19	18
Provision for uncertain tax position	11	11
Operating lease liabilities	502	31
Other liabilities	212	211
Total long-term liabilities	7,017	7,218
COMMITMENTS (note 2)		
STOCKHOLDERS' EQUITY:		
Common stock, $0.012 par value (60,000,000 authorized shares; 23,810,530 and 23,675,530 shares issued and outstanding as of November 30, 2020 and August 31, 2020, respectively)	286	284
Additional paid-in capital	126,110	125,209
Accumulated deficit	(98,184)	(92,614)
Total stockholders' equity	28,212	32,879
Total liabilities and stockholders' equity	$ 40,971	$ 44,633

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

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

	Three months ended	
	November 30, 2020	November 30, 2019
REVENUES	$ 674	$ 674
COST OF REVENUES		
RESEARCH AND DEVELOPMENT EXPENSES	5,774	2,022
GENERAL AND ADMINISTRATIVE EXPENSES	727	1,081
OPERATING LOSS	5,827	2,429
FINANCIAL INCOME (EXPENSES), NET	257	(114)
NET LOSS FOR THE PERIOD	$ 5,570	$ 2,543
LOSS PER SHARE OF COMMON STOCK:		
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	$ 0.23	$ 0.15
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	23,745,980	17,472,315

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

ORAMED PHARMACEUTICALS INC.
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
	Shares	$			
	In thousands				
BALANCE AS OF AUGUST 31, 2020	23,675	$ 284	$ 125,209	$ (92,614)	$ 32,879
CHANGES DURING THE THREE MONTH PERIOD ENDED NOVEMBER 30, 2020:					
ISSUANCE OF COMMON STOCK, NET	135	2	584	-	586
STOCK-BASED COMPENSATION	-	*	317	-	317
NET LOSS	-	-	-	(5,570)	(5,570)
BALANCE AS OF NOVEMBER 30, 2020	23,810	$ 286	$ 126,110	$ (98,184)	$ 28,212

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	$			
	In thousands				
BALANCE AS OF AUGUST 31, 2019	17,383	$ 208	$ 100,288	$ (81,103)	$ 19,393
CHANGES DURING THE THREE MONTH PERIOD ENDED NOVEMBER 30, 2019:					
SHARES ISSUED FOR SERVICES	5	*	17	-	17
EXERCISE OF WARRANTS AND OPTIONS	12	1	12	-	13
STOCK-BASED COMPENSATION	-	*	280	-	280
NET LOSS	-	-	-	(2,543)	(2,543)
BALANCE AS OF NOVEMBER 30, 2019	17,400	$ 209	$ 100,597	$ (83,646)	$ 17,160

* Represents an amount of less than $1.

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

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

	Three months ended November 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,570)	$ (2,543)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	2	-
Exchange differences and interest on deposits and held to maturity bonds	(114)	(92)
Changes in fair value of investments	(162)	303
Stock-based compensation	317	280
Shares issued for services		17
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,104)	433
Accounts payable, accrued expenses and related parties	1,153	(714)
Deferred revenue	(675)	(675)
Liability for employee rights upon retirement	1	(5)
Total net cash used in operating activities	(6,152)	(2,996)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of short-term deposits	(7,460)	(3,000)
Purchase of held to maturity securities	(658)	-
Purchase of corporate bonds designated as fair value	(1,004)	-
Proceeds from sale of short-term deposits	7,960	4,600
Proceeds from maturity of held to maturity securities	1,900	1,225
Proceeds from sale of mutual funds	775	-
Funds in respect of employee rights upon retirement	(1)	3
Purchase of property and equipment	(313)	(3)
Total net cash provided by investing activities	1,199	2,825
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	586	1
Proceeds from exercise of options	-	12
Total net cash provided by financing activities	586	13
EFFECT OF EXCHANGE RATE CHANGES ON CASH	2	0
DECREASE IN CASH AND CASH EQUIVALENTS	(4,365)	(158)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	19,296	3,329
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 14,931	$ 3,171
(A) SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -		
Interest received	$ 92	$ 112
(B) **SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES:**		
Right of use assets and lease liabilities recognition	$ 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 subsidiary, the "Company", unless the context indicates otherwise) was incorporated on April 12, 2002, under the laws of the State of Nevada. From incorporation until March 3, 2006, the Company was an exploration stage company engaged in the acquisition and exploration of mineral properties. 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 March 11, 2011, the Company was reincorporated from the State of Nevada to the State of Delaware.

On July 30, 2019, the Subsidiary incorporated a wholly-owned subsidiary in Hong Kong, Oramed HK Limited (the "Hong Kong Subsidiary"). As of November 30, 2020, the Hong Kong Subsidiary has no operations.

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 "License Agreement"). According to the 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 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 License Agreement shall remain in effect until the expiration of the Royalty Term. The License Agreement contains customary termination provisions.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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 November 30, 2020, 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 revenues in each of the consolidated balance sheets for the three months ended November 30, 2020 and for the fiscal years ended August 31, 2020, and 2019. 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 a Stock Purchase Agreement with HTIT (the "SPA"). According to the SPA, the Company issued 1,155,367 shares of common stock to HTIT for $12,000. The transaction closed on December 28, 2015.

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 License Agreement.

For revenue recognition policy see note 1c.

2) 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.

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 5,278,347 and 4,366,806 for the three month periods ended November 30, 2020 and 2019, respectively.

c. Revenue recognition

The License Agreement and the SPA were considered a single arrangement with multiple deliverables. The Company allocated the total consideration of $49,500 between the 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 License Agreement.

Under Accounting Standards Codification ("ASC") 605 (which was the authoritative revenue recognition guidance applied for all periods prior to September 1, 2018) given the Company's continuing involvement through the expected product submission in June 2023, amounts received relating to the License Agreement were recognized over the period from which the Company was entitled to the respective payment, and the expected product submission date using a time-based model approach over the periods that the fees were earned.

On September 1, 2018, the Company adopted Accounting Standards Update ("ASU") 2014-09 "Revenue from Contracts with Customers (Topic 606)" ("ASC 606"), using the modified retrospective method of adoption. Under this method, the Company applied ASC 606 to the License Agreement at the adoption date and was required to make an adjustment to the September 1, 2018 opening accumulated deficit balance and all prior periods continue to be presented under ASC 605. The most significant impact from adopting ASC 606 was the impact of the timing of recognition of revenue associated with the milestone payment. Under ASC 605 (which was the authoritative revenue recognition guidance applied for all periods prior to September 1, 2018) given the Company's continuing involvement through the expected product submission in June 2023, amounts received relating to the License Agreement were recognized over the period from which the Company was entitled to the respective payment, and the expected product submission date using a time-based model approach over the periods that the fees were earned. However, under ASC 606, the Company is required to recognize the total transaction price (which includes consideration related to milestones once the criteria for recognition have been satisfied) using the input method over the period the performance obligation is fulfilled. Accordingly, once the consideration associated with a milestone is included in the transaction price, incremental revenue is recognized immediately based on the period of time that has elapsed towards complete satisfaction of the performance obligation. This method results in the recognition of revenue earlier than under ASC 605 and the resulting impact was recorded as a reduction of the opening balance of accumulated deficit at September 1, 2018 as further described below.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

Under 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.

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 the adoption date, the Company adjusted its accumulated deficit by $1,773 against deferred revenue due to the effect of variable consideration.

Amounts that were allocated to the License Agreement as of November 30, 2020 aggregated $22,382, all of which were received through the balance sheet date. Through November 30, 2020, the Company has recognized revenue associated with this agreement in the aggregate amount of $13,406, of which $674 was recognized in the quarter ended November 30, 2020, and deferred the remaining amount of $8,976 which is presented as deferred revenues on the condensed consolidated balance sheet.

d. Marketable securities

1. Equity securities

In January 2016, the Financial Accounting Standards Board ("FASB") issued guidance which updates certain aspects of recognition, measurement, presentation and disclosure of financial assets and financial liabilities ("ASU 2016-01"). The guidance requires entities to recognize changes in fair value in net income rather than in accumulated other comprehensive income. The Company adopted the provisions of this update in the first quarter of fiscal year 2019. Following the adoption, as of September 1, 2018, the Company classified the available for sale securities to financial assets measured in fair value through profit or loss. The impact of this adoption on the Company's accumulated losses as of the adoption date was $702.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

2. Debt securities

During the three months ended November 30, 2020, a small portion of the debt securities, which were purchased by the Company were classified as corporate bonds designated as fair value due to the nature of such securities. As such, these securities are presented by their fair market value and not by their amortized cost as the rest of the debt securities are presented. For more information, please see note 4(e) below.

e. 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, 2020 (the "2020 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 2020 Form 10-K. The results for interim periods are not necessarily indicative of a full fiscal year's results.

f. Recently adopted standards

3. In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)", which supersedes the existing guidance for lease accounting, Leases (Topic 840). The new standard requires a lessee to record assets and liabilities on its balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the lessee's income statement. The Company adopted this standard as of September 1, 2019 on a modified retrospective basis and will not restate comparative periods. The Company elected the package of practical expedients permitted under the transition guidance within the new standard which, among other things, allows the Company to carry forward the historical lease classification. The Company made an accounting policy election to keep leases with an initial term of 12 months or less off of its balance sheet. The Company recognized those lease payments in its statements of operations on a straight-line basis over the lease period. As of the adoption date, the Company recognized an operating lease asset and liability of $168 and $168, respectively, as of September 1, 2019 on its balance sheet.

4. On September 1, 2019, the Company adopted ASU No. 2018-07, "Compensation-Stock Compensation (Topic 718) Improvements to Nonemployee Share-based Payments". This ASU was issued to simplify the accounting for share-based transactions by expanding the scope of Topic 718 from only being applicable to share-based payments to employees to also include share-based payment transactions for acquiring goods and services from nonemployees. As a result, nonemployee share-based transactions are being measured by estimating the fair value of the equity instruments at the grant date, taking into consideration the probability of satisfying performance conditions. The adoption of this standard had no material impact on the Company's consolidated financial statements.

g. Standards issued but not yet adopted

In June 2016, the FASB issued ASU 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 will not 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 (the "Patent Transfer Agreement") according to which the Subsidiary assigned to Entera all of its right, title and interest in and to a certain patent application related to the oral administration of proteins that it has licensed to Entera since August 2010. Under this agreement, the Subsidiary is entitled to receive from Entera royalties of 3% of Entera's net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza. As of November 30, 2020, 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 (the "Amgen License") with Amgen related to the research of inflammatory disease and other serious illnesses. As reported by Entera, under the terms of the Amgen License, Entera will receive a modest initial technology access fee from Amgen and will be responsible for preclinical development at Amgen's expense. Entera will be eligible to receive up to $270,000 in aggregate payments, as well as tiered royalties up to mid-single digits, upon achievement of various clinical and commercial milestones if Amgen decides to move all of these programs forward. Amgen is responsible for clinical development, manufacturing and commercialization of any of the resulting programs. 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.

In addition, 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. 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 $1,542 was recognized in research and development expenses through November 30, 2020.

c. On August 2, 2020, the Subsidiary entered into a new lease agreement for its facilities in Israel. The new lease agreement is for 263 square meters and is for a period of 60 months commencing September 1, 2020. The Company has the option to extend the period by another 60 months. The annual lease payment, including management fee, is NIS 435,000 ($131). As security for its obligation under this lease agreement, the Company provided a bank guarantee in an amount equal to three monthly lease payments.

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 $2,381 was recognized in research and development expenses through November 30, 2020.

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 $1,294 was recognized in research and development expenses through November 30, 2020.

f. **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 that was received through November 30, 2020 was $2,207 ($2,486 including interest).

The royalty expenses which are related to the funded project were recognized in cost of revenues in the quarter ended November 30, 2020 and in prior periods.

g. **Grants from the European Commission ("EC")**

During fiscal year 2020, the Company received an aggregate payment of €50 from the EC under The European Innovation Council Accelerator (previously known as SME Instrument) of the European Innovation Programme Horizon 2020.

As part of the grant terms, the Company is required to use the proceeds from the grant in Europe. The Company intends on using the grant to explore the possibility of running clinical trials in Europe.

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 November 30, 2020, the assets measured at fair value are comprised of equity securities (Level 1) and debt securities which are classified as corporate bonds designated as fair value (Level 2). The fair value of held to maturity bonds as presented in note 4 was based on a Level 2 measurement.

As of November 30, 2020, 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 November 30, 2020, 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 three month periods ended November 30, 2020 and 2019.

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

NOTE 4 - MARKETABLE SECURITIES:

The Company's marketable securities include investments in equity securities of D.N.A and Entera, held to maturity bonds, corporate bonds designated as fair value, preferred equity and mutual funds.

a. Composition:

	November 30, 2020	August 31, 2020
Short-term:		
D.N.A (see b below)	$ 414	$ 246
Entera (see c below)	144	150
Held to maturity bonds (see d below)	4,169	5,369
Corporate bonds designated as fair value (see e below)	1,082	-
Preferred equity	-	481
Mutual funds*	3,016	3,298
	$ 8,825	$ 9,544
Long-term:		
Held to maturity bonds (see d below)	$ 3,878	$ 3,928
	12,703	$ 13,472

* Mutual funds include equity funds only

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 November 30, 2020, the Company owns approximately 5.5% of D.N.A's outstanding ordinary shares.

The cost of the securities as of November 30, 2020 and August 31, 2020 is $595.

c. Entera

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

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

NOTE 4 - MARKETABLE SECURITIES (continued):

d. Held to maturity securities

The amortized cost and estimated fair value of held-to-maturity securities as of November 30, 2020, are as follows:

	November 30, 2020			
	Amortized cost	Gross unrealized gains (losses)	Estimated fair value	Average yield to maturity rate
Short-term:				
Commercial bonds	$ 4,089	$ (15)	$ 4,074	2.37%
Accrued interest	80	-	80	
Long-term	3,878	6	3,884	2.34%
	$ 8,047	$ (9)	$ 8,038	

The amortized cost and estimated fair value of held-to-maturity securities as of August 31, 2020, are as follows:

	August 31, 2020			
	Amortized cost	Gross unrealized gains (losses)	Estimated fair value	Average yield to maturity rate
Short-term:				
Commercial bonds	$ 5,295	$ (29)	$ 5,266	2.26%
Accrued interest	74	-	74	
Long-term	3,928	56	3,984	2.20%
	$ 9,297	$ 27	$ 9,324	

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.

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

NOTE 4 - MARKETABLE SECURITIES (continued):

e. Corporate bonds designated as fair value

The cost and estimated fair value of corporate bonds designated as fair value securities as of November 30, 2020, are as follows:

	November 30, 2020
Amortized cost	$ 1,086
Accrued Interest	12
Revaluation	(16)
Estimated fair value	$ 1,082

NOTE 5 - STOCKHOLDERS' EQUITY:

1. On September 5, 2019, the Company entered into an Equity Distribution Agreement (the "Sales Agreement"), pursuant to which the Company could, from time to time and at the Company's option, issue and sell shares of Company common stock having an aggregate offering price of up to $15,000, through a sales agent, subject to certain terms and conditions. Any shares sold would be sold pursuant to the Company's effective shelf registration statement on Form S-3 including a prospectus and prospectus supplement, each dated February 10, 2020 (which superseded a prior registration statement, prospectus and prospectus supplement that related to shares sold under the Sales Agreement). 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 Sales Agreement. As of November 30, 2020, 974,357 shares were issued under the Sales Agreement for aggregate net proceeds of $4,508. As of January 14, 2021, 3,212,621 shares were issued under the Sales Agreement for aggregate net proceeds of $14,397.

2. On February 27, 2020, the Company entered into an underwriting agreement ("Agreement") with National Securities Corporation ("Underwriter"), in connection with a public offering ("Offering") of 5,250,000 shares of the Company's common stock, at an offering price of $4.00 per share. Under the terms of the Agreement, the Company granted the Underwriter a 45-day option to purchase from the Company up to an additional 787,500 shares of common stock at the public offering price ("Over-Allotment Option"). In connection with the Offering, the Company also agreed to issue to the Underwriter, or its designees, warrants ("Underwriter's Warrants"), to purchase up to an aggregate of 7% of the shares of common stock sold in the Offering (including any additional shares sold during the 45-day option period), at an exercise price of $4.80 per share. The Underwriter's Warrants issued in the Offering will be exercisable at any time and from time to time, in whole or in part, commencing six months from issuance for a period of three years from the date of issuance. The closing of the sale of the Offering occurred on March 2, 2020. On April 9, 2020, the Company issued 180,561 shares of Common Stock and 12,640 Underwriter's Warrants pursuant to a partial exercise by the Underwriter of the Over-Allotment Option ("Partial Over-Allotment Option Exercise"). The net proceeds to the Company from the Offering, including from the Partial Over-Allotment Option Exercise, after deducting the underwriting discount and the Company's estimated Offering expenses were $19,894.

3. On December 1, 2020, the Company entered into a new equity distribution agreement (the "New Sales Agreement"), pursuant to which the Company may, from time to time and at the Company's option, issue and sell shares of Company common stock having an aggregate offering price of up to $40,000, 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 February 10, 2020 and prospectus supplement dated December 1, 2020. The Company will pay 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 New Sales Agreement. As of January 14, 2021, 612,210 shares were issued under the New Sales Agreement for aggregate net proceeds of $2,557.

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 November 30, 2020:

	November 30, 2020
Operating right-of-use assets	$ 640
Operating lease liabilities, current	138
Operating lease liabilities long-term	502
Total operating lease liabilities	$ 640

For more information about our office lease terms, please see note 2(c).

Minimum lease payments for the Company's right-of-use assets over the remaining lease periods as of November 30, 2020 are as follows:

	November 30, 2020
2021	$ 125
2022	163
2023	134
2024	132
2025	132
Total undiscounted lease payments	685
Less: Interest*	45
Present value of lease liabilities	$ 640

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

NOTE 7 - RELATED PARTIES - 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 (the "CSO"), whereby the Chief Executive Officer (the "CEO") and the CSO, 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 CEO and the CSO is NIS 127,570 ($39) and NIS 92,522 ($28), respectively.

In addition to the Consulting Agreements, based on a relocation cost analysis prepared by consulting company ORI - Organizational Resources International Ltd., the Company pays for certain direct costs, related taxes and expenses incurred in connection with the relocation of the CEO to New York. During the three months ended November 30, 2020, such relocation expenses totaled $74, compared to $86 for the three months ended November 30, 2019.

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 (as defined below).

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. Words such as "expects," "anticipates," "intends," "plans," "planned expenditures," "believes," "seeks," "estimates" 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:

- 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;
- 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; and
- information with respect to any other plans and strategies for our business; and
- our expectations regarding the impact of the coronavirus, or COVID-19, pandemic, including on our clinical trials and operations.

Although forward-looking statements in this Quarterly Report on Form 10-Q reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended August 31, 2020, or our Annual Report, as filed with the Securities and Exchange Commission, or the SEC, on November 24, 2020, 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.

Overview of Operations

We are a pharmaceutical company currently engaged in the research and development of innovative pharmaceutical solutions, including an oral insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules for delivery of other polypeptides. We utilize clinical research organizations, or CROs, to conduct our clinical studies.

Recent business developments

Product Candidates

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 bloodstream, revolutionizing the manner in which insulin is delivered. It enables the passage in a more physiological manner than current delivery methods 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 IIb Trial: In May 2018, we initiated a three-month dose-ranging Phase IIb clinical trial of ORMD-0801 (Cohort A). This placebo controlled, randomized, 90-day treatment clinical trial was conducted on 269 type 2 diabetic patients in multiple centers throughout the United States pursuant to an Investigational New Drug application, or IND, with the FDA. The primary endpoints of the trial were to assess the safety and evaluate the effect of ORMD-0801 on HbA1c levels over a 90-day treatment period. Secondary endpoints of the trial included measurements of fasting plasma glucose, or FPG, post-prandial glucose, or PPG levels, during a mixed-meal tolerance test, or MMTT, and weight. In May 2019, we initiated an extension of this protocol for approximately 75 type 2 diabetic patients, who were dosed using a lower dosage of insulin (Cohort B).

Cohort A: In November 2019, we announced positive results from the initial cohort of the Phase IIb trial. Patients randomized in the trial to once-daily ORMD-0801 achieved a statistically significant (p-value 0.036) reduction from baseline in HbA1c of 0.60% (0.54% with placebo adjustment). This 0.54% reduction in HbA1c is clinically meaningful. Treatment with ORMD-0801 demonstrated an excellent safety profile, with no serious drug-related adverse events and with no increased frequency of hypoglycemic episodes when compared to placebo. In addition, during this 90-day trial, no weight gain was observed. In the initial cohort, 269 U.S.-based patients were enrolled and treated with a dose-increasing approach: 16 mg initial dose, titrated to 24 mg per dose, and then titrated to 32 mg per dose. Patients were randomized into three groups to assess dosing frequency: once-daily (32 mg per day), twice-daily (64 mg per day), thrice daily (96 mg per day). There was a corresponding placebo for each treatment arm. Two hundred nine (209) patients completed treatment to the 12-week endpoint and were included in the data analysis (24 subjects did not complete the full 12 weeks of treatment). The twice-daily arms achieved statistically significant (p-value 0.042) reductions from baseline in HbA1C of 0.59% (0.53% with placebo adjustment). The thrice-daily arm did not meet statistical significance (p-value 0.093). In addition, due to evidence of treatment-by-center interaction, two sites (36 patients (13.4% of enrolled subjects)) were excluded from the statistical analysis as they showed results opposite from the rest of the statistically significant results. Our internal investigation as well as an independent investigation did not find a cause for such discrepancy.

Cohort B: In February 2020, we announced positive topline data from the second and final cohort of the Phase IIb trial with a different regimen across three daily dose ranges (8 mg, 16 mg, 32 mg). Patients randomized in the trial treated with 8 mg of ORMD-0801 once-daily achieved a statistically significant (p-value 0.028) observed mean reduction of 1.29% from baseline and a least square mean reduction of 0.95% from baseline, or 0.81% adjusted for placebo. Patients who had HbA1c readings above 9% at baseline and received 8 mg of oral insulin once-daily experienced a 1.26% reduction in HbA1c by week 12. 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. The primary efficacy endpoint was a reduction in HbA1c at week 12.

Phase III Trial: Based on guidance received from the FDA as part of the End-of-Phase 2 meeting process for our oral insulin candidate, ORMD-0801, we have submitted to the FDA the protocols for our pivotal Phase III studies. In line with the FDA's expectations and recommendations, we intend to conduct two Phase 3 studies in patients with type 2 diabetes, or T2D. These studies 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 will be recruited from multiple sites throughout the U.S., European Union countries, and Israel. Our phase III trial will be composed of 2 protocols:

ORA-D-013-1: This trial will treat T2D patients with inadequate glycemic control who are currently on 1, 2, or 3 oral glucose-lowering agents. This U.S. trial will recruit 675 patients from 75 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 glycemic 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 the fourth quarter of 2020.

ORA-D-013-2: This trial will include T2D patients with inadequate glycemic control who are manage their condition with either diet alone or with diet and metformin 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 glycemic 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 expect to initiate this trial in the first half of 2021.

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 2023. A BLA would grant us 12 years of marketing exclusivity from the date of approval in the U.S.

NASH trial: In June 2020, we presented topline data from an open-label trial of 8 patients that assessed the safety, tolerability, and early effects of 16 mg ORMD-0801 (2x8 mg capsules) on liver fat in T2D patients with nonalcoholic steatohepatitis, or NASH. The 12-week dosing had no serious adverse events and it induced an observed mean 6.9±6.8% reduction in liver fat content (p-value: 0.035), and the relative reduction of 30%, as measured by MRI-derived proton density fat fraction (MRI-PDFF). In parallel, concentrations of gamma-glutamyltransferase (GGT), a key marker of chronic hepatitis, were significantly lower after 12 weeks of treatment as compared to baseline (-14.6±13.1 U/L; p value: 0.008).

In December 2020, based on the NASH trial results, we initiated a follow-on clinical trial of our oral insulin capsule ORMD-0801 for the treatment of NASH. This 40 patients multi-center trial will be comprised of eight clinical sites: three in the EU, three in the U.S. and two in Israel. The follow-on clinical trial will measure efficacy endpoints via MRI-PDFF for 12-week dosing.

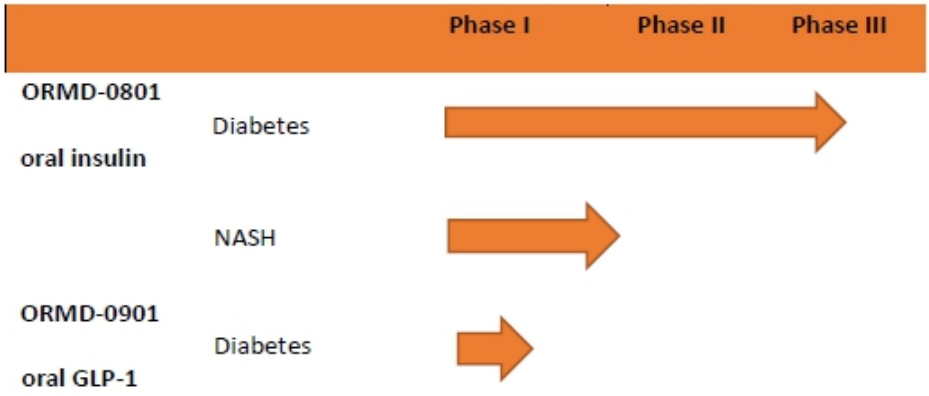
Oral Glucagon-Like Peptide-1: GLP-1 is an incretin hormone, which stimulates the secretion of insulin from the pancreas. In addition to our flagship product, the ORMD-0801 insulin capsule, we use our technology for an orally ingestible GLP-1 capsule, or ORMD-0901.

In February 2019, we completed a Phase I pharmacokinetic trial to evaluate the safety and pharmacokinetics of ORMD-0901 compared to placebo. We intend on initiating a follow-on trial in T2D patients, which is expected to start during the first half of 2021 in the U.S. under an IND submitted to the FDA.

Other products

We are developing a new drug candidate, a weight loss treatment in the form of an oral leptin capsule. We anticipate initiating a proof of concept single-dose trial for this candidate to evaluate its pharmacokinetics and pharmacodynamics (glucagon reduction) in 10 type 1 adult diabetic patients. During the third quarter of 2020, we finalized the trial without any safety issues. Patients who received leptin on average had a decrease in glucose as compared to the placebo group during the first 30-180 minutes following dosing. At different time periods, the leptin treated patients on average had glucagon values that were either lower than or similar to, those in the placebo group.

The table below gives an overview of our primary R&D pipeline:



Out-Licensed Technology

On November 30, 2015, we, our Israeli subsidiary 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, or the License Agreement. According to the License Agreement, we granted HTIT an exclusive commercialization license in the territory of the People's Republic of China, Macau and Hong Kong, or the Territory, related to our oral insulin capsule, ORMD-0801, or the Product. Pursuant to the License Agreement, HTIT will conduct, at its own expense, certain pre-commercialization and regulatory activities with respect to our subsidiary's technology and ORMD-0801 capsule, and will pay (i) royalties of 10% on net sales of the related commercialized products to be sold by HTIT in the Territory, or Royalties, and (ii) an aggregate of $37.5 million, of which $3 million was payable immediately, $8 million will be paid subject to our entry into certain agreements with certain third parties, and $26.5 million will be paid upon achievement of certain milestones and conditions. In the event that we will not meet certain conditions, the Royalties rate may be reduced to a minimum of 8%. Following the final expiration of our 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, or the Royalty Term. The License Agreement shall remain in effect until the expiration of the Royalty Term. The License Agreement contains customary termination provisions. Through November 30, 2020, we received aggregate milestone payments of $20.5 million out of the aggregate amount of $37.5 million.

On August 21, 2020, we received a letter from HTIT, disputing certain pending payment obligations of HTIT (we estimate this obligation between $2 million to $6 million) under the TLA. We wholly dispute said claims and we are in discussions with HTIT in an attempt to reach a mutually agreeable solution.

On November 30, 2015, we also entered into a separate Securities Purchase Agreement with HTIT, or the SPA, pursuant to which, in December 2015, we issued to HTIT 1,155,367 shares of our common stock for total consideration of $12 million. In connection with the License Agreement and the SPA, we received a non-refundable payment of $500,000 as a no-shop fee.

Results of Operations

Comparison of three month periods ended November 30, 2020 and 2019

The following table summarizes certain statements of operations data of the Company for the three month periods ended November 30, 2020 and 2019 (in thousands of dollars except share and per share data):

	Three months ended November 30,	
	2020	**2019**
Revenues	$ 674	$ 674
Cost of revenues	-	-
Research and development expenses	5,774	2,022
General and administrative expenses	727	1,081
Financial income (expenses), net	257	(114)
Net loss for the period	$ 5,570	$ 2,543
Loss per common share - basic and diluted	$ 0.23	$ 0.15
Weighted average common shares outstanding	23,754,980	17,472,315

Revenues

Revenues consist of proceeds related to the 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 for each of the three month periods ended November 30, 2020 and 2019 were $674,000.

Cost of revenues

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

There was no cost of revenues for the three month period ended November 30, 2020 and November 30, 2019.

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 studies.

Clinical activities, which relate principally to clinical sites and other administrative functions managing 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-study 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 three month period ended November 30, 2020, increased by 186% to $5,774,000, from $2,022,000 for the three month period ended November 30, 2019. The increase is primarily attributable to expenses related to the initiation of our Phase III six-month treatment clinical trial. Stock-based compensation costs for the three month period ended November 30, 2020 totaled $137,000, as compared to $95,000 during the three month period ended November 30, 2019. The increase is mainly attributable to new award grants in fiscal 2020.

Government grants

In the three month periods ended November 30, 2020 and 2019, we did not recognize any research and development grants. As of November 30, 2020, we incurred liabilities to pay royalties to the Israel Innovation Authority of the Israeli Ministry of Economy & Industry of $317,000.

General and administrative expenses

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

General and administrative expenses for the three month period ended November 30, 2020 decreased by 33% to $727,000 from $1,081,000 for the three month period ended November 30, 2019. The decrease in costs related to general and administrative activities is primarily attributable to a decrease in legal expenses, which was partially offset by an increase in expenses related to our patents and our directors and officers insurance policy. Stock-based compensation costs for the three month period ended November 30, 2020 totaled $180,000, as compared to $184,000 during the three month period ended November 30, 2019.

Financial income (expenses), net

Net financial income increased from net expense of $114,000 for the three month period ended November 30, 2019 to net income of $257,000 for the three month period ended November 30, 2020. The increase is primarily attributable to an increase in fair value of the ordinary shares of D.N.A Biomedical Solutions Ltd.

Liquidity and capital resources

From inception through November 30, 2020, we have incurred losses in an aggregate amount of $98,184,000. During that period and through January 14, 2021, 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 $114,540,000, net of transaction costs. During that period, we also received cash consideration of $5,892,000 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 November 30, 2020, we had $14,931,000 of available cash, $10,592,000 of short-term bank deposits and $12,703,000 of marketable securities.

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.

As of November 30, 2020, our total current assets were $36,024,000 and our total current liabilities were $5,742,000. On November 30, 2020, we had a working capital surplus of $30,282,000 and an accumulated loss of $98,184,000. As of August 31, 2020, our total current assets were $40,511,000 and our total current liabilities were $4,536,000. On August 31, 2020, we had a working capital surplus of $35,975,000 and an accumulated loss of $92,614,000. The decrease in working capital from August 31, 2020 to November 30, 2020 was primarily due to the cash used in operating activities.

During the three month period ended November 30, 2020, cash and cash equivalents decreased to $14,931,000 from the $19,296,000 reported as of August 31, 2020, which is due to the reasons described below.

Operating activities used cash of $6,152,000 in the three month period ended November 30, 2020, as compared to $2,996,000 used in the three month period ended November 30, 2019. Cash used in operating activities primarily consisted of net loss resulting from research and development and general and administrative expenses, as well as changes in deferred revenue due to the License Agreement and is partially offset by changes in accounts payable and accrued expenses.

Investing activities provided cash of $1,199,000 in the three month period ended November 30, 2020, as compared to $2,825,000 provided in the three month period ended November 30, 2019. Cash provided by investing activities consisted primarily of the maturity of short-term deposits and held to maturity securities and is partially offset by the purchase of short-term deposits.

Financing activities provided cash of $586,000 in the three month period ended November 30, 2020, as compared to $13,000 provided in the three month period ended November 30, 2019. Financing activities in the three month period ended November 30, 2019 consisted of aggregate net proceeds of $12,253, from our issuance of 12,253 shares of common stock as a result of exercise of options.

On February 27, 2020, we entered into an underwriting agreement with National Securities Corporation, or the Underwriter, in connection with a public offering, or the Offering, of 5,250,000 shares of our common stock, at an offering price of $4.00 per share. We also granted the Underwriter a 45-day option to purchase from us up to an additional 787,500 shares of common stock at the public offering price, or the Over-Allotment Option. In connection with the Offering, we also agreed to issue to the Underwriter, or its designees, warrants, or the Underwriter's Warrants, to purchase up to an aggregate of 7% of the shares of common stock sold in the Offering (including any additional shares sold during the 45-day option period), at an exercise price of $4.80 per share. The Underwriter's Warrants issued in the Offering will be exercisable at any time and from time to time, in whole or in part, commencing six months from issuance for a period of three years from the date of issuance. The closing of the Offering occurred on March 2, 2020. On April 9, 2020, we issued 180,561 shares of our common stock and 12,640 Underwriter's Warrants pursuant to a partial exercise by the Underwriter of the Over-Allotment Option, or the Partial Over-Allotment Option Exercise. The net proceeds to us from the Offering, including from the Partial Over-Allotment Option Exercise, after deducting the underwriting discount and our Offering expenses, were $19,894,000.

On September 5, 2019, we entered into an equity distribution agreement, or the Sales Agreement, pursuant to which we could, from time to time and at our option, issue and sell shares of our common stock having an aggregate offering price of up to $15,000,000, through a sales agent, subject to certain terms and conditions. Any shares sold were sold pursuant to the Company's effective shelf registration statement on Form S-3 including a prospectus and prospectus supplement, each dated February 10, 2020 (which superseded a prior registration statement, prospectus and prospectus supplement that related to shares sold under the Sales Agreement). 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 Sales Agreement. As of November 30, 2020, 974,357 shares were issued under the Sales Agreement for aggregate net proceeds of $4,508,000. As of January 14, 2021, 3,212,621 shares were issued under the Sales Agreement for aggregate net proceeds of $14,397,000.

On December 1, 2020, we entered into an equity distribution agreement, or the New Sales Agreement, pursuant to which we may, from time to time and at our option, issue and sell shares of our common stock having an aggregate offering price of up to $40,000,000, 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 February 10, 2020 and prospectus supplement dated December 1, 2020. We will pay 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 New Sales Agreement. As of January 14, 2021, 612,210 shares were issued under the New Sales Agreement for aggregate net proceeds of $2,557,000.

Off-balance sheet arrangements

As of November 30, 2020 we had no off-balance sheet arrangements that have had or that we expect would be reasonably likely to have a future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

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 quarter ended November 30, 2020. 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 November 30, 2020. 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 November 30, 2020 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	
10.1	Equity Distribution Agreement, dated December 1, 2020, by and between the Company and Canaccord Genuity (incorporated by reference from our current report on Form 8-K filed December 1, 2020).
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 Quarterly Report on Form 10-Q for the quarter ended November 30, 2020 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.

* 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: January 14, 2021

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

Date: January 14, 2021

By: /s/ Avraham Gabay
Avraham Gabay
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

I, Nadav Kidron, certify that:

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

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

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

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

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

Dated: January 14, 2021

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

Exhibit 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

I, Avraham Gabay, certify that:

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

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

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

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

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

Dated: January 14, 2021

/s/ Avraham Gabay
Avraham Gabay
Chief Financial Officer

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
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 November 30, 2020 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 and 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.

Dated: January 14, 2021

/s/ Nadav Kidron
Nadav Kidron,
President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
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 November 30, 2020 as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Avraham Gabay, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

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

Dated: January 14, 2021

/s/ Avraham Gabay
Avraham Gabay,
Chief Financial Officer