

AVI BIOPHARMA INC
Form 8-K
April 14, 2010

**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 14, 2010**

AVI BioPharma, Inc.

(Exact name of registrant as specified in its charter)

Oregon
(State or other
jurisdiction of
incorporation)

001-14895
(Commission File Number)

93-0797222
(I.R.S. Employer
Identification No.)

3450 Monte Villa Parkway, Suite 101

Bothell, WA 98021

(Address of principal executive offices)

(425) 354-5038

Registrant's telephone number, including area code

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(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:

- 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 7.01. Regulation FD Disclosure.

On April 14, 2010, at the 2010 American Academy of Neurology Annual Meeting, AVI BioPharma, Inc. (AVI or the Company) presented the poster entitled *AVI-5038: Initial Efficacy and Safety Evaluation in Cynomolgus Monkeys*.

AVI-5038 is AVI s lead pre-clinical PPMO, or peptide-conjugated phosphorodiamidate morpholino oligomer, drug candidate for the potential treatment of Duchenne muscular dystrophy (DMD) and is intended to cause a skip of exon 50 in the gene coding for the protein dystrophin. PPMOs are one of a series of different chemical analogs being developed from AVI s core PMO, or phosphorodiamidate morpholino oligomer, chemistry.

The American Academy of Neurology poster includes previously reported data of a preclinical study in which cynomolgus monkeys were dosed intravenously for four weeks with AVI-5038 given up to 9mg/kg. In that study, the candidate drug appeared to be well tolerated with findings generally limited to the kidney, and included basophilic granule accumulation and evidence of tubular degeneration/regeneration that was dose dependent. Clinical chemistry and urinalysis did not detect a change in kidney function. Significant levels of exon skipping were detected by RT-PCR in the diaphragm, heart and quadriceps after four weeks of dosing at 9mg/kg.

A preliminary summary of the findings from an ongoing 12-week preclinical study in which cynomolgus monkeys were dosed intravenously with AVI-5038 at doses of 1.5, 6 and 15mg/kg was also presented. Significant toxicological findings were observed following bolus intravenous administration at 6 and 15mg/kg. The preliminary results suggest that the toxicities seen in this study are also dose dependent and primarily involve the kidney. The in life portion of the study is complete, but the collection and analysis of data from the study is still ongoing. The Company believes that the data set is not yet sufficient to determine the ultimate impact these findings might have on the future development of AVI-5038.

PPMOs are chemically distinct from PMOs. AVI-4658 is AVI s lead PMO drug candidate for the potential treatment of DMD by skipping exon 51. AVI-4658 is currently being evaluated in an ongoing Phase 1b/2 clinical trial at two sites in the United Kingdom and has been generally well tolerated to date in all patients dosed up to 20mg/kg for 12 weeks.

The information in this Item 7.01 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall this Item 7.01 or any of the information contained therein be deemed incorporated by reference in any filing under the Securities Exchange Act of 1934 or the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Bothell, State of Washington, on April 14, 2010.

AVI BioPharma, Inc.

By:

/s/ Leslie Hudson, Ph.D.

Leslie Hudson, Ph.D.
President and Chief Executive Officer
(Principal Operating Officer)