# 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) June 19, 2007

# 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.)

# 2 Elza Street, Jerusalem, Israel 93706

(Address of principal executive offices and Zip Code)

## 972-54-790-9058

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

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:

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

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

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

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

#### Item 1.01. Entry into a Material Definitive Agreement

On June 19, 2007 we approved a proposal with the Encorium Group Inc. ("Encorium") to develop the Company's product for the treatment of diabetes mellitus (the "Proposal"). Under the terms of the Proposal, Encorium will be paid an hourly fee ranging from US \$283 to US \$450 depending on level of expertise of the medical personnel. The Company will also cover out of pocket expenses.

# Item 9.01 Financial Statements and Exhibits

- 10.1 proposal with Encorium Group Inc.
- 99.1 <u>news release dated June 19, 2007</u>

# 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.

<u>/s/ Nadav Kidron</u> Nadav Kidron President, CEO and Director

Date: June 19, 2007





# Oramed Pharmaceuticals Signs Agreement With Encorium Group To Commence Investigational New Drug Application

JERUSALEM and WAYNE, PA., June 19 /PRNewswire-FirstCall/ -- Oramed Pharmaceuticals, Inc. (OTC Bulletin Board: ORMP - News), an Israeli company focused on the development of oral delivery solutions based on proprietary technology and Encorium Group, Inc. (Nasdaq: ENCO - News), an international full service contract research organization (CRO) that provides comprehensive clinical and drug development solutions for pharmaceutical, biotechnology and medical device companies today announced an agreement that is intended to expedite the development of Oramed's lead product for treatment of diabetes mellitus. Encorium Group has extensive worldwide experience in the drug/biologics development process for a multitude of agents and disease conditions and specifically in diabetes, including preclinical to post-marketing support studies. This agreement engages Encorium Group to assist Oramed in the design, implementation, advancement, and oversight of a sound scientific and regulatory strategic plan for the filing and ultimate approval of Oramed's oral insulin product on a worldwide basis. The initial focus of this combined effort between Oramed and Encorium Group is to assemble the information required for the opening of an investigational new drug application (IND) and its subsequent filing with the FDA.

Nadav Kidron, Chief Executive Officer for Oramed Pharmaceutical, Inc., stated, "We are delighted to be working with Encorium Group, a company with a strong track record of successfully integrating early stage development, consulting services, and clinical trial execution for small as well as large biopharmaceutical companies on a global basis. We believe that by working closely with Encorium Group, we can proactively reach our immediate goal of filing an IND in the United States. Subsequently, we intend to move forward quickly to systematically evaluate the oral bioavailability of our insulin product from the gastrointestinal tract in humans as well as evaluate the impact of our oral formulation on blood glucose levels."

Kenneth M. Borow, M.D., President and Chief Executive Officer for Encorium Group, Inc. commented, "We are enthusiastic about the opportunity to work with Oramed Pharmaceuticals. Its oral delivery technology for insulin is both timely and innovative. This is especially important when considered within the framework of a worldwide epidemic of diabetes and the trend towards earlier use of insulin in type 2 diabetic patients. Based on numerous in vivo preclinical studies, Oramed Pharmaceutical's

oral insulin technology is unique and holds the promise for being of significant therapeutic benefit in the management of diabetes. We at Encorium Group look forward to working with Oramed on this exciting and potentially medically important product."

# About Diabetes Mellitus:

The incidence of diabetes has increased significantly in recent years at least in part due to changes in obesity rates and lifestyle. Obesity and weight gain are leading risk factors for diabetes. In turn, diabetes and obesity are significant risk factors for cardiovascular disease and stroke. In the United States, Canada, and Europe, type 2 diabetes accounts for approximately 90 percent of all cases of diabetes. More than 6 percent of all people between the ages of 20 and 74 years and more than 12 percent of persons over age 40 have type 2 diabetes; these numbers continue to increase. Insulin is used in the treatment of patients with diabetes of all types. The need for insulin depends upon the balance between insulin secretion and insulin resistance. All patients with type 1 diabetes need insulin treatment permanently, unless they receive an islet or whole organ pancreas transplant; many patients with type 2 diabetes will require insulin as their pancreatic beta cell function declines over time. Recently, there has been growing interest in the concept of earlier treatment with insulin in patients with type 2 diabetes.

# About Oramed Pharmaceuticals:

Oramed Pharmaceuticals' is an Israeli based company focused on the development of oral delivery solutions based on proprietary technology. Diabetes is one of the most rapidly growing diseases in the world and is one that requires constant and often unpleasant monitoring and drug therapy regimen. Oramed is currently developing an orally ingestible soft gel insulin capsule for the treatment of diabetes. The Company is also pursuing the development of oral delivery solutions for other drugs and vaccines. For more information please visit our website at www.oramedpharma.com.

# About Encorium Group, Inc.

Encorium Group, Inc. is a global clinical research organization that is a leader in the design and management of complex clinical trials and Patient Registries for the pharmaceutical, biotechnology and medical device industries. The Company's mission is to provide its clients with high guality, full-service support for their biopharmaceutical and medical device development programs. Encorium offers therapeutic expertise, experienced team management and advanced technologies. The Company has drug and biologics development as well as clinical trial experience across a wide variety of therapeutic such as diabetes, cardiovascular, vaccines, infectious diseases, oncology, areas endocrinology/metabolism, gene therapy, immunology, neurology, gastroenterology, dermatology, hepatology, women's health and respiratory medicine. Encorium believes that its leadership in the design of complex clinical trials, its extensive early stage development capabilities, its broad therapeutic expertise and commitment to excellence, and its application of innovative technologies offer its clients a means to more quickly and cost effectively move products through the clinical development process. Encorium is headquartered in Wayne, Pennsylvania with its European base of operations in Espoo, Finland. The Company has a geographic footprint that includes over one billion people in North America, Western/Central/Eastern Europe, Scandinavia, and the Baltics. For more information please visit our website at www.encorium.com.

#### Legal Notice and Forward Looking Statements For Oramed Pharmaceuticals

This news release contains statements, which may constitute "forward- looking statements". Those statements include statements regarding the intent, belief or current expectations of Oramed Pharmaceutical Inc., and members of our management as well as the assumptions on which such statements are based. Forward-looking statements in this release include: that we are currently developing an orally ingestible soft gel insulin capsule for the treatment of type 1 and 2 diabetes; that we are pursuing the development of oral delivery solutions for other drugs and vaccines; that by working closely with Encorium Group, we can proactively reach our immediate goal of filing an IND in the United States; and that subsequently, we intend to move forward quickly to systematically evaluate the oral bioavailability of our insulin product from the gastrointestinal tract in humans as well as evaluate the impact of our oral formulation on blood glucose levels. Factors which may significantly change or prevent our forward looking statements from fruition include that we may be unsuccessful in developing any products and we may not continue our collaboration with Encorium; that human trials may suffer unforeseen difficulties or adverse medical effects on participants; that our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; that we are unable to retain or attract key employees whose knowledge is essential to the development of our products; that unforeseen scientific difficulties develop with our process; that our patents are not sufficient to protect essential aspects of our technology; that competitors may invent better technology to treat or cure diabetes or that the market for diabetes drugs does not increase; that studies are cut short by unexpected problems with our methodology; that our products may not work as well as hoped or worse, that our products may harm recipients; and that we may not be able raise funds for development or working capital when we require it. As well, our products may never develop into useful products and even if they do, they may not be approved for sale to the public. For further risk factors see the Company's latest 10-KSB filed with the SEC and the 8-K announcing our acquisition of the Oramed technology filed March 8, 2006.

## Legal Notice and Forward Looking Statements For Encorium Group, Inc.

This press release contains forward-looking statements identified by words such as "estimate," "project," "expect," "intend," "believe," "anticipate" and similar expressions. Actual results might differ materially from those projected in, expressed in or implied by the forward-looking statements. Potential risks and uncertainties that could affect the Company's future operating results and financial condition include, without limitation: (i) our success in attracting new business and retaining existing clients and projects; (ii) the size, duration, and timing of clinical trials we are currently managing may change unexpectedly; (iii) the termination, delay or cancellation of clinical trials we are currently managing could cause revenues to decline unexpectedly; (iv) the timing difference between our receipt of contract milestone or scheduled payments and our incurring costs to manage these trials; (v) outsourcing trends in the pharmaceutical, biotechnology and medical device industries; (vi) the ability to maintain profit margins in a competitive marketplace; (vii) our ability to attract and retain qualified personnel; (viii) the sensitivity of our business to general economic conditions; (ix) other economic, competitive, governmental and technological factors affecting our operations, markets, products, services and prices; (x) announced awards received from existing and potential customers are not definitive until fully negotiated contracts are executed by the parties;(xi) our backlog

may not be indicative of future revenues and may not generate the revenues expected; (xii) our ability to successfully integrate the businesses of Encorium and Remedium Oy which we acquired on November 1, 2006; and (xiii) the ability of the combined businesses to operate successfully, generate revenue growth and operating profits. You should not place any undue reliance on these forward looking statements which speak only as of the date of this press release. Additional information concerning factors that might affect our business or stock price which could cause actual results to materially differ from those in forward-looking statements is contained in Encorium Group's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2006 and other periodic reports under the Securities Exchange Act of 1934, as amended, copies of which are available upon request from Encorium Group's investor relations department or The Equity Group Inc.

#### For further information, please contact:

#### FOR ORAMED PHARMACEUTICALS, INC.:

# **Investor Relations:**

Vinisha Agnihotri (646) 467-2252 (Office) info@oramedpharma.com www.oramedpharma.com

# FOR ENCORIUM GROUP, INC.

#### **Investor Relations:**

The Equity Group Inc. Adam Prior (212) 836-9606 aprior@equityny.com www.theequitygroup.com

# OR

## **Business Development:**

Helen Springford V.P., Global Business Development +44 1344 769011 (Office) +44 7785 366604. (Cell phone) hspringford@encorium.com www.encorium.com



Kenneth M. Borow, M.D. President and CEO Encorium Group, Inc. 1275 Drummers Lane Wayne, PA 19087 Office: 610-975-9533 Mobile: 610-299-7855 kborow@encorium.com www.encorium.com

TO:	Nadav Kidron
	President and CEO
	Oramed Pharmaceuticals, Inc.

FROM: Kenneth M. Borow, M.D.

DATE: 27 April 2007

RE: Encorium Proposal to Oramed Pharmaceuticals, Inc.

Encorium is a full service multi-national contract research organization with both clinical and developmental expertise covering an array of disease states and indications. Our breath of experience is far reaching and includes drugs and biologics, pharmacogenomics, gene and stem cell therapies, and medical devices as well as conventional and non-conventional (peptide/proteins/antibodies) new chemical entities. Our trials experience includes efficacy and safety evaluations for all phases of clinical development from Phase I to Phase IV. We have been involved in more than 30 NDAs and multiple European filings over the past 15 years. For many of these programs, beyond the conventional clinical related services, we have also provided preclinical (toxicological, pharmacology, pharmaceutics etc), pharmacokinetic and clinical pharmacology services including biopharmaceutics and subsequent human evaluation studies for a variety of dosage forms and routes of administration. We believe that all of these experiences are directly applicable to Oramed's insulin program.

With a staff of nearly 300 worldwide, Encorium Group, Inc. is large enough to meet almost any development program needs yet small enough to allow us to provide individualized services to our clients and their programs. Our responsiveness to our client's needs and our attention to detail are our hallmarks. Collectively, Encorium's early stage development group has over 100 man/woman years of drug development experience. We believe that our expertise is not characterized by indication but by an intimate and sometimes painful knowledge of the drug approval process itself. While specific indication expertise may be available in the CRO marketplace, expertise on how to make a drug is a rare commodity and much more difficult to find. This is where we at Encorium believe we excel.

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Unlike other CROs, Encorium dedicates a substantial amount of its internal resources and time to assist early stage and small size pharmaceutical/biotechnology companies in their drug or medical device programs. We believe that this makes us unique among our peers. We approach our relationships with smaller organizations as co-development opportunities rather than from the perspective of a conventional service provider although we are flexible and work within the structure our clients' desire. Our goal is to advance the project to its next development stages whether judged on financial, clinical, scientific, or regulatory progress. To that end many of Encorium's management, including both senior and even lower level employees, have first-hand experience working in or with smaller pharmaceutical/biotech organizations. This experience translates into Encorium having a unique appreciation and understanding of the practical realities and priorities required by these smaller organizations. These priorities are frequently quite different and often in conflict with those of large pharmaceutical organizations. We are not only committed to conducting the requisite human and animal studies necessary for ultimate regulatory and commercial approval but also to further the advancement of the company's technology and innovation. Encorium's management team and company-wide drug development expertise can assist a company's internal management in balancing the need for proof-ofconcept programs with scientifically valid and acceptable development studies.

Oramed's oral delivery technology for insulin is both timely and innovative. Although much of the data generated at this stage in its development cycle is, by necessity, preliminary in nature, it is evident that the technology is both unique and has a reasonable probability of success. Encorium believes that its expertise in drug development and specifically diabetes will be of great benefit to the advancement of Oramed's technology to the next stages in its development. With respect to Oramed's specific needs, our experience in clinical trials involving diabetic patients is quite extensive including approximately 15 studies at almost 400 sites worldwide enrolling over 6000 patients. Encorium has completed over 30 Phase I studies in the past 2 years many being conventional safety and dose ranging experiments. These studies were conducted with various therapeutic agents at a variety of clinical centers worldwide. Approximately one-third of these studies were first in man trials for NCEs and many were conducted in support of original IND filings. We also have extensive experience in aiding our smaller clients in their fund raising/commercialization efforts via enhancement of their technical portfolio as well as in presentations and negotiations.

The following is a brief preliminary outline of the services and programs that Encorium can provide to assist in the product development and commercialization activities of Oramed's oral insulin product. Our intent is to complement the expertise and resources currently available within Oramed with our own. If the need arises, we will assist Oramed in identifying and monitoring external resources in support of the US IND approval.

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## **Project and Technical Management**

Encorium can assist in the development, implementation, and oversight of a scientifically and regulatory sound strategic project plan for the filing and approval of Oramed's oral insulin product on a worldwide basis. The current focus is obtaining the required information to open an IND and file this with the FDA. The program will include preliminary studies, costs and timelines. Although it is highly likely that Oramed will be able to progress directly into Phase IIa studies in diabetic patients, standardized dose ranging/safety studies will still have to be performed in these patients. Acceptance by the FDA for this accelerated development strategy will therefore be required. Encorium's project management and scientific expertise in the areas of biopharmaceutics, clinical pharmacology, and diabetes will aid substantially in the development and acceptance of this strategic development plan. Encorium will assign individual project managers who will provide the necessary scientific and operational oversight to Oramed's program

## **Regulatory Filings**

Given the preliminary nature of the program to date and its necessary focus on formulation development the available preclinical animal and CMC information, both proprietary and published, will need to be evaluated and appropriate studies performed if necessary. Encorium will use its internal and external resources to assist in generating the necessary studies and documentation suitable for IND and/or European filings. These activities will include CMC, preclinical pharmacology summarization, toxicological evaluations and regulatory support documentation included prior human experience and safety information. The role of Oramed's "excipients" in the formulation would also have to be clearly identified and documented. Communications and other interactions with the FDA and other regulatory authorities worldwide will be initiated in order to determine the necessary development programs requirements and gain their generalized acceptance.

#### **Pre Clinical Program**

Details of the manufacturing and production of preclinical and clinical supplies will be required to support any regulatory filings. Documentation, translation, and summarization may have to be performed in support of the CMC component of the IND. All material will be required to meet US GLP/GMP standards and appropriate audits may have to be performed. The presence of biologically significant excipients will require additional oversight and analysis. Encorium staff has extensive experience in such activities having performed similar services on numerous IND filings in the past. The presence of regional representatives in various European countries will facilitate the organization of this section of the regulatory filings.

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Formal toxicology studies to US-GLP standards will have to be performed in two animal species. The physical limitations of the dosage form and its components will require an innovative yet scientifically valid program be conducted Encorium has extensive experience in the conduct of such trials. Appropriate internal and external expertise is available to support the preclinical toxicological activities. Identification and oversight of appropriate research facilities, detailed audits, pharmacokinetics and toxicokinetic drug studies, data analysis and report generation etc. will be required.

## **Clinical Program**

To date, extensive information is available on the action of insulin however, oral administration and the use of novel "excipients" may require unique scientific, toxicological, and regulatory support programs. The current clinical experience with the product will need to be summarized and presented in context. Encorium, in conjunction with Oramed, will design, write, and execute the necessary Phase I/II trials not only to gain regulatory approval of the IND but also in order to advance Oramed to the next stages in its fund raising activities. If Oramed so desires, we would be willing to support it in its fund raising activities.

These clinical services will include development of necessary protocols, approvals, site identification/management and analysis/reporting of the necessary studies to support the development of Oramed's products. Our extensive staff of regional CRAs and medical officers will provide the necessary medical and data oversight. Complete data and facilities audits can be performed if deemed necessary.

#### **Data Management**

Encorium has extensive resources in the production, organization, management and data analysis both for individual studies as well as complete submissions. Detailed audits of Encorium and Encorium sponsored studies have been conducted by the majority of our clients as well as by the FDA and European Regulatory authorities. Encorium has the prerequisite document management services to meet any study or regulatory requirement in support of Oramed's preclinical and clinical activities.

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#### **Business/Commercial Opportunities**

As we discussed, your pharmacologic concepts and proposed indications are highly inventive and innovative. The concept of evening dosing, the need for 3 or 4 times a day dosing or the presence of enhancers may either be considered advantageous or hinder the commercial viability of the product. A detailed market assessment of the product and its proposed use may aid substantially in the company's fund raising activities. Encorium can perform such analysis including small focus groups of patients and physicians. Encorium will also use it's extensive range of contacts, both within the investment community as well as at various pharmaceutical companies to aid Oramed in its fund raising/commercialization of its oral delivery technology.

Encorium would like to formalize a relationship with Oramed with the specific goals of filing an IND in the United States and completion of the necessary Phase I/II studies. We at Encorium are committed to seeing that Oramed is successful. To that end, we would like to propose that Encorium be retained to conduct the necessary studies and support services required for a US IND filing for Oramed's oral insulin program. These services will include all necessary preclinical and clinical (Phase I/II) studies and related support services.

We would like to propose a multi-stage development collaboration. The first Stage of this program will entail establishing the magnitude of the program, its technical issues and subsequent regulatory requirements by performing a detailed analysis/critique of its current status. This analysis will also allow for the generation of an initial development plan including budget estimates, resources and timeline requirements. My senior staff and I will perform this technical analysis and related plan development.

Encorium estimates that the following time will be required to reach the end of Stage I:

Encorium Personnel	Tasks	Estimated Time
		Required
Dr. John Ziemniak and Possible Outside Consultants for Pertinent Regulatory and Toxicology Issues	Review of oral insulin data available to date Review of CMC for components of oral insulin Review of information available in the public domain on all components of oral insulin Development of status document Development of pre-clinical requirements and selection of GLP facilities Development of clinical requirements and selection of study centers Initiation of discussions with regulatory	200 hours @ \$283/hr
	authorities	

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Liz Mead	Review of status document Review of pre-clinical requirements Development of clinical requirements and selection of clinical centers Support for regulatory discussions	60 hours @ \$283/hr
Dr. Ken Borow	Review of status document Review of pre-clinical requirements Development of clinical requirements and selection of clinical centers Support for regulatory discussions Medical oversight and strategic consulting	60 hours @ \$450/hr

In order to initiate this first stage, a non-refundable retainer fee of \$100,000 is required to cover Encorium's professional fees as outlined above. These fees are associated with the preparation of a detailed development plan, budget, timeline and review of existing technical information. Pass through expenses will be tracked and billed independently of professional fees are <u>not</u> included as part of the retainer fee. Pass through expenses for travel will conform with Encorium's usual Sponsor-related policies for travel within and outside of continental United States. Any remainder or unused portion of the retainer fee will be credited to additional future professional services for the oral insulin or other Oramed sponsored programs. Upon completion and acceptance of the initial development plan and budget, additional services will be compensated for with a combination of cash and equity. Details of this compensation arrangement will be determined as the program progresses. The technological expertise, leadership, and commitment to developing oral insulin that Oramed brings are substantial. We at Encorium would like to participate in the co-development of the Oramed's oral insulin product. I am certain that we can arrive at an innovative and mutually beneficial compensation model. I would like to discuss this or any alternate proposals with you at your earliest convenience.

Sincerely, /s/ Kenneth M. Borow, M.D. Kenneth M. Borow, M.D.

The terms and conditions stated herein are agreed and accepted.

Name

Title

Date

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