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 February 28, 2018

☐ 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.)
142 W. 57th Street New York, New York	**10019**
(Address of Principal Executive Offices)	(Zip Code)

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

Hi-Tech Park 2/4 Givat Ram, PO Box 39098, Jerusalem, Israel 91390
(Former Name, Former Address and Former Fiscal Year, If Changed Since Last Report)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 ☐ (Do not check if a smaller reporting company)
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 April 6, 2018, there were 14,442,683 shares of the issuer's common stock, $0.012 par value per share, outstanding.

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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 Israeli subsidiary, Oramed Ltd., unless otherwise indicated. All dollar amounts refer to U.S. Dollars unless otherwise indicated.

On February 28, 2018, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.485 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 FEBRUARY 28, 2018

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

	February 28, 2018	August 31, 2017
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,295	$ 3,969
Short-term deposits	14,379	13,293
Marketable securities	3,229	2,860
Restricted cash	-	16
Prepaid expenses and other current assets	224	159
Total current assets	21,127	20,297
LONG-TERM ASSETS:		
Long-term deposits and investment	13,788	16,232
Marketable securities	3,306	2,151
Amounts funded in respect of employee rights upon retirement	15	14
Property and equipment, net	18	18
Total long-term assets	17,127	18,415
Total assets	$ 38,254	$ 38,712
Liabilities and stockholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 2,156	$ 2,716
Deferred revenues	2,449	2,449
Payable to related parties	113	-
Total current liabilities	4,718	5,165
LONG-TERM LIABILITIES:		
Deferred revenues	12,622	13,837
Employee rights upon retirement	19	18
Provision for uncertain tax position	11	11
Other liabilities	404	443
Total long-term liabilities	13,056	14,309
COMMITMENTS (note 2)		
STOCKHOLDERS' EQUITY:		
Common stock, $0.012 par value (30,000,000 authorized shares; 14,405,892 and 13,668,530 shares issued and outstanding as of February 28, 2018 and August 31, 2017, respectively)	171	163
Additional paid-in capital	81,939	75,170
Accumulated other comprehensive income	313	401
Accumulated loss	(61,943)	(56,496)
Total stockholders' equity	20,480	19,238
Total liabilities and stockholders' equity	$ 38,254	$ 38,712

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)

	Six months ended		Three months ended	
	February 28, 2018	February 28, 2017	February 28, 2018	February 28, 2017
REVENUES	$ 1,215	$ 1,221	$ 604	$ 611
COST OF REVENUES	-	187	-	-
RESEARCH AND DEVELOPMENT EXPENSES	5,051	5,478	2,724	3,125
GENERAL AND ADMINISTRATIVE EXPENSES	2,007	1,319	991	851
OPERATING LOSS	5,843	5,763	3,111	3,365
FINANCIAL INCOME	439	389	217	203
FINANCIAL EXPENSES	43	45	22	21
LOSS BEFORE TAXES ON INCOME	5,447	5,419	2,916	3,183
TAXES ON INCOME	-	400	-	-
NET LOSS FOR THE PERIOD	5,447	5,819	2,916	3,183
UNREALIZED LOSS (INCOME) ON AVAILABLE FOR SALE SECURITIES	88	(105)	414	(168)
TOTAL OTHER COMPREHENSIVE LOSS (INCOME)	88	(105)	414	(168)
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	$ 5,535	$ 5,714	$ 3,330	$ 3,015
LOSS PER SHARE OF COMMON STOCK:				
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	$ 0.38	$ 0.44	$ 0.20	$ 0.24
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	14,342,024	13,242,676	14,445,844	13,279,788

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

ORAMED PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
U.S. Dollars in thousands
(UNAUDITED)

	Common Stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated loss	Total stockholders' equity
	Shares	$				
	In thousands					
BALANCE AS OF AUGUST 31, 2017	13,668	$ 163	$ 75,170	$ 401	$ (56,496)	$ 19,238
CHANGES DURING THE SIX-MONTH PERIOD ENDED FEBRUARY 28, 2018:						
SHARES ISSUED FOR SERVICES	5	*	43	-	-	43
ISSUANCE OF COMMON STOCK, NET	533	6	4,875	-	-	4,881
EXERCISE OF WARRANTS AND OPTIONS	189	2	995	-	-	997
STOCK-BASED COMPENSATION	11	*	856	-	-	856
NET LOSS	-	-	-	-	(5,447)	(5,447)
OTHER COMPREHENSIVE LOSS	-	-	-	(88)	-	(88)
BALANCE AS OF FEBRUARY 28, 2018	14,406	$ 171	$ 81,939	$ 313	$ (61,943)	$ 20,480

* 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)

	Six months ended February 28,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,447)	$ (5,819)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	3	2
Exchange differences and interest on deposits and held to maturity bonds	106	(57)
Stock-based compensation	856	494
Shares issued for services	43	32
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(65)	47
Accounts payable, accrued expenses and related parties	(447)	1,025
Deferred revenues	(1,215)	2,755
Liability for employee rights upon retirement	1	3
Other liabilities	(39)	91
Total net cash used in operating activities	(6,204)	(1,427)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(3)	(2)
Purchase of short-term deposits	(4,351)	(1,500)
Purchase of long-term deposits	(5,540)	(9,000)
Purchase of held to maturity securities	(2,879)	(2,090)
Proceeds from sale of short-term deposits	11,216	10,344
Proceeds from maturity of held to maturity securities	1,207	900
Funds in respect of employee rights upon retirement	(1)	(1)
Total net cash used in investing activities	(351)	(1,349)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	4,881	-
Proceeds from exercise of warrants and options	997	320
Total net cash provided by financing activities	5,878	320
EFFECT OF EXCHANGE RATE CHANGES ON CASH	3	1
DECREASE IN CASH AND CASH EQUIVALENTS	(674)	(2,455)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,969	3,907
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 3,295	$ 1,452
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -		
Interest received	$ 457	$ 288

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. ("Hadasit") 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 November 30, 2015, the Company entered into a Technology License Agreement with Hefei Tianhui Incubation 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.

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

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.

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.

Amounts that were allocated to the License Agreement as of February 28, 2018 aggregated $19,383, all of which were received through the balance sheet date. Through February 28, 2018, the Company recognized revenue in the amount of $4,312, and deferred the remaining amount of $15,071.

The following table sets forth the transactions in deferred revenues balances for the six-month period ended February 28, 2018 and the year ended August 31, 2017:

	Six months ended February 28, 2018	Year ended August 31, 2017
Deferred revenue at the beginning of period	$ 16,286	$ 14,766
Amounts received	-	4,000
Amounts due to the Company	-	(24)
Revenue recognized	(1,215)	(2,456)
Deferred revenue at the end of period	15,071	16,286
Less – current deferred revenue portion	(2,449)	(2,449)
Non-current deferred revenue portion	$ 12,622	$ 13,837

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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. Continued operation of the Company is contingent upon obtaining sufficient funding until it becomes profitable. 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.

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 1,406,175 and 2,053,153 for the six-month periods ended February 28, 2018 and 2017, respectively, and 1,388,122 and 1,631,174 for the three-month periods ended February 28, 2018 and 2017, respectively.

c. 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, 2017 (the "2017 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 2017 Form 10-K. The results for interim periods are not necessarily indicative of a full fiscal year's results.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

d. Newly issued and recently adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09 (Topic 606) "Revenue from Contracts with Customers" that will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle of this ASU is that an entity will recognize revenue upon the transfer of goods or services to customers in an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. The guidance is effective in annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. The Company will implement the guidance for the annual period ending on August 31, 2019. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

In January 2016, the FASB issued guidance on recognition and measurement of financial assets and financial liabilities (ASU No. 2016-01) that will supersede most current guidance. Changes to the U.S. GAAP model primarily affect the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting for other financial instruments, such as loans, investments in debt securities, and financial liabilities, is largely unchanged. The classification and measurement guidance will be effective September 1, 2018. The Company is currently evaluating the impact of the guidance on its 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 a 3% interest as of March 2011, which is accounted for as a cost method investment (amounting to $1). In consideration for the shares sold to D.N.A, the Company received, among other payments, 4,202,334 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 right, title and interest in and to the patent application 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 February 28, 2018, Entera had not yet realized any revenues and had not paid any royalties to the Subsidiary.

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 January 3, 2017, the Subsidiary entered into a lease agreement for its office facilities in Israel. The lease agreement is for a period of 60 months commencing October 1, 2016.

The annual lease payment is New Israeli Shekel ("NIS") 119,000 ($34) from October 2016 through September 2018 and NIS 132,000 ($38) from October 2018 through September 2021, and is linked to the increase in the Israeli consumer price index ("CPI") (as of February 28, 2018, the future lease payments until the expiration of the lease agreement will be $134, based on the exchange rate as of February 28, 2018).

As security for its obligation under this lease agreement, the Company provided a bank guarantee in an amount equal to three monthly lease payments.

c. On March 3, 2016, the Subsidiary entered into an agreement with a vendor for process development and production of its capsules and on November 24, 2016, April 3, 2017 and July 10, 2017 into amendments to such agreement in an amount of up to Swiss Franc ("CHF") 1,000,000 ($1,061), CHF 665,000 ($675) of which was recognized through February 28, 2018.

d. On May 11, 2016, the Subsidiary entered into a Master Service Agreement with a vendor to retain its services for a pre-clinical toxicology trial for an oral GLP-1 analog capsule for type 2 diabetes patients. As consideration for its services, the Subsidiary will pay the vendor a total amount of $1,283 during the term of the engagement and based on achievement of certain milestones, of which $1,275 was recognized through February 28, 2018.

e. On June 13, 2016, the Subsidiary entered into a four-year service agreement with a third party and on December 19, 2016, this agreement and all of the third party rights and obligations thereunder were assigned to another third party. This agreement is required by the License Agreement as described in note 1 and will support the Company's research and development. The Subsidiary is obligated to pay the third party a total amount of up to €2,360,000 ($2,780), of which €1,187,390 ($1,347) was recognized in research and development through February 28, 2018.

f. On July 24, 2016, the Subsidiary entered into a General Technical Agreement with a vendor for the scale-up process development and production of one of its oral capsule ingredients in the amount of $4,300 that will be paid over the term of the engagement and based on the achievement of certain development milestones, $3,989 of which were recognized in research and development expenses through February 28, 2018. This agreement is part of the requirements of the License Agreement as described in note 1.

g. On February 21, 2017, the Subsidiary entered into an agreement with a vendor to retain its services for a pre-clinical toxicology trial for an oral insulin capsule for type 2 and type 1 diabetes patients. As consideration for its services, the Subsidiary will pay the vendor a total of up to $952 during the term of the engagement and based on achievement of certain milestones, of which $786 was recognized through February 28, 2018.

NOTE 2 - COMMITMENTS (continued):

h. On May 3, 2017, the Company entered into a consulting agreement with a third party advisor for a period of one year, pursuant to which such advisor will provide investor relations services and will be entitled to receive a monthly cash fee and 10,000 shares of the Company's common stock that will be issued in four equal quarterly installments commencing August 1, 2017. As of February 28, 2018, the Company had issued to such advisor 7,500 shares. The fair value of the shares at the grant date was $64.

i. On June 5, 2017, the Subsidiary entered into a clinical research agreement with a vendor, for the conduct of its clamp clinical trial for an oral insulin capsule for type 1 diabetes patients. As consideration for its services, the Subsidiary will pay the vendor a total amount of $958 during the term of the engagement and based on achievement of certain milestones, $160 of which was recognized through February 28, 2018.

j. 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, $109 of which were recognized in research and development expenses through February 28, 2018.

k. On February 14, 2018, the Subsidiary entered into a Clinical Research Organization Services Agreement with a third party, effective as of November 1, 2017, to retain it as a clinical research organization ("CRO") for the Subsidiary's three-month dose-ranging clinical trial for its oral insulin capsule for type 2 diabetes patients. As consideration for its services, the Subsidiary will pay the CRO a total amount of approximately $7,030 during the term of the engagement and based on achievement of certain milestones, $547 of which were recognized through February 28, 2018.

l. Grants from the Bio-Jerusalem Fund ("Bio-Jerusalem")

The Subsidiary is committed to pay royalties to Bio-Jerusalem on proceeds from future sales at a rate of 4% and up to 100% of the amount of the grant received (Israeli CPI linked) at the total amount of $65. The Company received no grants from Bio-Jerusalem since fiscal year 2013.

As of February 28, 2018, the royalty expenses which are related to the funded project were recognized in cost of revenues in prior periods.

m. Grants from the Israel Innovation Authority ("IIA")

Under the terms of the Company's funding from the IIA, royalties of 3.5% 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 February 28, 2018 was $2,194.

As of February 28, 2018, the royalty expenses which are related to the funded project were recognized in cost of revenues in prior periods.

NOTE 3 - FAIR VALUE:

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

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

As of February 28, 2018, the assets or liabilities measured at fair value are comprised of available for sale equity securities (Level 1).

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible.

As of February 28, 2018, the carrying amount of cash equivalents, short-term deposits and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term maturities of these instruments.

As of February 28, 2018, the carrying amount of long-term deposits approximates their fair values due to the stated interest rates which approximate market rates.

The fair value of held to maturity bonds as presented in note 4 was based on a Level 1 measurement.

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 six-month periods ended February 28, 2018 and 2017.

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 in held to maturity bonds.

a. Composition:

	February 28, 2018	August 31, 2017
Short-term:		
D.N.A (see b below)	$ 908	$ 996
Held to maturity bonds (see c below)	2,321	1,864
	$ 3,229	$ 2,860
Long-term:		
Held to maturity bonds (see c below)	$ 3,306	$ 2,151

b. D.N.A

The investment in D.N.A is reported at fair value, with unrealized gains and losses, recorded as a separate component of other comprehensive income in equity until realized. Unrealized losses that are considered to be other-than-temporary are charged to statement of operations as an impairment charge and are included in the consolidated statement of operations under impairment of available-for-sale securities.

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 February 28, 2018, the Company owns approximately 6.9% of D.N.A's outstanding ordinary shares.

The cost of the securities as of February 28, 2018 and August 31, 2017 is $595.

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

NOTE 4 - MARKETABLE SECURITIES (continued):

c. Held to maturity securities

The amortized cost and estimated fair value of held-to-maturity securities as of February 28, 2018, are as follows:

	February 28, 2018		
	Amortized cost	Gross unrealized losses	Estimated fair value
Short-term:			
Commercial bonds	$ 2,284	$ (11)	$ 2,273
Accrued interest	37	-	37
Long-term	3,306	(42)	3,264
	$ 5,627	$ (53)	$ 5,574

As of February 28, 2018, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, $3,306, and the yield to maturity rates vary between 1.40% to 1.90%.

The amortized cost and estimated fair value of held-to-maturity securities as of August 31, 2017, are as follows:

	August 31, 2017		
	Amortized cost	Gross unrealized losses	Estimated fair value
Short-term:			
Commercial bonds	$ 1,823	$ (1)	$ 1,822
Accrued interest	41	-	41
Long-term	2,151	-	2,151
	$ 4,015	$ (1)	$ 4,014

As of August 31, 2017, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, $2,151 and the yield to maturity rates vary between 1.30% to 1.87%.

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:

On April 2, 2015, the Company entered into an At The Market Issuance Sales Agreement (the "Sales Agreement") with B. Riley FBR, Inc., as successor to FBR Capital Markets & Co. ("FBR"), as amended, pursuant to which the Company may, from time to time and at its option, issue and sell shares of its common stock having an aggregate offering price of up to $25,000 through FBR as its 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 2, 2017, as supplemented by a prospectus supplement dated April 5, 2017. The Company will pay FBR a commission of 3.0% of the gross proceeds of the sale of any shares sold through FBR. Through February 28, 2018, 535,771 shares were sold under the Sales Agreement for aggregate net proceeds of $4,906 and an additional 35,001 shares were subsequently sold during March 2018 for aggregate net proceeds of $243.

NOTE 6 - 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 performance of the Consulting Agreements and that the monthly consulting fee paid to the CEO and the CSO is NIS 127,570 ($37) and NIS 80,454 ($23), respectively.

In addition to the Consulting Agreement, based on a relocation cost analysis prepared by consulting company ORI - Organizational Resources International Ltd., the Company pays for certain direct costs and expenses incurred in connection with the relocation of the CEO to New York, up to an aggregate yearly amount of $365 in addition to any double taxation.

NOTE 7 - TAXES ON INCOME:

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act (the "TCJA"), which among other changes reduces the federal corporate tax rate to 21%. Deferred taxes are determined based on temporary differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The reduction of the tax rate and TCJA had no impact on the net deferred taxes of the Company.

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;
- future milestones, conditions and royalties under the license agreement with Hefei Tianhui Incubation of Technologies Co. Ltd., or HTIT;
- our research and development plans, including pre-clinical and clinical trials plans and the timing of enrollment, obtaining results and conclusion of trials, including without limitation, our expectation that we will initiate two six-month Phase III clinical trials if our Phase IIb three-month dosing clinical trial is successful, and our expectation to file a New Drug Application 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 the 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.

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, 2017, or our Annual Report, as filed with the Securities and Exchange Commission, or the SEC, on November 29, 2017, as well as those discussed elsewhere in our Annual Report and this Quarterly Report on Form 10-Q 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 or pills for delivery of other polypeptides.

Recent business developments

Product Candidates

Oral Insulin

We anticipate the initiation in the second quarter of calendar year 2018 of a three-month dose-ranging Phase IIb clinical trial of our proprietary flagship product, an orally ingestible insulin capsule, or ORMD-0801. This placebo controlled, randomized, 90 day treatment clinical trial will be conducted on approximately 240 type 2 diabetic patients in multiple centers throughout the U.S. pursuant to an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA. The primary endpoints of the trial are to assess the safety and evaluate the effect of ORMD-0801 on HbA1c levels over a 90 day period of treatment. Secondary endpoints of the trial include measurements of fasting plasma glucose (FPG), post-prandial glucose (PPG levels) during a mixed-meal tolerance test (MMTT) and weight.

We also plan to initiate in the second quarter of calendar year 2018 a glucose clamp study which will quantify insulin absorption in type 1 diabetic patients treated with ORMD-0801. The glucose clamp is a method for quantifying insulin absorption in order to measure a patient's insulin sensitivity and how well a patient metabolizes glucose. This exploratory, randomized, double-blind glucose clamp study will evaluate exposure-response profiles of type 1 diabetes patients dosed with ORMD-0801. Patients with HbA1c levels of 10% or below, aged 18-70, will be enrolled in the study.

In August 2017, we had a call with the FDA, regarding ORMD-0801. During the call, the FDA advised that the regulatory pathway for the submission of ORMD-0801 would be a Biologics License Application, or 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 if the product also receives approval for use in pediatric patients. The FDA confirmed that the approach to nonclinical toxicology, chemistry manufacturing controls and qualification of excipients would be driven by their published guidance documents.

In February 2017, we completed a Phase IIa dose finding clinical trial which was initiated in October 2016. This randomized, double-blind trial was conducted on 32 type 2 adult diabetic patients in order to better define the optimal dosing of ORMD-0801 moving forward. The results of the trial indicated a positive safety profile and potentially meaningful efficacy of ORMD-0801, as the efficacy data suggest ORMD-0801 improves glucose control.

In March 2017, we initiated a six month toxicology study to allow for the use of our oral insulin capsule for a longer period than previously performed, in preparation for our proposed upcoming three-month clinical trial for type 2 diabetes. We anticipate receiving the final report of this study in the second quarter of calendar year 2018.

In April 2016, we completed a Phase IIb clinical trial on 180 type 2 adult diabetic patients that was initiated in June 2015 and conducted in 33 sites in the United States. This double-blind, randomized, 28-day dosing clinical trial was conducted under an IND with the FDA. The clinical trial, designed to assess the safety and efficacy of our ORMD-0801, investigated ORMD-0801 over a 28 day treatment period and had statistical power to give us greater insight into the drug's efficacy. The trial indicated a statistically significant lowering of blood glucose levels versus placebo across several endpoints, with no serious or severe adverse issues related to the drug. The trial successfully met all of its primary and most of its secondary and exploratory endpoints for both safety and efficacy.

Should our Phase IIb three-month dose-ranging clinical trial successfully meet its primary endpoints, we anticipate initiating two six-month Phase III clinical trials on both type 1 and type 2 diabetic patients, following which we expect to file a New Drug Application with a potential FDA approval by the third quarter of calendar year 2023.

Oral GLP-1 Analog

In September 2013, we submitted a pre-IND package to the FDA for ORMD-0901, our oral GLP-1/exenatide capsule, for a Phase II clinical trial on healthy volunteers and type 2 diabetic patients. In August 2015, we began a non-FDA clinical trial outside of the United States on type 2 diabetic patients. The trial was completed during the second quarter of calendar year 2016 and indicated positive results as it showed ORMD-0901 to be safe and well tolerated and demonstrated encouraging efficacy data. We completed a three-month pre-clinical toxicology study in March 2017 and the final report will be submitted to the FDA with our IND. We expect to file an IND during the second quarter of calendar year 2018 and move directly into a small pharmacokinetics study on healthy volunteers followed by a large Phase II trial on type 2 diabetic patients which will be conducted in the United States under an IND.

Other products

During the first quarter of calendar 2017, we began developing a new drug candidate, a weight loss treatment in the form of an oral leptin capsule, and in April 2017, Israel's Ministry of Health approved our commencement of a proof of concept single dose study for our oral leptin drug candidate to evaluate its pharmacokinetic and pharmacodynamics (glucagon reduction) in 10 type 1 adult diabetic patients. The study is projected to initiate in the third quarter of calendar year 2018 and be completed during calendar year 2019.

In November 2017, Israel's Ministry of Health approved us to initiate an exploratory clinical study of our oral insulin capsule, ORMD-0801, in patients with nonalcoholic steatohepatitis (NASH). The proposed three-month treatment study will assess the effectiveness of ORMD-0801 in reducing liver fat content, inflammation and fibrosis in patients with NASH. We expect to initiate the study in the second quarter of calendar year 2018 and complete it during calendar year 2019.

The table below gives an overview of our primary product pipeline (calendar quarters):

		Phase I	Phase II	Phase III	Timeline
ORMD-0801 oral insulin	Type 2 diabetes				Q1 ’14: Phase IIa completed Q2 ’16: Phase IIb multi-center study completed Q1 ’17: Phase IIa - dose finding study completed Q2 ’18: Phase IIb 90-day multi-center study projected initiation (projected completion Q2 ’19) Q1 ’20: Phase III study projected initiation (projected completion Q3 ’22)
	Type 1 diabetes				Q3 ’14: Phase IIa study completed Q2 ’18: Clamp study projected initiation (projected completion Q4 ’18) Q1 ’20: Phase III projected initiation (projected completion Q3 ’22)
ORMD-0901 oral GLP-1	Type 2 diabetes				Q2 ’16: Phase Ib non-US study completed Q3 ’18: Pharmacokinetics clinical study projected initiation (projected completion Q1 ’19) Q4 ’18: Phase II projected initiation (projected completion Q2 ’20)

Out-Licensed Technology

On November 30, 2015, we, our Israeli subsidiary and HTIT entered into a Technology License Agreement, 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 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 is payable immediately, $8 million will be paid subject to our entry into certain agreements with certain third parties, and $26.5 million will be payable 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 final expiration of the last-to-expire licensed patent 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 February 28, 2018, we received aggregate milestone payments of $17.5 million.

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 six and three month periods ended February 28, 2018 and 2017

The following table summarizes certain statements of operations data of the Company for the six and three month periods ended February 28, 2018 and 2017 (in thousands of dollars except share and per share data):

	Six months ended February 28,		Three months ended February 28,	
	2018	2017	2018	2017
Revenues	$ 1,215	$ 1,221	$ 604	$ 611
Cost of revenues	-	187	-	-
Research and development expenses	5,051	5,478	2,724	3,125
General and administrative expenses	2,007	1,319	991	851
Financial income, net	396	344	195	182
Taxes on income	-	400	-	-
Net loss for the period	$ 5,447	$ 5,819	$ 2,916	$ 3,183
Loss per common share - basic and diluted	$ (0.38)	$ (0.44)	$ (0.20)	$ (0.24)
Weighted average common shares outstanding	14,342,024	13,242,676	14,445,844	13,279,788

Revenues

Revenues consist of proceeds related to the License Agreement that are recognized over the term of the License Agreement through June 2023.

Revenues for the six month period ended February 28, 2018 totaled $1,215,000, consistent with $1,221,000 for the six month period ended February 28, 2017.

Revenues for the three month period ended February 28, 2018 totaled $604,000, consistent with $611,000 for the three month period ended February 28, 2017.

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.

No cost of revenues was recognized during the six month period ended February 28, 2018 compared to cost of revenues of $187,000 for the six month period ended February 28, 2017. The decrease is due to no additional milestone payments having been received during the six month period ended February 28, 2018.

No cost of revenues was recognized during the three month periods ended February 28, 2018 and 2017.

Research and development expenses

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

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

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-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 manufacturing of the oral insulin and exenatide capsules, payments for patient recruitment and treatment, as well as salaries and related expenses of research and development staff.

Research and development expenses for the six month period ended February 28, 2018 decreased by 8% to $5,051,000, from $5,478,000 for the six month period ended February 28, 2017. The decrease is mainly due to less expenses related to our scale-up process development and production of our oral capsule ingredients as well as progress in toxicology studies and is partially offset by an increase in expenses related to preparations for our Phase IIb three-month treatment clinical trial. Stock-based compensation costs for the six month period ended February 28, 2018 totaled $296,000, as compared to $308,000 during the six month period ended February 28, 2017. The decrease is mainly attributable to the progress in amortization of awards granted in prior periods and is partially offset by an increase due to awards granted to employees and a consultant during fiscal years 2018 and 2017.

Research and development expenses for the three month period ended February 28, 2018 decreased by 13% to $2,724,000, from $3,125,000 for the three month period ended February 28, 2017. The decrease is mainly due to less expenses related to our scale-up process development and production of our oral capsule ingredients as well as progress in toxicology studies and is partially offset by an increase in expenses related to preparations for our Phase IIb three-month treatment clinical trial. Stock-based compensation costs for the three month period ended February 28, 2018 totaled $125,000, as compared to $172,000 during the three month period ended February 28, 2017. The decrease is mainly attributable to the progress in amortization of awards granted in prior periods and is partially offset by an increase due to awards granted to employees and a consultant during fiscal years 2018 and 2017.

Government grants

In the six month periods ended February 28, 2018 and 2017, we did not recognize any research and development grants. As of February 28, 2018, we incurred liabilities to pay royalties to the Israel Innovation Authority of the Israeli Ministry of Economy & Industry of $494,000.

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 six month period ended February 28, 2018 increased by 52% to $2,007,000 from $1,319,000 for the six month period ended February 28, 2017. The increase in costs related to general and administrative activities during the six month period ended February 28, 2018 is mainly attributable to an increase in stock-based compensation costs, consulting and travel expenses related to the relocation of our Chief Executive Officer to New York, where the Company has leased an office and moved its principal executive office. Stock-based compensation costs for the six month period ended February 28, 2018 totaled $560,000, as compared to $185,000 during the six month period ended February 28, 2017. The increase is mainly attributable to awards granted to employees and directors during fiscal years 2018 and 2017.

General and administrative expenses for the three month period ended February 28, 2018 increased by 16% to $991,000 from $851,000 for the three month period ended February 28, 2017. The increase in costs related to general and administrative activities during the three month period ended February 28, 2018 is mainly attributable to an increase in stock-based compensation costs and travel expenses related to the relocation of our Chief Executive Officer to New York, where the Company has leased an office and moved its principal executive office. Stock-based compensation costs for the three month period ended February 28, 2018 totaled $208,000, as compared to $163,000 during the three month period ended February 28, 2017. The increase is mainly attributable to awards granted to employees and directors during fiscal years 2018 and 2017.

Financial income, net

Net financial income increased by 15% from net income of $344,000 for the six month period ended February 28, 2017 to net income of $396,000 for the six month period ended February 28, 2018. The increase is mainly attributable to an increase in income from bank deposits and held to maturity bonds as a result of an increase in interest rates.

Net financial income increased by 7% from net income of $182,000 for the three month period ended February 28, 2017 to net income of $195,000 for the three month period ended February 28, 2018. The increase is mainly attributable to an increase in income from bank deposits and held to maturity bonds as a result of an increase in interest rates.

Taxes on income

No taxes on income were recognized for the six month period ended February 28, 2018 as compared to $400,000 for the six month period ended February 28, 2017. The decrease is due to the absence of withholding taxes during the more recent period as compared to the prior period, as withholding taxes were recorded during the six months ended February 28, 2017 related to the receipt of a milestone payment.

No taxes on income were recognized for the three month periods ended February 28, 2018 and 2017.

Other comprehensive income

Unrealized losses on available for sale securities for the six month period ended February 28, 2018 of $88,000, compared to gains of $105,000 for the six month period ended February 28, 2017, resulted from the decrease in fair value of the ordinary shares of D.N.A Biomedical Solutions Ltd., or D.N.A, that we hold.

Unrealized losses on available for sale securities for the three month period ended February 28, 2018 of $414,000, compared to gains of $168,000 for the three month period ended February 28, 2017, resulted from the decrease in fair value of the ordinary shares of D.N.A that we hold.

Liquidity and capital resources

From inception through February 28, 2018, we have incurred losses in an aggregate amount of $61,943,000. During that period 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 $60,960,000, net of transaction costs. During that period, we also received cash consideration of $5,877,000 from the exercise of warrants and options. We will seek to obtain additional financing through similar sources in the future, as needed. As of February 28, 2018, we had $3,295,000 of available cash, $28,167,000 of short-term and long-term bank deposits and $6,535,000 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 and beyond.

As of February 28, 2018, our total current assets were $21,127,000 and our total current liabilities were $4,718,000. On February 28, 2018, we had a working capital surplus of $16,409,000 and an accumulated loss of $61,943,000. As of August 31, 2017, our total current assets were $20,297,000 and our total current liabilities were $5,165,000. On August 31, 2017, we had a working capital surplus of $15,132,000 and an accumulated loss of $56,496,000. The increase in working capital from August 31, 2017 to February 28, 2018 was primarily due to investment in short-term deposits and the re-classification of long-term marketable securities to short-term.

During the six month period ended February 28, 2018, cash and cash equivalents decreased to $3,295,000 from the $3,969,000 reported as of August 31, 2017, which is due to the reasons described below.

Operating activities used cash of $6,204,000 in the six month period ended February 28, 2018, as compared to $1,427,000 used in the six month period ended February 28, 2017. Cash used in operating activities in the six month period ended February 28, 2018 primarily consisted of net loss resulting from research and development and general and administrative expenses, as well as changes in deferred revenues due to the License Agreement and is partially offset by changes in stock-based compensation, while cash used in operating activities in the six month period ended February 28, 2017 primarily consisted of net loss resulting from research and development and general and administrative expenses and is partially offset by changes in deferred revenues, accounts payable, accrued expenses and stock-based compensation.

Investing activities used cash of $351,000 in the six month period ended February 28, 2018, as compared to $1,349,000 used in the six month period ended February 28, 2017. Cash used in investing activities in the six month periods ended February 28, 2018 and 2017 consisted primarily of the purchase of short-term and long-term bank deposits and marketable securities and is partially offset by the maturity of short-term deposits and held to maturity securities.

Financing activities provided cash of $5,878,000 in the six month period ended February 28, 2018, as compared to $320,000 that were provided in the six month period ended February 28, 2017. Financing activities in the six month period ended February 28, 2018 consisted of aggregate net proceeds of $4,881,000 from our issuance of 532,801 common stock under an At The Market Issuance Sales Agreement, dated April 2, 2015, or the Sales Agreement, with B. Riley FBR, Inc., as successor to FBR Capital Markets & Co., or FBR, as amended, and proceeds from exercise of warrants and options while financing activities in the six month period ended February 28, 2017 consisted of proceeds from the exercise of options. Pursuant to the Sales Agreement, 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 $25,000,000 through FBR as 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 February 2, 2017, as supplemented by a prospectus supplement dated April 5, 2017. We will pay FBR a commission of 3.0% of the gross proceeds of the sale of any shares sold through FBR.

Off-balance sheet arrangements

As of February 28, 2018, 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.

Significant Accounting Policies

Our significant accounting policies are described in the notes to the consolidated financial statements as of August 31, 2017 included 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 six month period ended February 28, 2018. 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 February 28, 2018. 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 February 28, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

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

On February 1, 2018, we issued 2,500 shares of our common stock to Corporate Profile, LLC, or Corporate Profile, in payment of a portion of the consulting fee for investor relations services owed to Corporate Profile pursuant to a Stock Purchase Agreement and Letter Agreement, each dated May 3, 2017, between us and Corporate Profile.

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

ITEM 6 - EXHIBITS

Exhibit Number	
10.1*	Clinical Research Organization Services Agreement dated February 14, 2018 and effective as of November 1, 2017, between Oramed Ltd. and Integrium, LLC. (Confidential treatment has been requested for portions of this document. The confidential portions will be omitted and filed separately, on a confidential basis, with the Securities and Exchange Commission.)
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 February 28, 2018, 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: April 8, 2018

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

Date: April 8, 2018

By: /s/ Hilla Eisenberg
Hilla Eisenberg
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

****Confidential portions have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission (the "Commission")****

CLINICAL RESEARCH ORGANIZATION SERVICES AGREEMENT

By and Between

Oramed Ltd.

and

Integrium, LLC

Effective Date: November 1, 2017

CRO Agreement

EFFECTIVE DATE: November 1, 2017

Name and Address of the Contact for Integrium, LLC

Name: Jessica Coutu

Title: Sr. V.P. of Clinical Operations

Address: 100 East Hanover Avenue, Suite 401
Cedar Knolls, NJ 07927

Telephone: (908) 357-2010

Cell Phone: (908) 458-3058

e-mail: jessica.coutu@integrium.com

Name and Address of the Contact for Oramed Ltd.

Name: Dr. Miriam Kidron

Title: Chief Medical and Technology Officer

Address: Hi-Tech Park 2/4 Givat-Ram,
P.O. Box 39098
Jerusalem, 91390, Israel

Telephone: 972 2 566001

Facsimile: 972 2 566004

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Oramed Ltd. ("**Sponsor**"), an Israeli company, with principal offices at Hi-Tech Park 2/4 Givat-Ram, P.O. Box 39098, Jerusalem, 91390, Israel and Integrium, LLC, ("**Integrium**"), a California limited liability company, located at 14351 Myford Road, Suite A, Tustin, California, 92780, hereby agree as follows:

1. Term

1.1 The term of this Agreement shall be for the period beginning as of November 1, 2017 and ending upon the satisfactory performance of all the Services (as hereinafter defined) unless terminated sooner as provided for herein.

2. Scope of Work

2.1 Sponsor is conducting a Study pursuant to Protocol No. ORA-D-015, ("**Protocol**") entitled "A Placebo-controlled, Multi-center, Randomized, Phase 2b Study to Evaluate the Efficacy and Safety of ORMD-0801 in Type 2 Diabetes Mellitus Patients with Inadequate Glycemic Control on Oral Therapy" (the "**Study**"). The Protocol was submitted by Sponsor to the FDA in December, 2017, such Protocol being set out in Exhibit 1 attached hereto.

2.2 Integrium shall perform services ("**Services**") as required for the execution of the Protocol according to the Study Specifications (Study Assumptions, Timeline and Task Ownership Matrix), Exhibit 2, attached hereto and made fully a part hereof. The designation of personnel to perform the Services, shall be within Integrium's discretion, but Sponsor reserves the right, at its sole discretion, to reject any personnel so designated by Integrium, and require replacement of such personnel. Prior to performing the Services under this Agreement, Integrium will inform Sponsor of the identity of the personnel designated and Integrium shall make reasonable efforts to assure that the personnel designated to perform the Services shall not be changed until the Services are completed; *provided, however*, that where any such personnel ceases to be employed by Integrium, Integrium shall promptly notify Sponsor of such cessation and use its best efforts to locate replacement personnel acceptable to Sponsor.

3. Conditions of Work/Sponsor Responsibilities

3.1 In order for Integrium to perform the Services properly and timely, unless otherwise agreed in writing, Sponsor shall provide Integrium with those materials and take those actions as described in the Study Specifications, set out in Exhibit 2 attached hereto and made a part hereof. In addition, Sponsor shall cause all Sponsor contracted designees to (i) reasonably cooperate with Integrium, and (ii) perform their services and supply to Integrium their study materials and deliverables in a timely manner. Any failure under this Section 3.1 shall not constitute a breach of this Agreement by Sponsor, but may require changes in the budget/compensation and/or timelines for the Services in accordance with Section 4.3.

3.2 Sponsor and/or its representatives may, during the Term, visit Integrium's facilities (and those of Integrium's approved contractors) at reasonable times and with reasonable frequency during normal business hours to (i) observe the progress of the Study at Integrium's facilities and all Study sites (it being clarified that Integrium shall ensure that Sponsor has such rights viz-a-viz each Study site), (ii) monitor the accuracy and completeness of the Services, including, but not limited to, quality control and assurance, and/or (iii) review the responsibilities and/or performance obligations of Integrium personnel. Integrium will assist Sponsor in scheduling such visits and will make records and any other relevant information available to Sponsor and/or its representatives.

3.3 Both Sponsor and Integrium enter into the Agreement for the express purpose of transferring from Sponsor to Integrium the responsibilities and obligations of a Sponsor to conduct, coordinate, manage, and/or develop the Study in accordance with United States Food and Drug Administration ("**FDA**") regulations set forth in 21 CFR Section 312, Subpart D, as such may be amended from time to time. Accordingly, if Sponsor is transferring to Integrium the responsibility for various regulatory responsibilities under the U.S. laws and regulations as set forth in Exhibit 5 (sample form), a Transfer of Regulatory Obligations Form will be completed. Any regulatory responsibilities not specifically stated as transferred to Integrium shall remain the regulatory responsibility of Sponsor. Sponsor shall file the Transfer of Regulatory Obligations with the FDA or as otherwise required by law or regulation. If an amendment to this Agreement affects the scope of regulatory obligations that have been transferred to Integrium, Integrium and Sponsor shall execute a corresponding amendment. Such amendment shall be filed by Sponsor with the appropriate government bodies.

4. Compensation

4.1 In consideration for Integrium's satisfactory performance of any and all of the Services, Sponsor shall pay Integrium a fee in the amount and on the terms specified in Exhibit 3 (the "**Study Budget and Payment Schedule**") attached hereto and made fully a part hereof. All fees will be invoiced by Integrium and Sponsor shall pay each invoice within thirty (30) days of receipt. If any portion of an invoice is disputed, then Sponsor shall pay the undisputed amounts as provided above and the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. If any undisputed invoice is not paid within forty five (45) days Sponsor will be considered in material breach. If the breach is not cured within ten (10) days of written notice thereof provided by Integrium, Integrium will suspend all activity until the breach is cured. If any breach extends beyond forty five (45) days Integrium will terminate this Agreement. Any 3rd Party Vendor late fee charges resulting from Sponsor delays in providing payment to Integrium will be passed on to Sponsor.

4.2 Any statement or invoice for services or expenses shall be stated with sufficient specificity for Sponsor to be able to determine the services performed, the work done, the related charges, and summary of pass through expenses.

4.3 Any material change in the Services, or the Assumptions set out in Exhibit 2 (including, but not limited to, changes in an agreed starting date or suspension of the Study by the Sponsor) may require changes in the budget/compensation and/or timelines and shall require a written amendment to this Agreement. Each amendment shall detail the changes to the Services, Conditions, Compensation, Timeline or other matter. Sponsor agrees that it will not unreasonably withhold approval of an amendment even if it involves a fixed price contract if the proposed changes in compensation or timelines result from, among other appropriate reasons, changes in the assumptions upon which current compensation or timelines were based. Integrium shall not implement any change in the Project scope without Sponsor's prior written approval. Integrium reserves the right to postpone effecting material changes in the Project's scope until such time as the parties agree to and execute the corresponding Change Order.

5. Representations of CRO

5.1 Integrium represents that it has the requisite facilities, equipment, and personnel with the requisite expertise, experience and skill, to render the desired Services, and it shall render the Services, in a timely, competent and efficient manner. Integrium further represents that the Services to be provided pursuant to this Agreement will represent Integrium's best efforts and will be of the highest professional standards and quality. Integrium further represents that it shall abide by all laws, rules and regulations including, but not limited to, GCP Guidelines issued by the FDA that apply to the performance of the Services at the time they are provided, including applicable requirements regarding equal employment opportunity and, when on Sponsor's premises, Integrium's employees shall comply with Sponsor's policies with respect to conduct of visitors.

5.2 Integrium certifies that neither Integrium nor any person employed by Integrium has been debarred under Section 335a of Title 22 of the United States Code, and that no debarred person will in future be employed or utilized to perform any Services. Integrium certifies that, to the best of its knowledge, no person performing any Services, including any investigator, has a conviction which could lead to debarment under Section 335a. Furthermore, Integrium agrees to notify Sponsor immediately of any action toward conviction or debarment of any person performing any Services. Integrium understands that Sponsor shall have the right to terminate this Agreement immediately upon receipt of notice that any employee or agent of Integrium has been debarred or is subject to any action toward conviction or debarment.

5.3 Integrium shall maintain accurate and complete records specifically relating to the Services provided hereunder in accordance with generally accepted accounting principles and practices, consistently applied. To the extent that such records may be relevant in Sponsor's reasonable opinion in determining whether Integrium is complying with its obligations pursuant to this Agreement, Sponsor, or Sponsor's authorized representative, may audit such records during Integrium's normal working hours and at Sponsor's expense, upon providing five (5) working days' written notice to Integrium. Integrium shall retain such records for a period of three (3) years from the date of final payment by Sponsor pursuant to the Agreement.

5.4 Integrium represents and warrants that in any and all contracts between Integrium and a third party with respect to the performance by such third party of clinical trials or tests and services associated with any such clinical trials or tests (a "Third Party Contractor"), and in which Integrium acts as an agent or general contractor for Sponsor and to which such contract Sponsor is not a party, Integrium will include a third party beneficiary provision naming Sponsor as the third party beneficiary under such agreement. Notwithstanding anything to the contrary in this Agreement, prior to entering into any contract or arrangement with any Third Party Contractor or with any subcontractor with respect to the performance by such subcontractor of any of Integrium's obligations under this Agreement, Integrium shall notify Sponsor thereof and be required to obtain the written consent of Sponsor to any such contract or arrangement (such consent not to be unreasonably withheld, delayed or conditioned).

6. Confidentiality

6.1 It is understood by the parties hereto that during the performance of the Services, Integrium may receive from Sponsor, or otherwise acquire, certain Confidential, Proprietary, and/or Trade Secret Information which is the property of Sponsor ("**Confidential Information**"). Confidential Information shall include without limitation the Investigator's brochure, the Protocol, the data recorded during the Study and data, formulae and information on the Study drug. For purposes of this Agreement, Confidential Information shall be understood to include all written or electronically transferred information received from Sponsor by Integrium, and unless expressly described in this section 6.1 such written material shall be marked "Confidential." Confidential Information which is disclosed orally shall be deemed confidential if it is confirmed to be confidential by a writing provided to Integrium by Sponsor within a reasonable amount of time following oral disclosure or if such information is known or reasonably should be known by Integrium to be deemed to be Confidential Information (even without such written confirmation). Integrium hereby warrants and affirms that it shall neither use nor disclose Confidential Information for any purpose other than as is specifically allowed by this Agreement.

6.2 Integrium shall disclose Confidential Information only to such of its employees or third parties (approved by Sponsor in writing) as may reasonably be required to assist Integrium in the performance of this Agreement and who have agreed to be bound by confidentiality and non-use terms and conditions similar to those in this Agreement. In the event of such disclosure, Integrium shall advise its employees, of the confidential nature of the information and shall instruct them to take all necessary and reasonable precautions to prevent the unauthorized use or disclosure thereof at least consistent with those precautions undertaken by Integrium hereunder.

6.3 Upon the expiration or termination of this Agreement, Integrium shall either destroy or return to Sponsor all tangible and electronic forms of Confidential Information, including any and all copies and/or derivatives of Confidential Information made by Integrium (or Integrium's employees or agents), as well as any writings, drawings, specifications, manuals or other printed material made by Integrium (or Integrium's employees or agents) and based on, or derived from, Confidential Information; *provided, however*, that Integrium shall retain all information it is required by law to retain. Such information shall be retained for the amount of time required by law using the same amount of care and diligence to protect Sponsor's information as it uses to protect its own confidential information but in any case not less than reasonable care and diligence.

6.4 The foregoing obligations shall not apply to Confidential Information to the extent that it: (a) is or becomes generally available to the public other than as a result of a disclosure by the receiving party; (b) becomes available to the receiving party on a non-confidential basis from a source which is not prohibited from disclosing such information; (c) was developed independently of any disclosure by the disclosing party or was known to the receiving party prior to its receipt from the disclosing party, as shown by contemporaneous written evidence; or (d) is required by law or regulation to be disclosed (in which case notice of such disclosure shall be given promptly to Sponsor and Integrium shall reasonably cooperate with Sponsor in seeking to obtain assurances that any such information will be treated confidentially).

6.5 Integrium shall not disclose, or otherwise make public, the terms of this Agreement, except as may be necessary to secure enforcement of the terms of this Agreement or in response to a lawful subpoena or to comply with applicable regulations.

6.6 All of Integrium's obligations set forth in this Article 6, including the obligations of confidentiality and non-use, shall continue through the term of this Agreement and shall survive for a period of ten (10) years following the expiration or termination of this Agreement.

7. Conflicts of Interest

7.1 Integrium hereby warrants and represents that it has advised Sponsor, prior to the date of signing of this Agreement, of any relationship with any third parties, including competitors of Sponsor, which would prevent Integrium from performing the Services contemplated by this Agreement in accordance with the legal and ethical standards set out herein or as otherwise mandated by applicable law.

7.2 Integrium undertakes to advise Sponsor of any such relationships that might arise during the Term of this Agreement. In the event such a relationship arises, the parties will discuss in good faith options to minimize or eliminate possible effects of such conflicts of interest.

8. Independent Contractor

8.1 The parties hereto agree that Integrium is being retained and shall perform as an "Independent Contractor". Neither Integrium nor any of its employees performing Service's, shall be employees of Sponsor, it being understood and agreed that Integrium is an independent contractor for all purposes and at all times. All matters of compensation and benefits and terms of employment for Integrium's employees shall be solely a matter between Integrium and its employees. Nothing contained herein shall be deemed or construed to create between the parties hereto a partnership or joint venture or employment relationship. No party shall have the authority to act on behalf of any other party, or to commit any other party in any manner or cause whatsoever or to use any other party's name in any way not expressly authorized by this Agreement. No party shall be liable for any act, omission, representation, obligation or debt of any other party, even if informed of such act, omission, representation, obligation or debt.

8.2 It is further understood that all Integrium services will be performed in accordance with Integrium's SOPs; *provided, however*, that in the event that the performance of such services according to such SOPs conflict with the terms of this Agreement, performance of such services shall follow the terms of this Agreement.

8.3 Integrium acknowledges and agrees that its employees are not eligible to participate in any benefits programs offered by Sponsor to its employees, or in any pension plans, profit sharing plans, insurance plans (including but not limited to, worker's compensation insurance), or any other employee benefit or perquisite plans offered from time to time by Sponsor to its employees or to receive Sponsor stock directly from Sponsor or its officers, directors, or employees.

8.4 Nothing contained in this Agreement shall be construed as making the parties joint venturers or as granting to either party the authority to bind or contract any obligations in the name of or on the account of the other party or to make any representations, guarantees or warranties on behalf of the other party except to the extent such authority is expressly provided in writing and agreed by the parties.

9. Tax Reporting and Payment

9.1 Integrium acknowledges and agrees that it shall be solely responsible for paying the appropriate amount of all federal, state and local taxes with respect to all compensation paid to Integrium pursuant to this Agreement, and that Sponsor shall have no responsibility whatsoever for withholding or paying any such taxes for or on behalf of Integrium.

9.2 Integrium further agrees to indemnify and hold Sponsor harmless from and against any and all damages, losses, expenses, or penalties arising from or in connection with any claim brought by any federal, state or local taxing authority with regard to Integrium's failure to pay required taxes or failure to file required forms with regard to compensation paid to Integrium by Sponsor pursuant to this Agreement.

10. Ownership, Disclosure and Transfer of Developments and Study Data

10.1 Sponsor acknowledges that Integrium possesses certain computer technical expertise, software and methodologies for administration of clinical trials, data collection, data management and statistical analyses methods which have been independently developed by Integrium without the benefit of any information provided by Sponsor. Sponsor and Integrium agree that any computer software programs, methodologies or other formulae or analyses or methodologies developed by Integrium in the administration and the conduct of clinical trials used by Integrium under or during the term of this Agreement are the product of Integrium's technical expertise possessed and developed by Integrium prior to the date of this Agreement and remain the sole property of Integrium and Sponsor agrees that such technology is commercially valuable to Integrium and Sponsor agrees not to disclose such technology to any other party without Integrium's prior written consent.

10.2 All written materials and other works which may be subject to copyright and all patentable and un-patentable inventions, discoveries, data, and ideas (including but not limited to any computer software) which are made, conceived or reduced to practice or written by Integrium or Integrium's employees or third party contractors authorized by Integrium pursuant to the terms hereof and which are based upon or arise from the Services performed by Integrium specifically for Sponsor ("**Developments**") shall become Sponsor's exclusive property, and may be used by Sponsor as Sponsor deems appropriate in its sole discretion without any obligation of any nature (including financial, reporting, accounting or otherwise) to Integrium. Integrium, by signing this Agreement, expressly agrees to Sponsor's ownership of all Developments, and represents and warrants that it has appropriate provisions in its agreements with third party contractors approved to provide services hereunder that would enable Integrium to meet the obligations set out in this Article 10.

10.3 Integrium agrees to hold all Developments in strict confidence in accordance with Article 6 of this Agreement.

10.4 Integrium shall disclose promptly to Sponsor each Development and, upon Sponsor's request and at Sponsor's expense, Integrium shall assist Sponsor, or its designees, in filing patent or copyright applications in any country in the world. Each copyrightable work, to the extent permitted by law, shall be considered a work made for hire and the authorship and copyright of the work shall be in Sponsor's name and, if not so considered, Integrium hereby assigns to Sponsor all of Integrium's rights, title, and interests in such works, and agrees to the waiver of all moral rights therein - to the extent that same may exist. Integrium shall execute or cause to be executed by the inventor(s) or a duly authorized agent of Integrium, as the case may be, all papers and do all things which may be necessary or advisable, in the opinion of Sponsor, to prosecute such applications and to vest in Sponsor, or its designee, all the right, title and interest in and to the Developments.

10.5 To avoid doubt, Integrium acknowledges and agrees that Sponsor and its licensors retain all right, title and interest in and to the Confidential Information**,** the Investigator's brochure, the Protocol, and all rights and information underlying and related to the Study drug, and that no license (whether express or implied) to any of the foregoing is granted to Integrium under this Agreement.

10.6 Upon the expiration or termination of this Agreement, Integrium shall transfer to Sponsor all Developments including any and all copies and/or derivatives hereof, made by Integrium (or Integrium employees) as well as any writings, drawings, specifications, manuals or other printed material made by Integrium (or Integrium employees or contractors), to the extent such Development is not already transferred prior to expiration or termination. Notwithstanding the reason for expiration or termination of this Agreement, Integrium shall under no circumstances be entitled to retain Confidential Information.

10.7 All data developed relating to the Study shall be the sole and exclusive property of Sponsor, and Sponsor may use all data relating to the Study for any lawful purpose, including but not limited to submission to the FDA or other regulatory agencies. All agreements with Investigators and/or Trial Sites shall provide for the foregoing rights of Sponsor.

10.8 Sponsor's authorised representative(s) and, to the extent permitted by law, regulatory authorities may, during regular business hours, arrange in advance with Integrium and/or the respective Principal Investigator(s) and/or Trial Site(s) to inspect all data and work products relating to the respective Study and to examine Integrium's facilities required for performance of this Agreement.

11. Relationship with Investigators and Third Party Contractors

11.1 If this Agreement requires Integrium to contract with investigators or investigative sites (collectively, "**Investigators**"), then any such contract shall be in a form mutually acceptable to Integrium and Sponsor. If an Investigator requests any material changes to such form effecting Sponsor's rights, Integrium shall submit the proposed change to Sponsor, and Sponsor shall promptly review, comment on and/or approve such proposed change(s). The parties acknowledge and agree that Investigators shall not be considered the employees, agents, or subcontractors of Integrium or Sponsor, and that Investigators shall exercise their own independent medical judgement. Integrium's responsibilities with respect to Investigators shall be limited to those responsibilities specifically set forth in this Agreement and any amendments hereto.

11.2 It is hereby agreed that Exhibit 3 (the "**Study Budget and Payment Schedule**") represents the entire consideration that will be paid by Sponsor to Integrium on behalf of the Study, and that the Sponsor will not pay directly or indirectly to any third party, including Investigators, and/or any other third party vendors (IRBs, labs, meeting planners, subcontracting CROs, IVRS, etc.), any amount that is not included in Exhibit 3. Sponsor acknowledges that Integrium shall not be responsible for any Study timeline delays as a result of site enrollment delays due to lack of payment or late payment from Sponsor. Integrium warrants that all up-front and advance payment or any monies made by Sponsor to Integrium will be allocated only to the Sponsor study specified on the invoice and will not be used for any other purposes. Integrium will provide Sponsor with a monthly pass-through reconciliation report indicating the status of these funds. Notwithstanding anything contained herein to the contrary, Sponsor agrees to indemnify and hold Integrium harmless for any and all claims from any sites and 3rd Party Vendors for unpaid invoices submitted to Sponsor.

11.3 Sponsor agrees that, although Integrium will assume responsibility for disbursing fees and/or expenses to Investigators, and Third Party Contractors, Integrium is not liable for payment to Investigators and Third Party Contractors until Sponsor has pre-paid Integrium in advance for these fees and expenses. Upon contract execution of this Agreement, Sponsor agrees to provide the start-up and vendor advance requirements in accordance with Exhibit 4, Payment Schedule.

11.4 Reserved

11.5 Sponsor acknowledges and agrees that Integrium will not be responsible for delays in a Study or Project to the extent that such delays are caused by Sponsor's failure to make adequate pre-payment for Investigators' services. Sponsor further acknowledges and agrees that payments for Investigator's/vendors' services are pass-through payments at actual costs to Third Party Contractors and are separate from payments for Integrium's Services. Sponsor agrees that it will not withhold Investigator payments except to the extent that it has reasonable questions about the services performed by a particular Investigator.

12. Indemnification

12.1 Sponsor hereby agrees to indemnify, defend, and hold Integrium, and its respective agents, servants, employees, officers, and directors ("**Integrium Indemnities**") harmless from and against any and all losses, costs, damages, expenses, claims, actions, liability, and/or suits (including court costs and reasonable attorney fees) ("**Liabilities**") suffered or incurred by Integrium or any of the foregoing as a result of personal injury to or death of a participant in any Study, and such personal injury or death arises from or is, by unappealable judgment or binding settlement between the parties, attributed to: (a) a claim of product liability or claim arising from the design, production, manufacture, or instructions for use of any Study Product; (b) a claim of strict liability in tort; (c) the design of the Study; and (d) Sponsor's negligence with respect to performance of its obligations under this Agreement; *provided, however*, that if a claim with respect to the matters set forth in this Section 12.1 hereof arises in whole or in part from Integrium's negligence or intentional misconduct or fraud, then the amount of Claim that Sponsor shall indemnify Integrium pursuant to this Section 12.1 shall be reduced by an amount in proportion to the percentage of Integrium's responsibilities for such Claim as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the parties. Under no circumstances shall Integrium be liable for any Third Party Contractor's (i) adherence to the Study Protocol, (ii) adherence to project specifications or the Study timeline, (iii) breach of contract, (iv) the negligence or willful misconduct, or (v) any infringement, misappropriation or violation by Third Party Contractors of any right of any other party.

12.2 Integrium hereby agrees to indemnify, defend, and hold Sponsor and its respective affiliates, employees, directors, agents, approved subcontractors and consultants ("**Sponsor Indemnitees**") harmless from and against any and all Liabilities suffered or incurred by and Sponsor Indemnitee arising out of (a) any Integrium Indemnitee's error, omission, gross negligence or willful misconduct, or (b) any breach of any covenant or warranty, or the inaccuracy of any representation of Integrium in this Agreement, or (c) Integrium's failure to comply with the terms of this Agreement.

12.3 Integrium Indemnitees agree: (a) to promptly notify Sponsor of any such Liability or Liabilities; (b) to cooperate fully in the handling of such Liability or Liabilities and, in the event of litigation, to attend hearings and trials and assist in securing and giving evidence, and obtaining the attendance of necessary and proper witnesses, and (c) to Sponsor's control of the defense and settlement, with Integrium's consent which shall not be unreasonably withheld, of all Liability or Liabilities by Sponsor. Sponsor will reimburse Integrium for all reasonable expenses incurred at Sponsor's request in connection with this Section 12.2 (b) except to the extent and in the proportion that Integrium is responsible under 12.1 Sponsor shall carry out the management and defense of such claims or suits at their own expense.

12.4 In the event that a patient participating in a Study suffers an illness or injury that the Investigator(s) and Sponsor determine to be directly associated with Study participation, and for which Sponsor would be obligated to indemnify Integrium under section 12.1, then – provided such illness or injury is not excluded by Sponsor's insurance policy -Sponsor shall pay all medical and hospital expenses directly associated with the medical treatment of such adverse reaction which are in excess of that portion covered by the patient's own insurance. In the event diagnostic procedures are required to determine the etiology of the patient's symptoms, Sponsor shall pay the reasonable expense of such diagnostic workup without regard to the final diagnosis, but up to the amount covered by the Sponsor's insurance policy and in accordance with its terms.

13. Limitation of Liability; Damages

13.1 Except in the case of gross negligence, willful misconduct, fraud or non-adherence to the Protocol, neither Integrium, nor its affiliates, nor any of its or their respective directors, officers, employees or agents shall have any liability of any type (including, but not limited, to contract, negligence, and tort liability), for any special, incidental, indirect or consequential damages, including, but not limited to the loss of opportunity, loss of use, or loss of revenue or profit, in connection with or arising out of this Agreement, or any service order, even if such damages may have been foreseeable to Integrium. In addition, except in the case of gross negligence, willful misconduct, fraud or non-adherence to the Protocol, in no event shall the collective, aggregate liability (including, but not limited to, contract, negligence and tort liability) of Integrium and its affiliates and its and their respective directors, officers, employees and agents under this Agreement or any service order hereunder exceed the CRO Service Fees Grand Total amount set out in the Study Budget.

13.2 **For Failure to Perform.** In the event that the Services provided hereunder (or any portion thereof) do not meet the specifications or other performance criteria agreed to by Integrium and Sponsor in writing, then Integrium will, at Sponsor's option, promptly (i) re-perform such Services at Integrium's cost, or (ii) refund to Sponsor all amounts paid by Sponsor to Integrium in connection with such Services.

13.3 Except in the case of gross negligence, willful misconduct or fraud, neither Sponsor, nor its affiliates, nor any of its or their respective directors, officers, employees or agents shall have any liability of any type (including, but not limited, to contract, negligence, and tort liability), for any special, incidental, indirect or consequential damages, including, but not limited to the loss of opportunity, loss of use, or loss of revenue or profit, in connection with or arising out of this Agreement, or any service order, even if such damages may have been foreseeable to Sponsor.

14. Insurance

14.1 Each party will maintain, for the duration of this Agreement, insurance in an amount reasonably adequate to cover its obligations under this Agreement and any and all Service Orders then in effect, and, upon request, each party will provide to the other party a certificate of insurance showing that such insurance is in place.

14.2 Sponsor will supply Integrium with the Clinical Trial Insurance Certificate for each Study covered under a Service Order prior to commencement of subject screening for each Service Order. Integrium will not be responsible for enrollment delays due to Sponsor's delay in providing said Certificate.

15. Termination

15.1 In the event that a party hereto shall commit a material breach of this Agreement, the other party hereto shall have the right to terminate this Agreement immediately unless the breaching party can cure its breach and provide full performance within thirty (30) days of notice to it that a material breach has been declared. Upon termination of this Agreement, the non-breaching party shall have no further obligation to the breaching party, other than for Sponsor to pay for Services performed by Integrium as of the date of such termination and any rights and duties which the parties expressly stated herein as surviving termination.

15.2 Sponsor may terminate this Agreement at any time by giving Integrium thirty (30) days written notice of such termination. If Sponsor should terminate pursuant to this Article 15.2, Sponsor will pay for all Service units performed up to the point of termination in accordance with the Budget, as well as costs reasonably incurred for the Services and which Integrium is unable to cancel (for the avoidance of doubt, Sponsor shall be responsible for any and all 3rd Party Vendor cancellation fees due upon Study cancellation), and all administrative costs incurred in the conduct of this Agreement up to the point of termination for those Services which are necessary to be performed for patient safety, government requirement compliance and/or expressly requested by Sponsor; *provided, however*, that no amounts shall be required to be paid which are in excess of the corresponding amounts set forth for such activities in this Agreement. Integrium shall use its best efforts to minimize the costs incurred following its receipt of notice of such termination.

15.3 Either party may terminate this Agreement upon receipt of written notice to the other party and regard the other party as in breach of this Agreement, if the other party becomes insolvent, makes a general assignment for the benefit of creditors, files a voluntary petition of bankruptcy, suffers or permits the appointment of a voluntary petition of bankruptcy, suffers or permits the appointment of a receiver for its business or assets, or becomes subject to any proceeding under any bankruptcy or insolvency law, whether domestic or foreign, or has wound up or liquidated, voluntary or otherwise. In the event that any of the above events occur, that party shall immediately notify the other, in writing, of its occurrence.

15.4 Upon receipt of notice of termination of this Agreement by either party: (i) Integrium will, as soon as reasonably practicable discontinue providing the applicable Services, except to the extent reasonably required to safely close out a Study or to transfer the remaining Services to another Service Provider selected by Sponsor, and (ii) Integrium will terminate or, if requested by Sponsor, assign existing 3rd Party obligations to the extent cancelable or assignable, as applicable. Any amounts paid by Sponsor which exceed the amounts owed to Integrium as of expiration or termination of this Agreement shall be refunded to Sponsor within thirty (30) days after expiration or termination. Any amounts owed by Sponsor, including 3rd Party Vendor cancellation fees, shall be paid to Integrium within thirty (30) days after expiration or termination.

16. Personnel Recruitment

16.1 Neither Sponsor nor Integrium will solicit or make offers of employment to or enter into consultant relationships with employees or consultants of the other party if such person was involved, directly or indirectly, in the performance of this Agreement, at any time during the term of this Agreement; *provided, however*, that nothing contained herein will prevent a party from hiring any such employee or consultant who responds to a general hiring program conducted in the ordinary course of business or who approaches such party on a wholly unsolicited basis.

17. Reserved

18. Miscellaneous Provision

18.1 Assignment. This Agreement may not be assigned by either party without the prior written consent of the other party, except that either of the parties may assign this Agreement to a successor in connection with the merger, consolidation or sale of all or substantially all of its assets. No assignment whether consensual or permissive shall relieve either party of its responsibility for performance of its obligations under this Agreement.

18.2 Complete Agreement. This Agreement, together with its exhibits and Change Orders then in effect, supersedes all prior Agreements and understandings between the parties related to the subject matter of this Agreement.

18.3 Waiver. No waiver by Sponsor with respect to any breach or default or of any right or remedy, and no course of dealing by Sponsor shall be deemed to constitute a continuing waiver of any other breach or default or of any other right or remedy, unless such waiver be expressed in writing, signed by Sponsor. No payment made by Sponsor shall be considered as acceptance of satisfactory performance of the Services, or as in any way relieving Integrium from its full responsibility pursuant to this Agreement.

18.4 Amendment. This Agreement may not be altered, changed or amended except in writing signed by each of the parties hereto.

18.5 Survival. The provisions of this Agreement dealing with confidentiality, independent contractor, ownership of developments, indemnification, limitations of liability, termination, governing law and survival shall survive the expiration and/or termination of this Agreement.

18.6 Severability. In the event that any provision of this Agreement is held illegal or invalid for any reason, such provision shall not affect the remaining parts of this Agreement, but this Agreement shall be construed and enforced as if that illegal and invalid provision had never been inserted herein.

18.7 Extraordinary Relief. In the event of the actual or threatened breach by Integrium of any of the terms of the Articles 6, 7, and 11 hereof, Sponsor shall have the right to specific performance and injunctive relief. The remedies in this paragraph are in addition to all other remedies and rights available at law or in equity.

18.8 Force Majeure. Performance of this Agreement by each party shall be pursued with due diligence in all requirements hereof; however, neither party shall be liable for any loss or damage for delay or nonperformance due to causes not reasonably within its control. In the event of any delay resulting from such causes, the time for performance and payment hereunder shall be extended for a period of time necessary to overcome the effect of such delays. In the event of any delay or nonperformance caused by such uncontrollable forces, the party affected shall promptly notify the other in writing of the nature, cause, date of commencement thereof, and the anticipated extent of such delay, and shall indicate whether it is anticipated that the completion date of the Agreement would be affected thereby.

18.9 Captions and Headings. The captions, numbering and headings in this Agreement are for convenience and reference only, and they shall in no way be held to explain, modify, or construe the meaning of the terms of this Agreement.

18.10 Counterpart Originals. This Agreement may be executed in any number of counterparts, each of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document.

18.11 Governing Law. It is understood and agreed that this Agreement shall be governed by the laws of the State of Delaware in all respects of validity, construction and performance without regard to its conflict of laws rules.

18.12 Arbitration. Any controversy or claim arising out of or relating to this Agreement, or the breach thereof, may be submitted to binding arbitration under the auspices of, and in accordance with, the then existing rules of JAMS, in a forum selected by the party to whom a request for arbitration is directed. Notwithstanding the foregoing, either party may seek injunctive or equitable relief from any court of competent jurisdiction.

18.13 Notices. Except as otherwise provided, all communications and notices concerning payments required under this Agreement shall be mailed by certified mail, return receipt requested postage prepaid, or sent by Federal Express or telecopy to the addresses set forth below, or to such other addresses as the parties from time to time specify in writing.

If to Integrium for contractual matters:
Integrium, LLC
100 East Hanover Ave., Suite 401
Cedar Knolls, NJ 07927
Attn: Jessica Coutu, Sr. VP Clinical Operations

If to Integrium for financial matters:
Integrium, LLC
100 East Hanover Ave., Suite 401
Cedar Knolls, NJ 07927
Attn: Ewa Olesiak-Deptuch, Sr. VP Finance & Accounting

If to Sponsor: Oramed Ltd.
Hi-Tech Park 2/5 Givat-Ram
P.O. Box 39098
Jerusalem 91390, Israel
Attn: Dr. Miram Kidron

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IN WITNESS WHEREOF, the parties hereto have executed, or have caused their duly authorized representatives to execute, this Agreement as of its initial effective date.

For and on behalf of **Integrium, LLC**	For and on behalf of **Oramed Ltd.**	
/s/ Jessica Coutu	/s/ Nadav Kidron	/s/ Joshua Hexter
By: Jessica Coutu Title: Sr. Vice President, Clinical Operations Date: January 23, 2018	By: Nadav Kidron Title: CEO January 23, 2018	Joshua Hexter COO

Integrium/ Oramed

Exhibit 1

Protocol Number: ORA-D-015
Version: Original 1.0
Date: 27 October 2017

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Integrium/ Oramed

Exhibit 2

Study Specifications

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Project Identifiers	
Sponsor Company	Oramed Ltd.
Protocol Number	ORA-D-015
Protocol Title	A Placebo-controlled, Multi-center, Randomized, Phase 2b Study to Evaluate the Efficacy and Safety of ORMD-0801 in Type 2 Diabetes Mellitus Patients with Inadequate Glycemic Control on Oral Therapy
Investigational Product(s)	ORMD-0801
Indication	Type 2 Diabetes Mellitus
Therapeutic Area	Metabolic
Study Phase	III
Sponsor Country	Israel
Country Locations	US
Study Assumptions	
Subjects	
# Subjects Screened	445
% Screen Failure Rate	40%
# Screen Failures	178
# Subjects Entering Run-In Phase	267
% Run-In Failure Rate	10%
# Run-In Failures	27
# Subjects Entering Treatment Phase	240
% Early Termination Rate	12%
# Early Terminations	29
# Subjects Complete	211
Sites	
# Sites Identified	40
Total Sites	40
# Central IRB Sites	40
# Local IRB Sites	0
Enrollment	
# Screened/site	11.13
# Screened/site/week	0.43
# Enrolled/site	6.68
# Enrollment Rate (per site/per month)	1.12
# Randomized/site	6.00
# Randomization Rate (per site/ month)	1.01
Third Party Vendors	
Meeting Planner	1
Central IRB	1
Central Lab	1
CGM Monitors/Supply Vendor	1 - Contracted by Sponsor

Centralized CGM Reader Vendor	1 - Contracted by Sponsor	
eDiary/Glucometer Vendor	1 - Contracted by Sponsor	
Product Packaging & Distribution	1 - Contracted by Sponsor	
IWRS	1 – Contracted by Sponsor	
Project Meetings	# Meetings	Assumptions
Investigator/CRA Training Meeting	1	Assumes 1-day Investigators' Webex, a 0.5 day CRA/EDC training meeting at the same venue
Launch Meeting	1	Assumes 6-hour launch Meeting
Sponsor Team Teleconferences	39	Assumes calls will be every other week for the duration of the study
Internal Team Teleconferences	6	Monthly for the first six months
CRA Teleconferences	12	Assumes monthly from FPFV to Database Lock
Monitoring Assumptions		
# CRAs	6	
# Pre-Study Selection Visits	40	
# Initiation Visits	8	
	For sites where PI and Study Coordinator do not attend Invest. Meeting	
# Interim Monitoring Visits Monitoring Interval (Maximum - weeks)	Assumed every 6-8 weeks dependent upon enrollment	
# Interim Monitoring Visits/site	7.5	
# Additional Days on-site/site	4	
# 1-day Interim Monitoring Visits	300	
# Additional Days	160	
# Close-out Visits	40	
Safety Assumptions		
SAE rate (%)	5%	
Estimated # SAEs	13	
Estimated # Expedited SAEs	0	
Data Management		
CRF pgs per randomized patient	106	
Unique CRFs/Subject	22	
Non-Unique CRFs/Subject	84	
CRF pgs per early term	80	
CRF pgs per screen failure	27	
Total CRF Pages	31652	
Complete subjects	22366	
Early Terms	4480	
Screen Failures	4806	
Total DM Datasets	23	
Total Edit Checks	440	

Estimated # Total Queries	6330
Estimated # Queries/Patient (1/5 pages)	23.71
Manual Coding	
# Medical History/Subject	5
# ConMeds/Subject	3
# AEs/Subject	2
Data Transfers	
# Sponsor Transfers	2 test, final
# Lab Transfers	18 test, monthly, final
# PK Transfers	N/A
# Electronic Diary Lab Transfers	7 test, quarterly, final
# Central CGM Reader Transfers	7 test, quarterly, final
# IWRS Transfers	No charge, integrated with EDC
Statistical Analysis	The following assumptions are estimates. The total number of TLGs will be defined upon the finalization of the Statistical Analysis Plan. An amendment to the budget will be issued at that time, if applicable.
# SAS Datasets	10
Estimated Tables	
# Standard and Non-Standard Repeat	80
# Non-Standard Unique	20
Estimated Listings	
# Standard and Non-Standard Repeat	30
# Non-Standard Unique	10
Estimated Graphs	
# Standard and Non-Standard Repeat	20
# Non-Standard Unique	12
Exploratory Output	
# Exploratory Tables	20
# Exploratory Listings	20
# Exploratory Graphs	0
pK Parameters	0
Post-hoc Analysis	120
EDC - DSG	
Number of Screens	
Unique Screens	22
Redundant Screens	84
Site Patient Activity Duration (Months)	4.4
Enrollment Duration (Months)	6

Server Activity Duration (Months)	15
Usage Fee/Help Desk Fees	
Product Usage Fee/Month	$2,500
Integrium Archiving Pricing	
CD/DVD per site	$100
Clinical Study Report	**The budget is based on one draft and one final version of the CSR, assuming there will be no hyperlinking. If hyperlinking and/or additional versions of the CSR are requested, they will be provided at the study hourly rate for the actual additional hours.**

Project Timeline

Project Activity	Date	Month #	Week #
Study Start Date	November 1, 2017	0.0	0.0
Final Protocol Date	November 22, 2017	0.7	3.0
First Patient enrolled at OCRC	December 18, 2017		
EDC Set-Up Complete	January 24, 2018	2.8	12.0
Investigators' Meeting	January 26, 2018		
First Patient Screened For Other Sites	January 29, 2018	2.9	12.7
First Patient Enter Run-In Period	February 19, 2018	3.6	15.7
First Patient Enter Part 1 Titration	March 5, 2018	4.1	17.7
First Patient Enter Part 2 Maintenance	March 19, 2018	4.5	19.7
First Patient Last Visit	June 11, 2018	7.3	31.7
Last Patient Screened	July 29, 2018	8.9	38.6
Last Patient Enter Run-In Period	August 19, 2018	9.6	41.6
Last Patient Enter Part 1	September 2, 2018	10.0	43.6
Last Patient Enter Part 2	September 16, 2018	10.5	45.6
Last Patient Last Visit	December 9, 2018	13.3	57.6
Last IMV	January 6, 2019	14.2	61.6
Database Lock	February 3, 2019	15.1	65.6
Draft Final TLGs	February 10, 2019	15.3	66.6
Final TLGs	February 24, 2019	15.8	68.6
Draft CSR	March 24, 2019	16.7	72.6
Final CSR	April 21, 2019	17.6	76.6
CRO End Date	May 1, 2019	18.0	78.0
Total Project Duration (Months)	18.0		

	Months	**Weeks**	**Phase**
Start-up	2.9	12.7	I
Enrollment	6.0	25.9	II
Treatment	4.4	19.0	III
LPLV-DBL	1.8	8.0	IV
DBL-CRO End	2.9	12.4	V
	18.0	78.0	

Integrium/Oramed

EXHIBIT 3

Study Budget

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Study Budget

	STUDY START-UP	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
1	Project Management (Start Up)	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	2.9	Month	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
2	Develop/Finalize Project Management Plan		1	Plan	
3	Project Launch Webcast Meeting/Training		1	Meeting	
41	Study Materials Management		40	Site	
42	Source Documentation Development		1	Total	
43	Site Identification		40	Site	
44	Pre-study Site Evaluation Visit		40	Visit	
45	Develop/Finalize CRA Monitoring Plan		1	Plan	
46	Study Manual/Quality Plan		1	Total	
47	Data Management Plan ("DMP")		1	Total	
48	Regulatory Document Collection - Start Up		40	Site	
49	Investigator Budget/Contract Negotiations		40	Site	
50	Investigator Meeting and Preparation		1	Meeting	
51	Clinical System Set-Up Configuration & Maintenance		40	Total	
52	Generate Randomization Codes		1	Randomization	
	STUDY START-UP FEES TOTAL				**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
	EDC STUDY START-UP	***UNIT COST***	***UNITS***	***MEASURE OF UNIT***	***TOTAL***
17	eCRF Development	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	1	Total	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
18	eCRF Completion Instructions		1	Total	
19	Edits Specifications and Programming		1	Total	
20	Validate/Test Data Entry Screens (UAT)		1	Total	
21	Annotate CRF		1	Total	
22	Clinical Database Development-SDTM Dataset Creation/Documentation		1	Total	
23	Platform Study Set-up Fee		1	Total	
24	Database Design and Validation Specifications		1	Database	
25	EDC Kick-Off Meeting		1	Meeting	
26	Set-up Standard Data Entry Screens		1	Total	
27	Training Session		1	Study	
28	Project Manage all aspects of EDC start-up		1	Start-up	
29	Create Enrollment Screen		1	Total	
30	Integrating EDC System with IWRS System		1	Total	
31	Data Export Programming		23	Dataset	
32	Create Custom Reports		1	Report	
33	Register users and maintain passwords for life of study (per user (4 per site + 6 for sponsor))		166	Per User	
	EDC START-UP FEES TOTAL				**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**

	CLINICAL MONITORING	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
34	Project Management (enrollment phase)	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	6.0	Month	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
35	Project Management (treatment phase)		4.4	Month	
36	Project Management Study (LPLV to DBL)		1.8	Month	
37	Project Management Study (DBL to CRO end)		2.9	Month	
38	Sponsor Team Teleconferences		39	Telecon	
39	Internal Team Teleconferences		6	Telecon	
40	CRA Teleconferences		12	Telecon	
41	Trial Master File		41	Site	
42	Regulatory Document Maintenance		527	Month	
43	Site Initiation Visits		8	Site	
44	Site Management/Patient Review/Query Resolution		520	Site*Month	
45	Interim Monitoring Visits - One Day		300	Visit	
46	Interim Monitoring Visits - Additional Day On-site		160	Day	
47	Close-out Visits		40	Visit	
48	Site Grant Administration		10	Month	
	CLINICAL MONITORING/LOGISTICS SERVICES SUBTOTAL				**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
	MEDICAL/SAE MANAGEMENT	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
49	Medical Management	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	12	Month	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
50	Create Safety Plan		1	Plan	
51	Review Protocol Deviation Log		12	Month	
52	Tracking Protocol Waivers		12	Month	
53	Lab Alert/Patient Review		12	Month	
54	Review of AE Data Listings on a Monthly basis		12	Month	
55	Create Safety Database		1	Database	
62	SAE Management		13	SAE	
	MEDICAL/SAE MANAGEMENT SERVICES SUBTOTAL				**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**

	DATA MANAGEMENT	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
56	Data Entry Activities	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	31,652	CRF Pg	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
57	Generate/Track/Resolve Queries		6,330	Query	
58	Data Cleaning/Manual Listing Review		267	Patient	
59	Import Other Data		25	Transfer	
60	Export Data to Sponsor		2	Transfer	
61	Manual Coding		2,670	Manual Code	
63	Archive Study Records, Database		1	Database	
64	Data Base Lock Activities		1	Total	
	DATA MANAGEMENT FEES SUBTOTAL				**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
	EDC SYSTEM MAINTAINANCE	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
65	Coding System (Set-up Cost) [WHO/MEDRA]	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	1	Access User	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
66	Third Party Data Integrations		32	Transfer	
67	SAS Platform (months)		18	Month	
68	Help Desk Support		12	Month	
	EDC SYSTEM MAINTAINANCE	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
69	Ongoing Support Project Management	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	15	Month	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
70	CRF Export Programming (Site Archives, eCRFs for Submission)		1	Total	
71	Provide End of Study Archives to All Sites and 2 Copies to Sponsor		1	Total	
	EDC SYSTEM SET-UP AND MAINTAINANCE SUBTOTAL				**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**

	BIOSTATISTICAL ANALYSIS	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
72	Draft & Final Statistical Analysis Plan (SAP)	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	1	SAP	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
73	Analysis DataSets		10	Dataset	
74	Create/Document ADaM (Submission Ready) Datasets		10	Dataset	
75	Statistical Programming Deliverables (TLGs)		172	T/L/G	
76	Generate/QC TLFs		182	Appendix	
77	Output Review/Dry Runs		3	Dry Run	
78	Post-hoc Analysis Hours		120	Hour	
	BIOSTATISTICAL ANALYSIS SUBTOTAL				**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
	MEDICAL WRITING	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
79	Finalize Protocol	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	1	Protocol	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
80	Develop/Finalize ICF		1	Total	
81	Final CSR		1	Total	
	MEDICAL WRITNG SUBTOTAL				**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
	CRO SERVICE FEES GRAND TOTAL				

	PASS THROUGH COSTS	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
1	Pre-study Site Evaluation Visit	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	40	Visit	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
2	Site Initiation Visit		8	Visit	
3a	Interim Monitoring Visits - One Day		300	Visit	
3b	Interim Monitoring Visits - Additional Day On-site		160	Day	
4	Close-out Visits		40	Visit	
5	Investigators' Meeting Planner		1	Meeting	
6	Investigator Grants				
6a	# Patients Completed		211	Patient	
6b	# Screen Failures		178	Patient	
6c	# Run-In Failures		27	Patient	
6d	# Early Terminations		29	Patient	
6e	# Rescue Visits		1	Visit	
6f	# Unscheduled visits		1	Visit	
7	Site: Advertising/Patient Recruitment		40	Site	
8	Site: Archive Fees		40	Site	
9	Site: Start-up Costs		40	Site	
10	Site: Estimated Rescue Meds		40	Site	
11	Site: Regulatory Fee		1	Site	
12	Site: Pharmacy Fee		1	Total	
13	Central Laboratory Fees		1	Total	
14	IWRS Fees		1	Total	
15a	Central IRB - Protocol & Advertising Submission		1	Protocol	
15b	Central IRB - Site Submissions		40	Protocol	
16	Mixed Meal Tolerance Test Supplies: Ensure		40	Site	
17a	EDC Platform Product Usage		15	Total	
17b	EDC Coding System Integration Fee [WHO/MEDRA]		1	Total	
18	End of study archive CDs to sites; 2 copies to Sponsor		42	Total	
19	Launch Binders		41	Binder	
20	Regulatory Binders		40	Binder	
21	Copying/ Printing		1	Total	
22	Postal & Shipping Fees		1	Total	
23	Sponsor/Internal - Teleconferences		1	Total	
	PASS-THROUGH COSTS TOTAL				**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
	PROJECT'S OVER-ALL TOTAL COST				**$ 7,030,303.09**

Pass Through Advance Payment Schedule

	Contract Execution	Feb-18	TBD	Study Total
Investigators' Meeting Planner: 40% invoiced start-up payment 40% payment 1 month prior to meeting 20% paid upon final reconciliation	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**
Site Start-up Costs: **[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**/site x 30 sites				
Site Grant Payments: Advance Payment = **[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**/site X 30 sites				
Central Lab Vendor: Start-up payment				
Pass-Through Advance Payment				

Exhibit 4
Study Payment Schedule

Monthly Management Fees	Month	$ Amount	Verification of Milestone Completion/Deliverables
Project Management Fees	**November 2017**	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	Invoiced Monthly
Project Management Fees	**December 2017**		Invoiced Monthly
Project Management Fees	**January 2018**		Invoiced Monthly
Project Management Fees	**February 2018**		Invoiced Monthly
Project Management Fees	**March 2018**		Invoiced Monthly
Project Management Fees	**April 2018**		Invoiced Monthly
Project Management Fees	**May 2018**		Invoiced Monthly
Project Management Fees	**June 2018**		Invoiced Monthly
Project Management Fees	**July 2018**		Invoiced Monthly
Project Management Fees	**August 2018**		Invoiced Monthly
Project Management Fees	**September 2018**		Invoiced Monthly
Project Management Fees	**October 2018**		Invoiced Monthly
Project Management Fees	**November 2018**		Invoiced Monthly
Project Management Fees	**December 2018**		Invoiced Monthly
Project Management Fees	**January 2019**		Invoiced Monthly
Project Management Fees	**February 2019**		Invoiced Monthly
Project Management Fees	**March 2019**		Invoiced Monthly
Project Management Fees	**April 2019**		Invoiced Monthly
Project Management Fees	**May 2019**		Invoiced Monthly
	Total Monthly Management Fees:		

Monthly Service Fees	Date	% Total Service Budget	% Milestone Service Budget	$ Amount	Verification of Milestone Completion/Deliverables
Contract Execution	12/1/2017	**6.88%**	**10.48%**	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	Contract Execution
1 Subject Entered	12/27/2017	**3.04%**	**6.07%**		Enrollment log
25% Subjects Randomized	2/10/2018	**4.05%**	**8.10%**		Enrollment log
50% Subjects Randomized	3/27/2018	**4.05%**	**8.10%**		Enrollment log
75% Subjects Randomized	5/11/2018	**4.05%**	**8.10%**		Enrollment log
100% Subjects Randomized	7/29/2018	**4.05%**	**8.10%**		Enrollment log
1st Subject Last Visit	4/30/2018	**3.04%**	**6.07%**		Enrollment log
25% Subjects Last Visit	6/23/2018	**3.04%**	**6.07%**		Enrollment log
50% Subjects Last Visit	8/7/2018	**3.04%**	**6.07%**		Enrollment log
75% Subjects Last Visit	9/21/2018	**3.04%**	**6.07%**		Enrollment log
100% Subjects Last Visit	12/9/2018	**3.04%**	**6.07%**		Enrollment log
Database Lock	2/3/2019	**6.07%**	**12.15%**		Database Lock
Draft Final TLGs	2/24/2019	**2.63%**	**5.26%**		Draft Final TLGs
Total Milestone Based Services:		**50.00%**	**100.00%**		

Unit Based Payments: Actual Units Invoiced Monthly	% Total Services Budget	# Units	Unit Cost	$ Amount	Verification of Milestone Completion/Deliverables
SAE Management	**0.79%**	13	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	Invoiced monthly as occurred
			Total Unit Based Services:		
			Total Services:		

Pass-through expenses	**$ Amount**	**Verification of Milestone Completion/Deliverables**
Monitoring Visit Travel Expenses	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	Invoiced as Actuals Monthly
Investigator Grants		Invoiced and Paid in Advance of Payment to Vendor
Site Start-up Costs		Invoiced and Paid in Advance of Payment to Sites
Site Advertising		Invoiced as Actuals Monthly
Site Archiving Fees		Invoiced as Actuals Monthly
IRB Fees		Invoiced as Actuals Monthly
Meeting Planner	**[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**	Invoiced and Paid in Advance of Payment to Vendor
Central Lab Vendor		Invoiced and Paid in Advance of Payment to Vendor
EDC Platform Usage Fees		Invoiced as Actuals Monthly
Copying/Printing/Supplies		Invoiced as Actuals Monthly
Postal & Shipping Fees		Invoiced as Actuals Monthly
Sponsor/Internal - Teleconference System		Invoiced as Actuals Monthly
Total Pass-through Budget:		

Grand Total Budget:	**$7,030,303.09**

Any changes to the timeline and/or budget will result in an amendment to the contract and payment schedule.

EXHIBIT 5

Transfer of Regulatory Obligations

TRANSFER OF US FDA REGULATORY OBLIGATIONS FOR INVESTIGATIONAL PHARMACEUTICAL AND BIOLOGIC PRODUCTS UNDER AN INVESTIGATIONAL NEW DRUG (IND) APPLICATION (21 CFR 312.52 and ICH E6)

Study Drug: ORMD-0801
IND #:
Protocol Title: A Placebo-controlled, Multi-center, Randomized, Phase 2b Study to Evaluate the Efficacy and Safety of ORMD-0801 in Type 2 Diabetes Mellitus Patients with Inadequate Glycemic Control on Oral Therapy.

Pursuant to 21 CFR 312.52 and ICH E6, the following obligation(s) of the Sponsor, Oramed Ltd. have been transferred to:

CRO Name: Integrium, LLC
CRO Address: 14351 Myford Road
Tustin, CA 92780

Responsibility	Reference	Obligation Assigned to:[1]		
		Integrium	**Oramed**	**Third Party Vendor**
A. 1. Preparation of all or part of an IND application	312.23 21CFR	N/A	N/A	N/A
2. Submission of IND application to FDA, submit all Amendments to FDA		☐	☒	☐
B. Maintain an IND with the following amendments, as necessary:				
1. Preparation of Protocol amendments (includes new protocols, changes in protocols, adding new investigators)	312.30 21CFR	☐	☒	☐
2. Preparation of Chemistry, Manufacturing, and Control amendments	312.31 21CFR	☐	☒	☐
3. Preparation of Pharmacology and Toxicology amendments	312.31 21CFR	☐	☒	☐
4. Preparation of Clinical amendments	312.31 21CFR	☐	☒	☐
5. Safety Reports	312.32 21CFR			
(a) Preparation of initial report		☒	☐	☐
(b) Preparation of follow-up reports		☒	☐	☐
(c) Notifications to FDA (phone/fax or written)		☐	☐	☒
(d) Notifications to investigators		☒	☐	☐
6. Preparation of Annual Reports	312.33 21CFR	☐	☐	☒
7. Preparation of response to request for information or clinical hold	312.41, 312.42 CFR	☐	☒	☐
8. Preparation of letter to withdraw an IND	312.38 CFR	☐	☒	☐

Responsibility	Reference	Obligation Assigned to:[1]		
		Integrium	**Oramed**	**Third Party Vendor**
C. Preparation and Update Investigative Brochure	21 CFR 312.55 (a) ICH E6 5.12, 7.3	☐	☒	
D. Selecting investigators and monitors	21 CFR 312.53	☒	☒	☐
1. Select qualified investigators	21 CFR 312.53 (a);	☒	☒	☐
(a) Identify qualified investigators/sites	ICH E6 5.6.1	☒	☒	☐
(b) Approve investigators/sites for participation				
2. Control of drug				
(a) Obtain required information from investigator (including signed Form FDA 1572, CV)	21 CFR 312.53 (c); ICH E6 5.14.2, 8.2	☒	☐	☐
(b) Approved investigators for receipt of drug shipment	21 CFR 312.53 (b); ICH E6 5.14.2	☒	☐	☐
(c) Ship drug to approved investigators	21 CFR 312.53 (b); ICH E6 5.14.1, 5.14.4(a)	☒	☐	☒
(d) Maintain shipment records	21 CFR 312.57 (a); ICH E6 5.14.4(b)	☒	☐	☒
3. Provide qualified monitors	21 CFR 312.53 (d); ICH E6 5.18.2	☒	☐	☐
4. Informing investigators				
(a) Review with investigators their regulatory responsibilities	Guideline for the Monitoring of Clinical Investigations; ICH E6 5.18.4 (f)(g)	☒	☐	☐
(b) Deliver investigator's brochure	21 CFR 312.55 (a); ICH E6 5.6.2	☒	☐	☐
(c) Inform participating investigators of new safety information about the study drug	21 CFR 312.55 (b); ICH E6 5.16.2	☒	☐	☐
(d) Notify participating investigators of all serious unexpected adverse drug reactions	21 CFR 312.32 (c); ICH E6 5.17.1	☒	☐	☐
E. Review of ongoing investigations				
1. Monitoring the investigation	21 CFR 312.56 21 CFR 312.56 (a); ICH E6 5.18.4	☒	☐	☐
2. Discontinue investigator participation if not compliant	21 CFR 312.56 (b);	☒	☒	☐
(a) Notify FDA	ICH E6 5.20	☒	☐	☐
(b) Assure disposal or return of investigational drug		☒	☐	☐
3. Provide medical expertise to evaluate safety information	21 CFR 312.56 (c); ICH E6 5.16.1	☒	☐	☐
4. Upon premature termination or suspension of a trial:	21 CFR 312.56 (d);			
(a) Notify IRBs or notify investigators of their responsibility to notify IRBs	ICH E6 5.21	☒	☐	☐
(b) Notify investigators		☒	☐	☐
(c) Assure disposition of drug from sites to sponsor		☒	☐	☐
(d) Notify FDA		☐	☐	☒

Responsibility	Reference	Obligation Assigned to:[1]		
		Integrium	**Oramed**	**Third Party Vendor**
F. Trial Data Handling and Reporting				
(a) Manage an independent date safety monitoring committee	ICH E6 5.5.2	NA	NA	NA
(b) Data Management	ICH E6 5.5.1	☒	☐	☐
(c) Statistical plan and/or analysis	ICH E6 5.5.1	☒	☐	☐
(d) Final study report	ICH E6 5.5.1	☒	☒	☐
G. Recordkeeping and record retention	21 CFR 312.57			
1. Maintain sponsor records and reports, other than shipment records (see C.2.d), during the course of the investigation	21 CFR 312.57 (b), 312.58 (a); ICH E6 5.5.6, 5.5.7, 8	☒	☐	☐
2. Archive sponsor records and reports according to applicable regulatory requirements.	21 CFR 312.57 (a)(b)(c), 312.58 (a); ICH E6 5.5.8, 5.5.11, 8	☐	☒	☐
3. Retain reserve samples of the test articles and reference standards used in bioequivalence or bioavailability studies	21 CFR 312.57 (d); ICH E6 5.14.5(b)	☐	☒	☐
H. Disposition of unused supply of investigational drug				
1. Assure return of drug from site to sponsor	21 CFR 312.59; ICH	☒	☐	☒
2. Conduct final disposition or destruction of drug	E6 5.14.4 (c)(d), 5.18.4 (c)(iv)(v)	☐	☐	☒
I. Application for FDA approval to export investigational drug	21 CFR 312.110; ICH			
(a) Content	E6 5.14.2	☐	☒	☐
(b) Format		☐	☒	☐
J. Obtain investigator financial disclosure information	21 CFR 312.53 (c)(4)			
1. Initial collection prior to study participation		☒	☐	☐
2. Responsibility for the one year follow-up financial disclosure collection shall remain with the Sponsor (one year following the completion of the study)		☐	☒	☐

1 If responsibility for an item is shared between Oramed and Integrium, both boxes will be checked.

According to 21 CFR 312.52(b), "A contract research organization that assumes any obligation of a sponsor shall comply with the specific regulations in this chapter applicable to this obligation and shall be subject to the same regulatory action as a sponsor for failure to comply with any obligation assumed under these regulations." The assignment of responsibility does not preclude either the sponsor or the CRO from participating in the requirements of the CFR.

Oramed Ltd.

	/s/ Miriam Kidron	**14-Feb-2018**
	Name:	**Date**
	Title:	

Integrium LLC.

	/s/ Jessica Coutu	**23-JAN-2018**
	Name: Jessica Coutu	**Date**
	Title: Sr. V.P. Clinical Operations	

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: April 8, 2018

/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, Hilla Eisenberg, 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: April 8, 2018

/s/ Hilla Eisenberg
Hilla Eisenberg
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 February 28, 2018 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: April 8, 2018

/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 February 28, 2018 as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Hilla Eisenberg, 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: April 8, 2018

/s/ Hilla Eisenberg
Hilla Eisenberg,
Chief Financial Officer