

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): April 22, 2009

ORAMED PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction
of incorporation)

000-50298
(Commission File Number)

98-0376008
(IRS Employer
Identification No.)

Hi-Tech Park 2/5 Givat Ram
PO Box 39098
Jerusalem, Israel 91390
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: 972-2-566-0001

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 (see General Instruction A.2. below):

- 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))
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ITEM 1.01 ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT

On April 21, 2009, Oramed Ltd., an Israeli subsidiary of Oramed Pharmaceuticals Inc., entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. (“ADRES”). According to the agreement, ADRES will provide consulting services relating to quality assurance and regulatory processes and procedures in order to assist Oramed in submission of a U.S. IND according to FDA regulations.

In consideration for the services provided under the agreement, ADRES will be entitled to an estimated cash compensation of \$211,000 that will be paid in part as a monthly fixed fee and in part based on achievement of certain milestones.

The preceding is qualified in its entirety by reference to the consulting services agreement that is filed with this Current Report on Form 8-K as Exhibit 10.1 and is incorporated by reference herein.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(c) Exhibits

10.1 Consulting Services Agreement by and between Oramed Ltd. and ADRES Advanced Regulatory Services Ltd. entered into as of April 21, 2009

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.

Dated: April 22, 2009

ORAMED PHARMACEUTICALS INC.

By: /s/ Nadav Kidron
Nadav Kidron
President, CEO and Director

CONSULTING SERVICES AGREEMENT

THIS CONSULTING SERVICES AGREEMENT is made and entered into as of April 21, 2009 (the "**Effective Date**"), by and between ADRES Advanced Regulatory Services Ltd., an Israeli company #514239045, with its principal office and place of business at Hacramim 2, Ness Ziona ("**Consultant**") and Oramed Ltd., an Israeli company #513076712, with its principal office and place of business at Givat Ram, Jerusalem, Israel ("**Company**") (each a "**Party**" and collectively the "**Parties**").

Consultant provides consulting services relating to quality assurance and regulatory processes and procedures. Company desires to engage the services of Consultant and Consultant desires to accept such engagement to perform the Consulting Services described herein upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual promises set forth herein, Company and Consultant hereby agree as follows:

1 Services and Scope of Work

- 1.1 Services and Scope of Work. Consultant agrees to provide to Company consulting services as described on **Schedule 1** attached hereto ("**Consulting Services**" or "**Services**"). The parties may amend the Services and Scope of Work to increase, decrease, redefine or clarify the Services and/or the Scope of Work at anytime during the term of this Agreement. However, the amendment must be provided in writing and signed by both Consultant and Company prior to implementation of the change.
- 1.2 Performance of Services. Consultant has the right to (i) control and direct the means, manner and method by which the Consulting Services are performed, in particular, Company acknowledges and agrees to the use of subcontractors by Consultant for performance of the Consulting Services or portions thereof, including, CBR International Corp., and (ii) perform the Consulting Services at any place or location and at such time as Consultant may reasonably determine. Unless otherwise agreed to by the Parties in writing or on a Schedule, Consultant shall (i) observe the work rules and policies of Company while working on Company's premises, (ii) furnish all equipment and materials used to perform the Consulting Services, including but not limited to telephone lines, personal computers and modems, and (iii) comply with Company's policies, guidelines, and specifications with respect to computer security, network connectivity, and acceptable use, which have been provided to Consultant in writing.
- 1.3 Other Work. Consultant has the right to perform services for others during the term of this Agreement as long as such other engagement or performance does not interfere with the timely performance of the Consulting Services to be performed hereunder or compromise Company's Confidential Information, as defined herein.

2 Independent Contractor

- 2.1 Independent Contractor; No Agency. Consultant is an independent contractor. Consultant shall not be deemed for any purpose to be an employee of Company. Company shall not be responsible to Consultant or any governing body for any payroll-related taxes related to the performance of services hereunder, including but not limited to, withholding or other taxes related to income tax, social security benefits or unemployment compensation. Neither Party is an agent, representative or partner of the other Party. Neither Party shall have any right, power or authority to enter into any agreement for or on behalf of, or incur any obligation or liability on behalf of, or to otherwise bind, the other Party. This Agreement shall not be interpreted or construed to create an employment relationship, an association, agency, joint venture or partnership between the Parties or to impose any liability attributable to such a relationship upon either Party.
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2.2 Consultant's Employees and Assistants. From time to time, Consultant may, subject to the terms and conditions set forth in this Agreement engage independent contractors or consultants (collectively, "Assistants") to aid Consultant in performing Consultant's duties under this Agreement. Company has no relationship with or to Consultant's employees or such Assistants and all such parties are not employees, agents, consultants, representatives, assistants or independent contractors of Company. Consultant, at its sole expense and without additional charges to the Company, shall be fully and solely responsible for the supervision and payment of its employees and such Assistants and for all work performed by its employees and such Assistants and any third party subcontractors approved by Company as provided in this Agreement.

3 Fees, Expenses, Records, and Taxes

- 3.1 Fees. **Schedule 2** sets forth the fee due for the Consulting Services and Consultant agrees to invoice Company as set forth in **Schedule 2**.
- 3.2 Budget. The budget provided in **Schedule 2** is a "Not to Exceed" (NTE) Budget. Any increase in the costs above the Budget in **Schedule 2** requires written pre-approval by Company subject to a presentation by Consultant of an updated Budget.
- 3.3 Expenses. Company shall reimburse Consultant for any travel expenses incurred in carrying out the services under this Agreement, provided that such expenses were pre-approved by Company in writing. Consultant shall invoice for expenses once per month. Payment is due 30 days after receipt of the expenses invoice.
- 3.4 Consultant shall be entitled to reimbursement of the categories of expenses set forth on **Schedule 2**. Consultant shall invoice Company on a monthly basis for expenses incurred as a result of performing Consulting Services in accordance with **Schedule 2**.
- 3.5 Payment Terms. The charges and/or expenses invoiced in accordance with this Section 4 shall be payable in US\$ by Company within thirty (30) days of Company's receipt of each invoice.
- 3.6 Taxes. Consultant shall clearly and separately state Value Added Tax (VAT) on Consultant's invoice to Company for corresponding Consulting Services. Company shall pay VAT on the invoice or, in lieu of the payment of VAT, Company may provide Consultant with a certificate acceptable to the taxing authorities exempting Company from payment of VAT.

4 Term and Termination

- 4.1 Term. This Agreement shall commence on the Effective Date and shall continue in full force and effect thereafter until the completion of the Consulting Services, unless it is terminated or expires sooner in accordance with the provisions of this Agreement.
- 4.2 Termination at will. This Agreement may be terminated in its entirety without cause by either Party on thirty (30) days' prior written notice to the other Party.
- 4.3 Termination For Breach. Either Party may terminate this Agreement at any time in the event of a material breach by the other Party that remains uncured after thirty (30) days written notice thereof (or such shorter period as may be specified in this Agreement or in any applicable Schedule).
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4.4 Termination for Bankruptcy/Insolvency. Either Party may terminate this Agreement immediately following written notice to the other Party if the other Party (i) ceases to do business in the normal course, (ii) becomes or is declared insolvent or bankrupt, (iii) is the subject of any proceeding related to its liquidation or insolvency (whether voluntary or involuntary) which is not dismissed within ninety (90) calendar days or (iv) makes an assignment for the benefit of creditors.

4.5 Payment Upon Termination. If either Party terminates the Agreement, Company agrees to pay Consultant for all fees and expenses incurred by the Consultant up to the effective date of termination

4.6 Survival. Sections 5 and 6 shall survive expiration or termination of this Agreement.

5 Confidentiality

The parties shall be bound by obligations of confidentiality regarding confidential information received by either party. Such obligations are set forth in the Company's standard Nondisclosure Agreement attached hereto as Schedule C (the "NDA"), the terms of which are incorporated herein by reference and shall apply to any Confidential Information (as defined therein) disclosed or acquired by either party during the term of this Agreement.

6 Ownership

Consultant agrees that all data, know-how, inventions and discoveries (whether or not patentable), that are developed, generated, conceived or first reduced to practice by or on behalf of either Party as a result of performing the services pursuant to this Agreement (collectively, "**Inventions**") shall be the sole and exclusive property of Company. Consultant shall promptly disclose any and all Inventions and, if and when requested by Company, deliver to Company any tangible embodiments thereof, and Consultant hereby assigns and agrees to assign to Company all of its right, title and interest in, to and under the Inventions, and to execute any documents or undertake any further actions if requested by Company to evidence such transfer of title thereto and to assist in securing legal protection therefore. Company shall reimburse Consultant for any expenses incurred at Company's request to secure title or legal protection for any such Inventions. Nothing in this Agreement shall be deemed to grant Consultant or any of its Subcontractors any license or similar right to use or practice any of the Inventions, or any intellectual property of Company not resulting from the performance of the services. Consultant shall also continue to own the copyright to all forms previously created by Consultant, including those modified for use by Company. It is further agreed by Consultant, that any improvements to existing inventions owned by Company resulting from the trials will be reassigned to Company at the end of the clinical study, regardless of any future business relationship.

7 Reports

7.1 Reports. The Company shall be entitled to full transparency insofar such data pertains to the Services, including performance thereof by the Consultant.

8 Representations and Warranties

8.1 Consultant represents and warrants that:

- 8.1.1 it has full corporate power and authority to enter into and carry out its obligations under this Agreement;
- 8.1.2 this Agreement has been duly executed and delivered by Consultant and constitutes the legal, valid and binding obligation of Consultant enforceable against it in accordance with its terms; and
- 8.1.3 it has never been and, to the best of its knowledge, none of its employees or contractors assigned to perform the Services has ever been (i) debarred or threatened to be debarred or (ii) indicted for a crime or otherwise engaged in conduct for which a person can be debarred under 21 U.S.C. 335a, as amended.
- 8.2 Consultant warrants that it will perform the Services in a (i) good faith, timely, professional, cost effective, and diligent manner; (ii) in accordance with the project requirements set forth in Schedule A; (iii) in compliance with all applicable domestic and international laws and regulations; and (iv) in compliance with acceptable scientific standards and practices and (v) in accordance with the purpose of this Agreement as set forth in Schedule 1. Consultant further warrants that it will negotiate all third party vendor agreements in a cost effective manner and make all reasonable efforts to ensure fair and reasonable pricing.
- 8.3 Disclaimer. Except as otherwise stated in the Agreement or its Schedules, each party makes no representations or warranties and hereby expressly disclaims all implied warranties (including the warranties of merchantability and fitness for a particular purpose).

9 **Limitation of Liability**

NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES OF ANY KIND OR NATURE, INCLUDING WITHOUT LIMITATION LOST REVENUES OR LOST PROFITS, WHETHER SUCH LIABILITY IS ASSERTED ON THE BASIS OF CONTRACT (INCLUDING, WITHOUT LIMITATION, THE BREACH OF THIS AGREEMENT OR ANY TERMINATION OF THIS AGREEMENT), TORT (INCLUDING NEGLIGENCE OR STRICT LIABILITY), OR OTHERWISE, EVEN IF THE OTHER PARTY HAS BEEN WARNED IN ADVANCE OF THE POSSIBILITY OF ANY SUCH LOSS OR DAMAGE.

IN NO EVENT SHALL CONSULTANT'S MAXIMUM LIABILITY TO COMPANY UNDER THIS AGREEMENT EXCEED THE AMOUNTS ACTUALLY PAID BY COMPANY TO CONSULTANT PURSUANT TO THIS AGREEMENT.

10 **Indemnification**

Consultant shall, at all times indemnify, hold harmless, and defend Company, its officers, directors, insurers, Affiliates, agents and employees (collectively, the "**Indemnified Parties**") from and against any and all loss, cost, liability or expense (including costs and reasonable fees of attorneys and other professionals) arising out of or in connection with the performance of the Services hereunder. The Company will provide prompt written notice to Consultant of any claim or the assertion of a claim by a third party giving rise to indemnification, provided, however, that any failure to do so shall not limit any of the rights of the Company (except and only to the extent such failure materially prejudices the defence of such legal proceeding). Upon such notice, Consultant shall have the right to defend against any such claims or actions filed against the Company, and to select counsel for such defence reasonably acceptable to the Company, and Consultant, at its expense, shall pay all costs and expenses associated therewith. The Company shall cooperate reasonably with Consultant, in supporting the defense against the claim or assertion. Consultant shall have no obligation to indemnify any of the Indemnified Parties under this Section 10 to the extent any such loss, cost, liability or expense is caused by and/or resulting from (i) the use of any materials provided to Consultant by the Company; (ii) performing the Services in accordance with the information, instructions and/or guidelines provided to Consultant by the Company; or (iii) the Company's failure to substantially comply with Consultant's reasonable instructions which if implemented would have prevented such loss, cost, liability or expense.

- 11.1 **Notice.** Any notice, approval, request, authorization, direction or other communication under this Agreement will be given in writing and will be deemed to have been delivered and given for all purposes (i) on the delivery date if delivered by confirmed facsimile; (ii) on the delivery date if delivered personally to the party to whom the same is directed; (iii) one business day after deposit with a commercial overnight carrier, with written verification of receipt; or (iv) five business days after the mailing date, whether or not actually received, if return receipt requested, postage and charges prepaid, or any other means of rapid mail delivery for which a receipt is available. The notice address shall be the address for the Party set forth in the first paragraph of this Agreement, with the other relevant notice information.
- 11.2 **No Waiver.** No waiver under this Agreement shall be valid or binding unless set forth in writing and duly executed by the Party against whom enforcement of such waiver is sought. The failure of either Party to insist upon or enforce strict performance by the other Party of any provision of this Agreement or to exercise any right under this Agreement shall not be construed as a waiver or relinquishment to any extent of such Party's right to assert or rely upon any such provision or right in that or any other instance; rather, the same shall be and remain in full force and effect.
- 11.3 **Entire Agreement.** This Agreement sets forth the entire agreement and supersedes any and all prior agreements of the Parties with respect to the transactions set forth herein. Neither Party shall be bound by, and each Party specifically objects to, any term, condition or other provision which is different from or in addition to the provisions of this Agreement (whether or not it would materially alter this Agreement) and which is proffered by the other Party in any correspondence or other document, unless the Party to be bound thereby specifically agrees to such provision in writing.
- 11.4 **Amendment.** No change, amendment or modification of any provision of this Agreement shall be valid unless set forth in a written instrument signed by the Party subject to enforcement of such amendment.
- 11.5 **Assignment.** Neither Party shall assign or transfer this Agreement or any of its rights and obligations hereunder whether in whole or in part without the prior written consent of the other Party. Company hereby consents to the use by Consultant of sub-contractors, at its choice, including CBR International Corp. Notwithstanding the foregoing, neither Party need obtain the consent of the other Party prior to assigning this Agreement (a) to an affiliate of the assigning Party, or (b) to any third party acquiring all or substantially all of the assets relating to this Agreement or a controlling interest in the voting stock or voting interest of the assigning party or any controlling affiliate of the assigning party. Except as permitted by the foregoing, any attempted assignment or delegation shall be null, void, and of no effect. Subject to the foregoing, this Agreement shall be fully binding upon, inure to the benefit of and be enforceable by the Parties hereto and their respective successors and assigns.
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- 11.6 **Force Majeure.** Neither Party shall be responsible for failure to perform the terms of this Agreement and/or Schedule thereto, when performance is prevented by force majeure. The term force majeure shall mean acts of God, earthquakes, flood, or any other cause whatsoever, whether similar or dissimilar to the causes herein enumerated, not within the reasonable control of either party which through the exercise of due diligence, a party is unable to foresee or overcome but specifically excluding financial distress. In no event shall the term force majeure include normal or reasonable foreseeable or reasonably avoidable operational delays.
- 11.7 **Construction; Severability.** In the event that any provision of this Agreement conflicts with the law under which this Agreement is to be construed or if any such provision is held invalid by a court with jurisdiction over the Parties to this Agreement, (i) such provision shall be deemed to be restated to reflect as nearly as possible the original intentions of the Parties in accordance with applicable law, and (ii) the remaining terms, provisions, covenants and restrictions of this Agreement shall remain in full force and effect.
- 11.8 **Applicable Law; Jurisdiction.** This Agreement shall be interpreted, construed and enforced in all respects in accordance with the laws of the State of Israel, except for its conflicts of laws principles. Each Party irrevocably consents and submits to the exclusive jurisdiction of the courts of State of Israel situated in Tel-Aviv-Jaffa, in connection with any action to enforce the provisions of this Agreement, to recover damages or other relief for breach or default under this Agreement, or otherwise arising under or by reason of this Agreement.
- 11.9 **Headings; Interpretations.** The captions and headings used in this Agreement are inserted for convenience only and shall not affect the meaning or interpretation of this Agreement. This Agreement shall be construed fairly according to its terms, without regard to the drafter of any provision hereof.
- 11.10 **Counterparts; Facsimile.** This Agreement may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same document. Delivery of an executed signature page to this Agreement by facsimile shall be effective to the same extent as if such Party had delivered a manually executed counterpart.

IN WITNESS WHEREOF, the Parties hereto, each acting under due and proper authority, have executed this Agreement as of the date first written above.

ADRES Advanced Regulatory Services Ltd.

By: /s/ Rivka Zaibel
Print Name: Rivka Zaibel
Title: CEO
Date: April 21, 2009

COMPANY

By: /s/ Nadav Kidron
Print Name: Nadav Kidron
Title: CEO
Date: April 21, 2009

Schedule 1

The Services

The Services and Scope of Work is outlined in the following table. Consultant is responsible for all regulatory document preparation and appropriate strategic development to support pre-IND activities, and the submission of a U.S. IND according to FDA regulations. The consultant is responsible to guide the company to act according to FDA recommendations resulting from the pre-IND meeting. The following outlines the Scope and Timelines for this effort.

Tasks	Timelines
1. Prepare Pre-IND Type B Meeting Request Letter	Six working weeks from the Effective Date
2. Submit Pre-IND Type B Request Letter	60 days prior to pre-IND meeting
3. Prepare Strategic Development Plan	Throughout the term of the Agreement
4. Prepare Pre-IND Meeting Package	For the first 60-90 days
5. Submit Pre-IND Meeting Package	30 days prior to the pre-IND meeting
6. Attend/Conduct Pre-IND Meeting with FDA	August 1, 2009
7. Prepare CMC Technical Writing, Review and Revision for the IND submission	November 1, 2009
8. Preparation of the Clinical Development Plan (CDP)	Throughout the term of the Agreement
9. Prepare Clinical Protocol (CTO ready for the pre-IND package)	Prior to IND
10. Draft and ensure completeness and compliance of the IND application with all FDA requirements*	November 1, 2009 provided tox study results available
11. Serve as U.S. Representative to the FDA (CBR)	Throughout the term of the Agreement
12. Prepare any response and correspondence required to the U.S. FDA including any IND amendments required until the IND approval **	Throughout the term of the Agreement
13. Quality Assurance Services (ADRES)	Throughout the term of the Agreement

* This includes but is not limited to the following sections of the IND application and any parts of complementary U.S. FDA requirements:

- a. Introductory Statement and General Investigational Plan
- b. Investigator Brochure
- c. Protocols
- d. Chemistry, Manufacturing, Control information
- e. Pharmacology and Toxicity Information
- f. Previous Human Experience with the IND

** Limited to 20 hours, starting 30 days after IND submission; additional working hours will be charged as per CBR and ADRES hourly rates.

Schedule 2

Budget and Payment Milestones

The consulting NTE Budget for this program is \$211,000 (US). The type of agreement is both fixed fee (retainer) and milestone based.

Costs

All supplies, postage and photocopy charges will be billed as direct pass through costs in addition to the Consulting Costs provided that, any single expense or cost exceeding the amount of \$1000 shall require the prior written consent of the Company.

Milestones and Retainer Payments

Milestone	Estimated Timeline	Milestone \$	Monthly Retainer (11 Months)
1. Pre-IND Meeting Letter Submitted	June 1, 2009	\$10,000	\$10,000/Month
2. Pre-IND Meeting Package Submitted	July 1, 2009	\$10,000	
3. Pre-IND Meeting Conducted	August 1, 2009	\$10,000	
4. IND Submitted	November 1, 2009	\$71,000	
Total		\$101,000	\$110,000

- A. Milestones payments will be invoiced upon completion of each milestone indicated. Payment of each milestone invoices is due Net 30 days. Payment of milestone invoices must be received before the deliverable of the next milestone
- B. Payment of monthly retainer is due at the beginning of each month in the 11 month period.
- C. A delay in a completion of any milestone of more then 60 days of dates above, will enable Company to withhold the monthly retainer payment, until such time when such milestone will be completed.
- D. The last monthly payment will be invoiced 30 days after IND submission. If IND submission is done before the elapse of 12 months, the entire balance of the retainer will be due and payable upon the IND submission
- E. If cost of work performed is less than the milestone budget, the difference will be credited to Company at the end of the project.
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Schedule 3

NDA
