

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

FORM 10-Q

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

For the quarterly period ended November 30, 2015

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

(State or Other Jurisdiction of Incorporation or Organization)

98-0376008

(I.R.S. Employer Identification No.)

**Hi-Tech Park 2/4 Givat Ram
PO Box 39098
Jerusalem, Israel**

(Address of Principal Executive Offices)

91390

(Zip Code)

+ 972-2-566-0001

(Registrant's Telephone Number, Including Area Code)

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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

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

Yes No

As of January 12, 2016, there were 13,095,661 shares of the issuer's common stock, \$0.012 par value per share, outstanding.

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

On November 30, 2015, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.877 to \$1.00. Unless indicated otherwise by the context, statements in this Quarterly Report on Form 10-Q that provide the dollar equivalent of NIS amounts or provide the NIS equivalent of dollar amounts are based on such exchange rate.

PART I – FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

ORAMED PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF NOVEMBER 30, 2015

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

	<u>November 30,</u> <u>2015</u>	<u>August 31,</u> <u>2015</u>
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,949	\$ 3,213
Short term deposits	11,127	11,928
Marketable securities	1,984	2,088
Restricted cash	16	16
Prepaid expenses and other current assets	112	127
Total current assets	<u>15,188</u>	<u>17,372</u>
LONG TERM ASSETS:		
Long term deposits and investment	8,051	8,022
Marketable securities	623	940
Amounts funded in respect of employee rights upon retirement	9	9
Property and equipment, net	12	11
Total long term assets	<u>8,695</u>	<u>8,982</u>
Total assets	<u>\$ 23,883</u>	<u>\$ 26,354</u>
Liabilities and stockholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 768	\$ 953
Advance on account of license agreement (see note 1a1)	500	500
Related parties	36	36
Total current liabilities	<u>1,304</u>	<u>1,489</u>
LONG TERM LIABILITIES:		
Employee rights upon retirement	12	11
Provision for uncertain tax position	26	26
	<u>38</u>	<u>37</u>
COMMITMENTS (note 2)		
STOCKHOLDERS' EQUITY:		
Common stock, \$0.012 par value (30,000,000 authorized shares; 11,602,652 and 11,563,077 shares issued and outstanding as of November 30, 2015 and August 31, 2015, respectively)	138	138
Additional paid-in capital	59,693	59,184
Accumulated other comprehensive income	152	558
Accumulated loss	(37,442)	(35,052)
Total stockholders' equity	<u>22,541</u>	<u>24,828</u>
Total liabilities and stockholders' equity	<u>\$ 23,883</u>	<u>\$ 26,354</u>

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

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

	Three months ended	
	November 30, 2015	November 30, 2014
RESEARCH AND DEVELOPMENT EXPENSES, NET	\$ 1,901	\$ 1,302
GENERAL AND ADMINISTRATIVE EXPENSES	548	600
OPERATING LOSS	<u>2,449</u>	<u>1,902</u>
FINANCIAL INCOME	(76)	(27)
FINANCIAL EXPENSES	17	21
NET LOSS FOR THE PERIOD	<u>\$ 2,390</u>	<u>\$ 1,896</u>
UNREALIZED LOSS ON AVAILABLE FOR SALE SECURITIES	406	359
TOTAL OTHER COMPREHENSIVE LOSS	<u>406</u>	<u>359</u>
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	<u><u>\$ 2,796</u></u>	<u><u>\$ 2,255</u></u>
LOSS PER SHARE OF COMMON STOCK:		
BASIC AND DILUTED LOSS PER COMMON SHARE	<u>\$ 0.21</u>	<u>\$ 0.19</u>
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER COMMON STOCK	<u>11,572,809</u>	<u>10,142,013</u>

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

ORAMED PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
U.S. Dollars in thousands (except for share data)
(UNAUDITED)

	Common Stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated loss	Total stockholders' equity
	Shares	\$				
	In thousands					
BALANCE AS OF AUGUST 31, 2015	11,563	\$ 138	\$ 59,184	\$ 558	\$ (35,052)	\$ 24,828
SHARES ISSUED FOR SERVICES	4	*	25	-	-	25
EXERCISE OF WARRANTS	27	*	164	-	-	164
STOCK BASED COMPENSATION	9	*	320	-	-	320
NET LOSS	-	-	-	-	(2,390)	(2,390)
OTHER COMPREHENSIVE LOSS	-	-	-	(406)	-	(406)
BALANCE AS OF NOVEMBER 30, 2015	<u>11,603</u>	<u>\$ 138</u>	<u>\$ 59,693</u>	<u>\$ 152</u>	<u>\$ (37,442)</u>	<u>\$ 22,541</u>

* Represents an amount of less than \$1.

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

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

	Three months ended	
	November 30,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (2,390)	\$ (1,896)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	1	1
Exchange differences and interest on investments	(34)	(9)
Stock based compensation	320	300
Common stock issued for services	25	26
Changes in operating assets and liabilities:		
Prepaid expenses, other current assets and related parties	15	325
Accounts payable, accrued expenses and related parties	(185)	(146)
Liability for employee rights upon retirement	1	-
Total net cash used in operating activities	(2,247)	(1,399)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(2)	(2)
Purchase of short term deposits	(600)	(820)
Proceeds from sale of short term deposits	1,420	2,300
Other	-	(2)
Total net cash derived from investing activities	818	1,476
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	164	-
Proceeds from issuance of common stock - net of issuance expenses	-	4,833
Net cash derived from financing activities	164	4,833
EFFECT OF EXCHANGE RATE CHANGES ON CASH	1	(16)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,264)	4,894
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,213	1,762
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 1,949	\$ 6,656

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

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:

a. General:

1) Incorporation and operations

Oramed Pharmaceuticals Inc. (the "Company") 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 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. Unless the context indicates otherwise, the term "Group" refers to Oramed Pharmaceuticals Inc. and its Subsidiary.

On March 11, 2011, the Company was reincorporated from the State of Nevada to the State of Delaware.

On November 30, 2015, the Company and the Subsidiary entered into Technology License Agreement (the "License Agreement") with Hefei Tianhui Incubation of Technologies Co. Ltd. ("HTIT"). According to the License Agreement, the Company will grant HTIT an exclusive commercialization license in the territory of the Peoples Republic of China, Macau and Hong Kong (the "Territory"), related to the Company's oral insulin capsule, ORMD-0801. Pursuant to the License Agreement, HTIT will conduct, at its own expense, certain pre-commercialization and regulatory activities with respect to the Company's technology and ORMD-0801 capsule, and will pay to the Company (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 is payable immediately, \$8,000 will be paid by September 2016, subject to the Company entering into certain agreements with certain third parties, and \$26,500 will be payable upon achievement of certain milestones and conditions. In the event that the Company will not meet certain conditions the Royalties rate may be reduced to a minimum of 8%. Following the expiration of the Company's patents covering the technology in the Territory (the "Patents"), the Royalties rate may be reduced, under certain circumstances, to 5%.

The Royalties term will commence upon the commercialization of the product and will end upon the later of the expiration of the Patents or fifteen years after the first commercialization of the product in the Territory.

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

The closing of the License Agreement was conditioned upon the approval of the Israeli Chief Scientist, which was received on December 21, 2015.

In July 2015, according to the letter of intent signed between the parties or their affiliates, HTIT's affiliate paid the Subsidiary a non-refundable amount of \$500 as a no-shop fee. The no-shop fee is presented as an advance on account of the License Agreement among current liabilities.

On December 21, 2015, the Company, its Subsidiary and HTIT entered into an Amended and Restated Technology License Agreement (the "A&R License Agreement"), which replaced the License Agreement between the parties. The material terms of the A&R License Agreement are the same as of the License Agreement. The closing conditions of the A&R License Agreement were met during December 2015, and the initial payment of \$3,000 was received in January 2016.

In addition, on November 30, 2015, the Company entered into a Stock Purchase Agreement ("SPA") with HTIT. For details see note 5.

The Company is evaluating the future revenue recognition of the agreement with HTIT.

2) Development and liquidity risks

The Group 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 any 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, and foreign regulatory approvals must be obtained to sell its products internationally. 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.

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

Based on its current cash resources and commitments, and cash received in private and public offerings in the three month period ended November 30, 2015 and in the year ended August 31, 2015, as well as the investment made by HTIT, the Company believes it will be able to maintain its current planned development activities and the corresponding level of expenditures for at least the next 12 months beyond the date that the financial statements are issued, although no assurance can be given that it will not need additional funds prior to such time. If there are unexpected increases in general and administrative expenses or research and development expenses, the Company may need to seek additional financing during the next 12 months.

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. Outstanding stock options, warrants and restricted stock units have been excluded from the calculation of the diluted loss per share because all such securities are anti-dilutive for all periods presented. The total number of common stock options, warrants and restricted stock units excluded from the calculation of diluted net loss was 2,940,137 and 1,933,520 for the three month periods ended November 30, 2015 and 2014, respectively.

c. Newly issued and recently adopted Accounting Pronouncements

- 1) In May 2014, the Financial Accounting Standards Board (“FASB”) issued guidance on revenue from contracts with customers that will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle 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 for the interim and annual periods beginning on or after December 15, 2017 (early adoption is permitted for the interim and annual periods beginning on or after December 15, 2016). The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

- 2) In January 2016, the FASB issued guidance on recognition and measurement of financial assets and financial liabilities (Accounting Standards Update No. 2016-01) that will supersede most current guidance. Changes to the current United States generally accepted accounting principles ("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 in fiscal years beginning after December 15, 2017, including interim periods within those fiscal years (early adoption of the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income is permitted). The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

d. Condensed Consolidated Financial Statements Preparation

The condensed consolidated financial statements included herein have been prepared in accordance with 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, 2015 (the "2015 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 2015 Form 10-K. The results for interim periods are not necessarily indicative of a full fiscal year's results.

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

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”) (see also note 4), 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 a promissory note issued by D.N.A in the principal amount of \$450, with an annual interest rate of 0.45% that was fully paid in November 2011, and 8,404,667 ordinary shares of D.N.A.

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 November 30, 2015, Entera had not yet realized any revenues and had not paid any royalties to the Subsidiary.

- b. On September 11, 2011, the Subsidiary entered into an agreement with Hadasit, the Company's Medical and Chief Technology Officer (the “CTO”) and Dr. Daniel Schurr (the “Hadasit Agreement”) to retain consulting and clinical trial services. According to the Hadasit Agreement, Hadasit will be entitled to consideration of \$200 to be paid by the Company in accordance with the actual progress of the studies, \$111 of which were recognized through November 30, 2015. See also note 1a(1).
- c. On April 28, 2013, the Subsidiary entered into a new lease agreement for its office facilities in Israel. The new lease agreement is for a period of 36 months commencing November 4, 2013.

The annual lease payment will be New Israeli Shekel 89 thousands from 2014 through 2016, and will be linked to the increase in the Israeli consumer price index (“CPI”) (as of November 30, 2015, the future annual lease payments under the new agreement will be \$23, based on the exchange rate as of November 30, 2015).

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

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

NOTE 2 - COMMITMENTS (continued):

- d. On July 22, 2014, the Subsidiary entered into a Clinical Research Organization Service Agreement with a third party, to retain it as a Clinical Research Organization (“CRO”), for its Phase 2b clinical trial for an oral insulin capsule for type 2 diabetes patients, which began in the second quarter of calendar year 2015. As consideration for its services, the Subsidiary will pay the CRO a total amount of approximately \$3,290 during the term of the engagement and based on achievement of certain milestones, \$2,388 of which were recognized through November 30, 2015.
- e. On March 3, 2014, the Subsidiary entered into a Master Service Agreement with a vendor for the process development and production of one of its oral capsule ingredients in the amount of \$311, \$40 of which was recognized through November 30, 2015, and bonus payments of up to \$600 that will be paid upon achieving certain milestones, as described in the agreement, none of which was recognized through November 30, 2015.

On December 12, 2014, the Subsidiary entered into an additional agreement with the same vendor, for the process development and production of the same capsule ingredients in the amount of \$550, \$430 of which was recognized through November 30, 2015.

- f. 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 by the Company (Israeli CPI linked) at the total amount of \$65.

During the three month period ended November 30, 2015, the Company received no grants from Bio-Jerusalem.

As of November 30, 2015, the Subsidiary had not yet realized any revenues and did not incur any royalty liability.

- g. Grants from the Office of Chief Scientist (“OCS”)

Under the terms of the Company’s funding from the OCS, royalties of 3%-3.5% are payable on sales of products developed from a project so funded, up to 100% of the amount of the grant received by the Company (dollar linked) with the addition of annual interest at a rate based on LIBOR.

At the time the grants were received, successful development of the related projects was not assured. In case of failure of a project that was partly financed as above, the Company is not obligated to pay any such royalties.

The total amount that was received through November 30, 2015 was \$2,194.

On November 30, 2015, the Subsidiary had not yet realized any revenues from the said project and did not incur any royalty liability.

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

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 November 30, 2015, 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 November 30, 2015, the carrying amount of cash and cash equivalents, short term deposits, prepaid expenses and other current assets and accounts payable and accrued expenses approximate their fair values due to the short-term maturities of these instruments.

As of November 30, 2015, the carrying amount of long term deposits approximates their fair values due to the stated interest rates which approximate market rates.

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

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

NOTE 4 - MARKETABLE SECURITIES:

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

a. Composition:

	November 30, 2015	August 31, 2015
	<u> </u>	<u> </u>
Short term:		
D.N.A (see b below)	\$ 747	\$ 1,153
Held to maturity bonds (see c below)	1,237	935
	<u>\$ 1,984</u>	<u>\$ 2,088</u>
Long term:		
Held to maturity bonds (see c below)	<u>\$ 623</u>	<u>\$ 940</u>

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 and have a quoted price. The fair value of those securities is measured at the quoted prices of the securities on the measurement date.

During the three month period ended November 30, 2015, the Group did not sell any of the D.N.A ordinary shares.

As of November 30, 2015, the Group owns approximately 8.7% of D.N.A's outstanding ordinary shares.

The cost of the securities as of November 30, 2015 and August 31, 2015 is \$590.

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

NOTE 4 - MARKETABLE SECURITIES (continued):

c. Held to maturity bonds

The amortized cost and estimated fair value of held-to-maturity securities at November 30, 2015, are as follows:

	November 30, 2015		
	Amortized cost	Gross unrealized losses	Estimated fair value
Short term:			
Commercial bonds	\$ 1,219	\$ 2	\$ 1,217
Accrued interest	18	-	18
Long term	623	2	621
	<u>\$ 1,860</u>	<u>\$ 4</u>	<u>\$ 1,856</u>

As of November 30, 2015, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, \$1,237, and the yield to maturity rates vary between 0.57% to 1.31%.

NOTE 5 - STOCK HOLDERS' EQUITY

On November 30, 2015, the Company entered into an SPA with HTIT, pursuant to which HTIT agreed to buy and the Company agreed to sell 1,155,367 restricted shares of common stock of the Company at a price of approximately \$10.39 per share, for the aggregate amount of \$12,000. The transaction closed and the consideration was received during December 2015.

NOTE 6 - STOCK BASED COMPENSATION

On November 19, 2015, options to purchase an aggregate of 22,000 of the Company's shares of common stock were granted to two consultants at an exercise price of \$7.36 per share (equivalent to the traded market price on the date of grant). 10,000 of the options vest in one installment on December 1, 2015, and the remaining 12,000 options vest in twelve equal quarterly installments, commencing January 1, 2016. All the options will expire on November 19, 2025. The fair value of the options as of November 30, 2015 was \$168, using the following assumptions: dividend yield of 0%; expected term of 9.98 years; expected volatility of 80.49%; and risk-free interest rate of 2.21%. The fair value of the unvested options is remeasured at each balance sheet reporting date and is recognized over the related service period using the straight-line method.

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

NOTE 7 - SUBSEQUENT EVENT

On January 4, 2016, the Company's President, Chief Executive Officer and director (the "CEO"), in his personal capacity as a shareholder of the Company, and a leading investor of the Company, terminated a letter agreement dated November 29, 2012, between the parties, which entitled the leading investor to certain stock compensation from the CEO under certain conditions.

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;
- our research and development plans, including pre-clinical and clinical trials plans and the timing of conclusion of trials;
- 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, 2015, or our Annual Report, as filed with the Securities and Exchange Commission, or the SEC, on November 25, 2015, as well as those discussed elsewhere in our Annual Report and in this Quarterly Report on Form 10-Q. 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

We initiated a Phase IIb clinical trial on approximately 180 type 2 diabetic patients in approximately 30 sites in the United States, beginning in June 2015. This double-blind, randomized, 28-day study clinical trial is conducted under an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA. The clinical trial is designed to assess the safety and efficacy of ORMD-0801, will investigate ORMD-0801 over a longer treatment period and will have statistical power to give us greater insight into the drug's efficacy. We anticipate that the last patient will complete this trial during the first quarter of calendar year 2016.

We are also conducting a glucose clamp study of our oral insulin capsule on type 2 diabetic volunteers that will be performed at The University of Texas Health Science Center at San Antonio and University Health System's Texas Diabetes Institute. 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. As previously announced, the first patient has been enrolled and we anticipate completing the study in the second quarter of calendar year 2016.

In September 2013, we submitted a pre-IND, package to the FDA, for ORMD-0901, our oral exenatide capsule, for a Phase 2 clinical trial on healthy volunteers and type 2 diabetic patients. We began pre-clinical studies in November 2014 and expect to begin IND-enabling studies in the second quarter of calendar year 2016. We then intend to file an IND and move immediately and directly into a large Phase II multi-center trial in the United States. In August 2015, we began a non-FDA approved clinical trial on type 2 diabetic patients, and we anticipate it will be completed during the first quarter of calendar year 2016.

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

		Phase I	Phase II	Phase III	Timeline
ORMD-0801					
oral insulin	Type 2 diabetes				Q1 '14: Phase IIa completed Q2 '15: Phase IIb multi-center study initiated
	Type 1 diabetes				Q3 '14: Phase IIa completed
ORMD-0901					
oral GLP-1	Type 2 diabetes				Q3 '14: Preclinical/IND studies initiated Q3 '15: Phase Ib ex-US study initiated Q4 '16: Phase II multi-center study projected initiation

Out-Licensed Technology

On November 30, 2015, we, our Israeli subsidiary and Hefei Tianhui Incubation of Technologies Co. Ltd., or HTIT, entered into a Technology License Agreement, or the License Agreement, according to which we will grant HTIT an exclusive commercialization license in the territory of the Peoples Republic of China, Macau and Hong Kong, or the Territory, related to our oral insulin capsule, ORMD-0801. 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 approximately \$37.5 million, of which \$3 million is payable immediately, \$8 million will be paid in near term installments 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%. We also entered into a separate securities purchase agreement with HTIT, or the SPA, pursuant to which HTIT invested \$12 million in us in December 2015 (see – “Liquidity and capital resources” below). In connection with the License Agreement and the SPA, we received a non-refundable payment of \$500,000 as a no-shop fee.

On December 21, 2015, the parties entered into an Amended and Restated Technology License Agreement, or the A&R License Agreement, which replaced the License Agreement. The material terms of the A&R License Agreement are the same as of the License Agreement. The closing conditions of the A&R License Agreement were met during December 2015, and the initial payment of \$3 million was received in January 2016.

Results of Operations

Comparison of three month periods ended November 30, 2015 and 2014

The following table summarizes certain statements of operations data for the Company for the three month periods ended November 30, 2015 and 2014 (in thousands of dollars except share and per share data):

	Three months ended November 30,	
	2015	2014
Research and development expenses, net	\$ 1,901	\$ 1,302
General and administrative expenses	548	600
Financial income, net	(59)	(6)
Net loss for the period	\$ 2,390	\$ 1,896
Loss per common share – basic and diluted	\$ (0.21)	\$ (0.19)
Weighted average common shares outstanding	11,572,809	10,142,013

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, payroll taxes, 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 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 three months ended November 30, 2015 increased by 46% to \$1,901,000, from \$1,302,000 for the three months ended November 30, 2014. The increase is mainly attributable to expenses related to clinical trials and mainly our Phase IIb clinical trial. Stock based compensation costs for the three months ended November 30, 2015 totaled \$184,000, as compared to \$164,000 during the three months ended November 30, 2014.

Government grants

In the three month period ended November 30, 2014, we recognized research and development grants in an amount of \$16,000, and in the three month period ended November 30, 2015, we did not recognize any research and development grants. As of November 30, 2015, we had no contingent liabilities to the Office of the Chief Scientist of the Ministry of Economy of Israel, or OCS.

General and administrative expenses

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

General and administrative expenses for the three months ended November 30, 2015, decreased by 9% to \$548,000 from \$600,000 for the three months ended November 30, 2014. The decrease in costs incurred related to general and administrative activities during the three months ended November 30, 2015 is mainly due to a decrease in professional fees and public relations expenses. Stock based compensation costs for the three months ended November 30, 2015 totaled \$136,000, as compared to \$137,000 during the three months ended November 30, 2014.

Financial income, net

Net financial income increased by 883% from net income of \$6,000 for the three months ended November 30, 2014 to net income of \$59,000 for the three months ended November 30, 2015. The increase is mainly due to an increase in income from bank deposits as well as to the decrease in exchange rate differences expenses.

Other comprehensive income

Subsequent decrease in the fair value of available for sale securities previously written down as impaired for the three months ended November 30, 2015 and November 30, 2014 of \$11,000 and \$9,000, respectively, 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 months ended November 30, 2015 and November 30, 2014 of \$395,000 and \$350,000, respectively, resulted from the decrease in fair value of our D.N.A ordinary shares.

Liquidity and capital resources

From inception through November 30, 2015, we have incurred losses in an aggregate amount of \$37,442,000. 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 \$45,460,000, net of transaction costs. During that period we also received cash consideration of \$2,034,000 from the exercise of warrants and options. We will seek to obtain additional financing through similar sources in the future as needed. As of November 30, 2015, we had \$1,949,000 of available cash, \$19,178,000 of short term and long term bank deposits and \$2,607,000 of marketable securities. We anticipate that we will require approximately \$10.9 million to finance our activities during the 12 months following November 30, 2015.

On November 30, 2015, we entered into the SPA with HTIT, pursuant to which HTIT agreed to buy and we agreed to sell 1,155,367 restricted shares of our common stock at a price of approximately \$10.39 per share, for the aggregate amount of \$12 million. The transaction closed on December 28, 2015.

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, including the recent investment by HTIT, 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 November 30, 2015, our total current assets were \$15,188,000 and our total current liabilities were \$1,304,000. On November 30, 2015, we had a working capital surplus of \$13,884,000 and an accumulated loss of \$37,442,000. As of August 31, 2015, our total current assets were \$17,372,000 and our total current liabilities were \$1,489,000. On August 31, 2015, we had a working capital surplus of \$15,883,000 and an accumulated loss of \$35,052,000. The decrease from August 31, 2015 to November 30, 2015 was primarily due to the cash used in operating activities.

During the three month period ended November 30, 2015, cash and cash equivalents decreased to \$1,949,000 from the \$3,213,000 reported as of August 31, 2015, which is due to the reasons described below.

Operating activities used cash of \$2,247,000 in the three month period ended November 30, 2015, as compared to \$1,399,000 used in the three months ended November 30, 2014. Cash used for operating activities in the three months ended November 30, 2015 and 2014 primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by stock based compensation amounts.

During the three month period ended November 30, 2014, we received \$68,000 in OCS grants towards our research and development expenses, while we recognized the amount of \$16,000 during such period. The amounts that were recognized but not received during the three month period ended November 30, 2014, were received from the OCS during calendar year 2015. The OCS has supported our activity until December 2014. During the three month period ended November 30, 2015, we received no grants from the OCS.

Investing activities provided cash of \$818,000 in the three month period ended November 30, 2015, as compared to \$1,476,000 that were provided in the three month period ended November 30, 2014. Cash provided by investing activities in the three months ended November 30, 2015 and 2014 consisted primarily of the proceeds from sale of short-term bank deposits.

Financing activities provided cash of \$164,000 in the three month period ended November 30, 2015, as compared to \$4,833,000 that were provided in the three month period ended November 30, 2014. Financing activities in the three month period ended November 30, 2015 consisted of proceeds from the exercise of warrants, while financing activities in the three month period ended November 30, 2014 consisted of proceeds from our issuance of common stock in the three months ended November 30, 2014.

Off-balance sheet arrangements

As of November 30, 2015, 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.

Planned Expenditures

The estimated expenses referenced herein are in accordance with our business plan. Since our technology is still in the development stage, it can be expected that there will be changes in some budgetary items. Our planned expenditures for the twelve months beginning December 1, 2015 are as follows (in thousands):

Category	Amount
Research and development	\$ 8,970
General and administrative expenses	2,090
Financial income, net	(170)
Total	\$ 10,890

In June 2015, we initiated a Phase IIb clinical trial for our orally ingested insulin and we are conducting, or planning to conduct, further clinical studies, including those with regard to our oral exenatide capsule. Our ability to complete these expected activities is dependent on several major factors including the ability to attract sufficient financing on terms acceptable to us.

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There has been no significant change in our exposure to market risk during the three months ended November 30, 2015. For a discussion of our exposure to market risk, refer to Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk,” contained in our Annual Report.

ITEM 4 - CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of November 30, 2015. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended November 30, 2015 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 November 1, 2015, we issued 3,750 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 Letter Agreement, dated July 1, 2015, between us and Corporate Profile and a Stock Purchase Agreement, dated July 1, 2015, 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

Number	Exhibit
10.1	Securities Purchase Agreement between Oramed Pharmaceuticals, Inc. and Hefei Tianhui Incubator of Technologies Co., Ltd., dated November 30, 2015 (incorporated by reference from Schedule 13D/A filed by Nadav Kidron on December 29, 2015).
10.2*	Amended and Restated Technology License Agreement between Hefei Tianhui Incubator of Technologies Co., Ltd., Oramed Pharmaceuticals, Inc. and Oramed Ltd., dated December 21, 2015 (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 November 30, 2015, formatted in XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Comprehensive Loss, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows and (v) the Notes to Condensed Consolidated Financial Statements.

* Filed herewith

** Furnished herewith

SIGNATURES

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

ORAMED PHARMACEUTICALS INC.

Date: January 13, 2016

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

Date: January 13, 2016

By: /s/ Yifat Zommer
Yifat Zommer
Chief Financial Officer
(principal financial and accounting officer)

****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")****

AMENDED AND RESTATED TECHNOLOGY LICENSE AGREEMENT

THIS AMENDED AND RESTATED TECHNOLOGY LICENSE AGREEMENT (the "**Agreement**") is entered into as of December 21, 2015 (the "**Execution Date**") between **HEFEI TIANHUI INCUBATOR OF TECHNOLOGIES CO., LTD.**, a corporation organized and existing under the laws of the People's Republic of China ("**PRC**") and having its principal place of business at No. 199 Fanhua Road, Heifei, Anhui, China ("**HTIT**" or "**Licensee**"); and **ORAMED PHARMACEUTICALS INC.**, a Delaware corporation and **ORAMED LTD.**, a company organized and existing under the laws of the State of Israel and having a principal place of business at 2/4 Hi-Tech Park, PO Box 39098, Jerusalem, 91390, Israel (collectively referred to as "**Oramed**"). HTIT and Oramed are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, Oramed is a clinical-stage biopharmaceutical company developing clinical candidates for the treatment of diabetes by way of oral insulin; and

WHEREAS, HTIT is engaged in the development, manufacture, distribution, sales and marketing of pharmaceutical products and medical devices in the PRC; and

WHEREAS, Oramed controls rights covering ORMD-0801 (as defined below) and is engaged in advanced clinical trials and pre-commercialization activities with respect thereto; and

WHEREAS, Oramed desires to grant Licensee, and Licensee desires to obtain, exclusive rights to pre-commercialize, manufacture and commercialize product(s) containing ORMD-0801 in the Licensee Territory, all on the terms and conditions set forth herein; and

WHEREAS, in the context of the commercialization of ORMD-0801, Licensee shall pursue and be solely responsible for obtaining Regulatory Approvals as required for commercializing such product in the Licensee Territory, pursuant to the terms and conditions of this Agreement.

Now THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Article 1.

1.1 **“Affiliate”** means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word **“control”** (including, with correlative meaning, the terms **“controlled by”** or **“under the common control with”**) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of 50% or more of the voting stock of such entity, or by contract or otherwise.

1.2 **“CFDA”** means the China Food and Drug Administration of the PRC, and any successors thereof.

1.3 **“Commercialization,”** with a correlative meaning for **“Commercialize”** and **“Commercializing,”** means all activities in the Licensee Territory undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, medical education and medical liaison activities, marketing, pricing, reimbursement, sale, and distribution of the Products in the Licensee Territory, including: (a) manufacturing or importing Products for distribution and sale; (b) strategic marketing, sales force detailing, advertising, medical education and liaison, and market and Product support; (c) any post-marketing clinical studies (other than those included in Pre-Commercialization) for use in generating data to be submitted to Regulatory Authorities (and all associated reporting requirements); and (d) all customer support, distribution, invoicing and sales activities.

1.4 **“Commercialization Milestones”** has the meaning set forth in Section 6.2(a).

1.5 **“Commercialization Plan”** has the meaning set forth in Section 6.1(a).

1.6 **“Commercially Reasonable Efforts”** means carrying out of obligations or tasks by a Party using a level of efforts consistent with the exercise of good faith and prudent scientific and business judgment in an active and ongoing program as applied by a Party to the pre-commercialization and commercialization of its own pharmaceutical products at a similar stage of development and with similar market potential.

1.7 **“Confidential Information”** means, with respect to a Party, all reports and other Information of such Party that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, or electronic form. All Information disclosed by a Party pursuant to the Mutual Non-Disclosure Agreement between the Parties dated June 24, 2014, as amended through the Effective Date, shall be deemed to be such Party’s Confidential Information disclosed hereunder.

1.8 **“Control”** means, with respect to any material, Information, or intellectual property right that a Party owns or to which a Party has a license, that such Party has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement.

1.9 **“Dollar”** means a U.S. dollar, and **“\$”** shall be interpreted accordingly.

1.10 “**Effective Date**” means the date immediately following the fulfillment of the following condition: the written consent of the OCS with respect to this Agreement has been obtained by Oramed in accordance with Section 2.1 (whether such OCS consent is granted for an associated form of Agreement modified in accordance with Section 2.1 or for the Execution Date Agreement).

1.11 “**Execution Date**” has the meaning set forth in the Preamble above.

1.12 “**Execution Date Agreement**” has the meaning set forth in Section 2.1.

1.13 “**Executives**” has the meaning set forth in Section 3.1(d).

1.14 “**Field**” means the use of the Product for the treatment of diabetes.

1.15 “**First Commercial Sale**” means the first sale of a Product by the Licensee or any of its Affiliates or Sublicensees to a Third Party in the Licensee Territory after Regulatory Approval for such Product has been obtained.

1.16 “**Governmental Authority**” means any multi-national, federal, state, local, municipal, provincial or other government authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.17 “**Indemnify**” has the meaning set forth in Section 11.1.

1.18 “**Information**” means any data, results, technology, business information and information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, test data (including pharmacological, biological, chemical, biochemical, toxicological, preclinical and clinical test data), manufacturing know-how and data, analytical and quality control data, stability data, other study data and procedures.

1.19 “**Initial Payment**” has the meaning set forth in Section 8.1.

1.20 “**Joint Steering Committee**” or “**JSC**” has the meaning set forth in Section 3.1(a)

1.21 “**Laws**” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

1.22 “**Licensee Inventions**” has the meaning set forth in Section 9.1.

1.23 “**Licensee Regulatory Data**” means Regulatory Data generated by or on behalf of the Licensee (or its Affiliates, Sublicensees and/or contractors) after the Effective Date in connection with the performance of Licensee’s activities pursuant to this Agreement.

1.24 “**Licensee Technology**” means all Information that is Controlled by Licensee, its Affiliates and/or Sublicensees as of the Effective Date or at any time during the Term and is necessary or useful for Pre-Commercialization, Commercialization or the manufacture of the Products in accordance with the terms of this Agreement. For the avoidance of doubt, Licensee Technology does not include Licensee Inventions.

1.25 “**Licensee Territory**” means the PRC, Macau and Hong Kong.

1.26 “**Losses**” has the meaning set forth in Section 11.1.

1.27 “**Milestones**” shall mean the Pre-Commercialization Milestones and the Commercialization Milestones.

1.28 “**Net Sales**” shall mean the gross amount invoiced by or on behalf of the Licensee, its Affiliates and Sublicensees (in each case, the “**Invoicing Entity**”) on sales of Products (whether made before or after the First Commercial Sale of the Product), less the following: (a) amounts repaid or credited by reason of rejection or return; (b) to the extent separately stated in the invoices, any taxes or other governmental charges levied on the production, sale and/or delivery of a Product which is paid by the Invoicing Entity; and (c) packing and shipping cost; provided that:

(i) in any transfers of Products between an Invoicing Entity and an Affiliate of such Invoicing Entity not for the purpose of resale by such Affiliate, Net Sales shall be equal to the higher of (A) the fair market value of the Products so transferred, assuming an arm’s length transaction made in the ordinary course of business; and (B) the actual transfer price; and

(ii) in the event that an Invoicing Entity receives non-monetary consideration for any Products or in the case of transactions not at arm’s length between an Invoicing Entity and a non-Affiliate of the Invoicing Entity, Net Sales shall be calculated based on the fair market value of such consideration or transaction, assuming an arm’s length transaction made in the ordinary course of business; and

(iii) sales of Products by an Invoicing Entity to an Affiliate of such Invoicing Entity for resale by such Affiliate shall not be deemed Net Sales and Net Sales shall be determined based on the total amount invoiced by such Affiliate on resale.

1.29 “**Notification Date**” has the meaning set forth in Section 4.8.

1.30 “**OCS**” has the meaning set forth in Section 2.1.

1.31 “**Oramed Inc.**” means Oramed Pharmaceuticals Inc., a Delaware corporation and the parent of Oramed.

1.32 “**Oramed Know-How**” means all Information that is Controlled by Oramed or its Affiliates as of the Effective Date and at any time during the Term and is necessary or useful for the Pre-Commercialization, Commercialization or manufacture of the Products in the Field in accordance with the terms of this Agreement. For clarity, Oramed Know-How excludes the Oramed Patents. A summary of Oramed Know-How as of the Effective Date is set forth on **Exhibit B** attached hereto.

1.33 “**Oramed Patents**” means, as of the Effective Date, the Patents set forth on **Exhibit B** attached hereto and all Patents in the Licensee Territory that are related to the foregoing and Controlled by Oramed or its Affiliates during the Term.

1.34 “**Oramed Regulatory Data**” means Regulatory Data generated by or on behalf of Oramed (or its Affiliates, licensees or sublicensees) after the Effective Date, and Controlled by Oramed during the Term.

1.35 “**Oramed Technology**” means the Oramed Patents and Oramed Know-How.

1.36 **“ORMD-0801”** means the compound known as ORMD-0801 and controlled by Oramed, described more fully in **Exhibit A** attached hereto.

1.37 **“Patent Infringement”** has the meaning set forth in Section 9.5(a).

1.38 **“Patents”** means (a) pending patent applications, issued patents, utility models and designs; (b) reissues, renewals, substitutions, confirmations, registrations, validations, re-examinations, additions, extensions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any patent applications, issued patents, utility models or designs; and (c) the equivalent or counterpart of the foregoing.

1.39 **“Pre-Commercialization,”** with a correlative meaning for **“Pre-Commercialize”** and **“Pre-Commercializing,”** means all activities in the Licensee Territory relating to preparing and conducting clinical and toxicology testing, human clinical studies and regulatory activities (such as submissions of regulatory applications and related activities) with respect to the Products, together with the manufacturing the Products for the purpose of conducting the foregoing activities and manufacturing scale-up of the Products necessary for Commercialization, all for the purpose of obtaining, maintaining or expanding Regulatory Approval in the Licensee Territory. The foregoing includes preparation, submission, review, and development of data or information for the purpose of submission to a Governmental Authority in the Licensee Territory to obtain Regulatory Approval of Products. Pre-Commercialization shall also include clinical development and regulatory activities for additional dosage forms or formulations of a Product after Regulatory Approval of such Product, including clinical trials initiated following receipt of Regulatory Approval for the purpose of maintaining or expanding Regulatory Approval or any clinical trial to be conducted after Regulatory Approval which was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval.

1.40 **“Pre-Commercialization Activities”** has the meaning set forth in Section 4.3(a).

1.41 **“Pre-Commercialization Costs”** has the meaning set forth in Section 4.6.

1.42 **“Pre-Commercialization Milestones”** has the meaning set forth in Section 4.3(a).

1.43 **“Pre-Commercialization Plan”** has the meaning set forth in Section 4.2(a).

1.44 **“Premas”** means PREMAS Biotech Pvt. Ltd.

1.45 **“Premas Agreement”** means an agreement between Oramed and Premas that will provide for the transfer by Premas to Oramed (or Oramed’s designee) of Premas technology for manufacture of the SBTI (Soybean Trypsin Inhibitor) for the Product.

1.46 **“Product(s)”** means ORMD-0801 in any dosage, form or formulation or mode of administration, alone or in combination with other therapeutically active ingredients.

1.47 **“Product Marks”** has the meaning set forth in Section 6.3.

1.48 **“Regulatory Approval”** means, with respect to a Product in the Licensee Territory or the Retained Territory, as applicable, all approvals, registrations, licenses or authorizations from the relevant Regulatory Authority in such country or jurisdiction that is specific to such Product and necessary to manufacture, market and/or sell such Product.

1.49 “Regulatory Authority” means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority responsible for granting Regulatory Approval. In the Licensee Territory, the primary Regulatory Authority is the CFDA and any other parallel or successor authority within the Licensee Territory.

1.50 “Regulatory Data” means data and filings generated and prepared for the purpose of obtaining Regulatory Approval including analytical and manufacturing data and clinical data relating to the Products.

1.51 “Regulatory Data Costs” means costs actually incurred or paid by a Party and reasonably attributable to the generation of Regulatory Data, including, by way of example, costs incurred or paid in the conduct of associated clinical trials, statistical analysis of clinical data, manufacturing scale-up and patient recruitment. The Parties shall consult with each other and mutually agree on an appropriate mechanism for establishing Regulatory Data Costs, which mechanism shall be approved by the JSC (or directly by the Parties if the JSC is disbanded).

1.52 “Regulatory Filings” means, with respect to the Products, any submission to a Regulatory Authority of any appropriate regulatory application specific to Products, and shall include any submission to a regulatory advisory board and any supplement or amendment thereto.

1.53 “Retained Territory” means all countries and territories in the world outside the Licensee Territory.

1.54 “Royalty Term” has the meaning set forth in Section 8.3(b).

1.55 “Sublicense” shall mean any right granted, license given, or agreement entered into, by the Licensee to or with any other person or entity, under or with respect to or permitting any use of any of the Oramed Technology (or any part thereof) or otherwise permitting the pre-commercialization, manufacture, marketing, distribution and/or sale of Products (regardless of whether such grant of rights, license given or agreement entered into is referred to or is described as a sublicense or as an agreement with respect to the pre-commercialization and/or manufacture and/or sale and/or distribution and/or marketing of Products) upon written approval from Oramed.

1.56 “Sublicense Agreement” has the meaning set forth in Section 2.4

1.57 “Sublicensee” shall mean a person or entity granted a Sublicense in accordance with Section 2.4, provided that in no event will the term “Sublicensee” include any sublicensee of Sublicensee.

1.58 “Subsequent Payment” shall have the meaning set forth in Section 8.2.

1.59 “Swisscaps” means SWISSCAPS AG.

1.60 “Swisscaps Agreement” means an agreement between Oramed and Swisscaps that will provide for the transfer by Swisscaps to Oramed (or Oramed’s designee) of Swisscaps technology for manufacture of Product capsules.

1.61 “Taxes” means taxes (other than income taxes), duties, tariffs or other governmental charges levied on the sale of Products, including consumption taxes.

1.62 “Term” means the term of this Agreement, as determined in accordance with Article 13.

1.63 “**Territory**” means the Licensee Territory or the Retained Territory, as applicable.

1.64 “**Third Party**” means any person or entity other than Oramed or HTIT or an Affiliate of any of them.

1.65 “**Valid Claim**” means, with respect to any country in the Licensee Territory: (a) a claim of an issued and unexpired patent (as may be extended through supplementary protection certificate or patent term extension or the like) included within the Oramed Patents to the extent such claim has not been (i) held invalid or unenforceable by a non-appealed or un-appealable decision of a competent court or government agency or other appropriate body of competent jurisdiction and has not been admitted invalid through disclaimer or dedication to the public, and (ii) has not expired, been determined to be unenforceable, been cancelled, withdrawn, abandoned, or (b) a claim of a pending patent application included within the Oramed Patents.

ARTICLE 2

EFFECTIVE DATE AND LICENSES

2.1 **Effective Date.** The Parties acknowledge that the Office of the Chief Scientist of the Ministry of Economy of the State of Israel (the “OCS”) must consent to this Agreement before this Agreement is made effective. Oramed shall use its best efforts to obtain the written consent of the OCS to this Agreement in the form executed by the Parties as of the Execution Date (“**Execution Date Agreement**”) within 60 days after the Execution Date. If the OCS has not provided such consent during such 60 day period, then Oramed shall have the right, and Licensee shall have the right to require Oramed, to continue to use its best efforts to obtain such consent. In addition, Oramed will keep Licensee informed as to the progress of such request for consent and shall consult with Licensee in good faith with respect thereto. The Parties acknowledge that it may be necessary prior to the Effective Date to modify the Execution Date Agreement to comply with the requests of the OCS and the Parties shall consider any such proposed modifications in good faith; *provided, however*, that (i) all financial obligations that may be imposed by the OCS as a pre-condition to obtaining OCS consent to this Agreement shall be the sole responsibility of Oramed; (ii) the Parties will cooperate in good faith to minimize financial and non-financial obligations (which obligations must be commercially reasonable) that may be imposed by the OCS as a pre-condition to obtaining OCS consent to this Agreement; and (iii) after the Parties have considered any such proposed modifications in good faith, no Party shall be required to agree to any modifications to the Execution Date Agreement that would have a material adverse impact on such Party whether under the Execution Date Agreement or otherwise. Notwithstanding anything herein to the contrary, other than this Section 2.1 and Sections 8.1 and 13.4, the provisions of this Execution Date Agreement shall not be effective until the Effective Date. From and after the Effective Date, the entire Agreement shall be in full force and effect.

2.2 **License Grant.** Subject to the terms of this Agreement, Oramed hereby grants to Licensee:

(a) **Pre-Commercialization License:** As of the Effective Date, and subject to Section 4.1(a), an exclusive, royalty-bearing license, with the right to grant sublicenses, subject to Section 2.4, under the Oramed Technology, solely to engage in Pre-Commercialization Activities in the Field in the Licensee Territory and to make and have made Products for such Pre-Commercialization Activities; and

(b) **Commercialization License:** Commencing following payment of the Subsequent Payment, an exclusive, royalty-bearing license, with the right to grant sublicenses, subject to Section 2.4, under the Oramed Technology, to Commercialize the Products in the Field in the Licensee Territory and to import, make and have made Products for Commercialization in the Licensee Territory; and

(c) **Oramed Regulatory Data:** As of the Effective Date, subject to Section 4.7(d), an exclusive, fully-paid, royalty-free license, with the right to grant sublicenses, subject to Section 2.4 below, to use Oramed Regulatory Data to Pre-Commercialize and Commercialize the Products in the Licensee Territory, including the right to use any and all such Oramed Regulatory Data in any Regulatory Filings in the Licensee Territory, subject to the terms and conditions of this Agreement.

For the avoidance of doubt, subject to the termination provisions in Section 8.2, the licenses set forth above shall be effective prior to Licensee's payment of the Service Agreement Milestone Payments. Notwithstanding the foregoing, it is expressly acknowledged, understood and agreed that Oramed retains all rights to Pre-Commercialize and Commercialize Products, and make and have made Products, and to exploit without limitation and grant licenses under its rights in the Oramed Technology and the Oramed Regulatory Data, outside of the Licensee Territory, at its sole discretion and without restriction or obligation to Licensee. Without the prior written consent of the Licensee, neither Oramed nor any Third Party shall Pre-Commercialize, make, have made, use, sell, offer for sale, have sold, import and otherwise Commercialize the Products in the Licensee Territory.

2.3 Licenses to Oramed. Subject to the effectiveness of this Agreement, Licensee hereby grants to Oramed an exclusive, fully-paid, royalty-free license, (with the right to grant sublicenses through multiple tiers), to use Licensee Regulatory Data to Pre-Commercialize, make, have made, use, sell, offer for sale, have sold, import and otherwise Commercialize the Products in the Retained Territory, including the right to use any and all Licensee Regulatory Data in any Regulatory Filings in the Retained Territory.

2.4 Sublicenses.

(a) Subject to the terms set out herein, Licensee shall have the right to grant sublicenses under the licenses granted in Section 2.2 to its Affiliates and/or Third Parties only with the prior written consent of Oramed; *provided, however*, that Licensee may not grant a sublicense *prior to* the completion by Licensee of a Phase I Clinical Trial. Oramed may not grant sublicenses under the licenses granted in Section 2.3 to its Affiliates and/or Third Parties without the prior written consent of the Licensee. Notwithstanding the foregoing, Licensee may sublicense under the license granted in Section 2.2 to Hefei Tianmai Biotechnology Development Co., Ltd. without the prior written consent of Oramed.

(b) The sublicensing Party shall remain responsible for the performance of the obligations hereunder by each of its respective Sublicensees. The sublicensing Party shall, within 30 days after granting any sublicense, notify the other Party in writing of the grant of such sublicense and provide the other Party with a true and complete copy of the sublicensing agreement. Each sublicense agreement shall be consistent with the terms and conditions under this Agreement. Each Party shall, in each agreement under which it grants a sublicense under the licenses set forth in Section 2.2 or 2.3, as applicable (each, a "**Sublicense Agreement**"), include the following terms and conditions: the Sublicensee is required to provide the following to the sublicensing Party if such Sublicense Agreement terminates: (i) the assignment and transfer of ownership and possession of all Regulatory Filings and Regulatory Approvals held or possessed by such Sublicensee, and (ii) the assignment of, or a freely sublicenseable exclusive license to, all intellectual property Controlled or developed by such Sublicensee with a Valid Claim covering the Pre-Commercialization or Commercialization of the Products in the Field in the applicable Territory that was created by or on behalf of such Sublicensee during the exercise of its rights or fulfillment of its obligations pursuant to such Sublicense Agreement. In no event may the sublicensing Party's Sublicensee be entitled to grant further sublicenses.

2.5 Negative Covenants. Licensee covenants that it will not, and it will not permit any of its respective Affiliates, Sublicensees or any Third Party to use or practice any Oramed Technology outside the scope of the license granted under Section 2.2 above or otherwise in contravention of the terms of this Agreement. Oramed covenants that it will not, and it will not permit any of its Affiliates, sublicensees or any Third Party to use or practice any Licensee Technology outside the scope of the license granted to it under Section 2.3 or otherwise in contravention of the terms of this Agreement.

2.6 Oramed Retained Rights; No Implied License. Oramed retains the right to practice and license the Oramed Technology outside the scope of the licenses granted to Licensees in Section 2.2. Except as set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any trademarks, patents or patent applications Controlled by the other Party.

2.7 Activities Outside of a Party's Territory. As to such countries outside of their respective Territory, each Party (i) shall not, and will ensure that its Affiliates and Sublicensees will not, engage in any advertising or promotional activities relating to the Product directed primarily to prospective purchasers of the Product located in the other Party's Territory, and shall use Commercially Reasonable Efforts to ensure that Commercialization activities conducted by or on behalf of such Party via the Internet or other global electronic means or methods are only targeted to persons within the Field and in its Territory, and (ii) shall not, and will ensure that its Sublicensees will not, take orders from any prospective purchaser of the Product located in countries in the other Party's Territory. If a Party or its Sublicensees receives any order from a prospective purchaser of Product located in a country in the other Party's Territory, such Party or Sublicensee shall promptly refer that order to the other Party and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) any Product under such order. If either Party has a reasonable basis to conclude that its customer, sublicensee or distributor, or a customer, sublicensee or distributor of the other Party, is engaged in the sale or distribution of Products outside of the selling Party's Territory, then the selling Party shall take all reasonable steps (including cessation of sales to such customer, sublicensee or distributor) necessary to limit such sale or distribution outside such Party's Territory.

2.8 Cooperation by the Parties. The Parties shall cooperate in good faith to effectively and efficiently implement the objectives of this Agreement.

ARTICLE 3

OVERVIEW AND MANAGEMENT

3.1 Joint Steering Committee.

(a) **Formation and Purpose.** Within 30 days of the Effective Date, the Parties will establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") to oversee and coordinate the Pre-Commercialization and Commercialization activities with respect to the Products in the Field in the Licensee Territory. The JSC shall also be a forum for the exchange of information between the Parties.

(b) **Members.** Not later than 30 days from the Effective Date, Oramed shall appoint 2 representatives to the JSC, and HTIT shall appoint 2 representatives to the JSC. Each Party shall ensure that its representative(s) shall have sufficient seniority and expertise within the applicable Party to make decisions arising with the scope of the JSC's responsibilities. The JSC may change its size from time to time by agreement of the Parties, provided that the JSC shall at all times consist of an equal number of representatives of Oramed, on the one hand, and Licensee. Each of Oramed and HTIT may replace its respective JSC representatives at any time upon written notice to the other Party. The JSC may invite non-members to participate in the discussions and meetings of the JSC where appropriate (and subject to such individuals being subject to mutually acceptable binders of confidentiality), *provided* that such participants shall have no voting authority at the JSC. The JSC shall have a chairperson, who shall serve for a term of one year, and who shall be selected alternately, on an annual basis, by Oramed or Licensee. The initial chairperson shall be selected by HTIT. The role of the chairperson shall be to convene and preside at meetings of the JSC and to ensure the preparation of minutes, but the chairperson shall otherwise have no additional powers or rights of any kind beyond those held by the other JSC representatives.

(c) **Meetings.** The JSC shall meet at least quarterly during the Term unless the Parties mutually agree in writing to a different frequency for such meetings; *provided, however*, that there should be an in-person meeting at least once per year at a location and time agreed by the Parties (the "**In-person Meeting**"). No later than 15 days prior to any scheduled meeting of the JSC, the chairperson of the JSC shall prepare and circulate an agenda for such meeting and, as soon as practicable, materials for the meeting; *provided, however*, that either Party may propose additional topics to be included on such agenda prior to such meeting. The JSC may meet in person, by videoconference or by teleconference (except for the In-person Meeting which shall, obviously, be in-person). Each Party will bear the expense of its respective JSC members' participation in JSC meetings. Meetings of the JSC shall be effective only if at least one representative of each of Oramed, on the one hand, and Licensee, on the other hand, is present or participating in such meeting. The chairperson of the JSC will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect, without limitation, material decisions made at such meetings. The JSC chairperson shall send draft meeting minutes to each member of the JSC for review within 15 days after each JSC meeting. The members of the Committee shall have 15 days to provide comments. The JSC chairperson shall incorporate timely received comments and distribute revised minutes to all members of the JSC for their final review and approval by the later of 45 days after the relevant meeting or the next regularly scheduled meeting of the JSC. For clarity, if the JSC is not able to approve any minutes, it shall thereafter be deemed to be a dispute and shall be subject to the dispute resolution set forth in Section 3.1(d).

(d) **JSC Actions.** Unless otherwise set forth in this Agreement, the JSC will take action by unanimous consent, with each of Oramed and Licensee having a single vote on the JSC, irrespective of the number of representatives actually in attendance at a meeting. In the event of a disagreement between the Oramed's representatives and Licensee's representatives of the JSC, the matter may be referred to one senior executive of each Party (i.e., the Chief Executive Officer or Chief Operating Officer of such Party or the chairman of the Board of Directors of such Party, the "**Executives**") for resolution. If such Executives cannot resolve the matter within 15 days, then (i) if the matter arises *prior to* the commencement by Licensee of a Phase I Clinical Trial in the Licensee Territory, the Executive of Oramed shall have the final decision-making authority on such matter; and (ii) if the matter arises *subsequent to* the commencement by Licensee of a Phase I Clinical Trial in the Licensee Territory, the Executive of HTIT shall have the final decision-making authority on such matter; *provided, further*, in all cases, that any final determination made by such Executive shall be consistent with the terms of this Agreement and involve close consultation with the JSC.

3.2 Costs of Governance. The Parties agree that the costs incurred by each Party in connection with its participation in the JSC shall be borne solely by such Party.

3.3 **Discontinuation of JSC.** The JSC shall continue to exist throughout the Term unless the Parties unanimously agree to disband the JSC.

3.4 **Technical Assistance.** Upon the request of reasonable request of Licensee, and on terms as may be agreed between the Parties, Oramed will provide technical assistance to Licensee to support the use of Oramed Technology by Licenses in the Licensee Territory.

ARTICLE 4

PRE-COMMERCIALIZATION

4.1 Overview of Pre-Commercialization.

(a) **Overview.** Oramed Ltd. shall be responsible for Pre-Commercialization Activities in the Licensee Territory, under the oversight of the JSC, as set forth in this Agreement, with the goal of obtaining Regulatory Approval for Products in the Licensee Territory. It is expressly agreed that HTTT shall be Oramed's exclusive designee for the fulfillment of Oramed's obligations as aforesaid and shall comply with the terms set out herein.

(b) **Consultation.** Oramed shall provide advice, suggestions and constructive feedback on Licensee's Pre-Commercialization strategy, plans and activities in the Licensee Territory (especially in view of Oramed's desire to achieve (to the extent appropriate) global harmonization of Product pre-commercialization activities worldwide), either through the JSC or directly to Licensee if the JSC is disbanded. Such consultation shall also include advice and assistance concerning Licensee's efforts to scale-up, as set forth in Section 4.2(a). Licensee will reasonably and in good faith consider any advice, suggestions, constructive feedback, comments and recommendations that Oramed may have in this regard.

4.2 Pre-Commercialization Plan.

(a) **General.** The initial plan for the Pre-Commercialization of the Products is set out in **Exhibit C** attached hereto, as the same may be further updated or amended from time to time as set forth in Section 4.2(b), (the "**Pre-Commercialization Plan**"). The Pre-Commercialization Plan describes (i) the proposed overall program of Pre-Commercialization in the Licensee Territory, including clinical trials and associated timelines; (ii) timelines for key Regulatory Authority meetings, filing of applications for Regulatory Approval, and receipt of Regulatory Approvals, (iii) the tasks and responsibilities of Licensee under the Pre-Commercialization Plan, and (iv) an associated comprehensive budget for Pre-Commercialization Costs of Licensee. In the event of any inconsistency between the Pre-Commercialization Plan and this Agreement, the terms of this Agreement shall prevail. Oramed shall on an ongoing basis afford Licensee access to complete Oramed Technology, associated manufacturing processes and updates thereto as necessary for Licensee to independently manufacture Products as detailed in the Pre-Commercialization Plan, such Products to be used solely within the scope of the licenses granted to Licensee in this Agreement. Licensee shall at its expense scale-up the Oramed Technology in order to manufacture the Agreed Batch Sizes on a reproducible basis as set forth in the Pre-Commercialization Plan. Oramed shall, until the parties succeed in manufacturing three consecutive batches of the Agreed Batch Size of substantially similar quality and content, be obligated to provide ongoing consulting, advice and assistance services in order to support the scale-up process, including cooperating to provide access to Oramed Technology, associated manufacturing processes and updates thereto as set forth in the Pre-Commercialization Plan. The "Agreed Batch Size" means any batch size, provided that Oramed's obligations hereunder shall not apply to batch sizes in excess of 100,000 capsules.

(b) **Updates to Pre-Commercialization Plan.** From time to time during the Term, and at least on a semi-annual basis, Oramed and/or Licensee may propose relevant and reasonable updates and amendments, as appropriate, to the then-current Pre-Commercialization Plan, and shall submit same to the JSC. Any such updates and amendments shall require the approval of the JSC. Following the granting of such approval, each updated or amended Pre-Commercialization Plan shall become effective and supersede the previous Pre-Commercialization Plan.

4.3 Pre-Commercialization Activities

(a) Licensee shall use Commercially Reasonable Efforts to carry out those activities designated for performance by Licensee in the Pre-Commercialization Plan, including all activities necessary to seek and obtain Regulatory Approval for the Products in the Field in the Licensee Territory (the “**Pre-Commercialization Activities**”). Notwithstanding anything to the contrary herein, provided that Oramed executes the Premas and Swisscaps Agreements, Licensee shall meet the Pre-Commercialization milestones set out in **Exhibit D** hereto (the “**Pre-Commercialization Milestones**”).

(b) Licensee shall conduct all Pre-Commercialization Activities in accordance with the Pre-Commercialization Plan, including milestones set out therein, and standard scientific principles.

(c) The status, progress and results of Pre-Commercialization Activities shall be discussed at meetings of the JSC, and Licensee shall provide the JSC with a written summary report on the status and progress of such Pre-Commercialization Activities at least 15 days prior to each scheduled JSC meeting, or, if the JSC meeting occurs less frequently than once per calendar quarter, on a quarterly basis. If the JSC has been disbanded, such status, progress and results shall be reviewed directly between the Parties on at least a quarterly basis. In addition, Licensee shall make available to Oramed such information about Pre-Commercialization Activities as may be reasonably requested by Oramed from time to time.

(d) **Clinical Trials.** As set forth in Exhibit C, Oramed will work with Licensee to initiate a Phase II study in the Licensee Territory under the same protocol used in Oramed’s Phase IIb United States clinical trial. This study will be fully funded by Licensee. Moreover, in the event that Oramed has not provided a third party with all rights to commercialize the Product in the United States, and as a result is managing the United States Phase III clinical study itself, at least one site involved in such clinical trial will be located in the Licensee Territory and such trial will be under the same protocol used in the Phase III United States study. This study in the Licensee Territory will be fully funded by Licensee.

4.4 Beginning on the Effective Date and continuing through receipt of first Regulatory Approval, Oramed shall have the right (but not the obligation) to have representatives of Oramed attend at the facilities of Licensee and Licensee’s Affiliates, Sublicensees and any authorized Third Parties involved in the Pre-Commercialization and manufacture of Products, for the purpose of visiting such facilities, meeting with personnel involved in Pre-Commercialization and manufacture, or accessing Product-related information available at these facilities. Licensee shall cooperate with Oramed and its representatives in all respects, and shall cause Licensee’s Affiliates, Sublicensees and any authorized Third Parties as aforesaid to cooperate in all respects with Oramed and its representative’s involved with the performance of the foregoing activities.

4.5 Compliance.

(a) Each Party agrees that in performing its obligations under this Agreement: (i) it shall comply in all material respects with all applicable Laws; and (ii) it will not employ or engage any Person who has been debarred by any regulatory authority, or, to such Party’s knowledge, is the subject of debarment proceedings by a regulatory authority.

(b) Licensee shall have the right to engage subcontractors for the performance of its obligations under the Pre-Commercialization Plan, provided that Licensee shall ensure that such subcontractor(s) are bound by written obligations of confidentiality and invention assignment consistent with those contained in this Agreement. Licensee shall remain fully liable to Oramed for any act or omission of any such subcontractors.

(c) Licensee shall maintain complete, current and accurate records of all work conducted by it under the Pre-Commercialization Plan (including all CMC-related activities), and all data and other Information resulting from such work. Such records shall fully and properly reflect all work done and results achieved in the performance of the Pre-Commercialization Activities in good scientific manner appropriate for regulatory and patent purposes. Oramed shall have the right to review all records maintained by Licensee at reasonable times, upon a reasonable written request.

4.6 Pre-Commercialization Costs. Licensee shall bear all costs incurred in carrying out the Pre-Commercialization activities (“**Pre-Commercialization Costs**”). All approvals and certificates from the Regulatory Authority in the Licensee Territory shall be applied for and issued in the name of the Licensee.

4.7 Performance of Clinical Trials and Access to Regulatory Data.

(a) Notwithstanding Section 2.7 (**Activities Outside of a Party’s Territory**), Oramed, its Affiliates and their Sublicensees, in coordination with Licensee, shall have the right to conduct clinical trials and other studies in connection with the Oramed Technology in the Licensee Territory for the purpose of generating Regulatory Data in support of regulatory submissions to the regulatory authorities in the Retained Territory.

(b) Licensee shall, in a timely manner and in compliance with all applicable Laws, provide Oramed with the right to use any and all Licensee Regulatory Data in accordance with Section 2.3.

(c) Oramed shall, in a timely manner and in compliance with all applicable Laws, provide Licensee with the right to use any and all Oramed Regulatory Data in accordance with Section 2.2(c).

(d) Licensee shall provide Oramed with summary reports generated in the conduct of Pre-Commercialization Activities, as well as written summaries of the regulatory filings regarding the Products in the Licensee Territory upon completion of applicable clinical trials. All Information provided hereunder (including such summary reports and written summaries) shall be in English and shall include sufficient information to enable Oramed to understand each study and its results. In addition, upon reasonable request by Oramed, Licensee shall provide access to its facility(ies) and to the facilities of Licensee’s Affiliates, Sublicensees and any authorized Third Parties involved in Pre-Commercialization Activities to the extent necessary to enable Oramed and its representatives to review on-site the study-specific portions of detailed Product-related analyses, raw data generated by such entities related to Products, Information, written Product-related reports, and regulatory filings that are made a part of, are related to, or are quoted in such summary reports or such written summaries.

(e) Licensee shall ensure that in the event that it enters into any agreement with one or more Third Parties for Pre-Commercialization and Commercialization activities (each a “**Third Party Partner**”), that its contractual agreement(s) with such Third Party Partners include the right to transfer to Oramed any additional Regulatory Data generated or developed by such Third Party Partner for use in seeking regulatory approval. Licensee shall remain fully liable to Oramed for any act or omission of any such Third Party Partners.

(f) **Confidentiality.** All pre-clinical, analytical, non-clinical, and clinical data and associated reports disclosed by one Party to the other under this Agreement shall be deemed Confidential Information of the disclosing Party, subject to the permitted uses and disclosures described in this Section 4.7 (including pursuant to the licenses granted under Section 2.2).

4.8 Performance of Phase IIb Study and Notification. Licensee acknowledges that, as of the Execution Date, Oramed is sponsoring a multi-center Phase IIb clinical study involving the Product outside the Licensee Territory (the “**Oramed Study**”). Oramed will keep Licensee reasonably informed about the progress of the Oramed Study from time to time. Oramed will provide Licensee with written notice upon the issuance by Oramed or the issuance by Oramed Inc. of a press release disclosing the top-line data from the Oramed Study. The date on which such notice is provided to Licensee shall be referred to herein as the “**Notification Date**”.

ARTICLE 5

REGULATORY MATTERS

5.1 Licensee’s Regulatory Responsibilities.

(a) Licensee shall own all Regulatory Filings and Regulatory Approvals in the Licensee Territory, and shall be solely responsible for preparing any and all Regulatory Filings at its sole expense in accordance with the Pre-Commercialization Plan, subject to the terms of this Article 5. Oramed shall consult with Licensee as Licensee may reasonably request from time to time in connection with the preparation and filing of such Regulatory Filings.

(b) Licensee shall keep Oramed informed of any material regulatory developments specific to Products throughout the Licensee Territory, and Oramed may contribute to the regulatory plans and strategies for the Products in the Licensee Territory, in each case through the JSC or directly to HTIT if the JSC has been disbanded.

(c) Licensee shall be solely responsible for any discussions with any Regulatory Authority related to any Pre-Commercialization in the Field in the Licensee Territory, provided that Licensee will inform Oramed of any material discussions in advance to the extent practicable, and will reasonably consider any input from Oramed in preparation for such discussions.

(d) To the extent permitted by the applicable Regulatory Authority in the Licensee Territory and as requested by Oramed, Licensee shall allow representatives of Oramed to participate in any material scheduled conference calls and meetings between Licensee and the Regulatory Authority at Oramed’s own expense. If Oramed elects not to participate in such calls or meetings, Licensee shall keep Oramed reasonably informed of the discussions between Licensee and the Regulatory Authority that take place during such calls or meetings.

(e) With respect to all Regulatory Filings made by Licensee and/or its Affiliates and Sublicensees and any authorized Third Parties on their behalf in the Licensee Territory, Licensee shall, and shall ensure that such entities will: (i) submit only data and information that are free from fraud or material falsity; (ii) not use bribery or the payment of illegal gratuities in connection with its Regulatory Filings for the Products; and (iii) submit only data and information that are accurate in all material respects for purposes of supporting Regulatory Approval.

5.2 Additional Regulatory Negative Covenants. If either Oramed or Licensee believes that the other Party, as the case may be, is taking or intends to take any action with respect to the Products that would reasonably be expected to have a material adverse impact upon the regulatory status of the Products in the Retained Territory or the Licensee Territory, as applicable, such Party shall have the right to bring the matter to the attention of the JSC (or directly to such Party if the JSC is disbanded). Without limiting the foregoing, with respect to the Products, unless the Parties otherwise agree in writing: (a) Licensee shall not communicate with any Regulatory Authority having jurisdiction in the Retained Territory, unless so ordered by such Regulatory Authority, in which case Licensee shall provide immediately to Oramed written notice of such order; (b) Licensee shall not submit any Regulatory Filings or seek Regulatory Approvals for the Products in the Retained Territory; (c) Oramed shall not communicate with any Regulatory Authority having jurisdiction in the Licensee Territory, unless so ordered by such Regulatory Authority, in which case Oramed shall provide immediately to Licensee written notice of such order; and (d) Oramed shall not submit any Regulatory Filings or seek Regulatory Approvals in the Licensee Territory (other than in connection with clinical trials as permitted pursuant to Section 4.7(a)).

5.3 Recalls. If any Regulatory Authority issues or requests a recall or takes a similar action in connection with the Product in a Party's Territory, or if a Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal of Product in such Party's Territory, such Party will promptly notify the other Party thereof in writing and by telephone, email or facsimile and use Commercially Reasonable Efforts to promptly discuss such event, incident or circumstance with the other Party in order to jointly determine the appropriate course of action (except in the case of a recall mandated by a Regulatory Authority in the applicable Territory, in which case a Party may act without such advance notice but will notify the other Parties as soon as possible), and shall provide to the other Party copies of all relevant correspondence, notices and the like. Subject to the foregoing sentence, Licensee will retain ultimate responsibility for deciding whether to conduct a recall of Products in the Licensee Territory and the manner in which any such recall will be conducted; and Oramed will retain ultimate responsibility for deciding whether to conduct a recall of Products in the Retained Territory and the manner in which any such recall will be conducted.

ARTICLE 6

COMMERCIALIZATION

6.1 Overview of Commercialization in the Licensee Territory.

(a) **Overview.** Licensee will be solely responsible for all aspects of the Commercialization of Products in the Licensee Territory, which shall be conducted in compliance with all applicable Laws and in accordance with a Commercialization plan for the Territory to be prepared by Licensee and provided to Oramed reasonably in advance of the First Commercial Sale (the "**Commercialization Plan**"). Such Commercialization Plan shall include the activities and timelines in preparation for the launch of each such Product and after such Product launch, and shall be updated on at least an annual basis by Licensee.

(b) **Consultation.** Oramed shall provide advice, suggestions and constructive feedback on the Licensee's commercialization strategy, plans and activities, either through the JSC or directly with Licensee once the JSC is disbanded. Licensee will reasonably and in good faith consider any advice, suggestions, constructive feedback, comments and recommendations that Oramed may have with respect to Licensee's commercialization of the Product.

6.2 Licensee's Performance.

(a) **Commercial Diligence.** Licensee shall use Commercially Reasonable Efforts to Commercialize Products throughout the Licensee Territory. Without limiting the generality of the foregoing, Licensee shall conduct all Commercialization activities in accordance with the Commercialization Plan, with a level of effort that is consistent with industry standards and is designed to maximize the overall commercial opportunity for the Product, and shall use Commercially Reasonable Efforts to launch the first Product in the Licensee Territory within six (6) months after obtaining Regulatory Approval and to market Products following such launch. Notwithstanding anything to the contrary herein, Licensee shall meet the Commercialization milestones set out in **Exhibit D** hereto (the "**Commercialization Milestones**").

(b) **Reports.** From and after the date that is six (6) months before the anticipated date of First Commercial Sale, Licensee shall update Oramed at least once in each calendar quarter regarding Licensee's Commercialization activities, including at Oramed's reasonable request providing annual sales guidance forecasts. In addition, from and after the date that is six (6) months before the anticipated date of First Commercial Sale, Licensee shall present a written quarterly report to Oramed summarizing Licensee's Commercialization activities pursuant to this Agreement, at a level of detail reasonably requested by Oramed and sufficient to enable Oramed to determine Licensee's compliance with its diligence obligations pursuant to this Section 6.2. In addition to such quarterly updates and written reports, upon the reasonable request of Oramed, Licensee shall provide to Oramed on an interim basis then-current Commercialization figures and data of Licensee and its Sublicensees and Affiliates that are reportable to Oramed under this Agreement. For clarity, all reports and information shared with Oramed pursuant to this Section 6.2(b) shall be deemed Licensee's Confidential Information as per Article 12.

6.3 Trademark. As soon as a Party determines the trademarks to be used in commercializing the Products in its respective Territory, such Party shall promptly notify the other Party and thereafter, as between the Parties, shall have the exclusive right to use such trademark(s) throughout its Territory. Licensee shall have the right to brand the Product in the Licensee Territory using Licensee's related trademarks and any other trademarks and trade names Licensee determines reasonably appropriate for the Product subject to the consent and approval of Oramed in connection thereto ("**Product Marks**"), which consent and approval shall not be unreasonably withheld. Licensee shall own all rights in and to the Product Marks and will be responsible for filing, prosecution, maintenance and defense of all registrations of the Product Marks, and will be responsible for the payment of any costs relating to filing, prosecution, maintenance and defense of all Product Marks, in the Territory. Licensee shall not, and shall ensure that its Affiliates and Sublicensees will not, make any use of any trademark similar to the trademark used by Oramed in commercializing the Products in the Retained Territory. Unless expressly required by applicable Law or otherwise expressly agreed in writing by Oramed, Licensee may **not** use the corporate name, trademark or logo of Oramed, Oramed Inc. or/and of their respective Affiliated entities for any purpose. Should such use become required as a result of applicable Law or other written agreement between the Parties, such usage shall be in strict compliance with Oramed's then-current guidelines for such name, trademark or logo usage.

ARTICLE 7

MANUFACTURING

7.1 Manufacture by or on Behalf of Licensee. Licensee shall be solely responsible for the manufacture and supply of Product for use in Pre-Commercialization and Commercialization, including for clinical and commercial purposes. Manufacture of Products for use in Pre-Commercialization and Commercialization will be performed in the Licensee Territory, and shall be performed solely by Licensee. Licensee shall ensure that all manufacture of Product meets GMP standards or their equivalent in the Licensee Territory and Oramed Product specifications. Licensee shall bear all costs and expenses incurred in connection with the manufacture and supply of the Products for the Licensee Territory, including all clinical manufacturing costs and the cost of qualifying its facilities.

7.2 Manufacture of Product for Oramed. Upon Oramed's request, Licensee agrees to manufacture and supply Product to Oramed (or Oramed's designee(s)) for resale in the Retained Territory on a cost-plus 8% basis.

ARTICLE 8

FINANCIAL TERMS AND REPORTING

8.1 Initial Payment. Within 20 days of the Execution Date, Licensee shall pay **US \$3,000,000** (the "**Initial Payment**") to Oramed. It is expressly agreed that, upon release to Oramed, the Initial Payment shall be non-refundable and non-creditable except as agreed in Section 13.4 of the Agreement.

8.2 Subsequent Payment. Except the Initial Payment, Licensee shall pay Oramed the subsequent payment in accordance with the Payment Schedule as set forth in **Exhibit F1** (the "**Subsequent Payment**"). In addition, Licensee shall pay Oramed the additional service agreement milestones payments in accordance with the Payment Schedules set forth in **Exhibit F2** and **F3** (the "**Service Agreement Milestone Payments**"). Failure to make the Subsequent Payment and the Service Agreement Milestone Payments in full upon satisfaction by Oramed of the applicable milestones shall be deemed a material breach of this Agreement giving rise to Oramed's right to terminate this Agreement pursuant to Section 13.2.

8.3 Royalties.

(a) **Royalty Rates.** The Licensee shall pay to Oramed a running royalty of the Applicable Rate on Net Sales during the Royalty Term. The "**Applicable Rate**" means 10%, *provided however*, that the Applicable Rate shall be reduced to (a) 8%, if neither of the Premas Agreement or Swisscaps Agreement is executed within 10 months of the Effective Date or (b) 9%, if only one of the Premas Agreement or Swisscaps Agreement is executed within 10 months of the Effective Date or (c) 5%, if following the expiration of the last-to-expire Valid Claim of an Oramed Patent covering the use, import, manufacture or Commercialization of such Product in the Licensee Territory, a generic equivalent for the Product is released in the Licensee Territory by a Third Party that is followed by a reduction of at least 50% in the retail price of the relevant Product in the Licensee Territory.

(b) **Royalty Term.** The royalty payment obligation under this Section 8.3 shall apply, on a Product-by-Product basis in the Licensee Territory, during the period of time beginning upon the First Commercial Sale of such Product in the Licensee Territory, and ending upon the later of: (i) the expiration of the last-to-expire Valid Claim of an Oramed Patent covering the use, import, manufacture or Commercialization of such Product in the Licensee Territory; and (ii) 15 years after the First Commercial Sale of such Product in the Licensee Territory (such period, the "**Royalty Term**").

8.4 Payments and Reports. Within 30 days after the end of each calendar quarter commencing from First Commercial Sale, Licensee shall deliver to Oramed a report containing the following information for the prior calendar quarter:

- (i) the number of units of Products sold by Licensee, its Affiliates and any party acting on its or their behalf (including Sublicensees);

- (ii) the gross amount invoiced for the Product sold by Licensee, its Affiliates and any party acting on its or their (including Sublicensees);
- (iii) a calculation of Net Sales, including an itemized listing of deductions permitted under the definition of Net Sales; and
- (iv) a calculation of the total amount payable to Oramed in U.S. Dollars, together with the exchange rates used for conversion.

Concurrent with the delivery of each report delivered pursuant to the foregoing, Licensee shall remit to Oramed all amounts due with respect to Net Sales and other payments due for the applicable calendar quarter. If no royalties or other payments are due to Oramed for such reporting period, the report shall so state. In addition, Licensee shall provide Oramed, within 60 days after the end of each calendar year during the Term, commencing at the end of the calendar year in which First Commercial Sale occurred, with a report, certified by an independent certified public accountant, relating to royalties and other payments due to Oramed pursuant to this Agreement in respect of the previous calendar year and containing the same details as those specified above in respect of the previous calendar year.

8.5 Payment Method, Currency and Late Payments. All payments due hereunder shall be made in U.S. Dollars by wire transfer of immediately available funds to Oramed's bank account, the details of which are set out in **Exhibit E** hereto. Payment shall be made directly from a Chinese bank account of Licensee. Where Net Sales are calculated in currencies other than U.S. Dollars, they will be converted into U.S. Dollars using the Bank of China "Middle Rate" on the last business day of the applicable calendar quarter. If Oramed does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due until the date of payment at the per annum rate of 10% or the maximum rate allowable by applicable Law, whichever is lower, compounded monthly.

8.6 Records; Audits. Licensee will maintain (and will cause its Affiliates and Sublicensees to maintain) complete and accurate records in sufficient detail to permit Oramed or its representatives to confirm the accuracy of the calculation of payments under this Agreement, as well as to confirm Pre-Commercialization Costs and Regulatory Data Costs. Upon reasonable prior notice, such records shall be available during regular business hours for a period of 3 years from the end of the calendar year to which they pertain for examination at the expense of Oramed, by an independent certified public accountant selected by Oramed and reasonably acceptable to Licensee, for the purpose of verifying the accuracy of the financial reports or payments furnished by Licensee pursuant to this Agreement. Any amounts shown to be owed but unpaid shall be paid within 30 days from the accountant's report, plus interest (as set forth in Section 8.5) from the original due date. Oramed shall bear the full cost of such audit unless such audit discloses an underpayment by Licensee of more than 3% of the amount due, in which case Licensee shall bear the full cost of such audit.

8.7 Taxes. Amounts due hereunder are exclusive of value added, sales, excise and similar taxes, all of which shall be added to payments made hereunder in accordance with applicable law and regulations. The Parties shall use all reasonable and legal efforts to reduce or eliminate Tax or similar obligations in respect of the Initial Payment, Subsequent Payment, royalties, and any other payments made by Licensee to Oramed under this Agreement, to the extent permitted by applicable law.

8.8 Withholding and Similar Taxes. Amounts due hereunder are inclusive of any withholding and similar taxes, all of which shall be withheld and deducted directly from payments made hereunder in accordance with applicable law and regulations. To the extent Licensee is required under applicable law in the Licensee Territory to withhold taxes from any amounts due to Oramed under this Agreement, Licensee shall (a) pay the amounts of such taxes to the proper governmental authority in the Licensee Territory in a timely manner, (b) promptly transmit to Oramed an official certificate or other documentation of the payment of any such withholding taxes paid, including copies of receipts or other evidence reasonably required and sufficient to enable Oramed to document such tax withholdings adequately for purposes of claiming foreign tax credits and similar benefits, if available. Oramed shall provide Licensee any tax forms that may be reasonably necessary in order for Licensee to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Oramed shall use reasonable efforts to provide any such tax forms to Licensee at least 30 days prior to the due date for any payment for which Oramed desires that Licensee apply a reduced withholding rate. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Law, of withholding taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax. Licensee shall require its Affiliates and Sublicensees to cooperate with Oramed in a manner consistent with this Section 8.8

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 Ownership of Inventions. It is expressly agreed that Oramed Ltd. is the exclusive owner of the Oramed Technology, and shall be the owner of any know-how and inventions related to the Products generated under this Agreement made by employees, agents, or independent contractors of Oramed, (“**Oramed Inventions**”), it being agreed that Oramed Inventions, if any, shall be included within the scope of the licenses granted pursuant to Section 2.2. Know-how and inventions *other than* Oramed Inventions that are made by employees, agents, or independent contractors of the Licensee (as well as know-how and inventions made by its Affiliates and/or Sublicensees), in the course of conducting their activities under this Agreement, together with all intellectual property rights therein, (“**Licensee Inventions**”) shall be the exclusive property of the Licensee.

9.2 Disclosure of Inventions. Licensee shall promptly disclose to Oramed any invention disclosures, or other similar documents, submitted to them by their respective employees, agents or independent contractors (as well their respective Affiliates and/or Sublicensees) describing Oramed Inventions.

9.3 Joint Inventions. Inventions *other than* Oramed Inventions that are jointly arrived at in the course of the Parties’ conducting their activities under this Agreement (“**Joint Inventions**”) shall be jointly owned by the Parties. In such event, Licensee may exploit such Joint Inventions in the Licensee Territory and Oramed may exploit such Joint Inventions in the Retained Territory. The parties shall collaborate in good faith with respect to seeking appropriate protection for Joint Inventions, if any. For the purpose of clarity, the Licensee shall have the exclusive right to further exploit the Oramed Inventions and/or the Joint Inventions in the Licensee Territory, according to the terms of this Agreement, without any payment to Oramed other than the payments agreed in this Agreement.

9.4 Prosecution of Patents.

(a) **General.** The Parties shall cooperate with each other to achieve (to the extent appropriate) global harmonization of filing, prosecution and maintenance of Oramed Patents.

(b) **Oramed Prosecuted Patents.** Subject to the terms of this section, Oramed shall have the sole right to prepare, file, prosecute and maintain all Oramed Patents in the Licensee Territory, (the “**Oramed Prosecuted Patents**”). All Oramed Prosecuted Patents shall be prepared, filed, prosecuted and maintained through a law or patent attorney firm selected by Oramed, at Oramed’s expense. Oramed will consult, or will instruct its patent counsel to consult with Licensee regarding the content of patent applications contained within the Oramed Prosecuted Patents, the prosecution thereof and the content of communications with the relevant patent agencies in the Licensee Territory. Oramed shall reasonably consider comments by Licensee with respect to the foregoing so long as such comments are received by Oramed a reasonable amount of time in advance of any filing deadlines. To avoid doubt, Oramed has and shall retain sole discretion with respect to the preparation, filing, prosecution and maintenance of all Oramed Patents in the Retained Territory; *provided, however*, that Oramed shall be required to obtain the prior written consent of Licensee prior to abandoning any Oramed Patents in the Licensee Territory, such consent not to be unreasonably withheld, conditioned or delayed.

(c) **HTIT Prosecuted Patents.** Subject to the terms of Section 9.1, HTIT shall have the sole right at its sole discretion to prepare, file, and prosecute the patent applications claiming the Licensee Inventions in the Licensee Territory (“**HTIT Prosecuted Patents**”). All HTIT Prosecuted Patents shall be prepared, filed, prosecuted and maintained through a law or patent attorney firm selected by HTIT, at HTIT’s expense.

(d) **Cooperation in Prosecution.** Each Party shall provide the other Party all reasonable assistance and cooperation in the efforts provided above in this Section 9.4, including providing any necessary powers of attorney and executing any other required documents or instruments for such efforts (without charge to the other Party).

(e) **No Warranty.** Nothing contained herein shall be deemed to be a warranty by any Party that such Party can or will be able to obtain patents on patent applications included in the Oramed Technology or the Licensee Technology, or that any of the Oramed Patents or HTIT Prosecuted Patents will afford adequate or commercially worthwhile protection.

9.5 Infringement of Patents by Third Parties.

(a) **Notification.** Each Party shall promptly notify the other Party in writing of any existing or threatened infringement of the Oramed Patents and/or Oramed Prosecuted Patents in the Licensee Territory through the Pre-Commercialization or Commercialization by a Third Party, of which such Party becomes aware, and of any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of any of the Oramed Patents and/or Oramed Prosecuted Patents in the Licensee Territory (collectively “**Patent Infringement**”).

(b) Patent Infringement.

(1) For any Patent Infringement, each Party shall share with the other Party all Information available to it regarding such alleged infringement. Licensee shall have the first right, but not the obligation, to bring an appropriate suit or other action in the Licensee Territory against any person or entity engaged in such Patent Infringement, subject to Section 9.5(b)(2) through 9.5(b)(4) below. If Licensee fails to institute and prosecute an action or proceeding in the Licensee Territory to abate the Patent Infringement within a period of 60 days after the first notice is delivered under Section 9.5(a), then Oramed shall have the right but not the obligation to commence a suit or take action in the Licensee Territory to enforce the applicable Oramed Prosecuted Patents against such Third Party perpetrating such Patent Infringement, at its own cost and expense. In the event that Oramed exercises such right to commence such suit or to take action in the Licensee Territory regarding such Patent Infringement, Licensee shall reasonably cooperate with Oramed in connection with such Oramed Prosecuted Patent enforcement efforts.

(2) Each Party shall provide to the Party enforcing any such rights under this Section 9.5(b) reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by applicable Law to pursue such action. The enforcing Party shall keep the other Parties regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any such efforts.

(3) Each Party shall bear all of its own internal costs incurred in connection with its activities under this Section 9.5(b). In the event a Party commences a Patent Infringement action in the Licensee Territory, it shall bear all external costs and expenses for such action.

(4) The Party not bringing an action with respect to Patent Infringement under this Section 9.5(b) shall be entitled to separate representation in such matter by counsel of its own choice, and its own expense, but such Party shall at all times cooperate fully with the Party bringing such action.

(c) **Infringement other than a Patent Infringement.** For any and all infringements of any Oramed Prosecuted Patent other than a Patent Infringement (including the enforcement of Oramed Patents against infringement in the Retained Territory), as between the Parties, Oramed shall have the sole and exclusive right to bring an appropriate suit or other action against any person or entity engaged in such other infringement, in its sole discretion, and as between the Parties Oramed shall bear all related expenses and retain all related recoveries. Oramed shall keep Licensee regularly informed of the status and progress of such enforcement efforts and shall reasonably consider Licensee's comments on any such efforts where appropriate, in Oramed's discretion.

(d) **Settlement.** Licensee shall not settle any claim, suit or action brought under this Section 9.5 involving Oramed Patents and/or Oramed Prosecuted Patents without the prior written consent of Oramed. In the Licensee Territory, Oramed shall not settle any claim, suit or action brought involving Oramed Patents and/or Oramed Prosecuted Patents without prior written consent of Licensee, such consent not to be unreasonably withheld, conditioned or delayed. Nothing in this Article 9 shall require Oramed to consent to any settlement that would have an adverse impact upon any Oramed Patent in the Retained Territory, or to the pre-commercialization, commercialization, manufacture, use, importation, offer for sale or sale of Products in the Retained Territory.

(e) **Allocation of Proceeds.** The enforcing Party shall retain monetary damages recovered from any Third Party in a suit or action brought by it under this Section 9.5 after first reimbursing the Parties for any expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel); *provided, however*, that, in the event Licensee is the Party bringing suit, Licensee shall pay Oramed 30% of the amount of such recovery which is retained by Licensee after such reimbursement.

9.6 Infringement of Third Party Rights in the Licensee Territory. If the Licensee becomes the subject of a lawsuit brought by a third party unaffiliated with Licensee or Licensee's customers or sublicensees, that the manufacture, use or sale of the Product or technology actually transferred under the Swisscap or Premas Agreements infringes the intellectual property rights of such unaffiliated third party in the Licensee Territory, then Oramed shall defend such lawsuit as required pursuant to Section 11.1 and shall make reasonable commercial efforts to procure for Licensee the intellectual property rights in the Licensee Territory necessary such that Licensee's manufacture, use or sale of the Product in the Licensee Territory shall not infringe the intellectual property rights of such third party. The foregoing shall not apply to the extent Oramed is not required to defend and indemnify the applicable claim pursuant to Section 11.1

ARTICLE 10

REPRESENTATIONS AND WARRANTIES

10.1 Mutual Representations and Warranties. Each Party hereby represents and warrants that, as of the Effective Date:

(a) **Corporate Existence and Power.** It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

(b) **Authority and Binding Agreement.** It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to and limited by: (i) applicable bankruptcy, insolvency, reorganization, moratorium, and other laws generally applicable to creditors' rights; and (ii) judicial discretion in the availability of equitable relief.

(c) **No Conflict.** The execution and delivery of this Agreement, and the performance by such Party of its obligations under this Agreement, including the grant of rights to the other Party pursuant to this Agreement, does not and will not: (i) conflict with, nor result in any violation of or default under any instrument, judgment, order, writ, decree, contract or provision to which such Party is otherwise bound; (ii) give rise to any lien, charge or encumbrance upon any assets of such Party or the suspension, revocation, impairment, forfeiture or non-renewal of any material permit, license, authorization or approval that applies to such Party, its business or operations or any of its assets or properties; or (iii) conflict with any rights granted by such Party to any Third Party or breach any obligation that such Party has to any Third Party.

(d) **Required Consents.** It has obtained, or is not required to obtain, the consent, approval, order, or authorization of any Third Party, or has completed, or is not required to complete, any registration, qualification, designation, declaration or filing with, any Governmental Authority, in connection with the execution and delivery of this Agreement and the performance by such Party of its obligations under this Agreement, including any grant of rights to the other Party pursuant to this Agreement.

10.2 Additional Representations and Warranties of Oramed. For purposes of this Section 10.2, the phrase "the knowledge of Oramed" means the actual knowledge of Oramed's executive officers, after reasonable inquiry. Oramed hereby represents and warrants that, as of the Execution Date:

(a) Oramed has all necessary rights in and to the Oramed Technology and has the right to grant Licensees the licenses set out in Section 2.2;

(b) It has not received any written notice from any Third Party asserting or alleging that research or development of any Product by Oramed infringed or misappropriated or infringes or misappropriates the intellectual property rights of such Third Party;

(c) There are no actual, pending, or to the knowledge of Oramed, alleged or threatened adverse actions, suits, claims, interferences or formal governmental investigations involving the Products or the Oramed Technology relating to the Products by or against Oramed in or before any court, governmental or regulatory authority; and

(d) To the knowledge of Oramed, there is not any pending claim or litigation which alleges that its use of the Oramed Technology has violated the intellectual property rights of any Third Party.

(e) Subject to Section 2.1, and to the knowledge of Oramed as of the Execution Date, there are no additional limitations or restrictions (including but not limited to the licensing of any Third Party, the paying to any Third Party and the reliance on the patent of any Third Party) which will affect the use of Oramed Technology by the Licensee.

10.3 Additional Representations and Warranties of Licensee. For purposes of this Section 10.3, the phrase “the knowledge of Licensee” means the actual knowledge of Licensee’s executive officers, after reasonable inquiry. Licensee hereby represents and warrants that, as of the Execution Date:

(a) Licensee has all necessary rights in and to the Licensee Technology and has the right to grant Oramed the licenses set out in Section 2.3;

(b) Licensee has not received any written notice from any Third Party asserting or alleging that the Licensee Technology infringed or misappropriated or infringes or misappropriates the intellectual property rights of such Third Party;

(c) There are no actual, pending, or to the knowledge of Licensee, alleged or threatened adverse actions, suits, claims, interferences or formal governmental investigations involving the Licensee Technology by or against Licensee in or before any court, governmental or regulatory authority; and

(d) To the knowledge of Licensees, there is not any pending claim or litigation which alleges that its use of the Licensee Technology has violated the intellectual property rights of any Third Party.

10.4 Disclaimer. Licensee acknowledges and understands that the Products are the subject of ongoing clinical trials and that Oramed cannot and does not assure the safety or efficacy of the Products, or that the Products will be approved by any Regulatory Authority in the Licensee Territory or elsewhere, or that the Products will be commercially viable or successful.

10.5 Oramed hereby makes the special warranties to the Licensee: (a) Oramed will grant Licensee rights to all Oramed Technology and Oramed Regulatory Data in accordance with the terms of this Agreement; and (b) to the knowledge of Oramed as of the Execution Date, the manufacture, sale, offer for sale, import of the Products by Licensee in the Licensee Territory would not infringe any intellectual property rights of any Third Party. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 10, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT (OTHER THAN AS SET FORTH ABOVE), OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY.

ARTICLE 11

INDEMNIFICATION

11.1 Indemnification by Oramed. Oramed hereby agrees to defend, hold harmless and indemnify (collectively, “**Indemnify**”) Licensee and its directors, officers, employees, sublicensees and customers (the “**Licensee Indemnitees**”) from and against any and all liabilities, expenses or losses, including reasonable legal expenses and attorneys’ fees (collectively “**Losses**”) in each case resulting from Third Party suits, claims, actions and demands (each, a “**Third Party Claim**”) arising out of (a) a breach of Oramed’s representations and warranties set forth in Article 10 or (b) any claim by a third party unaffiliated with Licensee or Licensee’s customers or sublicensees, that the manufacture, use or sale of the Product or technology actually transferred under the Swisscap or Premas Agreements infringes the intellectual property rights of such unaffiliated third party in the Licensee Territory. Oramed’s obligation to Indemnify the Licensee Indemnitees pursuant to this Section 11.1 shall not apply to the extent that (i) the Licensee Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and Oramed’s defense of the relevant Losses is materially prejudiced by such failure, or (ii) any Losses arise from, are based on, or result from the negligence, violation of law or willful misconduct of any Licensee Indemnitee or Licensee Sublicensee or from any activity for which Licensee is obligated to Indemnify Oramed under Section 11.2 or (iii) to the extent the Third Party Claim relates to any technology, materials or manufacturing processes that are not owned or developed by Oramed.

11.2 Indemnification by Licensee. Licensee hereby agrees to indemnify Oramed, its Affiliates, and their respective directors, officers and employees (the “**Oramed Indemnitees**”) from and against any and all Losses in each case resulting from Third Party Claims arising out of (a) a breach of any of Licensee’s obligations under this Agreement, including Licensee’s representations and warranties set forth in Article 10; and (b) the Pre-Commercialization, manufacture, use, handling, storage, sale or other Commercialization or disposition of Products in the Licensee Territory by or on behalf of Licensee, its Affiliates and/or Sublicensees, including as a result of any infringement claims or product liability claims. Licensee’s obligation to Indemnify the Oramed Indemnitees pursuant to this Section 11.2 shall not apply to the extent that (i) the Oramed Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and Licensee’s defense of the relevant Losses is materially prejudiced by such failure, or (ii) any Losses arise from, are based on, or result from the negligence or willful misconduct of any Oramed Indemnitee or from any activity for which Oramed is obligated to indemnify the Licensee Indemnitees under Section 11.1.

11.3 Procedure. The indemnified Party shall provide the indemnifying Party with prompt written notice of the Third Party Claim which might give rise to an indemnification obligation pursuant to this Article 11 indicating the nature of the claim and the basis therefore. The indemnifying Party shall have the right, at its option, to assume the defense of, at its own cost and by its own counsel, any such Third Party Claim involving the asserted liability of the indemnified Party. If any indemnifying Party shall undertake to compromise or defend any such asserted liability, it shall promptly notify the indemnified Party of its intention to do so, and the indemnified Party shall agree to cooperate with the indemnifying Party and its counsel in the compromise of, or defense against, any such asserted liability; *provided, however*, that the indemnifying Party shall not, as part of any settlement or other compromise, admit to liability for which the indemnifying Party is not fully indemnifying the indemnified Party or agree to an injunction with respect to activities of the indemnified Party without the written consent of the indemnified Party, not to be unreasonably withheld, conditioned or delayed. Notwithstanding an election by the indemnifying Party to assume the defense of any Third Party Claim as set forth above, such Indemnified Party shall have the right (at its own cost if the indemnifying Party has elected to assume such defense) to employ separate counsel and to participate in the defense of any Third Party Claim. All costs incurred by an indemnified Party in connection with enforcement of its rights under Sections 11.1 or 11.2, as applicable, shall also be reimbursed by the indemnifying Party promptly after final determination that such indemnified Party is entitled to such indemnification by the indemnifying Party.

11.4 Limitation of Liability. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, INDIRECT, OR CONSEQUENTIAL DAMAGES OR LOSS OF PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, AND TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, NOTHING IN THIS SECTION 11.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTIONS 11.1 OR 11.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 12, OR FOR LICENSEE'S BREACH OF THE SCOPE OF THE LICENSE RIGHTS GRANTED UNDER THIS AGREEMENT.

11.5 Insurance. Licensee shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations under this Agreement and which are consistent with normal business practices of global pharmaceutical companies at all times during which any Product is being clinically tested in human subjects or commercially distributed or sold by Licensee, its respective Affiliates and/or Sublicensees, and for a period of 7 years thereafter. It is understood that such insurance shall not be construed to create a limit of Licensee's liability with respect to its indemnification obligations under this Article 11.

ARTICLE 12

CONFIDENTIALITY

12.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for a period of 7 years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information of the other Party. The foregoing confidentiality and non-use obligations shall not apply to any portion of the Confidential Information that the receiving Party can demonstrate by competent written proof:

- (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;
- (d) is subsequently disclosed to the receiving Party by a Third Party who has a legal right to make such disclosure; or

(e) is subsequently independently discovered or developed by the receiving Party without the aid, application, or use of the disclosing Party's Confidential Information, as evidenced by a contemporaneous writing.

12.2 Authorized Disclosure. Notwithstanding the obligations set forth in Section 12.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement (which terms shall be the Confidential Information of both Parties) to the extent:

(a) such disclosure: (i) is reasonably necessary for filing or prosecuting Patent rights as contemplated by this Agreement; or (ii) is reasonably necessary for prosecuting or defending litigation as contemplated by this Agreement; or

(b) such disclosure is reasonably necessary: (i) to such Party's directors, attorneys, independent accountants or financial advisors for the sole purpose of enabling such individuals to provide advice to the receiving Party, provided that in each such case on the condition that such directors, attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations consistent with those contained in this Agreement; or (ii) to actual or potential investors or acquirers solely for the purpose of evaluating an actual or potential investment or acquisition; provided that in each such case on the condition that such actual or potential investors or acquirers are bound by confidentiality and non-use obligations consistent with those contained in the Agreement; or

(c) such disclosure is required by judicial or administrative process, provided that in such event such Party shall promptly inform the other Party of such required disclosure and provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Article 12, and the Party disclosing Confidential Information pursuant to law or court order shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information; or

(d) such disclosure is reasonably necessary to its collaborators in its respective Territory (including clinical research organizations, hospitals, doctors, consultants, subcontractors and Affiliates) for the purpose of Pre-Commercialization and/or Commercialization activities, solely for the purpose of carrying out such collaboration, on the condition that such collaborators are bound by confidentiality and non-use obligations consistent with those contained in the Agreement; or

(e) such disclosure is required by applicable Law, including without limitation U.S. federal or state securities laws and regulations.

12.3 Publication. In the event that Licensee, its Affiliates and/or Sublicensee, as may be applicable, desire to publish or otherwise present or disclose papers containing results of and other information regarding Pre-Commercialization and/or Commercialization of Products, including oral presentations and abstracts, (i) they shall ensure that such disclosures do not contain any Oramed Confidential Information; and (ii) they shall provide a copy of any such disclosures to Oramed and shall not make any such disclosures until they have received the prior written consent of Oramed which Oramed may give or withhold in its sole discretion.

12.4 Publicity; Use of Names. Subject to Section 12.2 and the rest of this Section 12.4, no disclosure of the terms of this Agreement may be made by any Party or its Affiliates, and no Party shall use the name, trademark, trade name or logo of any other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or other public disclosure relating to this Agreement or its subject matter, without the prior express written permission of such other Party, except as may be required by Law.

(a) Notwithstanding anything contained in this Agreement to the contrary, a Party may disclose this Agreement and its terms in securities filings with the U.S. Securities Exchange Commission (“**SEC**”), the China Securities Regulatory Commission (“**CSRC**”), Israel Securities Authority (“**ISA**”) or other regulatory agency (collectively, “**Securities Agencies**”) or exchange where a Party’s securities are traded (or equivalent foreign agency or exchange) (collectively, “**Exchanges**”) to the extent required by Law after complying with the procedure set forth in this Section 12.4. In such event, the Party seeking such disclosure will prepare a draft confidential treatment request and a proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party agrees to promptly (and in any event, no more than 7 days after receipt of such confidential treatment request and proposed redactions (or such lesser period of time as required by Law)) give its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines proscribed by applicable Securities Agencies and/or Exchanges. The Party seeking such disclosure shall exercise Commercially Reasonable Efforts to obtain confidential treatment of the Agreement from applicable agency or exchange as represented by the redacted version reviewed by the other Party.

(b) Further, each Party acknowledges that the other Party may be legally required to make public disclosures (including in filings with Securities Agencies and/or Exchanges) of the execution and delivery of this Agreement as well as certain material developments or material information generated under this Agreement and agrees that each Party may make such disclosures as required by Law; *provided, however*, that the Party seeking such disclosure first provides the other Party with a copy of the proposed disclosure, and *provided further* that (except to the extent that the Party seeking disclosure is required to disclose such information to comply with applicable Law) if the other Party demonstrates to the reasonable satisfaction of the Party seeking disclosure, within 3 days of such Party’s providing the copy, that the public disclosure of previously undisclosed information will materially adversely affect the pre-commercialization or commercialization of a Product being pre-commercialized or commercialized in the applicable Territory, the Party seeking disclosure will remove from the disclosure such specific previously undisclosed information as the other Party shall reasonably request to be removed.

(c) During the Term, each Party shall have the right to issue a press release or make a public announcement concerning the material terms of this Agreement or the Pre-Commercialization or Commercialization under this Agreement. If a Party desires to issue such a press release or make such a public announcement, it shall provide the other Party with reasonable advance notice of the content thereof. The other Party shall have the right to review and comment on such proposed press release or announcement and the Party proposing such press release or public announcement shall take into consideration and incorporate when appropriate the comment from the other Party; *provided, however*, that in the event that a Party does not respond within 3 days of the date on which the announcement was provided to such Party, the Party desiring to issue the release or make the announcement may proceed to do so.

(d) The Parties agree that after a public disclosure pursuant to Sections 12.4(a), (b) or (c) has been reviewed and approved by the other Party (or be deemed to have been approved), the disclosing Party may make subsequent public disclosures or issue a press release disclosing the same content as was contained in such public disclosure without having to obtain the other Party’s prior consent and approval.

(e) Licensee acknowledges and agrees that Oramed may furnish a fully executed copy of this Agreement to Oramed Inc.

12.5 Equitable Relief. Each Party acknowledges that a breach of this Article 12 may not reasonably or adequately be compensated in damages in an action at law and that such a breach shall cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party may be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to seek preliminary and permanent injunctive and other equitable relief from any court of competent jurisdiction to prevent or curtail any breach of the obligations relating to Confidential Information set forth herein by the other Party.

ARTICLE 13

TERM AND TERMINATION

13.1 Term. The Term of this Agreement will commence on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect until the cessation of all Commercialization in the Licensee Territory. Upon the expiration of the Royalty Term, the licenses granted to Licensee pursuant to Section 2.2 shall become fully-paid up, royalty-free.

13.2 Termination for Breach.

(a) **Notice.** If either Oramed believes that HTIT is in material breach of this Agreement, or if HTIT believes that Oramed is in material breach of this Agreement, then the Party holding such belief, as the case may be (the “**Non-Breaching Party**”) may deliver written notice of such breach to the other Party, as the case may be (the “**Notified Party**”). The Notified Party shall have 30 days after receipt of such notice to cure such breach.

(b) **Failure to Cure.** If the Notified Party fails to cure the breach as provided for in Section 13.2(a), then the Non-Breaching Party may terminate this Agreement immediately upon written notice to the Notified Party.

(c) **Disputes.** If a Party gives notice of termination under this Section 13.2 and the other Party disputes whether such termination is proper under this Section 13.2, then the issue of whether this Agreement may properly be terminated (i.e., whether a material breach occurred or whether a material breach was cured) shall be resolved in accordance with Article 14. If as a result of such dispute resolution process it is determined that the notice of termination was proper, then such termination shall be deemed to have been effective 30 days following the date of the notice of breach. If, as a result of such dispute resolution process, it is determined that the notice of termination was improper, then no termination shall have occurred and this Agreement shall remain in effect.

13.3 Termination for Convenience. Licensee shall have the right to terminate this Agreement in its entirety for any reason or no reason at all by providing Oramed with at least 90 days’ prior written notice of such termination; *provided, however*, that in no event may Licensee exercise such right to terminate hereunder following the First Commercial Sale.

13.4 Termination Prior to Effective Date. Notwithstanding anything to the contrary in this Article 13, (A) either Oramed or Licensee may terminate this Agreement upon written notice to the other following a response from the OCS and each Party's discharge of its obligations under Section 2.1, with no liability to any other Party (i) advising that the OCS does not grant its consent to the Execution Date Agreement or a modified Execution Date Agreement, as such modified Execution Date Agreement and the process for modification are described in Section 2.1; or (ii) as contemplated in Section 2.1(iii); (B) Oramed may terminate this Agreement upon written notice to Licensee in the event that the OCS imposes materially adverse obligations or consequences (with financial or otherwise) on Oramed as a pre-condition to obtaining OCS consent to this Agreement; or (C) either Oramed or Licensee may terminate this Agreement upon written notice to the other Party as set forth in the last paragraph of Section 13.2(b). The provisions of Sections 2.1, 8.1 and this Section 13.4 shall survive such termination, but all other terms, provisions, representations, rights and obligations contained in this Agreement shall terminate. If either party shall terminate this Agreement pursuant to this Section 13.4, then Oramed shall refund to HTIT the Initial Payment plus and additional USD500,000.

13.5 Effect of Termination of the Agreement.

(a) Upon any termination of this Agreement the following shall apply:

(1) **Transition Assistance.** Licensee shall provide such assistance, at Oramed's request and cost, as may be reasonably necessary for Oramed to commence or continue Pre-Commercializing or Commercializing Products in the Licensee Territory, to the extent Licensee is then performing or have performed such activities, including transferring or amending, as appropriate, upon request of Oramed, any agreements or arrangements with Third Party vendors to sell Products in the Licensee Territory. To the extent that any such contract between Licensee and Third Parties is not assignable to Oramed, Licensee shall arrange a transition period in which to provide such services with the goal of promptly transitioning the arrangement to Oramed.

(2) **Licenses.** Except as otherwise stated above in this Section 13.5, the licenses granted in Article 2 shall terminate.

(3) **No Refunds.** In no event shall Oramed be obligated to refund any amounts paid by Licensee under this Agreement except for the Initial Payment in the event of termination under Section 13.4.

(b) **Accrued Obligations.** In any event, expiration or termination of this Agreement shall not relieve the Parties of any liability which accrued hereunder prior to the effective date of such expiration or termination or to which a Party may be contractually committed as of such effective date nor preclude a Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any material breach of this Agreement, nor prejudice a Party's right to obtain performance of any obligation.

13.6 Bankruptcy. All rights and licenses granted under this Agreement by a Party to another Party are, and shall otherwise be deemed to be, for purposes of applicable bankruptcy laws, licenses of rights to "intellectual property". The Parties agree that a Party shall retain and may fully exercise all of its rights in the event of a bankruptcy by the other Party. The Parties further agree that in the event of the commencement of a bankruptcy proceeding by or against one Party under applicable law, the other Party shall be entitled to complete access to any such intellectual property pertaining to the rights granted in the licenses hereunder of the Party by or against whom a bankruptcy proceeding has been commenced and all embodiments of such intellectual property.

13.7 Survival. The following provisions shall survive any expiration or termination of this Agreement for the period of time specified: The provisions of Article 1, to the extent definitions are embodied in the following listed Articles and Sections of this Agreement; Articles 11, 12, 14 and 15; and Sections 4.7 (with respect to Regulatory Data generated prior to the effective date of termination or expiration), Sections 8.2 and 8.3 (with respect to milestones achieved, and royalty payments and reports concerning Net Sales made, prior to the effective date of termination or expiration), 8.4 through 8.8, 9.1 through 9.3, 10.5, 13.6, and this Section 13.7. In addition, any other provisions either required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement, or which by their express terms, survive such expiration or termination of this Agreement.

ARTICLE 14

DISPUTE RESOLUTION

14.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 14 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

14.2 Internal Resolution. With respect to all disputes arising between the Parties under this Agreement, including any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within 30 days after such dispute is first identified by a Party in writing to the other Parties, the Parties shall refer such dispute to the Executives of the Parties for attempted resolution by good faith negotiations within 30 days after such notice is received.

14.3 Binding Arbitration. If the Executives are not able to resolve such disputed matter within 30 days and either Party wishes to pursue the matter, each such dispute, controversy or claim shall be referred to and finally determined by arbitration by the Singapore International Arbitration Center ("SIAC") in accordance with its arbitration rules then in effect before a panel of three (3) arbitrators; it being clarified that Oramed shall select one arbitrator, Licensees (collectively) shall select one arbitrator, and the two arbitrators so selected shall select the third arbitrator who shall not be a national of either Israel or China; *provided, however*, that failure of a Party to select its arbitrator within a reasonable time (not to exceed 30 days) shall result in the arbitrator being selected by the SIAC Rules. The place of arbitration shall be Singapore. The language to be used in the arbitral proceedings shall be English. The dispute, controversy or claim shall be decided in accordance with the law of Hong Kong. Judgment on the arbitration award may be entered in any court having jurisdiction thereof. The Parties agree that:

(a) Either Party may apply to the arbitrator(s) for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damage (it being clarified that this shall not derogate from their right to award costs, as per the immediately following sentence). Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration; *provided, however*, that the arbitrators shall be entitled to award costs and, if so, they shall provide explanations for any such determination.

(b) A Party shall be entitled to deduct or otherwise offset any damage finally awarded under a proceeding initiated under this Section 14.3 against payments due under this Agreement, subject to any other decision of the arbitrators.

(c) Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of the other Party. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable statute of limitations under the laws of the Hong Kong.

(d) Notwithstanding the foregoing, neither Party shall be prevented from seeking injunctive relief from a court of competent jurisdiction including but not limited to the situation contemplated in Section 12.5 (to prevent or curtail any breach of the obligations relating to Confidential Information as set forth in Article 12).

ARTICLE 15

MISCELLANEOUS

15.1 Entire Agreement; Amendment. This Agreement, including the exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 Force Majeure. A Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the non-performing Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the reasonable control of the non-performing Party, including an act of God or terrorism, involuntary compliance with any regulation, law or order of any government, war, civil commotion, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure event persists for more than 90 days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

15.3 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and shall be deemed to have been sufficiently given for all purposes when received, if in writing and personally delivered, one (1) day following facsimile or email transmission (receipt verified) or two (2) days following overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below.

If to Oramed: **Oramed Ltd.**
2/4 Hi-Tech Village
PO Box 39098
Jerusalem, 91390, Israel
Attention: Chief Executive Officer
With a copy to: Chief Financial Officer
Fax: +972 (2) 566-0004
Email: yifat@oramed.com

With copies to (which shall not constitute notice):

Yigal Arnon & Co., Law Offices
22 Rivlin Street
Jerusalem, Israel
Attention: Daniel Green, Adv.
Fax: +972-2-623-9236
Email: danielg@arnon.co.il

If to HTIT:

Hefei TIANHUI INCUBATOR OF TECHNOLOGIES Co., Ltd.
No. 199 Fanhua Road, Heifei, Anhui, China
Attention: Ms. Coco Lee
Fax: +86-551-6384-9089
Email: lixiaopeng@htbt.com.cn

With copies to (which shall not constitute notice):

Grandall Law Firm
23-25F, No. 968 Beijing West Road, Shanghai, China
Attention: Mr. Simon Fang
Fax: +8621-52433323
Email: simonfang@grandall.com.cn

15.4 No Strict Construction; Headings. This Agreement has been prepared jointly and shall not be strictly construed against any Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

15.5 Assignment. Licensee may not assign or transfer this Agreement, in whole or in part, including by way of change of control, without the prior written consent of Oramed. Any permitted assignee shall, in writing to Oramed, expressly agree to be bound by the terms of this Agreement. Oramed may not assign or transfer its rights or obligations under this Agreement without the prior written consent of Licensee. Notwithstanding the foregoing, Oramed may without the consent of Licensee assign all of its rights and obligations hereunder to any of its Affiliates or to any purchaser of all or substantially all of its assets, or to any successor corporation resulting from any merger or consolidation of such party with or into such corporation; provided, however, that if Oramed executes the Premas Agreement or Swisscap Agreement within 10 months of the Effective Date then Oramed shall notwithstanding any such assignment retain all of its obligations under this Agreement towards Licensee until the date that Licensee succeeds in manufacturing three consecutive batches of the Agreed Batch Size of substantially similar quality and content. Any permitted assignee shall, in writing to Oramed and HTIT, expressly agree to be bound by the terms of this Agreement. Assignments in violation of this provision shall be void.

15.6 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates, and when any such Affiliate is discharging such obligations or exercising such right, the terms and conditions of this Agreement applicable to such Party also shall be applicable to such Affiliate; *provided, however*, that prior to HTIT engaging any of its Affiliates to so discharge HTIT's obligations and/or exercise any of HTIT's rights as aforesaid, as the case may be, HTIT shall obtain Oramed's prior written consent to such engagement. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations and/or exercise of such Party's rights under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations and/or exercise of such Party's rights under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

15.7 Further Actions. Both Parties agree to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.8 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

15.9 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

15.10 Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

15.11 No Third Party Beneficiaries. Except for rights and obligations specifically referred to herein that apply to Affiliates, sublicenses or licensees of the Parties, nothing in this Agreement is intended to confer on any Person other than Oramed or Licensee any rights or obligations under this Agreement, and there are no intended Third Party beneficiaries to this Agreement.

15.12 English Language. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. To the extent this Agreement requires a Party to provide to the other Party Information, correspondence, notice or other documentation, such Party shall provide such Information, correspondence, notice or other documentation in the English language.

15.13 Governing Law. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the Laws of Hong Kong without giving effect to any choice of law principles that would require the application of the laws of a different state. The applicability of the United Nations Convention on Contracts for the International Sale of Goods of 1980 is hereby expressly excluded.

15.14 Construction. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (a) “include,” “includes” and “including” are not limiting and shall be deemed to be followed by “without limitation”; (b) definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms; (c) references to an agreement, statute or instrument mean such agreement, statute or instrument as from time to time amended, modified or supplemented; (d) references to a Person are also to its permitted successors and assigns; (e) the plain meaning of the description for a defined term, and other headings to this Agreement are for convenience only, and shall have no force or effect in construing or interpreting any of the provisions of this Agreement or any other legal effect; (f) references to “Parties”, “Article”, “Section”, “Exhibit” or “Schedule” refer to the Parties to, an Article or Section of, or any Exhibit or Schedule to, this Agreement, unless otherwise indicated; (g) the word “will” shall be construed to have the same meaning and effect as the word “shall” and vice versa; (h) the word “or” has, except where otherwise indicated or where the context otherwise requires, the inclusive meaning represented by the phrase “and/or”; and (i) references to dollars are references to U.S. Dollars.

15.15 Counterparts. This Agreement may be executed in one or more counterparts by original or facsimile signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

15.16 Exhibits. The following exhibits, attached hereto, form an integral part hereof:

Exhibit A:	Description of ORMD-0801
Exhibit B:	Oramed Patents and Oramed Know-How
Exhibit C:	Pre-Commercialization Plan
Exhibit D:	Milestones
Exhibit E:	Oramed Banking Information
Exhibit F1:	License Payment Schedule
Exhibit F2:	Premas Agreement Payment Schedule
Exhibit F3:	Swisscaps Agreement Payment Schedule
Exhibit G	General Requirement and Document List

[Remainder of page left intentionally blank. Signature page follows immediately.]

[Signature page to License Agreement]

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Execution Date.

ORAMED LTD.

By: /s/ Nadav Kidron
Name: Nadav Kidron
Title: Chief Executive Officer

HEFEI TIANHUI INCUBATOR OF TECHNOLOGIES Co., LTD.

By: /s/ Gao Xiao Ming
Name: Gao Xiao Ming
Title: Chairman

ORAMED PHARMACEUTICALS INC.

By: /s/ Nadav Kidron
Name: Nadav Kidron
Title: Chief Executive Officer

Exhibit A

Description of ORMD-0801

ORMD-0801 is Oramed's proprietary insulin capsule. The capsule is made up of the following components:

- **[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]**

Exhibit B

Oramed Patents and Oramed Know-How

PATENTS

- Methods and Compositions for Oral Administration of Proteins
 - Patent #: ZL20098011 (China)
 - Grant Date: 10-July-2013
 - Priority: 61/064,779

- Methods and Compositions for Oral Administration of Proteins
 - Application #: 200680041231.00 (China)
 - Filing Date: 4-May-2008
 - Priority: 60/713,716

- Protease Inhibitor-Containing Compositions, Compositions Comprising Same, And Methods For Producing And Using Same
 - Application #: 201380018355.7 (China)
 - Filing Date: 31-Jan-2013

For the avoidance of doubt the license granted to use this last patent is only granted for the purposes of the Pre-Commercialization and Commercialization of the Product, and not for the purpose of manufacturing, using or selling any other products or any compounds or materials not used in the manufacture, use or sale of the Product.

ORAMED KNOW-HOW

Oramed "Know How" related to ORMD-0801 consists of:

- Manufacturing/Formulation know-how ("Cookbook")
- Know-how and capabilities for *in vitro*/animal testing
- Analytical capabilities and methods

Exhibit C

Pre-Commercialization Plan

[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]

Exhibit D

Milestones

	Milestone	Timeframe
Pre-Commercialization Milestones		
1	First patient in first CT2 clinical study as defined in the Pre-Commercialization Plan (Exhibit C) involving the administration of the Product in the Licensee Territory	November 2018
2	First patient in first CT3 clinical study as defined in the Pre-Commercialization Plan (Exhibit C) involving the administration of the Product in the Licensee Territory	August 2021
3	Receipt of CFDA marketing approval for a Product in the Licensee Territory	August 2023
Commercialization Milestones		
4	First Commercial Sale of a Product in the Licensee Territory	February 2024

Exhibit E

Oramed Banking Information

Oramed Ltd.

Bank Name: BankHapoalim, Israel

Branch address: 1 Hamrape St., Jerusalem, Israel.

Branch Number: 436

Swift: **[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**

IBAN: **[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**

Account Title/Beneficiary: Oramed Ltd.

Account Number: **[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]**

Exhibit F1

Payment Schedule

1	USD 3,000,000	To be paid to Oramed Ltd. upon the execution of the Technology License Agreement.
2	USD 6,500,000	[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]
3	USD 3,000,000	[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]

Exhibit F2: Subsequent Payments

Upon the Satisfaction of Milestones for the Premas Agreement

1	USD 4,000,000	[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]
2	USD 2,000,000	[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]
3	USD 2,000,000	[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]

Exhibit F3: Subsequent Payments

Upon the Satisfaction of Milestones for the Swisscaps Agreement

1	USD 4,000,000	[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]
2	USD 2,000,000	[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]
3	USD 8,000,000	[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]
4	USD 2,000,000	[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]
5	USD 1,000,000	[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]

Exhibit G

General Requirement and Document List

[THE CONFIDENTIAL PORTION HAS BEEN SO OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT AND HAS BEEN FILED SEPARATELY WITH THE COMMISSION]

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Nadav Kidron, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Oramed Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: January 13, 2016

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

**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, Yifat Zommer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Oramed Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: January 13, 2016

/s/ Yifat Zommer

Yifat Zommer
Chief Financial Officer

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350**

In connection with the quarterly report of Oramed Pharmaceuticals Inc., or the Company, on Form 10-Q for the period ended November 30, 2015 as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Nadav Kidron, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

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

Dated: January 13, 2016

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

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350**

In connection with the quarterly report of Oramed Pharmaceuticals Inc., or the Company, on Form 10-Q for the period ended November 30, 2015 as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Yifat Zommer, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

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

Dated: January 13, 2016

/s/ Yifat Zommer

Yifat Zommer, Chief Financial Officer