

NovaBay Pharmaceuticals, Inc.
Form 8-K
January 12, 2012
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 earliest event reported: January 9, 2012

NovaBay Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33678
(Commission File Number)

68-0454536
(I.R.S. Employer
Identification No.)

5980 Horton Street, Suite 550, Emeryville, CA 94608
(Address of Principal Executive Offices) (Zip Code)

(510) 899-8800
(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 (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))
-

Item 1.01 Entry into a Material Definitive Agreement.

NovaBay Pharmaceuticals, Inc. announced on January 9, 2012, that it has entered into a Distribution Agreement with Pioneer Pharma Co. Ltd., (“Pioneer”) a Shanghai-based company that markets high-end pharmaceutical products into China, for the commercialization of its product NeutroPhase, a U.S. Food and Drug Administration (FDA)-cleared wound cleanser developed by NovaBay to promote healing and improve clinical outcomes for patients with chronic non-healing wounds, including Stage I-IV pressure ulcers, stasis ulcers, leg ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, abrasions and minor irritations of the skin. The agreement covers distribution in the People’s Republic of China, excluding Hong Kong, Macau and Taiwan.

Under the terms of the agreement, NovaBay will receive an upfront payment of \$312,500, with the potential for additional payments totaling \$937,500 that may be triggered by certain regulatory milestones pre commercial launch. Under the exclusive agreement, NovaBay will be responsible for preparation and submission of a Marketing Approval Application (MAA) for NeutroPhase, which will be reviewed by China’s State Food and Drug Administration (SFDA). The MAA in China will be based on the data in the U.S. FDA 510(k) of NeutroPhase. NovaBay will be required to refund \$312,500 of the payments referenced above in the event that NovaBay does not submit the MAA or, underspecified circumstances, MAA approval is not obtained.

NovaBay will export NeutroPhase finished product to Pioneer for sale in Mainland China following its expected approval. NovaBay has retained rights to commercialize or partner NeutroPhase in select Chinese markets not covered by the agreement, including Hong Kong, Macau, and Taiwan. In addition, NovaBay will receive payments for units of NeutroPhase shipped, less deductions specified in the agreement.

The Agreement is for a term of five years and thereafter may be renewed for additional five years.

The statements in this Form 8-K relating to expected financial and other benefits to be received from the Pioneer agreement are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties include, among others: the risk that NeutroPhase may not prove to be effective in treating wounds; the risk that NovaBay may not be able to secure MAA approval from the China SFDA; unexpected adverse side effects or inadequate therapeutic efficacy of NeutroPhase may inhibit it from becoming a treatment for chronic wound; the risk of unexpected delays in the regulatory process which may delay the manufacturing and commercialization of NeutroPhase; as well other as risks relating to NovaBay and its Aganocide compounds detailed in NovaBay’s Quarterly Report on Form 10-Q, under the caption "Risk Factors" in Item 1A of Part II of that report, which was filed with the Securities and Exchange Commission on November 7, 2011. The forward-looking statements in this release speak only as of this date, and NovaBay disclaims any intent or obligation to revise or update publicly any forward-looking statement except as required by law.

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.

NovaBay Pharmaceuticals, Inc.
(Registrant)

By: /s/ Thomas J. Paulson
Thomas J. Paulson
Chief Financial Officer and
Treasurer

Dated: January 12, 2012