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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **September 18, 2020 (September 16, 2020)**

ORAMED PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**001-35813**	**98-0376008**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1185 Avenue of the Americas, Third Floor, New York, New York	**10036**
(Address of Principal Executive Offices)	(Zip Code)

844-967-2633
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 1.01. Entry into a Material Definitive Agreement.

On September 16, 2020, Oramed Ltd. (the "Subsidiary"), a wholly-owned subsidiary of Oramed Pharmaceuticals Inc. (the "Company"), entered into an additional Clinical Research Organization Services Agreement (the "Agreement") with Integrium, LLC ("Integrium"), effective as of January 15, 2020, to retain Integrium as a clinical research organization, covering the U.S. portion of the Subsidiary's planned upcoming Phase 3 clinical trial. The trial will be conducted under an Investigational New Drug application with the U.S. Food and Drug Administration and is designed to assess the safety and evaluate the efficacy of ORMD-0801 on approximately 600 type 2 diabetic patients. The Agreement will terminate upon the satisfactory performance of all the services as contemplated in the Agreement.

As consideration for its services, the Subsidiary will pay Integrium a total amount of up to approximately $12.3 million that will be paid over the term of the engagement and based on the achievement of certain milestones.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

10.1*	Clinical Research Organization Services Agreement dated September 16, 2020 and effective as of January 15, 2020, between Oramed Ltd. and Integrium, LLC.

* Certain identified information in the exhibit has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

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 hereunto duly authorized.

ORAMED PHARMACEUTICALS INC.

By: /s/ Nadav Kidron
Name: Nadav Kidron
Title: President and CEO

September 18, 2020

Exhibit 10.1

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO ORAMED PHARMACEUTICALS INC. IF PUBLICLY DISCLOSED. OMISSIONS ARE DENOTED IN BRACKETS WITH ASTERISKS THROUGHOUT THIS EXHIBIT.

CLINICAL RESEARCH ORGANIZATION SERVICES AGREEMENT

By and Between

Oramed Ltd.

and

Integrium, LLC

Effective Date: January 15, 2020

CRO Agreement

EFFECTIVE DATE: January 15, 2020

Name and Address of the Contact for Integrium, LLC

Name:	Jessica Coutu
Title:	Sr. V.P. of Clinical Operations
Address:	100 East Hanover Avenue, Suite 401 Cedar Knolls, NJ 07927
Telephone:	(908) 357-2010
Cell Phone:	(908) 458-3058
e-mail:	jessica.coutu@integrium.com

Name and Address of the Contact for Oramed Ltd.

Name:	Dr. Miriam Kidron
Title:	Chief Medical and Technology Officer
Address:	Hi-Tech Park 2/4 Givat-Ram, P.O. Box 39098 Jerusalem, 91390, Israel
Telephone:	972 2 566001
Facsimile:	972 2 566004
e-mail:	miriam@oramed.com

Project: Oramed Ltd.
ORA-D-013-2

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

1. Term

1.1 The term of this Agreement shall be for the period beginning January 15, 2020 and ending upon the satisfactory performance of all the Services (as defined herein) unless terminated sooner as provided herein. The initial term of this Agreement was for the period beginning as of January 15, 2020 and ending on April 28, 2020 (the "**Initial Term**") during which Start-up activities for the Project were initiated. This Agreement now represents the US portion of the study in its entirety. Any previous payments for the ORA-D-014 Start-up are incorporated and reconciled herein and represented in the payment schedule.

2. Scope of Work

2.1 Sponsor is conducting a Study pursuant to Protocol No. ORA-D-013-2, ("**Protocol**") entitled "A Double-Blinded, Placebo-controlled, Multi-center Randomized, Phase 3 Study to Evaluate the Efficacy and Safety of ORMD-0801 in Subjects with Type 2 Diabetes Mellitus with Inadequate Glycemic Control on Metformin Monotherapy." (the "**Study**").

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

3. Conditions of Work/Sponsor Responsibilities

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

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

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

4. Compensation

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

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

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

5. Representations of CRO

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

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

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

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

6. Confidentiality

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

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

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

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

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

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

7. Conflicts of Interest

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

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

8. Independent Contractor

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

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

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

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

9. Tax Reporting and Payment

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

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

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

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

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

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

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

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

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

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

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

11. Relationship with Investigators and Third Party Contractors

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

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

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

11.4 Reserved

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

12. Indemnification

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

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

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

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

13. Limitation of Liability; Damages

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

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

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

14. Insurance

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

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

15. Termination

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

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

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

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

16. Personnel Recruitment

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

17. Reserved

18. Miscellaneous Provision

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

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

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

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

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

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

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

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

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

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

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

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

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

If to Integrium for contractual matters:

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

If to Integrium for financial matters:

Integrium, LLC
14351 Myford Road, Suite A
Tustin, CA 92780
Attn: David Hyman, Financial Controller

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

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

For and on behalf of
Integrium, LLC

/s/ Jessica Coutu

By: Jessica Coutu

Title: Sr. Vice President, Clinical Operations

Date: September 16, 2020

For and on behalf of
Oramed Ltd.

/s/ Nadav Kidron /s/ Josh Hexter

By: Nadav Kidron Josh Hexter

Title: CEO COO

Date: September 16, 2020

Project: Oramed Ltd.
ORA-D-013-2

Integrium/ Oramed

Exhibit 1

Protocol Number: ORA-D-013-2
Version: 1
Date: 26 AUG 2020

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Integrium/Oramed

Exhibit 2

Study Specifications

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Project Identifiers	Version #2
Sponsor Company	Oramed Ltd.
Protocol Number	ORA-D-013-2
Protocol Title	A Double-Blinded, Placebo-controlled, Multi-center Randomized, Phase 3 Study to Evaluate the Efficacy and Safety of ORMD-0801 in Subjects with Type 2 Diabetes Mellitus with Inadequate Glycemic Control on Metformin Monotherapy.
Investigational Product(s)	ORMD-0801
Indication	Type 2 Diabetes Mellitus
Therapeutic Area	Metabolic
Study Phase	III
Sponsor Country	Israel
Country Locations	US, EU

Study Assumptions

Subjects	Total	US	EU, Israel
# Subjects Screened	1112	658	454
% Screen Failure Rate	46%	46%	46%
# Screen Failures	512	303	209
# Subjects Entering Run-In Phase	600	355	245
% Run-In Failure Rate	0%	0%	0%
# Run-In Failures	0	0	0
# Subjects Randomized	600	355	245
% Early Termination Rate	30%	30%	30%
# Early Terminations	179	106	73
# Subjects Complete	421	249	172

Country	US	Country 1	Country 2	Country 3	Israel
Sites/Country	36	5	5	5	2

Sites	Total	US	EU, Israel
# Sites Identified	79	39	40
Total Sites	61	36	25
# Central IRB Sites	59	36	23
# Local IRB Sites	2	0	2

Enrollment	
# Screened/site	18.23
# Screened/site/week	0.35
# Enrolled/site	9.84
# Enrollment Rate (per site/per month)	0.82
# Randomized/site	9.84
# Randomization Rate (per site/ month)	0.82

Third Party Vendors		
Meeting Planner		1
Central IRB		1
Central Lab		1
CGM Monitors/Glucometer Vendor		1 - Contracted by Sponsor
Product Packaging & Distribution		1 - Contracted by Sponsor
IWRS		1 - Contracted by Sponsor
Project Meetings	# Meetings	Assumptions
Webcast Investigators' Meeting	1	Assumes 1 3-hour WebEx meeting in US and 1 in EX-US (TBD)
Launch Meeting	1	Assumes 3-hour launch Meeting
Sponsor Team Teleconferences	67	Assumes calls will be every other week on start-up and enrollment period then for the duration of the study
Internal Team Teleconferences	6	Ad hoc as needed
CRA Training Teleconference	1	Assumes a 3-hour CRA training teleconference.
CRA Teleconferences	12	Assumes monthly from FPFV to Database Lock
Monitoring Assumptions - US		
# CRAs		6
# Pre-Study Selection Visits		0 – Cost included in ORA-D-013-1
# Initiation Visits		36
# In Person Site Initiation Visits		33
# Remote Site Initiation Visits		3
# Interim Monitoring Visits		
Monitoring Interval (Maximum - weeks)		Assumed every 6-8 weeks dependent upon enrollment
# Interim Monitoring Visits/site		11.18
# Additional Days on-site/site		2.45
# 1-day Interim Monitoring Visits		402
# Additional Days		88
# Close-out Visits		36
Safety Assumptions		
SAE rate (%)		6%
Estimated # SAEs		36
Data Management		
CRF pgs per randomized patient		115
Unique CRFs/Subject		53
Standard		24
Non-Standard		29
Non-Unique CRFs/Subject		62
Standard		53
Non-Standard		9

CRF pgs per early term	86
CRF pgs per screen failure	29
Total CRF Pages	78657
Complete subjects	48415
Early Terms	15394
Screen Failures	14848
Total DM Datasets	20
Total Edit Checks	300
Estimated # Total Queries	15731
Est. # Queries/Patient (1/5 pages)	26.22
Manual Coding	
# Medical History/Subject	2
# ConMeds/Subject	2
# AEs/Subject	2
Data Transfers	
# Sponsor Transfers	2 test, final
# Lab Transfers	26 test, monthly, final
# Central CGM Reader Transfers	10 test, quarterly, final
# IWRS Transfers	2 prior to primary lock and final lock
	The following assumptions are estimates. The total number of TLGs will be defined upon the finalization of the Statistical Analysis Plan. An amendment to the budget will be issued at that time, if applicable.
Statistical Analysis	
# SAS Datasets	22
Estimated Tables	
# Standard and Non-Standard Repeat	70
# Non-Standard Unique	0
Estimated Listings	
# Standard and Non-Standard Repeat	40
# Non-Standard Unique	0
Estimated Graphs	
# Standard and Non-Standard Repeat	20
# Non-Standard Unique	0
Exploratory Output	
# Exploratory Tables	0
# Exploratory Listings	0
# Exploratory Graphs	0
Post-hoc Analysis	200

EDC - ClinPlus	
Number of Screens	
Unique Screens	53
Redundant Screens	62
Site Patient Activity Duration (Months)	13.1
Enrollment Duration (Months)	12
Server Activity Duration (Months)	15
Usage Fee/Help Desk Fees	
Product Usage Fee/Month	[**]
Intregrium Archiving Pricing	
CD/DVD per site	[**]
Clinical Study Report	**The budget is based on one draft and one final version of the CSR, assuming there will be no hyperlinking. If hyperlinking and/or additional versions of the CSR are requested, they will be provided at the study hourly rate for the actual additional hours.**

Project Timeline

Project Activity	Date	Month #	Week #
Study Start Date	January 15, 2020	0.0	0.0
Create Site Feasibility Questionnaire	January 17, 2020	0.1	0.3
Draft Protocol Date	April 27, 2020	3.4	14.7
Identify 28 US sites	May 25, 2020	4.3	18.7
Final Protocol Date	June 29, 2020	5.5	23.7
Submission of Protocol to FDA	May 4, 2020	3.6	15.7
Response from FDA	June 24, 2020	5.3	23.0
Submission of Revised Protocol to FDA	July 31, 2020	6.5	28.3
Response from FDA	September 29, 2020	8.5	36.9
Submission of Protocol to EU Regulatory Authorities	August 30, 2020	7.5	32.6
Initial Paper Representation of eCRF	August 21, 2020	7.2	31.3
Final Paper Representation of eCRF	September 11, 2020	7.9	34.3
Programming of Database Complete	October 16, 2020	9.0	39.3
UAT/Pre-production Audit of Database Complete	November 2, 2020	9.6	41.7
Drug Available at US Sites	November 2, 2020	9.6	41.7
First Patient Screened in US	November 17, 2020	10.1	43.9
Response from EU RegulatoryAuthorities	November 28, 2020	10.5	45.4
First Patient Randomized to 26w Treatment Phase	December 8, 2020	10.8	46.9
Identify 25 EU sites	December 26, 2020	11.4	49.4
EU Pre-study Visits Complete	January 25, 2021	12.4	53.7
EU Investigators' Meeting	February 10, 2021	12.9	56.0
First Patient Screened in EU	February 12, 2021	13.0	56.3
First Patient Enter 26w Extension Phase	June 8, 2021	16.8	72.9
First Patient Last Visit	December 21, 2021	23.2	100.9
Last Patient Screened	November 16, 2021	22.1	96.0
Last Patient Randomized to 26w Treatment Phase	December 7, 2021	22.8	99.0
Last Patient Completes 26 Treatment Period	June 7, 2022	28.8	125.0
Last IMV 26w Treatment Phase	July 5, 2022	29.7	129.0
Primary Database Lock	September 13, 2022	32.0	139.0
Last Patient Enter 26w Extension Phase	June 8, 2022	28.8	125.1
Last Patient Last Visit	December 20, 2022	35.2	153.0
Last IMV	January 17, 2023	36.1	157.0
Final Database Lock	March 28, 2023	38.4	167.0
Draft Final TLGs	April 4, 2023	38.7	168.0
Final TLGs	April 18, 2023	39.1	170.0
Draft CSR	May 16, 2023	40.1	174.0
Final CSR	June 13, 2023	41.0	178.0
CRO End Date	June 23, 2023	41.3	179.4
Total Project Duration (Months)	41.3		

	Months	Weeks	Phase
Start-up	10.1	43.9	I
Enrollment	12.0	52.1	II
Treatment	13.1	57.0	III
LPLV-DBL	3.2	14.0	IV
DBL-CRO End	2.9	12.4	V
	41.3	179.4	

Project: Oramed Ltd.
ORA-D-013-2

Integrium/Oramed

EXHIBIT 3

Study Budget

	STUDY START-UP		*UNITS*	*MEASURE OF UNIT*	*TOTAL*
1	Project Management (Start Up)	[**]	10.1	Month	[**]
2	Develop/Finalize Project Management Plan	[**]	1	Plan	[**]
3	Project Launch Webcast Meeting/Training	[**]	1	Meeting	[**]
4	Study Materials Management	[**]	61	Site	[**]
5	CRA Training Teleconferences	[**]	1	Telecon	[**]
6	Source Documentation Development	[**]	1	Total	[**]
7	Site Identification	[**]	36	Site	[**]
8	Pre-study Site Evaluation Visit	[**]	0	Visit	[**]
9	Develop/Finalize CRA Monitoring Plan	[**]	1	Plan	[**]
10	Data Management Plan ("DMP")	[**]	1	Total	[**]
11	Regulatory Document Collection - Start Up	[**]	36	Site	[**]
12	Investigator Budget/Contract Negotiations	[**]	36	Site	[**]
13	WebEx Investigators' Meeting and Preparation	[**]	2	Meeting	[**]
14	Clinical System Set-Up Configuration/Maintenance	[**]	37	Total	[**]
	STUDY START-UP FEES TOTAL				[**]

	EDC STUDY START-UP	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
15	eCRF Development	[**]	1	Total	[**]
16	eCRF Completion Instructions	[**]	1	Total	[**]
17	Edits Specifications and Programming	[**]	1	Total	[**]
18	Validate/Test Data Entry Screens (UAT)	[**]	1	Total	[**]
19	Annotate CRF	[**]	1	Total	[**]
20	Clinical Database Development-SDTM Dataset Creation/Documentation	[**]	1	Total	[**]
21	Database Design and Validation Specifications	[**]	1	Database	[**]
22	EDC Kick-Off Meeting	[**]	1	Meeting	[**]
23	Set-up Standard Data Entry Screens	[**]	1	Total	[**]
24	Training Session	[**]	1	Study	[**]
25	Project Manage all aspects of EDC start-up	[**]	1	Start-up	[**]
26	Create Enrollment Screen	[**]	1	Total	[**]
27	Data Export Programming	[**]	20	Dataset	[**]
28	Register users and maintain passwords for life of study (per user (4 per site + 6 for sponsor))	[**]	250	Per User	[**]
	EDC START-UP FEES TOTAL				[**]

	CLINICAL MONITORING	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
29	Project Management (enrollment phase)	[**]	12.0	Month	[**]

	CLINICAL MONITORING	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
30	Project Management (treatment phase)	[**]	13.1	Month	[**]
31	Project Management Study (LPLV to DBL)	[**]	3.2	Month	[**]
32	Project Management Study (DBL to CRO end)	[**]	2.9	Month	[**]
33	Sponsor Team Teleconferences	[**]	67	Telecon	[**]
34	Internal Team Teleconferences	[**]	6	Telecon	[**]
35	CRA Teleconferences	[**]	24	Telecon	[**]
36	Trial Master File	[**]	37	Site	[**]
37	Regulatory Document Maintenance	[**]	1830	Month	[**]
38	Protocol Amendment	[**]	36	Amendment	[**]
39	Site Initiation Visits	[**]	33	Site	[**]
40	Remote Site Initiation Visits	[**]	3	Visit	[**]
41	Site Management/Patient Review/Query Resolution	[**]	1044	Site*Month	[**]
42	Interim Monitoring Visits - One Day	[**]	402	Visit	[**]
43	Interim Monitoring Visits - Additional Day On-site	[**]	88	Day	[**]
44	Close-out Visits	[**]	36	Visit	[**]
45	Site Grant Administration	[**]	936	Site*Month	[**]
	CLINICAL MONITORING/LOGISTICS SERVICES SUBTOTAL				[**]

	MEDICAL/SAE MANAGEMENT	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
46	Medical Management	[**]	28	Month	[**]
47	Create Safety Plan	[**]	1	Plan	[**]
48	Review Protocol Deviation Log	[**]	28	Month	[**]
49	Tracking Protocol Waivers	[**]	28	Month	[**]
50	Lab Alert/Patient Review	[**]	28	Month	[**]
51	Review of AE Data Listings on a Monthly basis	[**]	28	Month	[**]
52	Create Safety Database	[**]	2	Database	[**]
53	SAE Management	[**]	36	SAE	[**]
	MEDICAL/SAE MANAGEMENT SERVICES SUBTOTAL				[**]

	DATA MANAGEMENT	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
54	Data Entry Activities	[**]	78,657	CRF Pg	[**]
55	Generate/Track/Resolve Queries	[**]	15,731	Query	[**]
56	Data Cleaning/Manual Listing Review	[**]	600	Patient	[**]
57	Import Other Data	[**]	38	Transfer	[**]
58	Export Data to Sponsor	[**]	2	Transfer	[**]
59	Manual Coding	[**]	3,600	Manual Code	[**]
60	Archive Study Records, Database	[**]	1	Database	[**]
61	Data Base Lock Activities - Cohort A	[**]	2	Total	[**]
	DATA MANAGEMENT FEES SUBTOTAL				[**]

	EDC SYSTEM MAINTAINANCE	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
62	Coding System (Set-up Cost) [WHO/MEDRA]	[**]	1	Access User	[**]
63	Third Party Data Integrations	[**]	43	Transfer	[**]
64	SAS Platform (months)	[**]	41	Month	[**]
65	Ongoing Support Project Management	[**]	15	Month	[**]
66	CRF Export Programming (Site Archives, submission eCRFs)	[**]	1	Total	[**]
67	Provide End of Study Archives to All Sites; 2 Copies to Sponsor	[**]	1	Total	[**]
	EDC SYSTEM SET-UP AND MAINTAINANCE SUBTOTAL				[**]

	BIOSTATISTICAL ANALYSIS	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
68	Draft & Final Statistical Analysis Plan (SAP)	[**]	1	SAP	[**]
69	Analysis DataSets	[**]	22	Dataset	[**]
70	Create/Document ADaM (Submission Ready) Datasets	[**]	22	Dataset	[**]
71	Statistical Programming Deliverables (TLGs)	[**]	130	T/L/G	[**]
72	Generate/QC TLFs	[**]	152	Appendix	[**]
73	Output Review/Dry Runs	[**]	3	Dry Run	[**]
74	Post-hoc Analysis Hours	[**]	200	Hour	[**]
75	Annual IND Listings	[**]	3	Annual IND	[**]
	BIOSTATISTICAL ANALYSIS SUBTOTAL				[**]

	MEDICAL WRITING	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
76	Finalize Protocol	[**]	1	Protocol	[**]
77	Develop/Finalize ICF	[**]	1	Total	[**]
78	Final CSR	[**]	1	Total	[**]
	MEDICAL WRITNG SUBTOTAL				[**]
	CRO SERVICE FEES GRAND TOTAL				[**]

	PASS THROUGH COSTS	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
1	Pre-study Site Evaluation Visit	[**]	0	Visit	[**]
2a	Site Initiation Visit	[**]	36	Visit	[**]
2b	Remote Site Initiation Visits	[**]	3	Visit	[**]
3a	Interim Monitoring Visits - One Day	[**]	402	Visit	[**]
3b	Interim Monitoring Visits - Additional Day On-site	[**]	88	Day	[**]
4	Close-out Visits	[**]	36	Visit	[**]
5	WebEx Investigators' Meeting Planner	[**]	1	Meeting	[**]
6	Investigator Grants	[**]			[**]
6a	# Patients Completed	[**]	249	Patient	[**]
6b	# Screen Failures	[**]	303	Patient	[**]
6c	# Early Terminations	[**]	106	Patient	[**]
6d	# Rescue Visits	[**]	34	Visit	[**]
6e	# Unscheduled visits	[**]	34	Visit	[**]
7	Site: Advertising/Patient Recruitment	[**]	36	Site	[**]

	PASS THROUGH COSTS	*UNIT COST*	*UNITS*	*MEASURE OF UNIT*	*TOTAL*
8	Site: Archive Fees	[**]	36	Site	[**]
9	Site: Database Recruitment Fee	[**]	36	Site	[**]
10	Site: Start-up Costs	[**]	36	Site	[**]
11	Site: Regulatory Fee	[**]	0	Site	[**]
12	Site: Pharmacy Fee	[**]	36	Site	[**]
13	Site: IRB Fees	[**]	0	Total	[**]
14a	Central IRB - Protocol Submission	[**]	1	Protocol	[**]
14b	Central IRB - Site Submissions	[**]	36	Protocol	[**]
14c	Central IRB annual renewal	[**]	36	Amend.	[**]
14d	Central IRB - Site Specific Translations	[**]	10	Site	[**]
14e	Central IRB annual renewal	[**]	36	Total	[**]
14f	Central IRB Closeout Fee	[**]	36	Site	[**]
14g	Central IRB - Advertising Approval	[**]	36	Site	[**]
15	Estimated Central Laboratory Fees	[**]	1	Total	[**]
16	Estimated CGM/Glucometer Fees	[**]	0	Total	[**]
17	Estimated IWRS Fees	[**]	1	Total	[**]
18	EDC Platform Product Usage	[**]	31	Total	[**]
19	EDC Coding System Integration Fee [WHO/MEDRA]	[**]	1	Total	[**]
20	End of study archive CDs to sites; 2 copies to Sponsor	[**]	63	Total	[**]
21	Regulatory Binders	[**]	39	Binder	[**]
22	Copying/ Printing	[**]	1	Total	[**]
23	Postal & Shipping Fees	[**]	1	Total	[**]
	PASS-THROUGH COSTS TOTAL				[**]
	PROJECT'S OVER-ALL TOTAL COST				**$ 12,342,808.81**

Integrium/Oramed

EXHIBIT 4

Study Payment Schedule

Payment Schedule

Monthly Management Fees	Month	$ Amount	Verification of Milestone Completion/Deliverables
Project Management Fees	**January 2020**	[**]	Paid (ORA-D-014 Start-up)
Project Management Fees	**February 2020**	[**]	Paid (ORA-D-014 Start-up)
Project Management Fees	**March 2020**	[**]	Invoiced Monthly
Project Management Fees	**April 2020**	[**]	Invoiced Monthly
Project Management Fees	**May 2020**	[**]	Invoiced Monthly
Project Management Fees	**June 2020**	[**]	Invoiced Monthly
Project Management Fees	**July 2020**	[**]	Invoiced Monthly
Project Management Fees	**August 2020**	[**]	Invoiced Monthly
Project Management Fees	**September 2020**	[**]	Invoiced Monthly
Project Management Fees	**October 2020**	[**]	Invoiced Monthly
Project Management Fees	**November 2020**	[**]	Invoiced Monthly
Project Management Fees	**December 2020**	[**]	Invoiced Monthly
Project Management Fees	**January 2021**	[**]	Invoiced Monthly
Project Management Fees	**February 2021**	[**]	Invoiced Monthly
Project Management Fees	**March 2021**	[**]	Invoiced Monthly
Project Management Fees	**April 2021**	[**]	Invoiced Monthly
Project Management Fees	**May 2021**	[**]	Invoiced Monthly
Project Management Fees	**June 2021**	[**]	Invoiced Monthly
Project Management Fees	**July 2021**	[**]	Invoiced Monthly
Project Management Fees	**August 2021**	[**]	Invoiced Monthly
Project Management Fees	**September 2021**	[**]	Invoiced Monthly
Project Management Fees	**October 2021**	[**]	Invoiced Monthly
Project Management Fees	**November 2021**	[**]	Invoiced Monthly
Project Management Fees	**December 2021**	[**]	Invoiced Monthly
Project Management Fees	**January 2022**	[**]	Invoiced Monthly
Project Management Fees	**February 2022**	[**]	Invoiced Monthly
Project Management Fees	**March 2022**	[**]	Invoiced Monthly
Project Management Fees	**April 2022**	[**]	Invoiced Monthly
Project Management Fees	**May 2022**	[**]	Invoiced Monthly
Project Management Fees	**June 2022**	[**]	Invoiced Monthly
Project Management Fees	**July 2022**	[**]	Invoiced Monthly
Project Management Fees	**August 2022**	[**]	Invoiced Monthly
Project Management Fees	**September 2022**	[**]	Invoiced Monthly
Project Management Fees	**October 2022**	[**]	Invoiced Monthly
Project Management Fees	**November 2022**	[**]	Invoiced Monthly
Project Management Fees	**December 2022**	[**]	Invoiced Monthly
Project Management Fees	**January 2023**	[**]	Invoiced Monthly
Project Management Fees	**February 2023**	[**]	Invoiced Monthly
Project Management Fees	**March 2023**	[**]	Invoiced Monthly
Project Management Fees	**April 2023**	[**]	Invoiced Monthly
Project Management Fees	**May 2023**	[**]	Invoiced Monthly
Project Management Fees	**June 2023**	[**]	Invoiced Monthly
	Total Monthly Management Fees:	[**]	

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Monthly Service Fees	Date	% Total Service Budget	% Milestone Service Budget	$ Amount	Verification of Milestone Completion/Deliverables
Contract Execution	12/1/2017	**5.15%**	**10.49%**	[**]	Contract Execution
EDC System Complete	11/2/2020	**0.82%**	**1.68%**	[**]	UAT complete
1st Subject Randomized	12/8/2020	**2.06%**	**4.20%**	[**]	Enrollment log
25% Subjects Randomized	3/9/2021	**5.15%**	**10.49%**	[**]	Enrollment log
50% Subjects Randomized	6/8/2021	**5.15%**	**10.49%**	[**]	Enrollment log
75% Subjects Randomized	9/7/2021	**5.15%**	**10.49%**	[**]	Enrollment log
100% Subjects Randomized	12/7/2021	**5.15%**	**10.49%**	[**]	Enrollment log
1st Subject Last Visit	12/21/2021	**2.68%**	**5.45%**	[**]	Enrollment log
25% Subjects Last Visit	3/22/2022	**2.68%**	**5.45%**	[**]	Enrollment log
50% Subjects Last Visit	6/21/2022	**2.68%**	**5.45%**	[**]	Enrollment log
Primary Database Lock	9/13/2022	**3.71%**	**7.55%**	[**]	Database Lock
75% Subjects Last Visit	9/20/2022	**2.68%**	**5.45%**	[**]	Enrollment log
100% Subjects Last Visit	12/20/2022	**2.68%**	**5.45%**	[**]	Enrollment log
Final Database Lock	3/28/2023	**2.68%**	**5.45%**	[**]	Database Lock
Draft Final TLGs	4/4/2023	**0.69%**	**1.41%**	[**]	Draft Final TLGs
Total Milestone Based Services:		**49.09%**	**100.00%**	[**]	

Unit Based Payments: Actual Units Invoiced Monthly	% Total Services Budget	# Units	Unit Cost	$ Amount	Verification of Milestone Completion/Deliverables
SAE Management	**1.83%**	36	[**]	[**]	Invoiced monthly as occurred
			Total Unit Based Services:	[**]	
			Total Services:	[**]	

Pass-through expenses	$ Amount	Verification of Milestone Completion/Deliverables
Monitoring Visit Travel Expenses	[**]	Invoiced as Actuals Monthly
Investigator Grants	[**]	Invoiced and Paid in Advance of Payment to Vendor
Site Start-up Costs	[**]	Invoiced and Paid in Advance of Payment to Sites
Site Advertising	[**]	Invoiced as Actuals Monthly
Site Archiving Fees	[**]	Invoiced as Actuals Monthly
IRB Fees	[**]	Invoiced as Actuals Monthly
Meeting Planner	[**]	Invoiced and Paid in Advance of Payment to Vendor
Central Lab Vendor	[**]	Invoiced and Paid in Advance of Payment to Vendor
IWRS Vendor	[**]	Invoiced and Paid in Advance of Payment to Vendor
CGM/Glucometer Vendor	[**]	Invoiced and Paid in Advance of Payment to Vendor
EDC Platform Usage Fees	[**]	Invoiced as Actuals Monthly
Copying/Printing/Supplies	[**]	Invoiced as Actuals Monthly
Postal & Shipping Fees	[**]	Invoiced as Actuals Monthly
Total Pass-through Budget:	[**]	
Grand Total Budget:	**$ 12,342,808.81**	

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Pass Through Advance Payment Schedule

	Contract Execution	TBD	Study Total
Investigators' Meeting Planner: 80% invoiced start-up payment 20% paid upon final reconciliation	[**]	[**]	[**]
Site Start-up Costs: [**]/site x 36 sites	[**]	[**]	[**]
Site Grant Payments: Advance Payment = [**]/site X 36 sites	[**]	[**]	[**]
Site Pharmacy Fees: [**]/site x 36 sites	[**]	[**]	[**]
Central Lab Vendor: Start-up payment	[**]	[**]	[**]
Pass-Through Advance Payment	[**]	[**]	[**]

EXHIBIT 5

Transfer of Regulatory Obligations

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

Study Drug: ORMD-0801

IND #:

Protocol Title: A Double-Blinded, Placebo-controlled, Multi-center Randomized, Phase 3 Study to Evaluate the Efficacy and Safety of ORMD-0801 in Subjects with Type 2 Diabetes Mellitus with Inadequate Glycemic Control on Metformin Monotherapy.

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

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

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

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

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

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

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

Oramed Ltd.

	/s/ Miriam Kidron	September 16, 2020
	Name: Miriam Kidron **Title:** CSO	**Date**

Integrium LLC.

	/s/ Jessica Coutu	September 16, 2020
	Name: Jessica Coutu **Title:** Sr. VP of Clinical Operations	**Date**