NOVELION THERAPEUTICS INC.

FORM 8-K
(Current report filing)

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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): **March 15, 2018**

Novelion Therapeutics Inc.

(Exact Name of Registrant as specified in its charter)

British Columbia, Canada	**000-17082**	**98-0455702**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

c/o Norton Rose Fulbright
1800 - 510 West Georgia Street, Vancouver, BC V6B 0M3 Canada

(Address of principal executive offices)

Registrant's telephone number, including area code: **(877) 764-3131**

Not Applicable
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 15, 2018, Novelion Therapeutics Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2017. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 15, 2018

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated March 15, 2018.

SIGNATURE

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.

Novelion Therapeutics Inc.

By: /s/ Benjamin Harshbarger

Name: Benjamin Harshbarger

Title: General Counsel

Date: March 15, 2018

Exhibit 99.1

Novelion Therapeutics Reports Fourth Quarter and Full Year 2017 Financial Results

- *Novelion reports 2017 total net revenues of $138.4 million, in line with previously stated guidance*
- *Plans underway to address capital structure and advance metreleptin development program*

VANCOUVER, British Columbia, March 15, 2018 - Novelion Therapeutics Inc. (NASDAQ: NVLN), a biopharmaceutical company dedicated to developing and commercializing therapies for individuals living with rare diseases ("Novelion" or the "Company"), today reported financial results for the fourth quarter and full year ended December 31, 2017 and provided an overview of recent business activities.

Chief Operating Officer Jeff Hackman said, "We are focused on executing near-term plans that we believe will position our company for sustainable future growth. These priorities include cost control and expense management, reviewing our holding and capital structure with a view toward optimizing our assets for shareholders, advancing the metreleptin development program, and continuing to provide important therapies to our patients."

Business Update

- **JUXTAPID** : Novelion reported net revenues of JUXTAPID of $20.1 million in the fourth quarter of 2017, $14.2 million, or 71%, of which were from prescriptions written in the U.S.
- **MYALEPT** : Novelion reported net revenues of MYALEPT of $18.8 million in the fourth quarter of 2017, $13.3 million, or 71%, of which were from prescriptions written in the U.S.
- Novelion reported total consolidated net revenues of $138.4 million for the year ended December 31, 2017.
- Novelion ended 2017 with $55.4 million in unrestricted cash, compared with $70.5 million at the end of the third quarter of 2017.
- As announced separately today , subsidiary Aegerion Pharmaceuticals entered into a new secured financing facility with affiliates of Sarissa Capital Management and Broadfin Capital LLC providing for a $20 million term loan to Aegerion, strengthening Aegerion's balance sheet and liquidity, and positioning the Company for ongoing capital structure review.
- In January 2018, Novelion undertook significant cost reduction plans as it continues to manage its limited cash resources .
- With respect to its European application to register metreleptin for marketing authorization, after taking into account the results of an oral hearing of the European Medicines Agency's Committee for Medicinal Products for Human Use ("CHMP"), which occurred in February

2018, the Company expects the opinion of the CHMP in the second quarter of 2018 and the European Commission's approval decision in mid-2018.

Fourth Quarter 2017 Financial Results

On November 29, 2016, the Company completed its acquisition of Aegerion Pharmaceuticals, Inc. ("Aegerion"). The acquisition has been accounted for as a business combination in which Novelion was considered the acquirer of Aegerion. As such, under U.S. Generally Accepted Accounting Principles ("GAAP"), the financial statements of Novelion are treated as the historical financial statements of the consolidated companies, with the results of Aegerion being included from November 29, 2016. This release also includes pro forma adjusted non-GAAP financial information showing pro forma results of operations of Novelion as if the acquisition had occurred on January 1, 2016. Reconciliation of the financial results on a GAAP versus non-GAAP basis are provided below the financial information that follows.

GAAP total net revenues for the fourth quarter of 2017 were $38.9 million compared to the prior year's fourth quarter net revenues of $13.6 million. GAAP net revenues for JUXTAPID in the fourth quarter of 2017 were $20.1 million compared to $8.6 million in the prior year. GAAP net revenues for MYALEPT in the fourth quarter of 2017 were $18.8 million compared to $5.0 million for the same period in 2016.

GAAP total operating expenses for the fourth quarter of 2017 were $35.9 million compared to total operating expenses of $22.0 million for the same period in 2016. GAAP SG&A expenses were $24.1 million in the fourth quarter of 2017 compared to $16.0 million for the same period in 2016. GAAP R&D expenses were $11.8 million in the fourth quarter of 2017 compared to $6.0 million for the same period in 2016.

On a pro forma basis, during the fourth quarter of 2017, SG&A expenses were $22.5 million compared to $55.9 million for the same period in 2016. The decrease in pro forma SG&A expenses in the fourth quarter of 2017 compared with the same period in 2016 was primarily related to a reduction in headcount and legal and consulting fees .

On a pro forma basis, during the fourth quarter of 2017, R&D expenses were $11.6 million compared to $14.2 million for the same period in 2016. The decrease in pro forma R&D expenses in the fourth quarter of 2017 compared with the same period in 2016 was primarily related to a reduction in headcount and the timing of vendor related activities.

GAAP net loss in the fourth quarter of 2017 was $24.6 million compared to GAAP net loss of $19.9 million during the same period in 2016.

On a pro forma basis, net loss in the fourth quarter of 2017 was $3.3 million, compared to $20.1 million for the same period in 2016.

Full Year 2017 Financial Results

GAAP total net revenues for the year ended December 31, 2017 were $138.4 million compared to $13.6 million in 2016. GAAP net revenues for JUXTAPID for the year ended December 31, 2017 were $72.1 million compared to $8.6 million in 2016. GAAP net revenues for MYALEPT for the year ended December 31, 2017 were $66.3 million compared to $5.0 million in 2016.

GAAP total operating expenses for the year ended December 31, 2017 were $148.0 million compared to total operating expenses of $44.3 million in 2016. GAAP SG&A expenses were $96.5 million for the year ended December 31, 2017 compared to $29.5 million in 2016. GAAP R&D expenses were $49.0 million for the year ended December 31, 2017 compared to $14.8 million in 2016.

Cost of product sales were $77.2 million in the year ended December 31, 2017. Cost of product sales in the current year includes $18.8 million reserves recorded for excess and obsolete inventory, which are derived from projected sales activities, respective product shelf-life and their respective fair value. Additionally, cost of product sales was also comprised of the cost of inventory sold, amortization of acquired product rights, which resulted from the acquisition of Aegerion, and estimated royalties payable related to the sales of lomitapide and metreleptin. We expect cost of product sales for metreleptin to increase in 2018 and for the next several years, due primarily to an increasing time-based royalty rate on net sales of metreleptin in the U.S.

On a pro forma basis, for the year ended December 31, 2017, SG&A expenses were $90.7 million compared to $200.1 million in 2016. For the year ended December 31, 2017, R&D expenses on a pro forma basis were $48.2 million compared to $52.1 million in 2016.

GAAP net loss for the year ended December 31, 2017 was $126.7 million compared to GAAP net loss of $52.9 million in 2016.

On a pro forma basis, net loss for the year ended December 31, 2017 was $30.0 million, compared to $136.0 million in 2016.

As of December 31, 2017, the Company’s consolidated unrestricted cash balance was $55.4 million, compared to $70.5 million at September 30, 2017 and $108.9 million at December 31, 2016. As of December 31, 2017, there were 18.7 million shares outstanding. At December 31, 2017, total debt principal was $325 million, reflecting the principal amount of convertible debt, before discount, issued by Aegerion and consolidated as a result of the acquisition.

About Novelion Therapeutics

Novelion Therapeutics is a biopharmaceutical company dedicated to developing new standards of care for individuals living with rare diseases. Novelion has a rare disease product portfolio through its subsidiary, Aegerion Pharmaceuticals, Inc. The Company seeks to advance its portfolio of rare disease therapies by investing in science and clinical development.

Non-GAAP Results

The non-GAAP results in this press release, including, without limitation, non-GAAP net revenues, non-GAAP operating expenses, non-GAAP R&D expenses, non-GAAP SG&A expenses and non-GAAP net loss, are provided as a complement to results provided in accordance with GAAP because management believes, when considered together with the GAAP information, these non-GAAP financial measures help indicate underlying trends in the Company's business, are important in comparing current results with prior period results and provide additional information regarding the Company’s financial performance. In particular, management believes that the pro forma financial information facilitates the evaluation of the impact of Novelion’s acquisition of Aegerion on the business and performance of the Company. Management also uses these non-GAAP financial measures to establish budgets and operational goals that are communicated internally and

externally, and to manage the Company's business and evaluate its performance. The non-GAAP financial measures have no standardized meaning under GAAP and therefore may not be comparable to similar measures presented by other companies. The non-GAAP financial measures are not intended to be considered in isolation or as a substitute for, or superior to, the financial measures prepared and presented in accordance with GAAP and should be reviewed in conjunction with the relevant GAAP financial measures. A reconciliation of the GAAP financial results to non-GAAP financial results is included in the attached financial information.

Forward-Looking Statements

Certain statements in this press release constitute “forward-looking statements” of Novelion within the meaning of applicable laws and regulations and constitute “forward-looking information” within the meaning of applicable securities laws. Any statements contained herein which do not describe historical facts, including statements regarding expectations and beliefs about the Company’s near-term plans and the Company’s position for sustainable future growth; expectations as to the opinion of the CHMP and the European Commission’s approval decision, including timing; expectations that the cost of product sales for metreleptin will increase in 2018 and for the next several years; and our capital structure review are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements . Such risks and uncertainties include, among others, risks associated with Aegerion’s previously disclosed criminal plea agreement and other government settlement arrangements (including the government’s recitation of their assessment of the background of its case, the settlement itself and publicity related to the settlement), the risk that the government investigations and the settlement will give rise to third party demands, claims or litigation that could materially and adversely impact our results of operations, including demands or claims by, or litigation with, third party payers, healthcare providers, or patients or investors, for matters related to the subject matter of or disclosure in connection with the investigation or the settlement, the likelihood that the investigation could lead to potential investigations, claims or litigation by consumer protection agencies or groups, or provide a basis for product liability claims or litigation and the adverse effects the investigation and settlement could have on Aegerion’s commercial operations and contracts, along with those risks identified in our filings with the U.S. Securities and Exchange Commission (the “SEC”), including under the heading “Risk Factors” in our Annual Report on Form 10-K filed on March 30, 2017, our Quarterly Report on Form 10-Q filed on November 9, 2017, our Current Report on Form 8-K filed on January 31, 2018, and subsequent filings (including our upcoming Annual Report on Form 10-K), with the SEC, available on the SEC’s website at www.sec.gov. Any such risks and uncertainties could materially and adversely affect our results of operations, profitability and cash flows, which would, in turn, have a significant and adverse impact on our stock price. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Except as required by law, we undertake no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

This press release also contains “forward-looking information” that constitutes “financial outlooks” within the meaning of applicable Canadian securities laws. This information is provided to give investors general guidance on management’s current expectations of certain factors affecting our business, including our financial results. Given the uncertainties, assumptions and risk factors associated with this type of information, including those described above, investors are cautioned that the information may not be an appropriate subject of reliance for other purposes.

Investors and others should note that we communicate with our investors and the public using our company website, www.novelion.com, including, but not limited to, company disclosures, investor presentations and FAQs, SEC filings, press releases, public conference call transcripts and webcast transcripts. The information that we post on this website could be deemed to be material information. As a result, we encourage investors, the media and others interested to review the information that we post there on a regular basis. The contents of our website shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

U.S. INDICATIONS AND IMPORTANT SAFETY INFORMATION

JUXTAPID ® (lomitapide) capsules is a microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including low-density lipoprotein (LDL) apheresis where available, to reduce LDL cholesterol, total cholesterol, apolipoprotein B, and non-high-density lipoprotein cholesterol in patients with homozygous familial hypercholesterolemia (HoFH). LIMITATIONS OF USE: The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH). The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined.

JUXTAPID can cause elevations in transaminases, as well as increases in hepatic fat, with or without concomitant increases in transaminases. Because of the risk of hepatotoxicity, JUXTAPID is available only through a restricted distribution program called the JUXTAPID REMS PROGRAM. For more detailed information, please see additional Important Safety Information and the Prescribing Information for JUXTAPID.

MYALEPT® (metreleptin) for injection is a leptin analog indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy. LIMITATIONS OF USE: The safety and effectiveness of MYALEPT for the treatment of complications of partial lipodystrophy or for the treatment of liver disease, including nonalcoholic steatohepatitis (NASH), have not been established.

Anti-metreleptin antibodies with neutralizing activity have been identified in patients treated with MYALEPT. T-cell lymphoma has been reported in patients with acquired generalized lipodystrophy, both treated and not treated with MYALEPT. For more detailed information, please see additional Important Safety Information and the Prescribing Information for MYALEPT.

CONTACT:

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Novelion Therapeutics Inc.
Consolidated Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Net revenues	$ 38,908	$ 13,574	$ 138,438	$ 13,574
Cost of product sales	16,993	5,971	77,220	5,971
Operating expenses:				
Selling, general and administrative	24,111	15,953	96,472	29,525
Research and development	11,772	6,010	49,008	14,784
Restructuring charges	(4)	—	2,536	—
Total operating expenses	35,879	21,963	148,016	44,309
Loss from operations	(13,964)	(14,360)	(86,798)	(36,706)
Interest expense, net	(10,315)	(3,200)	(39,037)	(2,960)
Fair value loss on investment	—	—	—	(10,740)
Other expense, net	(468)	(1,791)	(292)	(1,999)
Loss before provision for income taxes	(24,747)	(19,351)	(126,127)	(52,405)
Benefit (Provision) for income taxes	179	(569)	(583)	(465)
Net loss	$ (24,568)	$ (19,920)	$ (126,710)	$ (52,870)
Net loss per common share—basic and diluted	$ (1.32)	$ (1.48)	$ (6.81)	$ (4.69)
Weighted-average shares outstanding—basic and diluted	18,666	13,423	18,616	11,284

Novelion Therapeutics Inc.
Consolidated Balance Sheets
(in thousands)

	December 31, 2017	December 31, 2016
Cash and cash equivalents	$ 55,430	$ 108,927
Restricted cash	253	390
Accounts receivable, net	22,191	9,339
Inventories	49,826	74,721
Insurance proceeds receivable	—	22,000
Prepaid expenses and other current assets	11,183	9,762
Property and equipment, net	2,920	4,159
Intangible assets, net	225,272	250,324
Other assets	2,247	1,160
Total assets	$ 369,322	$ 480,782
Accounts payable and accrued liabilities	$ 55,638	$ 54,789
Provision for legal settlement	39,612	64,010
Convertible notes, net	258,538	225,584
Other liabilities	596	612
Total liabilities	354,384	344,995
Total stockholders' equity	14,938	135,787
Total liabilities and stockholders' equity	$ 369,322	$ 480,782

Novelion Therapeutics Inc.
Reconciliation of GAAP to Non-GAAP Financial Information
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	**2016**	**2017**	**2016**
Net loss reconciliation:				
GAAP net loss	$ (24,568)	$ (19,920)	$ (126,710)	$ (52,870)
Stock-based compensation	1,118	412	4,537	665
Amortization of acquired intangible assets	6,274	2,134	25,052	2,134
Amortization of debt discount	8,750	3,253	32,954	3,253
Inventory fair value step-up	5,113	677	31,613	677
2016 Aegerion non-GAAP net loss (Note 1)	—	(6,830)	—	(90,024)
Restructuring charge related to acquisition	(4)	180	2,536	180
Non-GAAP net loss	$ (3,317)	$ (20,094)	$ (30,018)	$ (135,985)
GAAP net loss per common share - basic and diluted	$ (1.32)	$ (1.48)	$ (6.81)	$ (4.69)
Non-GAAP net loss per common share - basic	$ (0.18)	$ (1.50)	$ (1.61)	$ (12.05)
GAAP and Non-GAAP weighted-average common shares outstanding — basic	18,666	13,423	18,616	11,284
Net revenues reconciliation:				
GAAP net revenues	$ 38,908	$ 13,574	$ 138,438	$ 13,574
2016 Aegerion revenues (Note 1)	—	24,038	—	139,671
Non-GAAP net revenues	$ 38,908	$ 37,612	$ 138,438	$ 153,245
Cost of product sales reconciliation:				
GAAP cost of product sales	$ 16,993	$ 5,971	$ 77,220	$ 5,971
Amortization of acquired intangible assets	(6,274)	(2,134)	(25,052)	(2,134)
Inventory fair value step-up	(4,390)	(677)	(29,585)	(677)
Aegerion non-GAAP cost of product sales (Note 1)	—	(116)	—	33,417
Non-GAAP cost of product sales	$ 6,329	$ 3,044	$ 22,583	$ 36,577
Selling, general and administrative reconciliation:				
GAAP selling, general and administrative	$ 24,111	$ 15,953	$ 96,472	$ 29,525
Stock-based compensation	(907)	(382)	(3,721)	(541)
Inventory fair value step-up	(723)	—	(2,028)	—
Aegerion non-GAAP SG&A (Note 1)	—	40,316	—	171,114
Non-GAAP selling, general and administrative	$ 22,481	$ 55,887	$ 90,723	$ 200,098
Research and development reconciliation:				
GAAP research and development	$ 11,772	$ 6,010	$ 49,008	$ 14,784
Stock-based compensation	(211)	(30)	(816)	(124)
Aegerion non-GAAP R&D (Note 1)	—	8,244	—	37,417
Non-GAAP research and development	$ 11,561	$ 14,224	$ 48,192	$ 52,077

Note 1 - Includes financial information from pre-merger Aegerion for the two and eleven months ended November 29, 2016, excluding stock based compensation, amortization of acquired intangible assets, amortization of debt discount and deferred financing fees, inventory fair value step-up, restructuring expense and goodwill impairment.