

Edgar Filing: Retrophin, Inc. - Form 8-K

Retrophin, Inc.
Form 8-K
August 12, 2014

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) August 11, 2014

RETROPHIN, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36257
(Commission
File Number)

27-4842691
(I.R.S. Employer
Identification No.)

777 Third Avenue, 22nd Floor, New York, NY
(Address of principal executive offices)

10017
(Zip Code)

Registrant's telephone number, including area code (646) 837-5863

(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 240.13a-4(c))

Item 8.01 Other Events.

On August 11, 2014, Retrophin, Inc. (the “Company”) announced that a second Pantothenate kinase-associated neurodegeneration (“PKAN”) patient began dosing with RE-024 under a physician-initiated research protocol. The subject received the first dose of RE-024 on July 24, 2014. Soon after initiating RE-024, the treating physician reported qualitative clinical improvement in the subject’s motor exam, including speech, facial expression, and finger-tapping. The subject remains on a stable dose of RE-024. Preliminary clinical data from this subject are shown in Table 1 below. Further data points, including biochemical analysis, are pending at this time.

The first subject who began dosing under a physician-initiated protocol on May 21, 2014 remains on a stable dose of RE-024. The subject is clinically stable and has demonstrated sustained clinical improvement from baseline. The subject’s liver function tests remain normal after a temporary elevation, and the subject’s lactate levels, which were elevated at baseline, have decreased to normal levels. Clinical data from this subject are summarized in Table 1, and biochemical data are shown in Table 2.

The Company does not believe data on a small number of patients can be interpreted in a robust fashion and is releasing this data to accommodate investor requests. Further, the results are inconclusive at this time with regard to RE-024’s ability to treat patients that suffer from PKAN. Potential investors should not place undue reliance on these early data points.

TABLE 1: Clinical data summary (as of August 11, 2014)

	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 7	Week 11
SUBJECT 1								
UPDRS1								
(A+B+C)	74/118	56/118	56/118	63/118	58/118	56/118	48/118	50/118
Subscale A	8/10	3/10	3/10	3/10	4/10	3/10	2/10	3/10
Subscale B	36/52	26/52	26/52	27/52	26/52	26/52	23/52	22/52
Subscale C	30/56	27/56	27/56	33/56	28/56	27/56	23/56	25/56
BADS2								
	14/24	15/24	14/24	16/24	13/24	14/24	13/24	14/24
EQ-5D-3L								
	12/15	12/15	10/15	10/15	9/15	9/15	8/15	10/15
25 foot walk test								
# of steps	25.5	19.5	17.0	16.0	16.5	15.0	14.0	14.5
Time in seconds	10.5	11.3	8.6	11.1	8.9	8.2	7.6	7.8
SUBJECT 2								
	Week 0	Week 13						
UPDRS								
(A+B+C)	53/118	36/118						
Subscale A	4/10	4/10						
Subscale B	23/52	17/52						
Subscale C	26/56	15/56						
BADS								
	14/24	13/24						

TABLE 2: Biochemical data summary (as of August 11, 2014)

	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 7	Week 11
SUBJECT 1								
ALT	34	31	85	65	38	35	27	WNL ⁴
AST	26	23	55	32	29	30	26	WNL
Lactate	2.44	1.42	1.46	1.29	1.69	1.07	1.28	

1 Unified Parkinson's Disease Rating Scale

2 Barry-Albright Dystonia Scale

3 Subject 2 Week one measurements were obtained on August 5, 2014

4 Within Normal Limits per physician report

ABOUT PKAN

Pantothenate kinase-associated neurodegeneration or PKAN is the most common form of neurodegeneration with brain iron accumulation. Classic PKAN is a genetic disorder that is typically diagnosed in the first decade of life. Consequences of PKAN include dystonia, dysarthria, rigidity, retinal degeneration, and severe digestive problems. PKAN is estimated to affect 1 to 3 persons per million. PKAN typically manifests in childhood with a profound, progressive dystonia and is usually lethal. There are currently no viable treatment options for patients with PKAN.

ABOUT RE-024

RE-024 is a phosphopantothenate prodrug replacement therapy with the goal of restoring the supply of this operative substrate in PKAN patients. The results discussed in this Current Report on Form 8-K relate to the first two PKAN patients who have initiated treatment with RE-024 and are not indicative of future responses by these patients or by other patients.

SIGNATURE

Pursuant to the requirements 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 hereunto duly authorized.

RETROPHIN, INC.

Date: August 11, 2014

By: /s/ Marc Panoff
Name: Marc Panoff
Title: Chief Financial Officer