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): **May 10, 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 May 10, 2018, Novelion Therapeutics Inc. (the "Company") announced its financial results for the quarter ended March 31, 2018. 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 May 10, 2018

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated May 10, 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: May 10, 2018

Exhibit 99.1

Novelion Therapeutics Reports First Quarter 2018 Financial Results

VANCOUVER, British Columbia, May 10, 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 first quarter ended March 31, 2018 and provided an overview of business activities.

Chief Operating Officer Jeff Hackman said, "Thus far in 2018 we have executed a number of important initiatives, including finalizing the settlements with the DOJ, reducing costs, strengthening our balance sheet with a $20 million term loan, and reviewing our holding and capital structure with a goal of optimizing our assets for shareholders. We have a strong rare disease product portfolio that carries the opportunity to expand metreleptin into new disease areas, and which we believe will deliver meaningful future sales growth. We remain focused on continuing to market important therapies that will bring value to our patients."

Business Update

- **JUXTAPID** : Novelion reported net revenues of JUXTAPID of $13.4 million in the first quarter of 2018, $8.6 million, or 64%, of which were from prescriptions written in the U.S.

- **MYALEPT** : Novelion reported net revenues of MYALEPT of $14.1 million in the first quarter of 2018, $9.8 million, or 69%, of which were from prescriptions written in the U.S.

- Novelion reported total consolidated net revenues of $27.5 million in the first quarter of 2018.

- Novelion ended the first quarter of 2018 with $52.0 million in unrestricted cash, compared with $55.4 million at the end of 2017. The $52.0 million includes proceeds from a $20.0 million term loan to Aegerion Pharmaceuticals, Inc. ("Aegerion") provided by affiliates of Sarissa Capital Management and Broadfin Capital LLC, as announced in March 2018.

- The Company expects the opinion of the European Medicines Agency's Committee for Medicinal Products for Human Use ("CHMP") on the metreleptin marketing authorization application in the second quarter of 2018, followed by a mid-2018 European Commission approval decision.

- Novelion announced that a poster describing the results of a metreleptin study for weight loss in overweight and obese adults with low leptin levels will be presented at the American Diabetes Association's 78 th Annual Scientific Sessions which is being held from June 22 to June 26, 2018 in Orlando, Florida.

First Quarter 2018 Financial Results

GAAP total net revenues for the first quarter of 2018 were $27.5 million compared to $30.0 million for the same period of 2017. GAAP net revenues for JUXTAPID in the first quarter of 2018 were $13.4 million compared to $16.0 million for the same period in 2017. GAAP net revenues for MYALEPT in the first quarter of 2018 were $14.1 million compared to $14.0 million for the same period in 2017.

GAAP total operating expenses for the first quarter of 2018 were $35.5 million compared to total operating expenses of $35.2 million for the same period in 2017. GAAP SG&A expenses were $23.7 million in the first quarter of 2018 compared to $24.5 million for the same period in 2017. GAAP R&D expenses were $11.8 million in the first quarter of 2018 compared to $9.3 million for the same period in 2017.

On a pro forma basis, during the first quarter of 2018, SG&A expenses were $21.6 million compared to $23.0 million for the same period in 2017. The decrease in pro forma SG&A expenses in the first quarter of 2018 compared with the same period in 2017 was primarily related to a reduction in headcount and legal and consulting fees.

On a pro forma basis, during the first quarter of 2018, R&D expenses were $11.6 million compared to $9.0 million for the same period in 2017. The increase in pro forma R&D expenses in the first quarter of 2018 compared with the same period in 2017 was primarily related to additional spending in certain clinical activities.

GAAP net loss in the first quarter of 2018 was $32.8 million compared to GAAP net loss of $31.0 million during the same period in 2017.

On a pro forma basis, net loss in the first quarter of 2018 was $13.5 million, compared to a loss of $8.7 million for the same period in 2017.

As of March 31, 2018, the Company's consolidated unrestricted cash balance was $52.0 million, compared to $55.4 million at December 31, 2017. As of March 31, 2018, there were18.7 million shares outstanding. Convertible debt principal is $325.0 million, reflecting the amount of convertible debt, before discount, issued by subsidiary Aegerion. In addition, as described above, in March 2018, Novelion's subsidiary, Aegerion, entered into a secured financing facility with affiliates of Sarissa Capital Management and Broadfin Capital LLC providing for a $20.0 million term loan to Aegerion.

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 ("pro forma") 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. 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 expectations for future sales growth; the goal of optimizing the Company's assets for our shareholders; expectations as to the opinion of the CHMP and the European Commission's approval decision, including timing; and expectations about expanding metreleptin into new disease areas 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, 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 16, 2018, and subsequent filings, 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:

Amanda Murphy, Director, Investor Relations & Corporate Communications
Novelion Therapeutics
857-242-5024
amanda.murphy@novelion.com

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

	Three Months Ended March 31,	
	2018	**2017**
Net revenues	$ 27,484	$ 29,984
Cost of product sales	13,505	16,445
Operating expenses:		
Selling, general and administrative	23,689	24,451
Research and development	11,766	9,300
Restructuring charges	—	1,451
Total operating expenses	35,455	35,202
Loss from operations	(21,476)	(21,663)
Interest expense, net	(10,886)	(9,212)
Other (expense) income, net	(307)	52
Loss before provision for income taxes	(32,669)	(30,823)
Provision for income taxes	(159)	(139)
Net loss	$ (32,828)	$ (30,962)
Net loss per common share—basic and diluted	$ (1.76)	$ (1.67)
Weighted-average common shares outstanding—basic and diluted	18,703	18,540

Novelion Therapeutics Inc.
Unaudited Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2018	December 31, 2017
Cash and cash equivalents	$ 51,983	$ 55,430
Accounts receivable, net	16,065	22,191
Inventories	52,078	49,826
Prepaid expenses and other current assets	14,171	11,436
Property and equipment, net	2,766	2,920
Intangible assets, net	218,998	225,272
Other non-current assets	2,412	2,247
Total assets	$ 358,473	$ 369,322
Accounts payable and accrued liabilities	$ 50,291	$ 55,638
Provision for legal settlement	36,789	39,612
Long-term debt	15,218	—
Convertible notes, net	267,651	258,538
Other non-current liabilities	1,579	596
Total liabilities	371,528	354,384
Total stockholders' (deficit) equity	(13,055)	14,938
Total liabilities and stockholders' (deficit) equity	$ 358,473	$ 369,322

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

	Three Months Ended March 31	
	2018	**2017**
Net loss reconciliation:		
GAAP net loss	$ (32,828)	$ (30,962)
Stock-based compensation	906	1,399
Amortization of acquired intangible assets	6,274	6,231
Amortization of debt discount	9,113	7,742
Inventory fair value step-up	3,001	5,452
Restructuring charge related to acquisition	—	1,451
Non-GAAP net loss	$ (13,534)	$ (8,687)
GAAP net loss per common share - basic and diluted	$ (1.76)	$ (1.67)
Non-GAAP net loss per common share - basic and diluted	$ (0.72)	$ (0.47)
GAAP and Non-GAAP weighted-average common shares outstanding - basic and diluted	18,703	18,540
Net revenues reconciliation:		
GAAP and Non-GAAP net revenues	$ 27,484	$ 29,984
Cost of product sales reconciliation:		
GAAP cost of product sales	$ 13,505	$ 16,445
Amortization of acquired intangible assets	(6,274)	(6,231)
Inventory fair value step-up	(1,704)	(5,109)
Non-GAAP cost of product sales	$ 5,527	$ 5,105
Selling, general and administrative expense reconciliation:		
GAAP selling, general and administrative expenses	$ 23,689	$ 24,451
Stock-based compensation	(768)	(1,124)
Inventory fair value step-up	(1,297)	(343)
Non-GAAP selling, general and administrative expenses	$ 21,624	$ 22,984
Research and development expense reconciliation:		
GAAP research and development expenses	$ 11,766	$ 9,300
Stock-based compensation	(138)	(275)
Non-GAAP research and development expenses	$ 11,628	$ 9,025