NovaBay Pharmaceuticals, Inc.
Form 8-K
June 17, 2011

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: June 16, 2011

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

Delaware	001-33678	68-0454536
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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):

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 1.02. Termination of a Material Definitive Agreement.

On June 16, 2011, NovaBay Pharmaceuticals, Inc. ("NovaBay") and Alcon Research, Ltd. ("Alcon") entered into a termination agreement, dated June 15, 2011, (the "Termination Agreement"), pursuant to which they terminated their Collaboration and License Agreement, originally entered into on August 29, 2006, and amended November 4, 2010 by the First Amendment to Collaboration and License Agreement (as so amended, the "License Agreement"), related to NovaBay's proprietary Aganocide compounds.

The License Agreement provided Alcon with the exclusive rights to develop, manufacture and commercialize products incorporating NovaBay's Aganocide compounds for the treatment of eye, ear and sinus infections as well as for use in contact lens care. Under the terms of the License Agreement, Alcon paid an up-front technology access fee of $10.0 million upon the effective date of the License Agreement. Under the terms of the License Agreement NovaBay also received semi-annual payments from Alcon to support on-going research and development activities during the four year funding term of the License Agreement, which ended on August 2010. In November 2010 Alcon extended the funding term to December 2015, subject to earlier termination of the funding term, at Alcon's election, with six months prior written notice. The License Agreement also called for Alcon to pay for all developmental and clinical costs. The research and development support payments included amounts to fund a specified number of personnel engaged in collaboration activities and to reimburse for qualified equipment, materials and contract study costs. The License Agreement provided that as product candidates were developed and proceed through clinical trials and approval, NovaBay would receive milestone payments. If the products were commercialized, NovaBay would also receive royalties on any sales of products containing the Aganocide compounds.

During 2010, Alcon concluded a Phase 2 human proof of concept trial of NovaBay's lead compound, NVC-422, for the treatment of adenoviral conjunctivitis, a type of "Pink Eye". The results of the trial were analyzed for the safety, microbiological and clinical efficacy. NVC-422 did not meet the primary endpoints of the trial. However, other encouraging results were found in the 38% of patients infected with adenovirus serotypes commonly associated with epidemic keratoconjunctivitis. The trial results were released in May 2011.

Pursuant to the terms of the Termination Agreement, Alcon shall pay to NovaBay payments totaling $2,972,245 broken down as follows: (1) payment of $2,000,000 due to non-fulfillment of Milestone Event 1 for the otic and sinus sub-fields, (2) $726,450 for payment of Q3/Q4 2011 FTE related costs, (3) $168,039 for NovaBay's non-FTE related costs for 2011, and (4) $77,756 for a retroactive Q1/Q2 2011 FTE rate adjustment. The payments consist of a termination fee as well as final reimbursement for R&D and personnel costs related to the collaboration. Alcon will have no further financial obligations to NovaBay as a result of the termination of the License Agreement. All rights under the licenses that NovaBay granted to Alcon under the License Agreement are terminated and revert back to NovaBay, including rights to NovaBay's lead Aganocide compound, NVC-422, as well as other Aganocide® compounds developed as a result of the almost five-year collaboration. Rights returned to NovaBay include all previously licensed areas in ophthalmic, otic, and sinus applications. Alcon is also required to deliver and assign to NovaBay rights, title and interest it may have in all (i) clinical study reports in Alcon's possession or control related to NVC-422 for the treatment of adenoviral conjunctivitis including those arising from (A) the Phase 1 safety study and (B) the completed 452 patient Phase 2 study (when available), (ii) technical reports, e.g., pharmacology and toxicology, stability results for any solution incorporating NVC-422 and (iii) INDs (including clinical trial authorizations) with respect to NVC-422 whether approved or not, e.g., those filed in India and Brazil. In addition, NovaBay shall have the first right to control the prosecution and maintenance of patent applications and patents claiming subject matter jointly owned by NovaBay and Alcon. Moreover, Alcon will grant NovaBay a nonexclusive worldwide, irrevocable license, with the right to sublicense, for certain technologies that may be useful to the development of NovaBay's Aganocide compounds that were subject to the collaboration. Should NovaBay exercise its right to license such technology the agreement allows for negotiation of considerations to Alcon not to exceed low single digit royalties of net sales.

2

Item 8.01. Other Information.

As a result of the termination of the License Agreement, NovaBay is providing the following risk factors, to replace the risk factor entitled "Our current research collaborations with Alcon and Galderma may fail, and entering into additional collaborations may not happen, resulting in a decrease in funding and inhibition of our ability to continue developing products," previously disclosed in Part II, Item 1A, of NovaBay's Form 10-Q filed May 16, 2011:

Our research collaboration with Alcon has ended, which will result in a decrease in funding and may impede our ability to develop our Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solutions unless we are able to enter into a new collaboration with another collaboration partner.

In June 2011, we and Alcon terminated our collaboration and license agreement. Under the terms of the collaboration and license agreement prior to termination, we received semi-annual payments to support on-going research and development activities over the term of the agreement, which payments were reduced beginning in 2011. During 2010 we received $6.0 Million in funding payments from Alcon, and in the first five months of 2011 we received $2.1 Million in funding payments from Alcon. We received a payment of approximately $3.0 million in connection with the termination, but will not receive any additional payments from Alcon. As a result, we expect our revenues to be significantly less than we previously expected. Further, should we decide to continue the development of NVC-422 for application in connection with the eye, ear and sinus and for use in contact lens solutions, we have to fund such development unless we are able to enter into a new collaboration with another collaboration partner, which we may not be able to do. If we are not able to enter into a new collaboration with another collaboration partner and choose to proceed on our own the development of NVC-422 for application in connection with the eye, ear and sinus and for use in contact lens solutions, we will need to rely on our own funds, and any additional funds we may raise. If we are not able to enter into a new collaboration with another collaboration partner or are not able to raise additional funds, we may not be able to develop NVC-422 for these applications.

Our current research collaboration with Galderma may fail, resulting in a decrease in funding and inhibition of our ability to continue developing products.

We have entered into an agreement with Galderma S.A. to develop and commercialize our Aganocide compounds, which covers acne and impetigo and potentially other major dermatological conditions, excluding onychomycosis (nail fungus) and orphan drug indications. With the termination of our collaboration with Alcon, our collaboration with Galderma is our only collaboration, and so unless and until we enter into additional collaborations or are able to market products on our own, we will be dependent on Galderma for all of our revenues.

We cannot assure you that our collaboration with Galderma will be successful, or that we will receive the full amount of research funding, milestone payments or royalties, or that any commercially valuable intellectual property will be created, from this arrangement. If Galderma were to breach or terminate its agreement with us or otherwise fail to conduct its collaborative activities successfully and in a timely manner, the research contemplated by our collaboration with them could be delayed or terminated and our costs of performing studies may increase.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may not be able to negotiate additional collaborations on acceptable terms, if at all, and these collaborations may not be successful. Our current and future success depends in part on our ability to enter into successful collaboration arrangements and maintain the collaboration arrangement we currently have with Galderma. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons;
- our shortage of capital resources may impact a willingness on the part of potential companies to collaborate with us;
- our contracts for collaborative arrangements may be terminable for convenience on written notice and may otherwise expire or terminate, and we may not have alternative funding available;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we do not have day-to-day control over the activities of our partners and have limited control over their decisions;
- our ability to receive milestones and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of products developed from our drug candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- our partners may not devote sufficient capital or resources towards our product candidates; and
- our partners may not comply with applicable government regulatory requirements.

If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital. Consequently, if we are unable to enter into, maintain or extend successful collaborations, our business may be harmed.

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: June 17, 2011