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): **January 3, 2017**

Novelion Therapeutics Inc.

(Exact Name of Registrant as specified in its charter)

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

887 Great Northern Way, Suite 250, Vancouver, B.C.
Canada, V5T 4T5
(Address of principal executive offices)

Registrant's telephone number, including area code: **(604) 707-7000**

Not Applicable
(Registrant's name or former address, if change 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))

Item 2.02 Results of Operations and Financial Condition.

On January 9, 2017, Novelion Therapeutics Inc. (the " Company ") issued a press release reporting, among other things, its preliminary, unaudited net product sales for the year ended December 31, 2016, which is attached as Exhibit 99.1 to this Current Report on Form 8-K.

This information in this 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 8.01 Other Events

On January 3, 2017, the U.S. Food and Drug Administration (" FDA ") approved modifications to the JUXTAPID REMS Program (the " REMS Program "). The REMS Program was a requirement of the original FDA approval of JUXTAPID® (lomitapide) capsules ("JUXTAPID"), a product marketed and sold by Aegerion Pharmaceuticals, Inc. (" Aegerion "), a subsidiary of the Company. The goal of the REMS Program, as modified, is to mitigate the risk of hepatotoxicity associated with the use of JUXTAPID by ensuring that: a) prescribers are educated about the approved indication for JUXTAPID, the risk of hepatotoxicity associated with the use of JUXTAPID, and the need to monitor patients during treatment with JUXTAPID as per product labeling; b) JUXTAPID is dispensed only to patients with a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia; and c) patients are informed about the risk of hepatotoxicity associated with the use of JUXTAPID and the need for baseline and periodic monitoring.

The originally approved REMS Program consisted of elements to assure safe use (" ETASU "), an implementation system, a communication plan and a timetable for submission of assessments of the REMS Program. The ETASU require that healthcare providers who prescribe JUXTAPID and pharmacies that dispense JUXTAPID must be certified, and JUXTAPID must only be dispensed to patients with evidence or other documentation of safe-use conditions. In 2016, the FDA communicated to Aegerion specific modifications the FDA considered necessary to the REMS Program, including changes to the REMS summary document, changes to the existing REMS Program materials, and the following new REMS Program materials: Fact sheet for Health Care Professionals, Patient Guide and Patient-Prescriber Acknowledgment Form, Pharmacy Training Modules and a Pharmacy Certification Form. Aegerion submitted its response to the FDA's proposed modifications to the REMS Program as a prior approval supplement in 2016, which the FDA approved on January 3, 2017. The approved modifications to the REMS Program must be implemented within 60 calendar days of January 3, 2017, and healthcare professionals and pharmacies must complete the recertification process within 180 calendar days of January 3, 2017 in order to continue prescribing and dispensing JUXTAPID, respectively. The FDA's approval letter for the modified REMS Program also specifies that an authorized generic drug under this NDA must have an FDA-approved REMS program prior to marketing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated January 9, 2017.

SIGNATURES

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: January 9, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated January 9, 2017.

Novelion Therapeutics Reports Preliminary 2016 Net Product Sales and Provides 2017 Outlook

- *Company Reports Preliminary Total Net Product Sales Expected to be Between $150 million and $152 million, Exceeding High End of Prior Guidance*
- *Global Expansion Plans for Metreleptin Opportunity Underway*

VANCOUVER, British Columbia, January 9, 2017 - Novelion Therapeutics Inc. (NASDAQ: NVLN) (TSX: NVLN), a biopharmaceutical company dedicated to developing new standards of care for individuals living with rare diseases (the "Company"), today reported preliminary pro forma unaudited 2016 net product sales for its subsidiary and other business updates. Mary Szela, chief executive officer, plans to discuss these and other topics during a live presentation at the 35 th Annual J.P. Morgan Healthcare Conference in San Francisco scheduled for Wednesday, January 11, 2017, at 4 p.m. PST (7 p.m. EST). The presentation will be webcast live and accessible through the "Investors" section of Novelion's website, www.novelion.com .

"We enter 2017 with a highly-differentiated portfolio of marketed and development-stage rare disease products with near- and mid-term opportunities to grow the commercial pillars of our business," said Mary Szela, chief executive officer of Novelion.

"In 2017, we will focus on expanding access to metreleptin globally, and on development of the therapy's pleiotropic effects to explore new opportunities to treat patients suffering from a range of low leptin-mediated metabolic rare diseases. In addition, we will work closely with Japanese health care providers with the goal of providing JUXTAPID to the more than 160 registered HoFH patients in that market, over time, and with U.S. physicians to retain those adult HoFH patients for whom JUXTAPID represents an important and differentiated therapy," Szela continued.

2016 Preliminary Results & Business Update

- **MYALEPT® (metreleptin)** : Novelion, through its subsidiary, expects preliminary, pro forma unaudited net product sales of MYALEPT for the full year 2016 to be between $50 million and $51 million. As of December 31, 2016, there were approximately 125 active commercial patients on MYALEPT therapy globally, approximately 98 of whom are U.S. patients. Active patient numbers used in this press release are based upon internal estimates and criteria.

- **JUXTAPID ® (lomitapide)** : Novelion, through its subsidiary, expects preliminary, pro forma unaudited net product sales of JUXTAPID for full year 2016 to be between $100 million and $101 million. As of December 31, 2016, there were approximately 340 active commercial patients on JUXTAPID therapy globally, approximately 232 of whom are U.S. patients.

- Novelion ended 2016 with approximately $108 million (unaudited) in unrestricted cash.

- In November 2016, Novelion's subsidiary repaid all of its outstanding obligations and amounts under the $25 million credit facility with Silicon Valley Bank.

- On December 22, 2016, Novelion's subsidiary submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) seeking approval for metreleptin as replacement therapy to treat complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy (GL) and in a subset of patients with partial lipodystrophy (PL). As with GL patients, in the pivotal NIH study, the subset of PL patients saw significant improvement in key efficacy measures, including reductions in HbA1c and triglycerides. The Company, through its subsidiary, will seek to market metreleptin in the EU under the tradename MYALEPTA®. If approved, metreleptin would be the first medication available in the EU to treat GL and PL.

- On December 16, 2016, Novelion's subsidiary launched JUXTAPID in Japan. Japan represents a unique market opportunity for JUXTAPID, with an identified population of more than 160 patients with homozygous familial hypercholesterolemia (HoFH) and favorable pricing and reimbursement. The Company anticipates annual peak sales of approximately $30 million.

- Also in December 2016, Novelion's subsidiary entered into a licensing agreement with Amryt Pharma ("Amryt") for the exclusive rights to LOJUXTA® (lomitapide) hard capsules in certain European and Middle Eastern territories. Amryt will pay Novelion sales-related payments and royalties on product sales in the licensed territories, and will also be responsible for ongoing regulatory and post-marketing obligations and commitments in support of the brand.

2017 Outlook

- Novelion's subsidiary is planning to submit a supplemental biologics licensing application (sBLA) for MYALEPT to treat a subset of PL patients in the U.S. in the first half of 2017. If approved, this label expansion could double the addressable market in the U.S. for MYALEPT.
- Novelion's subsidiary plans to file applications for regulatory approval of MYALEPT to treat GL and a subset of PL in Brazil, Colombia, Argentina, Turkey and Canada.
- Novelion plans to meet with FDA and EMA in the first half of 2017 to gather feedback on its proposed development plans for zuretinol. Zuretinol, if approved, has the potential to receive a pediatric priority review voucher.

2017 Financial Guidance

The company provides the following revenue guidance for full year 2017:

- Total net products sales of between $155 million and $165 million;
- MYALEPT net product sales of between $75 million and $80 million; and
- JUXTAPID net product sales of between $80 million and $85 million.

About Novelion Therapeutics

Novelion Therapeutics is a biopharmaceutical company dedicated to developing new standards of care for individuals living with rare diseases. The company seeks to advance its portfolio of rare disease therapies by investing in science and clinical development. Novelion has a diversified commercial portfolio through its indirect subsidiary, Aegerion Pharmaceuticals, Inc., which includes MYALEPT® and JUXTAPID®, and is also developing zuretinol acetate for the potential treatment of inherited retinal disease caused by underlying mutations in RPE65 or LRAT genes.

Forward-Looking Statements

Certain statements in this press release constitute “forward-looking statements” of Novelion within the meaning of the Private Securities Litigation Reform Act of 1995 and constitute “forward-looking information” within the meaning of applicable Canadian securities laws, including statements regarding expectations such as sales of our products, cash usage, operating expense, planned regulatory filings and activities, drug development, marketing authorizations and label expansions, as well as long-term growth prospects. Forward-looking statements are based on estimates and assumptions made by Novelion in light of current conditions and expected future developments, as well as other factors that Novelion believes are appropriate in the circumstances, including but not limited to, our financial position and execution of our business strategy, post-merger synergies, resolution of litigation and investigations, receipt of regulatory approvals, and product competition, market acceptance, sales, pricing, reimbursement and side effects. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, which could cause actual results to differ materially from those contemplated in these forward-looking statements. Many such risks, uncertainties and other factors are taken into account as part of our assumptions underlying these forward-looking statements and include, among others, the following: the possibility that the anticipated benefits and synergies from the merger transaction between Novelion and Aegerion Pharmaceuticals, Inc. cannot be fully realized or may take longer to realize than expected; the possibility that costs or difficulties related to the integration of Aegerion and QLT operations will be greater than expected; the risk that market acceptance of Aegerion’s products, JUXTAPID and MYALEPT, in the U.S. may not continue at the levels we expect, and may be lower outside the U.S., including in Brazil and Japan, than we expect; the risk that the conversion of prescriptions for JUXTAPID or MYALEPT into patients on therapy may be lower than we expect or the drop-out rate may be higher than we expect; the risk that the prevalence of the diseases Aegerion's products treat, or that we are pursuing treatment for, may be lower than we estimate, and that it may be more difficult to identify patients than we expect; the risk that the side effect profile or other results for Aegerion's products in commercial use and in further clinical studies are inconsistent, in scope and severity, with the side effect profile and other results observed in the pivotal study of each drug; the risk that the negative impact of the launch of PCSK9 inhibitors on JUXTAPID sales will be greater than we currently expect, particularly in the U.S., where the negative impact has been greater than we expected to date, or that other competitive products will negatively impact our results; the risk that private or government payers may refuse to reimburse Aegerion's or our products, or may impose onerous restrictions that hinder reimbursement or significantly limit or cap the price Aegerion or we charge or the number of reimbursed patients who receive products; the risk that revisions to the JUXTAPID Risk Evaluation and Mitigation Strategies (REMS) Program may negatively impact U.S. sales; the risk that net revenues for MYALEPT in the U.S. may be negatively impacted if there are more Medicaid patients prescribed MYALEPT than we expect;

the risk that named patient sales for Aegerion's products in Brazil and other key countries outside the U.S. may not be at the levels we expect; the risk that regulatory authorities in regions or countries where either of Aegerion's products is not yet approved may refuse to approve such products or additional indications for such products, such approvals are not made on a timely basis or such approvals impose significant restrictions or require additional development; the risk that exchange rates will negatively impact the amount of net product sales recognized; the risk that the initiation of future clinical trials may be delayed; the risk that we will not be successful in our lifecycle management or business development efforts; the risk that Aegerion's and our patent portfolios and marketing and data exclusivity may not be as strong as we anticipate; the risk of unexpected manufacturing issues affecting future supply; the risk that Aegerion incurs more costs than we expect in responding to investigations, defending litigation and resolving litigation; the risk that any of the foregoing may cause product sales revenue to be lower than we expect, or that we may incur unanticipated expenses in connection with our activities; the risk that we may not be able to successfully execute strategic plans, including our cost-reduction program; and the other risks inherent in the commercialization, drug development and regulatory approval process; the risk associated with our ability to be granted a Rare Pediatric Disease Designation and any subsequent qualification for a Rare Pediatric Disease Priority Review Voucher, including the risk that zuretinol will not qualify under the current or any future applicable criteria for designation as a Rare Pediatric Disease or that an NDA for zuretinol will not qualify for a Priority Review Voucher, and the risk that future changes to the zuretinol program and/or the Voucher Program, including related to the transferability of the Priority Review Voucher, limit the future benefits of the Rare Pediatric Disease Designation and/or Priority Review Voucher. The terms of Aegerion's agreement in principle related to its class action litigation include risks related to the final approval by the court of the final settlement terms, including that the payment amount and availability of insurance could be amended and the amount and terms of any final settlement may be substantially higher and less favorable than we anticipate based on the terms of the preliminary agreement in principle, and the possibility that the court may materially alter or fail to approve the settlement terms. In addition, Aegerion's agreement in principle with the U.S. Department of Justice ("DOJ") and the U.S. Securities and Exchange Commission ("SEC") relating to the investigations by these agencies and the terms of potential final settlements with these agencies include risks associated with the required approvals of final settlement terms by relevant government agencies, such as the proposed settlement with the DOJ being subject to approval of supervisory personnel within the DOJ and relevant federal and state agencies and approval by a U.S. District Court judge of the criminal plea and sentence and the civil settlement agreement, and the proposed settlement with the SEC being subject to review by other groups in the SEC and approval by the Commissioners of the SEC. The terms of the preliminary agreements in principle may change following further negotiations. The amount and terms of any final settlement may be substantially higher and less favorable than we anticipate based on the terms of the preliminary agreements in principle. Final settlement terms could include the imposition of additional penalties, further limiting Aegerion's ability to conduct its business as currently conducted and as planned to be conducted. Additionally, the DOJ and the SEC each likely will outline their views of the factual background in connection with any final settlement. The government's recitation of their assessment of the background could lead to additional legal claims or investigations by state government entities or private parties and may have adverse effects on Aegerion's existing class action litigation, including the agreement in principle to settle such litigation, commercial operations and contracts.

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 appropriate for other purposes.

For additional disclosure regarding these and other risks we face, see the disclosure contained in the "Risk Factors" section of Aegerion's Quarterly Report on Form 10-Q filed on November 4, 2016, Novelion's Annual Report on Form 10-K filed on February 25, 2016 (and amended on April 29, 2016) and Quarterly Report on Form 10-Q filed on November 1, 2016 and each company's other public filings with the SEC, available on the SEC's website at www.sec.gov . 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.

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 calls transcripts and webcast transcripts. The information that we post on these websites 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

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.

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 LDL apheresis where available, to reduce low-density lipoprotein 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.

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