NovaBay Pharmaceuticals, Inc.
Form 8-K
September 17, 2013

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: September 16, 2013

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):

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 7.01. Regulation FD Disclosure.

On September 16, 2013, NovaBay Pharmaceuticals, Inc. issued a press release announcing results from its recently completed Phase 2 clinical study CL1001 for auriclosene (NVC-422) to prevent urinary catheter blockage and encrustation (UCBE) of indwelling urinary catheters. The press release is furnished as Exhibit 99.1 to this current report. NovaBay is also furnishing as Exhibit 99.2 to this current report its presentation that it will be presenting at an investor conference on September 17, 2013. NovaBay expressly disclaims any obligation to update this information and cautions that it is only accurate on the date it was presented. The inclusion of any data or statements in these documents does not signify that the information is necessarily considered material.

Item 8.01. Other Events.

On September 16, 2013, NovaBay Pharmaceuticals, Inc. announced positive top-line results from its recently completed Phase 2 clinical study CL1001 for auriclosene (NVC-422) to prevent urinary catheter blockage and encrustation (UCBE) of indwelling urinary catheters.

Study Results

This three part study utilized randomized double-blinded, placebo-controlled crossover design, where patients served as their own control and received both placebo and auriclosene. The study enrolled 67 subjects with chronic indwelling transurethral or suprapubic urinary catheters. There were a total of 125 treated catheters: 62 in the auriclosene arm and 63 in saline arm. In Part 3 of the study, which represents the clinical paradigm of four weeks of catheter duration use, subjects' catheters were irrigated twice weekly with a solution of either 0.2% auriclosene or saline for a total of eight treatments over four weeks, followed by a washout period and a similar cross-over treatment.

The top-line results show auriclosene was effective at reducing the degree of catheter encrustation and maintaining the catheter patency over the course of the study. Overall, the auriclosene irrigation solution reduced the average encrustation at the time of catheter removal from 77% encrusted (saline arm) to 22% encrusted (auriclosene arm). Importantly, a within-subject comparison for the degree of encrustation showed that the auriclosene arm demonstrated a statistically significant reduction ($p = 0.005$) in the degree of encrustation. Complete catheter blockage was not observed in any of the auriclosene-treated catheters, but was observed in 64% of the catheters treated with saline ($p = 0.0004$). Fifty percent of the saline-treated catheters had to be removed early because of laboratory-confirmed blockage, compared to none of the auriclosene-treated catheters. The drug was well tolerated; there were no treatment-related serious adverse events and only transient manageable adverse events in both treatment arms.

Based on these study results, NovaBay plans to continue discussions with the FDA and move toward registration.

Item 9.01. Financial Statements and Exhibits.

Exhibit Number	**Description**
99.1	Press release issued by NovaBay Pharmaceuticals, Inc. on September 16, 2013.
99.2	Investor Presentation by NovaBay Pharmaceuticals, Inc.

Caution Regarding Forward-Looking Statements.

This Current Report on Form 8-K and attached exhibits contain forward-looking statements made in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements regarding the potential for Auriclosene to benefit patients at risk of catheter blockage, and NovaBay's intent to continue discussions with the U.S. Food and Drug Administration. All such information and statements are subject to certain risks and uncertainties, the effects of which are difficult to predict and generally beyond the control of NovaBay, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include, but are not limited to, risks related to whether auriclosene or any of our therapeutic products will advance further in the clinical trials process and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration and equivalent foreign regulatory agencies and for which indications; whether auriclosene or any of our other therapeutic products will be successfully marketed if approved; and those risks identified and discussed by NovaBay in its filings with the U.S. Securities and Exchange Commission.

Forward-looking statements are not guarantees of performance. The future results of NovaBay could be affected by subsequent events and could differ materially from those expressed in the forward-looking statements. If future events and actual performance differ from NovaBay's assumptions, NovaBay's actual results could vary significantly from the performance projected in the forward-looking statements. Except as required by law, NovaBay undertakes no obligation to disclose any revisions to any forward-looking statements or to report events or circumstances after the date of this filing.

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: September 17, 2013

Exhibit Index

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Exhibit 99.1

Link to Press Release:

http://novabay.com/pressrelease/novabay-pharmaceuticals-announces-positive-results-phase-2-clinical-study-auriclosene-reduc

Exhibit 99.2

Link to Presentation:

http://novabay.com/investors/events