Novelion Therapeutics Reports Third Quarter 2018 Financial Results

November 9, 2018

VANCOUVER, British Columbia, Nov. 09, 2018 (GLOBE NEWSWIRE) -- 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 third quarter and nine months ended September 30, 2018. In a separate press release on November 8, 2018, Novelion announced a comprehensive business update.

Novelion's Chief Financial Officer Michael Price commented, "In the third quarter we saw a positive impact from the cost reduction initiatives that we implemented throughout 2018, reflecting significant improvements in our operating expenses and bottom line, with GAAP net loss improving by approximately 50% and non-GAAP net loss improving by approximately 79% when compared to the same period in 2017. Additionally, we are pleased that our operating subsidiary, Aegerion Pharmaceuticals, Inc. ("Aegerion"), was able to secure the bridge financing that we announced yesterday, which we believe positions Aegerion to achieve a more comprehensive capital restructuring - our primary near-term goal."

Third Quarter 2018 Financial Results

JUXTAPID®: Novelion reported net revenues of JUXTAPID of $14.3 million in the third quarter of 2018, $8.1 million, or 57%, of which were from prescriptions written in the U.S. and $0.6 million of which was royalty revenue from sales of JUXTAPID in the EMEA region.

MYALEPT®: Novelion reported net revenues of MYALEPT of $16.1 million in the third quarter of 2018, $12.3 million, or 76%, of which were from prescriptions written in the U.S.

GAAP total net revenues for the third quarter of 2018 were $30.3 million compared to $28.7 million for the same period of 2017. Revenue growth in Japan, Brazil and other foreign markets as well as growth of U.S. MYALEPT sales offset the decline of JUXTAPID sales in the U.S.

GAAP net revenues for JUXTAPID in the third quarter of 2018 were $14.3 million compared to $15.2 million for the same period in 2017.

GAAP net revenues for MYALEPT in the third quarter of 2018 were $16.1 million compared to $13.5 million for the same period in 2017. MYALEPT revenue growth in the third quarter was driven by increased sales in all key markets.

GAAP total operating expenses for the third quarter of 2018 were $29.5 million compared to total operating expenses of $38.6 million, a 23% reduction compared to the same period in 2017. GAAP SG&A expenses were $18.3 million in the third quarter of 2018 compared to $21.4 million for the same period in 2017. GAAP R&D expenses were $9.0 million in the third quarter of 2018 compared to $17.1 million for the same period in 2017. Restructuring charges for the third quarter of 2018 were $2.2 million compared to $0.1 million in the same period of 2017.

On a pro forma basis, during the third quarter of 2018, SG&A expenses were $16.2 million compared to $20.2 million for the same period in 2017. The 20% decrease in pro forma SG&A expenses in the third quarter of 2018 compared with the same period in 2017 was primarily related to cost reduction programs initiated throughout 2018.

On a pro forma basis, during the third quarter of 2018, R&D expenses decreased 47% to $8.9 million compared to $16.9 million for the same period in 2017, reflecting cost reduction initiatives.

GAAP net loss in the third quarter of 2018 was $24.8 million, an improvement of approximately 50% compared to GAAP net loss of $49.7 million during the same period in 2017.

On a pro forma basis, net loss in the third quarter of 2018 improved by approximately 79% to $3.5 million, compared to a net loss of $16.6 million for the same period in 2017.

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

First Nine Months of 2018 Financial Results

GAAP total net revenues for the first nine months of 2018 were $89.7 million compared to $99.5 million for the same period of 2017. Named patient sales in Brazil totaled $1.9 million in the first nine months of 2018, as compared to the first nine months of 2017, which benefitted from $11.0 million of named patient sales in Brazil.

GAAP net revenues for JUXTAPID for the first nine months of 2018 were $43.9 million compared to $51.9 million in same period in 2017. There were no named patient sales of JUXTAPID in the first nine months of 2018, as compared to the first nine months of 2017, which benefitted from $5.9 million of JUXTAPID named patient sales in Brazil. Revenue growth in Japan helped offset the decrease in the U.S. and other markets.

GAAP net revenues for MYALEPT for the first nine months of 2018 were $45.8 million compared to $47.6 million for the same period in 2017. MYALEPT sales benefitted from $2.3 million of deferred revenue recognition in the first nine months of 2017. MYALEPT revenues in Brazil totaled $5.1 million in the first nine months of 2017 compared to $1.9 million in the first nine months of 2018.

GAAP total operating expenses for the first nine months of 2018 were $99.1 million compared to total operating expenses of $112.1 million for the

same period in 2017. GAAP SG&A expenses were $65.8 million in the first nine months of 2018 compared to $72.4 million for the same period in 2017. GAAP R&D expenses were $31.2 million for the first nine months of 2018 compared to $37.2 million for the same period in 2017.

On a pro forma basis, for the first nine months of 2018, SG&A expenses decreased 13% to $59.4 million compared to $68.2 million for the same period in 2017, primarily as a result of cost reduction programs initiated throughout 2018. Restructuring charges in the first nine months of 2018 were $2.2 million, compared with restructuring charges of $2.5 million for the same period in 2017. The 2017 restructuring charges were related to the consolidation of similar positions during the integration of the business subsequent to the acquisition of Aegerion.

On a pro forma basis, for the first nine months of 2018, R&D expenses decreased 16% to $30.7 million compared to $36.6 million for the same period in 2017 due to cost reduction initiatives.

GAAP net loss for the first nine months of 2018 was $88.9 million compared to GAAP net loss of $102.1 million during the same period in 2017.

Net loss on a pro forma basis for the first nine months of 2018 was $28.2 million, compared to $26.7 million for the same period in 2017.

As of September 30, 2018, the Company's consolidated unrestricted cash balance was $27.4 million, compared to $55.4 million at December 31, 2017.

Other Financial Information

Novelion expects total net product sales in 2018 to be between $130 and $140 million and total net product sales in 2019 to be between $145 and $160 million.

As of September 30, 2018, Novelion had approximately $27.4 million in cash on a consolidated basis, including $13.7 million at Novelion and $13.7 million at the Aegerion subsidiary level. After giving effect to the consummation of the new secured financing by Aegerion and the application of proceeds from such financing and the payment of related fees and expenses, Novelion and Aegerion are anticipated to have approximately $15.7 million and $37.5 million, respectively, of cash as of November 8, 2018.

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 metabolic diseases. Our goal is to develop and bring to market transformational therapies that have the potential to significantly change the treatment paradigm for patients affected by a variety of rare and metabolic diseases, including diseases associated with low leptin, such as low-leptin associated obesity. 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.

Novelion is the parent company of Aegerion, our operating subsidiary. References to "we," "our" and the "Company" refer to the entire enterprise, whose assets and operations reside at Aegerion, whose interests may not always be aligned with those of Novelion or its shareholders.

Non-GAAP ("pro forma") Results

The non-GAAP results in this press release, including, without limitation, 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" within the meaning of applicable laws and regulations and constitute "forward-looking information" within the meaning of applicable Canadian securities laws. Any statements contained herein which do not describe historical facts, including statements regarding beliefs about the impact of cost reduction initiatives, including that such initiatives have led to significant improvements in operating expenses and bottom line; beliefs that the new loan arrangement positions us to achieve a more comprehensive capital restructuring; and expectations for 2018 and 2019 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; the possibility that the restrictions in and other terms of the new bridge facility and the related documents could have a negative impact on Novelion's business and its shareholders (whose interests may not be aligned with those of Aegerion's holders of convertible notes and other lenders); whether Novelion and/or Aegerion will be able to undertake a wholesale recapitalization, which is likely to include a debt for equity swap, and Novelion and/ or Aegerion may be forced to use the protections of the bankruptcy laws to effectuate such recapitalization or other alternative; 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; Novelion's and Aegerion's ability to continue as a going concern; the risks inherent in the development and commercialization of pharmaceutical products, as well as those identified in Novelion's filings with the U.S. Securities and Exchange Commission (the "Commission"), including under the heading "Risk Factors" in Novelion's Annual Report on Form 10-K filed on March 16, 2018 and subsequent filings with the Commission (including Novelion's upcoming Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 and Novelion's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018), available on the Commission's website at www.sec.gov. 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Net revenues	$ 30,334	$ 28,669	$ 89,722	$ 99,530
Cost of product sales	12,531	29,505	41,739	60,227
Operating expenses:				
Selling, general and administrative	18,348	21,395	65,773	72,360
Research and development	9,031	17,112	31,157	37,236
Restructuring charges	2,151	56	2,151	2,541
Total operating expenses	29,530	38,563	99,081	112,137
Loss from operations	(11,727)	(39,399)	(51,098)	(72,834)
Interest expense, net	(12,022)	(9,897)	(34,501)	(28,722)
Other (expense) income, net	(926)	49	(1,961)	176
Loss before provision for income taxes	(24,675)	(49,247)	(87,560)	(101,380)
Provision for income taxes	(133)	(497)	(1,338)	(762)
Net loss	$ (24,808)	$ (49,744)	$ (88,898)	$ (102,142)
Net loss per common share—basic and diluted	$ (1.32)	$ (2.67)	$ (4.74)	$ (5.49)
Weighted-average common shares outstanding—basic and diluted	18,854	18,648	18,772	18,599

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

	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 27,378	$ 55,430
Accounts receivable, net	21,560	22,191
Inventories	51,078	49,826
Prepaid expenses and other current assets	15,204	11,436
Property and equipment, net	1,967	2,920
Intangible assets, net	206,450	225,272
Other non-current assets	1,349	2,247
Total assets	$ 324,986	$ 369,322
Accounts payable and accrued liabilities	$ 57,296	$ 55,638
Short-term debt	16,367	—
Convertible notes, net	287,030	258,538
Provision for legal settlement	32,845	39,612
Other non-current liabilities	636	596
Total liabilities	394,174	354,384
Total shareholders' (deficit) equity	(69,188)	14,938
Total liabilities and shareholders' (deficit) equity	$ 324,986	$ 369,322

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss reconciliation:				
GAAP net loss	$ (24,808)	$ (49,744)	$ (88,898)	$ (102,142)
Stock-based compensation	618	926	2,461	3,419
Amortization of acquired intangible assets	6,274	6,274	18,822	18,778
Amortization of debt discount and debt issuance costs	9,996	8,399	28,728	24,205
Inventory fair value step-up	2,227	17,472	8,543	26,500
Restructuring charge	2,151	56	2,151	2,541
Non-GAAP net loss	$ (3,542)	$ (16,617)	$ (28,193)	$ (26,699)
GAAP net loss per common share - basic and diluted	$ (1.32)	$ (2.67)	$ (4.74)	$ (5.49)
Non-GAAP net loss per common share - basic and diluted	$ (0.19)	$ (0.89)	$ (1.50)	$ (1.44)
GAAP and Non-GAAP weighted-average common shares outstanding — basic and diluted	18,854	18,648	18,772	18,599
Cost of product sales reconciliation:				
GAAP cost of product sales	$ 12,531	$ 29,505	$ 41,739	$ 60,227
Amortization of acquired intangible assets	(6,274)	(6,274)	(18,822)	(18,778)
Inventory fair value step-up	(602)	(16,989)	(4,338)	(25,195)
Non-GAAP cost of product sales	$ 5,655	$ 6,242	$ 18,579	$ 16,254
Selling, general and administrative expense reconciliation:				
GAAP selling, general and administrative expenses	$ 18,348	$ 21,395	$ 65,773	$ 72,360
Stock-based compensation	(454)	(710)	(1,969)	(2,814)
Inventory fair value step-up	(1,625)	(483)	(4,205)	(1,305)
Amortization of debt issuance costs	(109)	0	(235)	0
Non-GAAP selling, general and administrative expenses	$ 16,160	$ 20,202	$ 59,364	$ 68,241
Research and development expense reconciliation:				
GAAP research and development expenses	$ 9,031	$ 17,112	$ 31,157	$ 37,236
Stock-based compensation	(164)	(216)	(492)	(605)

Non-GAAP research and development expenses	$ 8,867	$ 16,896	$ 30,665	$ 36,631

Source: Novelion Therapeutics, Inc.