

**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 7, 2019**

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, without par value	NVLN	the NASDAQ Global Select Market

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 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 7, 2019, Novelion Therapeutics Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2019. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 7, 2019

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: Interim Chief Executive Officer and General Counsel

Date: May 7, 2019



Novelion Therapeutics Reports First Quarter 2019 Financial Results

- Company reiterates 2019 guidance of total net revenues between \$160.0 and \$175.0 million, including approximately \$30.0 million of licensing revenues

VANCOUVER, British Columbia, and CAMBRIDGE, MA, May 7, 2019 - 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, 2019.

Novelion’s Interim Chief Executive Officer Ben Harshbarger commented, “We continue to execute on our goals of achieving target revenues, maximizing the impact of the operating cost reductions that we implemented in late 2018, working with the FDA on the development program for the potential expansion of the metreleptin label in the U.S. to include the partial lipodystrophy (PL) indication, and pursuing a comprehensive capital restructuring.”

Business Update

- Sales growth was supported by the launch of MYALEPTA® (metreleptin) in Germany in the fourth quarter of 2018. Following marketing authorization of MYALEPTA for generalized lipodystrophy (GL) and PL by the EMA, Novelion’s subsidiary Aegerion Pharmaceuticals commenced the pricing and reimbursement processes in key EU markets. Reimbursement decisions in many of the key EU markets are anticipated throughout 2019.
 - In January 2019, Aegerion held a meeting with the U.S. Food and Drug Administration (FDA) to obtain feedback on the design of the placebo-controlled study for the PL indication for MYALEPT® in the U.S. Aegerion is assessing feedback on the study design and integrating it into the Phase 3 study protocol.
 - Aegerion plans to file for regulatory approvals for metreleptin in GL and PL in certain key markets outside the U.S. and EU, including Brazil, in 2019.
 - As previously announced, Novelion and Aegerion have each engaged advisors to independently explore and advise them on all available strategic alternatives regarding the Company’s capital structure, such as a restructuring of Aegerion’s Convertible Notes due August 2019 (including a restructuring that would likely involve a debt for equity exchange), a sale or merger of Novelion or Aegerion, or the sale or other disposition of certain businesses or assets. The implementation of one or more of such transactions (or the failure to complete any such transaction or transactions) will likely require Aegerion, and could require Novelion, to seek the protections of applicable bankruptcy laws allowing for corporations to seek to restructure their debts and other affairs under a court supervised reorganization process.
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First Quarter 2019 Financial Results

JUXTAPID®: The Company reported net revenues of JUXTAPID of \$14.2 million in the first quarter of 2019, compared to \$13.4 million for the same period in 2018, \$9.1 million, or 64.1%, of which was from prescriptions written in the U.S. and \$0.8 million of which was royalty revenue from sales in the EMEA region. Growth in JUXTAPID revenue in the first quarter of 2019 compared to the same period in 2018 was due to an increase in revenues in the U.S., primarily resulting from a price increase, and a greater number of patients on therapy in Japan.

MYALEPT®/MYALEPTA®: The Company reported net revenues of MYALEPT/MYALEPTA of \$18.0 million in the first quarter of 2019, compared to \$14.1 million for the same period in 2018, \$11.4 million, or 63.3%, of which was from prescriptions written in the U.S. MYALEPT/MYALEPTA revenue growth in the first quarter was driven by increased sales in Germany, as a result of the recent launch, and the U.S., as a result of a greater number of shipments to patients as well as a price increase, partially offset by a decline in sales in Brazil.

GAAP total net revenues for the first quarter of 2019 were \$32.2 million compared to \$27.5 million for the same period in 2018.

Cost of product sales for the first quarter of 2019 was \$15.2 million compared to \$13.5 million for the same period in 2018. The increase is primarily attributed to higher stability testing costs and higher supply chain costs as well as a higher royalty rate on U.S. sales of metreleptin, partially offset by a lower inventory cost basis in the first quarter of 2019. Despite the increase, gross margin improved from 50.9% to 52.7% as a result of higher revenues in comparison to certain fixed costs.

GAAP total operating expenses for the first quarter of 2019 were \$33.0 million compared to total operating expenses of \$35.5 million, a 7.0% reduction compared to the same period in 2018. GAAP selling, general and administrative (SG&A) expenses were \$26.0 million in the first quarter of 2019, including approximately \$13.8 million of costs related to the Company's ongoing debt restructuring and strategic review processes, compared to \$23.7 million for the same period in 2018. GAAP R&D expenses were \$6.9 million in the first quarter of 2019 compared to \$11.8 million for the same period in 2018.

On a non-GAAP basis, during the first quarter of 2019, SG&A expenses were \$11.7 million compared to \$21.6 million for the same period in 2018. In the first quarter of 2019, we incurred \$12.3 million of non-ordinary course expenses, which primarily consist of legal, financial/restructuring advisory, and consulting fees, in connection with our ongoing strategic alternatives review, as well as a \$1.5 million payment to extend the maturity date of Aegerion's bridge loans. The 45.8% decrease in non-GAAP SG&A expenses in the first quarter of 2019 compared with the same period in 2018 is primarily the result of cost reduction initiatives implemented in late 2018 as well as the delay of certain ordinary course projects and initiatives to later in the year.

On a non-GAAP basis, during the first quarter of 2019, R&D expenses decreased 41.4% to \$6.8 million compared to \$11.6 million for the same period in 2018, reflecting cost reduction initiatives, as well as the delay of certain ordinary course projects and initiatives to later in the year, partially offset by higher spending related to pharmacovigilance activities.

On a non-GAAP basis, during the first quarter of 2019, total operating expenses were \$18.6 million compared to \$33.3 million for the same period in 2018, reflecting a decrease in expenses for the reasons set forth above.

GAAP net loss in the first quarter of 2019 was \$31.8 million, an improvement of approximately 3.0% compared to GAAP net loss of \$32.8 million during the same period in 2018.

On a non-GAAP basis, net income was \$1.9 million in the first quarter of 2019 compared to a net loss of \$13.5 million for the same period in 2018.

A full reconciliation of the GAAP financial results to non-GAAP financial results is included in the financial information tables below.

Debt and Government Settlement Payments

As of March 31, 2019, Aegerion's debt liabilities and government settlement payments included \$302.5 million in outstanding principal under Aegerion's Convertible Notes due August 15, 2019, \$74.4 million in outstanding principal (including paid in kind fees and interest) under Aegerion's secured term loans having a maturity date of June 30, 2019, \$35.7 million outstanding under Aegerion's secured intercompany term loan with Novelion, as lender, which has a maturity date of July 1, 2019, as well as \$29.3 million owed under Aegerion's settlements with the Department of Justice and the U.S. Securities and Exchange Commission (the "Commission"), payable in prescribed installments until the first quarter of 2021.

Financial Guidance

Novelion expects total net revenues in 2019 to be between \$160.0 and \$175.0 million, including approximately \$30.0 million of licensing revenues, in the form of the \$25.0 million upfront licensing payment and \$5.0 million payment upon transfer of the marketing authorization to Recordati Rare Diseases Inc. ("Recordati"), resulting from the licensing agreement entered into between Aegerion and Recordati for the commercialization of JUXTAPID in Japan in February 2019.

About Novelion Therapeutics

Novelion Therapeutics is a global biopharmaceutical company dedicated to developing and commercializing therapies that deliver new standards of care for people living with rare and underserved diseases. With a global footprint and an established commercial portfolio, including MYALEPT® (metreleptin) and JUXTAPID® (lomitapide), our business is supported by differentiated treatments that treat severe and rare diseases.

Cautionary Note

Novelion is the parent company of Aegerion, our operating subsidiary and the source of the consolidated company's revenues. References to "we," "our" and the "Company" refer to the entire enterprise, whose assets and operations reside primarily at Aegerion. As described above, Aegerion has a substantial amount of debt, including a secured term loan entered into in November 2018, which matures on June 30, 2019, its 2% Convertible Notes, which mature on August 15, 2019, and a secured intercompany term loan from Novelion, which matures on July 1, 2019. In light of these arrangements and their provisions, which prohibit Aegerion from making certain payments,

including payments in cash, to Novelion (including for out-of-pocket costs incurred, and services rendered, by or on behalf of Novelion, for the benefit of Aegerion), investors are cautioned that Aegerion's interests may not always be aligned, and may in certain circumstances be in conflict, with those of Novelion or its shareholders. The risks attendant to these conflicts of interest are described below under the caption "Forward Looking Statements and Risk Factors," which section you should read carefully and in its entirety.

Non-GAAP Results

The non-GAAP results in this press release, including, without limitation, non-GAAP R&D expenses, non-GAAP SG&A expenses, non-GAAP total operating expenses and non-GAAP net income (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 and Risk Factors

Certain statements in this press release constitute "forward-looking statements" and "forward-looking information" within the meaning of applicable laws and regulations, including U.S. and Canadian securities laws. Any statements contained herein which do not describe historical facts, including statements regarding beliefs about the impact of cost reduction initiatives, plans to undertake and complete a comprehensive restructuring, recapitalization or other strategic alternative (including the likelihood of seeking the protections of applicable bankruptcy reorganization laws in order to effectuate such a transaction or otherwise), expectations for the Recordati license, expectations for pursuit of the PL indication, expectations for approvals and decisions on pricing and reimbursement for MYALEPTA in the EU, plans to file for regulatory approvals for metreleptin in GL and PL (including expected timing) and statements regarding financial guidance, including total net revenues, 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, Novelion's and Aegerion's ability to meet immediate operational needs and obligations, as well as long-term obligations; Novelion's and Aegerion's ability to continue as a going concern and the likelihood that Aegerion will and Novelion may seek the protections of bankruptcy reorganization laws in the near term; the possibility that the restrictions in and other terms of Aegerion's loan arrangements could have a negative impact on Novelion's business and its shareholders (whose interests may not be aligned, and may be in conflict, with those of Aegerion's holders of convertible notes and other lenders); whether Novelion and/or Aegerion will be able to undertake and complete a wholesale recapitalization or restructuring, which is highly speculative and which is likely to include a debt for equity exchange (which would

be highly dilutive to existing Novelion shareholders), and the likelihood that Aegerion will, and Novelion may, seek the protections of applicable bankruptcy reorganization laws to effectuate such recapitalization or other alternative or otherwise (which may apportion little or no value to Novelion shareholders); Novelion's and Aegerion's ability to identify, pursue and consummate any financial or strategic alternatives; Novelion's ability to maintain its listing status on Nasdaq (the failure of which would constitute an event of default under Aegerion's loan arrangements); the likelihood that Aegerion will be able to achieve positive cash flow or EBITDA, and whether Novelion and its shareholders will realize any benefit even if Aegerion is successful in doing so; the risks inherent in the development and commercialization of pharmaceutical products, as well as those risks identified in Novelion's filings with the Commission, including under the heading "Risk Factors" in Novelion's Annual Report on Form 10-K filed on March 15, 2019, and subsequent filings with the Commission, all of which are available on the Commission's website at www.sec.gov. Investors are also cautioned that, given the quantum and near-term maturity of Aegerion's outstanding debt obligations, the implementation of one or more transactions (or the failure to complete any such transaction or transactions) will likely require Aegerion, and could require Novelion, to seek the protections of applicable bankruptcy laws allowing for corporations to seek to restructure their debts and other affairs under a reorganization.

Any such risks and uncertainties could materially and adversely affect our results of operations, cash flows, and our ability to maintain our operations, any of which would 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, Commission 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.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2019	2018
Net revenues	\$ 32,200	\$ 27,484
Cost of product sales	15,219	13,505
Operating expenses:		
Selling, general and administrative	26,035	23,689
Research and development	6,934	11,766
Total operating expenses	32,969	35,455
Loss from operations	(15,988)	(21,476)
Interest expense, net	(15,510)	(10,886)
Other expense, net	(560)	(307)
Loss before provision for income taxes	(32,058)	(32,669)
Benefit from (provision for) income taxes	211	(159)
Net loss	\$ (31,847)	\$ (32,828)
Net loss per common share—basic and diluted	\$ (1.67)	\$ (1.76)
Weighted-average common shares outstanding—basic and diluted	19,022	18,703

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

	March 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	\$ 51,919	\$ 45,154
Accounts receivable, net	26,875	28,912
Inventories	51,489	48,947
Prepaid expenses and other current assets	14,018	15,732
Property and equipment, net	1,209	1,585
Intangible assets, net	193,903	200,176
Other non-current assets	2,707	1,209
Total assets	\$ 342,120	\$ 341,715
Liabilities and shareholders' deficit		
Accounts payable and accrued liabilities	\$ 46,623	\$ 50,207
Deferred revenues	24,167	—
Short-term debt	73,928	73,677
Convertible notes, net	285,525	274,815
Provision for legal settlement	29,319	31,080
Other non-current liabilities	1,507	796
Total liabilities	461,069	430,575
Total shareholders' deficit	(118,949)	(88,860)
Total liabilities and shareholders' deficit	\$ 342,120	\$ 341,715

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

	Three Months Ended March 31,	
	2019	2018
Net loss reconciliation:		
GAAP net loss	\$ (31,847)	\$ (32,828)
Stock-based compensation	645	906
Amortization of acquired intangible assets	6,256	6,274
Amortization of debt discount and debt issuance costs	12,462	9,113
Inventory fair value step-up	467	3,001
Non-ordinary course operating expenses (1)	13,904	—
Non-GAAP net income/(loss)	<u>\$ 1,887</u>	<u>\$ (13,534)</u>
GAAP net loss per common share - basic and diluted	<u>\$ (1.67)</u>	<u>\$ (1.76)</u>
Non-GAAP net income/(loss) per common share - basic and diluted	<u>\$ 0.10</u>	<u>\$ (0.72)</u>
GAAP weighted-average common shares outstanding — basic and diluted	<u>19,022</u>	<u>18,703</u>
Non-GAAP weighted-average common shares outstanding — basic	<u>19,022</u>	<u>18,703</u>
Non-GAAP weighted-average common shares outstanding — diluted	<u>19,149</u>	<u>18,703</u>
Cost of product sales reconciliation:		
GAAP cost of product sales	\$ 15,219	\$ 13,505
Amortization of acquired intangible assets	(6,256)	(6,274)
Inventory fair value step-up	(608)	(1,704)
Non-GAAP cost of product sales	<u>\$ 8,355</u>	<u>\$ 5,527</u>
Selling, general and administrative expense reconciliation:		
GAAP selling, general and administrative expenses	\$ 26,035	\$ 23,689
Stock-based compensation	(506)	(768)
Inventory fair value step-up	39	(1,297)
Non-ordinary course operating expenses (1)	(13,843)	—
Non-GAAP selling, general and administrative expenses	<u>\$ 11,725</u>	<u>\$ 21,624</u>
Research and development expense reconciliation:		
GAAP research and development expenses	\$ 6,934	\$ 11,766
Stock-based compensation	(139)	(138)
Inventory fair value step-up	102	—
Non-ordinary course operating expenses (1)	(61)	—
Non-GAAP research and development expenses	<u>\$ 6,836</u>	<u>\$ 11,628</u>

(1) Represents expenses incurred in connection with the ongoing strategic alternatives review