## 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): November 3, 2015

# **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.)

12255 El Camino Real, San Diego, CA (Address of principal executive offices) 92130 (Zip Code)

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

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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02 Results of Operations and Financial Condition.

On November 3, 2015, Retrophin, Inc. (the "*Company*") issued a press release announcing its financial results for the quarter ended September 30, 2015. A copy of the press release and accompanying information is attached as Exhibit 99.1 to this current report.

The information in this Item 2.02, and Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 2.02, and Exhibit 99.1 attached hereto, shall not be incorporated by reference into any registration statement or other document filed with the Securities and Exchange Commission, whether filed before or after the date hereof regardless of any general incorporated by reference therein.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release of Retrophin, Inc. dated November 3, 2015

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.

### **RETROPHIN, INC.**

By: /s/ Stephen Aselage

Name: Stephen Aselage Title: Chief Executive Officer

Dated: November 3, 2015



#### Contact:

Retrophin, Inc. Chris Cline, CFA Director, Investor Relations 646-564-3680 <u>IR@retrophin.com</u>

#### **Retrophin Reports Third Quarter 2015 Financial Results**

Third quarter revenue of \$28.0 million marks sixth consecutive quarter of growth

SAN DIEGO (November 3, 2015) – Retrophin, Inc. (NASDAQ: RTRX) today reported its third quarter 2015 financial results.

- Net product sales for the third quarter 2015 were \$28.0 million, compared to net product sales of \$8.3 million for the same period in 2014
- Non-GAAP operating income for the third quarter 2015 was \$3.7 million, compared to a non-GAAP operating loss of \$15.9 million for the same period in 2014
- Cash, cash equivalents, marketable securities, and notes receivable as of September 30, 2015 totaled \$327.1 million

"The third quarter marked further advancement of Retrophin's operational performance and the continued strengthening of our financial foundation," said Stephen Aselage, Chief Executive Officer of Retrophin. "Demand for our commercial products continues to grow, and we are making meaningful progress in advancing our key development candidates closer to regulatory approval."

#### Quarter Ended September 30, 2015

Net product sales for the third quarter of 2015 were \$28.0 million, compared to \$8.3 million for the same period in 2014 and \$69.4 million for the first nine months of 2015, compared to \$14.1 million in the same periods in 2014. The increase is due to the acquisition and subsequent commercial launch of two additional orphan disease therapies, Thiola<sup>®</sup> and Cholbam<sup>®</sup>. The Company continues to expect net product sales for the full year 2015 to be in the range of \$95 to \$100 million.

Selling, general and administrative expenses for the third quarter of 2015 were \$22.3 million, compared to \$17.4 million for the same period in 2014 and \$56.9 million for the first nine months of 2015, compared to \$42.1 million during the same periods in 2014. The increase is attributable to compensation and amortization related to the Company's orphan disease therapies, Thiola and Cholbam. On a non-GAAP adjusted basis, selling, general and administrative expenses were \$12.6 million for the third quarter of 2015, compared to \$12.7 million for the same period in 2014 and \$32.2 million for the first nine months of 2015, compared to \$12.7 million for the same period in 2014 and \$32.2 million for the first nine months of 2015, compared to \$12.7 million for the same period in 2014 and \$32.2 million for the first nine months of 2015, compared to \$12.7 million for the same period in 2014 and \$32.2 million for the first nine months of 2015, compared to \$12.7 million for the same period in 2014 and \$32.2 million for the first nine months of 2015, compared to \$12.7 million for the same period in 2014 and \$32.2 million for the first nine months of 2015, compared to \$30.1 million during the same periods in 2014.

Research and development expenses for the third quarter of 2015 were \$14.1 million, compared to \$12.6 million for the same period in 2014 and \$35.0 million for the first nine months of 2015, compared to \$32.9 million during the same periods in 2014. The increase is largely due to increased compensation and clinical trial expense in support of the Company's lead development candidate, sparsentan. On a non-GAAP adjusted basis, research and development expenses were \$11.2 million for the third quarter of 2015, compared to \$11.3 million for the same period in 2014 and \$27.7 million for the first nine months of 2015, compared to \$11.3 million for the same period in 2014 and \$27.7 million for the first nine months of 2015, compared to \$11.3 million for the same period in 2014 and \$27.7 million for the first nine months of 2015, compared to \$10.4

During the third quarter of 2015, the Company incurred a charge of \$6.9 million related to the change in valuation of acquisition related contingent consideration, and a \$4.7 million charge due to the write off of the entire value of intangible assets related to development candidate carbetocin, as the Company elected not to pursue internal development of the asset.

Total other income for the third quarter of 2015 was \$164.8 million, compared to other income of \$3.9 million for the same period in 2014. The increase is primarily due to a \$140.0 million net gain on disposal of assets and a net increase in benefit from the Company's derivative instruments of \$23.6 million, offset by a \$4.2 million expense due to the Company's prepayment of its \$45 million credit facility due 2018. The gain on disposal of assets is a result of completing the sale of the Company's Rare Pediatric Disease Priority Review Voucher ("Pediatric PRV") to Sanofi on July 2, 2015.

Tax expense of \$38.8 million for the third quarter of 2015 was primarily related to current and deferred tax expense accrued on the sale of the Pediatric PRV, partially offset by the release of valuation allowance pursuant to the utilization of net operating loss carryforwards which were applied against the gain from the Pediatric PRV sale.

Net income for the third quarter of 2015 was \$105.6 million, or \$2.95 per basic share, compared to a net loss of \$18.0 million, or \$0.67 per basic share for the same period in 2014. Non-GAAP adjusted net loss for the third quarter of 2015 was \$1.5 million, or \$0.04 per basic share, compared to a net loss of \$18.4 million, or \$0.69 per basic share for the same period in 2014.

As of September 30, 2015 the Company had cash, cash equivalents, marketable securities and notes receivable of \$327.1 million.

#### Prepayment of \$45 Million Credit Facility Due 2018

On July 1, 2015, the Company repaid its \$45 million credit facility in its entirety, and incurred an additional one-time charge of \$4.2 million related to the prepayment.

#### Sale of Rare Pediatric Disease Priority Review Voucher

On July 2, 2015, the Company completed the sale of the Pediatric PRV it received as a result of the U.S. Food and Drug Administration's (FDA) approval of Cholbam for the treatment of bile acid synthesis disorders due to single enzyme defects and peroxisomal disorders, and transferred title to Sanofi. Pursuant to the agreement, the Company will receive \$245 million, \$150 million of which was received on July 2, 2015. Retrophin will receive two additional payments of \$47.5 million each on the first and second anniversaries of the closing. The net gain from the sale of the asset was \$140.0 million, recorded as of September 30, 2015.

#### **Commercial Product Updates**

Thiola® (tiopronin)

- New patient starts on Thiola slowed moderately in July and August, but re-accelerated in September. The Company continues to add patients on a weekly basis.
- Retrophin has committed to development of a new, more patient-friendly formulation of Thiola and began acquiring additional safety stock to ensure on-going patient supply.
- The Company's expanded salesforce broadened its reach in the nephrology and urology communities.

Cholbam<sup>®</sup> (cholic acid)

- The number of patients beginning Cholbam therapy increased moderately as the salesforce continued its effort of reaching 70 centers of excellence.
- On September 24, 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a revised opinion, recommending the granting of a marketing authorization in the EU.

Chenodal<sup>®</sup> (chenodeoxycholic acid)

- The number of cerebrotendinous xanthomatosis (CTX) patients on Chenodal® treatment remained steady throughout the third quarter.
- Discussions with the FDA regarding the inclusion of CTX on the Chenodal label continue. Retrophin has not yet come to agreement with the
  FDA on acceptable pathway for the addition of CTX to the label. The Company will maintain its efforts of gathering data in support of the safety
  and efficacy of Chenodal for patients suffering from CTX.

#### **<u>Pipeline Updates</u>**

Sparsentan

- The DUET trial of sparsentan for the treatment of focal segmental glomerulosclerosis (FSGS) continues to enroll toward the target of 100 subjects. The Company estimates that the 100<sup>th</sup> subject will be randomized in early 2016.
- On October 8, 2015, the European Medicines Agency Committee for Orphan Medicinal Products (COMP) issued a positive opinion on the application for orphan drug designation of sparsentan for the treatment of FSGS. The final decision is expected in several months.

- Retrophin has completed dosing of its Phase 1 study of RE-024 to evaluate safety and tolerability in healthy volunteers, and the data analysis is being completed. The Company believes the results seen to date warrant moving forward into a trial in patients with pantothenate kinase-associated neurodegeneration (PKAN).
- The final Phase 1 data set will be utilized in an upcoming discussion with the FDA to help establish the design of a subsequent trial.
- Four ex-U.S. PKAN patients remain on RE-024 treatment under physician-initiated protocols in their respective countries.

#### RE-034

• Retrophin continues preclinical development of RE-034 and expects to reach a decision on the initiation of IND-enabling studies by mid-2016, after conducting exploratory *in vivo* studies and confirming scalability of material.

#### **Conference Call Information**

Retrophin will host a conference call and webcast today, Tuesday, November 3, at 4:30 p.m. ET to discuss third quarter 2015 financial results. To participate in the conference call, dial +1 855-219-9219 (U.S.) or +1-315-625-6891 (International), confirmation code 65067721 shortly before 4:30 p.m. ET. The webcast can be accessed at www.retrophin.com, in the Events and Presentations section. A replay of the call will be available 7:30 p.m. ET, November 3, 2015 to 11:59 p.m., November 10, 2015. The replay number is 855-859-2056 (U.S.) or 404-537-3406 (International), confirmation code 65067721.

#### **Use of Non-GAAP Financial Measures**

To supplement Retrophin's financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), the Company uses certain non-GAAP adjusted financial measures in this press release and the accompanying tables. The Company believes that these non-GAAP financial measures are helpful in understanding its past financial performance and potential future results. They are not meant to be considered in isolation or as a substitute for comparable GAAP measures, and should be read in conjunction with the consolidated financial statements prepared in accordance with GAAP. Retrophin's management regularly uses these supplemental non-GAAP financial measures internally to understand, manage and evaluate its business and make operating decisions. In addition, Retrophin believes that the use of these non-GAAP measures enhances the ability of investors to compare its results from period to period and allows for greater transparency with respect to key financial metrics the Company uses in making operating decisions.

Investors should note that these non-GAAP financial measures are not prepared under any comprehensive set of accounting rules or principles and do not reflect all of the amounts associated with the Company's results of operations as determined in accordance with GAAP. Investors should also note that these non-GAAP financial measures have no standardized meaning prescribed by GAAP and, therefore, have limits in their usefulness to investors. In addition, from time to time in the future the Company may exclude other items, or cease to exclude items that it has historically excluded, for purposes of its non-GAAP financial measures;

Because of the non-standardized definitions, the non-GAAP financial measures as used by the Company in this press release and the accompanying tables may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by the Company's competitors and other companies.

As used in this press release, (i) the historical non-GAAP net income (loss) measures exclude from GAAP net income (loss), as applicable, intangible asset amortization and impairment, revaluation of acquisition related contingent consideration, gain on disposal of asset, stock-based compensation expense, executive severance charges, change in fair value of derivative instruments, depreciation expense, non-cash interest and finance expenses; income tax provision; (ii) the historical non-GAAP SG&A expense measures exclude from GAAP SG&A expenses, as applicable, intangible asset amortization, stockbased compensation expense, executive severance charges, legal fee and settlements, and depreciation expense; (iii) the historical non-GAAP R&D expense measures exclude from GAAP R&D expenses, as applicable, intangible asset amortization, stock-based compensation expense, and depreciation expense.

#### **About Retrophin**

Retrophin is a pharmaceutical company focused on the development, acquisition and commercialization of drugs for the treatment of serious, catastrophic or rare diseases for which there are currently no viable options for patients. The Company's approved products include Chenodal<sup>®</sup>, Cholbam<sup>®</sup>, and Thiola<sup>®</sup>, and its pipeline includes compounds for several catastrophic diseases, including focal segmental glomerulosclerosis (FSGS), pantothenate kinase-associated neurodegeneration (PKAN), infantile spasms, nephrotic syndrome and others. For additional information, please visit <u>www.retrophin.com</u>.

#### **Forward-Looking Statements**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995, regarding the research, development and commercialization of pharmaceutical products. Without limiting the foregoing, these statements are often identified by the words "may", "might", "believes", "thinks", "anticipates", "plans", "expects", "intends" or similar expressions. In addition, expressions of our strategies, intentions or plans are also forward-looking statements. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with the Company's business and finances in general, as well as risks and uncertainties the Company faces with respect to its pre-clinical and clinical stage pipeline as well as its sales and marketing strategies. Specifically, the risks and uncertainties the Company faces with respect to its pre-clinical and clinical stage pipeline include risk that the Company's research programs will not identify pre-clinical candidates for further development and risk that the Company's clinical candidates will not be found to be safe or effective. Specifically, the Company faces risk that the sparsentan Phase 2 program will be delayed for regulatory or other reasons, risk that RE-024 will not progress to Phase 2 or later clinical trials for safety, regulatory or other reasons; risk that the Company will be unable to file an IND for RE-034 or initiate Phase 1 clinical trials for regulatory or other reasons, and for each of the programs risk associated with enrollment of clinical trials for rare diseases. The

Company faces risks associated with market acceptance and competition for its marketed products. The Company faces risk that it will be unable to raise additional funding required to complete development of any or all of its product candidates; risk relating to the Company's dependence on contractors for clinical drug supply and commercial manufacturing; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products. You are cautioned not to place undue reliance on these forward-looking statements as there are important factors that could cause actual results to differ materially from those in forward-looking statements, many of which are beyond our control. The Company undertakes no obligation to publicly update forward-looking statement, whether as a result of new information, future events, or otherwise. Investors are referred to the full discussion of risks and uncertainties as included in the Company's filings with the Securities and Exchange Commission.

#### RETROPHIN, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS September 30, 2015 (in thousands)

	September 30, 2015 (unaudited)		December 31, 2014	
Assets		<u>indudited)</u>		
Current assets:				
Cash	\$	140,596	\$	18,204
Marketable securities		94,681		9,556
Accounts receivable, net		13,499		7,960
Inventory, net		2,650		801
Prepaid expenses and other current assets		2,002		813
Note receivable		46,526		_
Total current assets		299,954		37,334
Property and equipment, net		478		671
Other asset		2,006		2,265
Intangible assets, net		162,997		94,265
Goodwill		936		936
Note receivable		45,259		
Total assets	\$	511,630	\$	135,471
Liabilities and Stockholders' Equity (Deficit)				
Current liabilities:				
Deferred technology purchase liability	\$	1,000	\$	1,000
Accounts payable		4,893		7,124
Accrued expenses		22,318		27,883
Other liability		1,027		938
Acquisition-related contingent consideration		5,069		2,118
Derivative financial instruments, warrants		42,120		27,990
Short term deferred income tax liability		15,892		—
Taxes payable		9,628		
Note payable				40,486
Total current liabilities		101,947		107,539
Convertible debt		43,747		43,288
Other liability		13,915		12,234
Acquisition-related contingent consideration, less current portion		48,651		9,520
Long term deferred income tax liability, net		12,358		141
Total liabilities		220,618		172,722
Commitments and contingencies				
Stockholders' Deficit:				
Preferred stock Series A \$0.001 par value; 20,000,000 shares authorized; 0 issued and outstanding				
Common stock \$0.0001 par value; 100,000,000 shares authorized; 36,008,096 and 26,428,071 issued and				
36,008,096 and 26,048,480 outstanding, respectively		4		3
Additional paid-in capital		353,794		140,851
Treasury stock, at cost, none and 379,591, respectively		—		(3,215)
Accumulated deficit		(62,684)		(179,175)
Accumulated other comprehensive income		(102)		4,285
Total stockholders' equity (deficit)		291,012		(37,251)
Total liabilities and stockholders' equity (deficit)	\$	511,630	\$	135,471

#### RETROPHIN, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS September 30, 2015 (in thousands)

	Three months ended September 30, 2015 2014 (unaudited) (restated)		Nine months ende 2015 (unaudited)	led September 30, 2014 (restated)	
Net product sales	\$ 28,005	\$ 8,349	\$ 69,444	\$ 14,118	
Operating expenses:					
Cost of goods sold	513	198	1,424	233	
Research and development	14,064	12,646	34,974	32,899	
Selling, general and administrative	22,308	17,372	56,856	42,097	
Change in valuation of contingent consideration	6,906	_	7,026	_	
Impairment of intangible assets	4,710	—	4,710	—	
Total operating expenses	48,501	30,216	104,990	75,229	
OPERATING LOSS	(20,496)	(21,867)	(35,546)	(61,111)	
OTHER INCOME (EXPENSE):					
Litigation settlement gain	_	_	15,500		
Other income (expense), net	(314)	170	35	545	
Interest income (expense), net	(695)	(2,629)	(7,415)	(4,808)	
Early prepayment penalty	—	—	(2,250)	—	
Loss on extinguishment of debt	(4,151)	—	(4,151)	—	
Finance expense	—	(13)	(600)	(4,721)	
Change in fair value of derivative instruments-loss	29,991	6,359	(36,180)	(14,276)	
Gain on disposal of assets	140,004	—	140,004	_	
Bargain purchase gain	<u> </u>		49,063		
Total other income (expense), net	164,835	3,887	154,006	(23,260)	
INCOME (LOSS) BEFORE INCOME TAXES	144,339	(17,980)	118,460	(84,371)	
Income tax benefit (provision)	(38,761)		1,246	2,460	
NET INCOME (LOSS)	\$ 105,578	\$ (17,980)	\$ 119,706	\$ (81,911)	
PER SHARE DATA:					
Net income (loss) per common share, basic	\$ 2.95	\$ (0.67)	\$ 3.67	\$ (3.25)	
Net income (loss) per common share, diluted	\$ 1.78	\$ (0.84)	\$ 3.30	\$ (3.25)	
Weighted average common shares outstanding, basic	35,741,877	26,682,510	32,650,408	25,229,847	
Weighted average common shares outstanding, diluted	42,752,859	28,210,225	36,800,536	25,229,847	

#### RETROPHIN, INC. AND SUBSIDIARIES RECONCILIATION OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION September 30, 2015 (in thousands) (unaudited)

	Three Months Ended September 30, 2015 2014			Nine Months Ended September 30, 2015 2014				
GAAP OPERATING LOSS	\$	(20,496)	\$	(21,867)	\$	(35,546)	\$	(61,111)
R&D Operating Expense		(14,064)		(12,646)		(34,974)		(32,899)
Stock Compensation		2,692		1,039		6,661		1,997
Amortization & Depreciation		200		261		614		566
Subtotal non-GAAP items		2,892		1,300		7,275		2,563
NON-GAAP R&D EXPENSE		(11,172)		(11,346)		(27,699)		(30,336)
SG&A Operating Expense		(22,308)		(17,372)		(56,856)		(42,097)
Legal Expense (A)		673		1,507		4,024		3,602
Stock Compensation		5,489		2,165		12,087		7,240
Amortization & Depreciation		3,524		953		8,545		1,132
Subtotal non-GAAP items		9,686		4,625		24,656		11,974
NON-GAAP SG&A EXPENSE		(12,622)		(12,747)		(32,200)		(30,123)
Change in valuation of contingent consideration		6,906				7,026		
Asset Impairment (Carbetocin) (A)		4,710		—		4,710		—
Subtotal non-GAAP items		24,194		5,925		43,667		14,537
NON-GAAP OPERATING INCOME (LOSS)		3,698		(15,942)		8,121		(46,573)
GAAP NET INCOME (LOSS)		105,578		(17,980)		119,706		(81,911)
Non-GAAP Operating Loss Adjustments		24,194		5,925		43,667		14,537
Finance Expense				13		1,650		4,721
Change in fair value of derivative instruments		(29,991)		(6,359)		36,180		14,276
Bargain purchase gain, net (A)		_		—		(49,063)		—
Gain on disposal of asset (A)		(140,004)				(140,004)		_
Income Tax (benefit)/provision		38,761				(1,246)		(2,460)
NON-GAAP NET INCOME (LOSS)	\$	(1,462)	\$	(18,401)	\$	10,890	\$	(50,837)
PER SHARE DATA:								
Net gain (loss) per common share, basic	\$	(0.04)	\$	(0.69)	\$	0.33	\$	(2.01)
Weighted average common shares outstanding, basic	3	5,741,877	2	26,682,510	3	32,650,408	2	5,229,847

(A) Non-recurring items