Novelion Therapeutics Reports Second Quarter 2018 Financial Results

August 7, 2018

Following recent marketing approval in both generalized and partial lipodystrophy indications, European launch of MYALEPTA® has commenced

VANCOUVER, British Columbia, Aug. 07, 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 second quarter and six months ended June 30, 2018 and provided an overview of business activities.

Interim Chief Executive Officer Jeff Hackman commented, "Under our new leadership team, we are laser focused on maximizing the potential of our two commercial assets, enhancing our operational efficiencies by reducing costs, and fixing our capital structure issues so we can invest in the long-term opportunity of our valuable rare disease therapies.

"On the commercial front, we expect sequential revenue growth in the second half of this year, bolstered by stabilizing JUXTAPID® sales in the U.S., and continued penetration of the Japan market, where there are more than 200 registered HoFH patients. We also expect initial contribution from the European launch of MYALEPTA® (metreleptin) for both generalized lipodystrophy (GL) and partial lipodystrophy (PL), which represents the largest market for metreleptin in terms of treatable patients, a number of whom have already been identified through our pre-approval compassionate use program and are expected to be converted onto therapy, subject to pricing and reimbursement approvals, where required. Further, we believe that we can leverage the EU approval data package to support our plans to expand the U.S. label to include the PL indication and to file in additional markets, including Brazil. We want to thank Murray Stewart, M.D., our head of R&D, and his team, along with all the employees that supported the filing and approval, for achieving this important approval. We look forward to their work on expanding the metreleptin opportunity."

Business Highlights

- On July 31, Novelion announced that the European Commission (EC) granted marketing authorization for MYALEPTA, as an adjunct to diet, as a replacement therapy to treat the complications of leptin deficiency in lipodystrophy (LD) patients with confirmed congenital GL or acquired GL in adults and children 2 years of age and above; or with confirmed familial PL or acquired PL, in adults and children 12 years of age and above for whom standard treatments have failed to achieve adequate metabolic control. MYALEPTA is the first and only licensed treatment in Europe in these indications. Pricing and reimbursement negotiations with healthcare authorities have commenced and will be pursued on a country-by-country basis.

- In August, the Company submitted a marketing application for JUXTAPID in Brazil. While the Company currently recognizes sales for JUXTAPID in Brazil via the pre-approval named patient sales program, the Company is seeking formal marketing approval which, if successful, will open the door for product promotion and should also result in more predictable sales trends.

- **JUXTAPID®**: Novelion reported net revenues of JUXTAPID of $16.3 million in the second quarter of 2018, $10.5 million, or 64%, of which were from prescriptions written in the U.S. and $0.8 million of which was royalty revenue from Amryt's sales of JUXTAPID in the EMEA region.

- **MYALEPT®**: Novelion reported net revenues of MYALEPT of $15.6 million in the second quarter of 2018, $12.5 million, or 80%, of which were from prescriptions written in the U.S.

- In June, clinical data from a metreleptin study assessing weight loss in overweight and obese adults with low leptin levels were featured in a poster presentation at the American Diabetes Association's (ADA) 78th Scientific Sessions. These data support potential metreleptin pipeline opportunities.

- In July, Novelion's Board of Directors appointed Mark Corrigan, M.D. as Executive Chair. Dr. Corrigan serves in a supervisory role to the Company's management team and will continue to perform the traditional duties of Board Chair. In addition, Jeff Hackman was appointed interim chief executive officer.

Dr. Corrigan commented, "The first half of 2018 has been filled with important milestones. Having finalized Aegerion's legal settlements earlier this year, our organization was pleased with the strong market receptivity of our continued launch of JUXTAPID in Japan, as well as the stabilization of our U.S. JUXTAPID franchise. More importantly, the MYALEPTA European approval creates a larger revenue opportunity for us than in the U.S. In addition to top-line growth, we intend to further our operational improvements with the goal of creating a pathway to sustainable positive cash flow and robust

EBITDA growth. Given our progress on these initiatives, we intend to re-engage with the investor and analyst community, and we also plan to resume revenue guidance for 2019."

Second Quarter 2018 Financial Results

GAAP total net revenues for the second quarter of 2018 were $31.9 million compared to $40.9 million for the same period of 2017, primarily as a result of the timing of orders for both products in Brazil. The second quarter of 2017 benefitted from $8.1 million of Brazil revenues derived from the named patient sales program, whereas the second quarter of 2018 does not reflect any named patient sales in Brazil. The Company expects that marketing approval of its products, if achieved, in Brazil will support more predictable sales. Revenue growth of $2.0 million in other foreign markets more than offset the $0.7 million decrease in U.S. revenues. The second quarter of 2017 also benefitted from a one-time recognition of previously deferred revenue totaling $2.3 million, related to a change in method of revenue recognition for MYALEPT.

GAAP net revenues for JUXTAPID in the second quarter of 2018 were $16.3 million compared to $20.7 million for the same period in 2017. JUXTAPID revenues representing named patient sales in Brazil totaled $4.3 million in the second quarter of 2017, while there were no named patient sales of JUXTAPID in Brazil in the second quarter of 2018. Growth of 8% in other foreign markets nearly offset the 5% decrease in U.S. revenues, where we continue to see stabilization of sales.

GAAP net revenues for MYALEPT in the second quarter of 2018 were $15.6 million compared to $20.2 million for the same period in 2017. MYALEPT revenues representing named patient sales in Brazil totaled $3.8 million in the second quarter of 2017, while there were no named patient sales of MYALEPT in Brazil in the second quarter of 2018. As mentioned previously, MYALEPT revenues of $20.2 million in the second quarter of 2017 included a one-time recognition of previously deferred revenue of $2.3 million. Excluding this effect, U.S. revenues were virtually unchanged compared to the comparable period of the prior year, while MYALEPT revenues in foreign markets other than Brazil more than doubled from $1.5 million to $3.2 million in the same timeframe.

GAAP total operating expenses for the second quarter of 2018 were $34.1 million compared to total operating expenses of $38.4 million for the same period in 2017. GAAP SG&A expenses were $23.7 million in the second quarter of 2018 compared to $26.5 million for the same period in 2017. GAAP R&D expenses were $10.4 million in the second quarter of 2018 compared to $10.8 million for the same period in 2017.

On a pro forma basis, during the second quarter of 2018, SG&A expenses were $21.7 million compared to $25.1 million for the same period in 2017. The 14% decrease in pro forma SG&A expenses in the second quarter of 2018 compared with the same period in 2017 was primarily related to cost reduction programs initiated in early 2018. Additionally, there were no restructuring charges incurred during the second quarter of 2018, compared to $1.0 million in restructuring charges incurred during the second quarter of 2017, related to the consolidation of similar positions during the integration of the business subsequent to the acquisition of Aegerion.

On a pro forma basis, during the second quarter of 2018, R&D expenses decreased 5% to $10.2 million compared to $10.7 million for the same period in 2017, reflecting cost savings initiatives.

GAAP net loss in the second quarter of 2018 was $31.3 million compared to GAAP net loss of $21.4 million during the same period in 2017.

On a pro forma basis, net loss in the second quarter of 2018 was $11.1 million, compared to a net loss of $1.4 million for the same period in 2017.

First Six Months of 2018 Financial Results

GAAP total net revenues for the first six months of 2018 were $59.4 million compared to $70.9 million for the same period of 2017, primarily as a result of timing of orders for both products in Brazil. The first six months of 2017 benefitted from $10.9 million of Brazil sales derived from the named patient sales program, whereas named patient sales in Brazil totaled $1.2 million in the first six months of 2018. Growth of $5.2 million, or 45%, in other foreign markets offset the $4.7 million, or 10% decrease in U.S. revenues, excluding the impact of the one-time deferred revenue recognition in 2017.

GAAP net revenues for JUXTAPID for the first six months of 2018 were $29.6 million compared to $36.7 million in same period in 2017. JUXTAPID revenues totaled $5.9 million in Brazil in the first half of 2017, whereas there were no named patient sales of JUXTAPID in the first half of 2018. Revenue growth of $1.7 million, or 19%, in other foreign markets helped offset the $2.8 million, or 13%, decrease in U.S. revenues in the most recent six month period compared to the comparable period of 2017.

GAAP net revenues for MYALEPT for the first six months of 2018 were $29.8 million compared to $34.1 million for the same period in 2017. MYALEPT revenues in Brazil totaled $5.0 million in the first half of the prior year compared to $1.2 million in the first half of 2018. Excluding the impact of the $2.3 million deferred revenue recognition in 2017, U.S. sales of MYALEPT declined $1.8 million, or 7%, which was more than offset by the growth in foreign markets other than Brazil where MYALEPT revenues more than doubled from $2.8 million in the first half of 2017 to $6.3 million in the same period of 2018.

GAAP total operating expenses for the first six months of 2018 were $69.6 million compared to total operating expenses of $73.6 million for the same period in 2017. GAAP SG&A expenses were $47.4 million in the first six months of 2018 compared to $51.0 million for the same period in 2017. GAAP R&D expenses were $22.1 million for the first six months of 2018 compared to $20.1 million for the same period in 2017.

On a pro forma basis, for the first six months of 2018, SG&A expenses decreased 10% to $43.3 million compared to $48.0 million for the same period in 2017 primarily as a result of cost reduction programs initiated in early 2018. There were no restructuring charges in the first six months of 2018, compared with restructuring charges of $2.5 million for the same period in 2017 which 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 six months of 2018, R&D expenses increased 11% to $21.8 million compared to $19.7 million for the same period in 2017 due to increased clinical activity, partially offset by cost savings initiatives.

GAAP net loss for the first six months of 2018 was $64.1 million compared to GAAP net loss of $52.4 million during the same period in 2017.

Net loss on a pro forma basis for the first six months of 2018 was $24.7 million, compared to $10.1 million for the same period in 2017.

As of June 30, 2018, the Company's consolidated unrestricted cash balance was $40.0 million, compared to $55.4 million at December 31, 2017. As of

June 30, 2018, there were 18.9 million shares outstanding. Consolidated debt principal is $345.0 million, reflecting the amount of aggregate convertible and term loan debt issued by subsidiary Aegerion.

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.

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" 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; plans to re-initiate revenue guidance and reengage with investors and the analyst community; plans with respect to reducing operating expense and making operational improvements; plans to fix our capital structure and invest in our therapies; plans to provide a pathway to sustainable positive cash flow and robust EBITDA growth; expectations about expanding metreleptin into new disease areas and plans to expand the metreleptin PL indication into new markets; and expectations about other regulatory approvals and the impact of such approvals; 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Net revenues	$ 31,904	$ 40,877	$ 59,388	$ 70,861
Cost of product sales	15,703	14,277	29,208	30,722
Operating expenses:				
Selling, general and administrative	23,735	26,514	47,424	50,965
Research and development	10,360	10,824	22,126	20,124
Restructuring charges	—	1,034	—	2,485
Total operating expenses	34,095	38,372	69,550	73,574
Loss from operations	(17,894)	(11,772)	(39,370)	(33,435)
Interest expense, net	(11,594)	(9,613)	(22,480)	(18,825)
Other (expense) income, net	(728)	75	(1,035)	127
Loss before provision for income taxes	(30,216)	(21,310)	(62,885)	(52,133)
Provision for income taxes	(1,046)	(126)	(1,205)	(265)
Net loss	$ (31,262)	$ (21,436)	$ (64,090)	$ (52,398)
Net loss per common share—basic and diluted	$ (1.67)	$ (1.15)	$ (3.42)	$ (2.82)
Weighted-average common shares outstanding—basic and diluted	18,759	18,609	18,731	18,575

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

	June 30, 2018	**December 31, 2017**
Cash and cash equivalents	$ 39,976	$ 55,430
Accounts receivable, net	18,363	22,191
Inventories	50,749	49,826
Prepaid expenses and other current assets	14,757	11,436
Property and equipment, net	2,375	2,920
Intangible assets, net	212,724	225,272
Other non-current assets	1,384	2,247
Total assets	$ 340,328	$ 369,322
Accounts payable and accrued liabilities	$ 56,173	$ 55,638
Provision for legal settlement	34,692	39,612
Long-term debt	15,787	—
Convertible notes, net	277,143	258,538
Other non-current liabilities	1,493	596
Total liabilities	385,288	354,384
Total stockholders' (deficit) equity	(44,960)	14,938
Total liabilities and stockholders' (deficit) equity	$ 340,328	$ 369,322

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Net loss reconciliation:				

GAAP net loss	$ (31,262)	$ (21,436)	$ (64,090)	$ (52,398)
Stock-based compensation	936	1,094	1,842	2,493
Amortization of acquired intangible assets	6,274	6,273	12,548	12,504
Amortization of debt discount and debt issuance costs	9,619	8,063	18,732	15,805
Inventory fair value step-up	3,315	3,576	6,316	9,028
Restructuring charge related to acquisition	—	1,034	—	2,485
Non-GAAP net loss	$ (11,118)	$ (1,396)	$ (24,652)	$ (10,083)
GAAP net loss per common share - basic and diluted	$ (1.67)	$ (1.15)	$ (3.42)	$ (2.82)
Non-GAAP net loss per common share - basic and diluted	$ (0.59)	$ (0.08)	$ (1.32)	$ (0.54)
GAAP and Non-GAAP weighted-average common shares outstanding — basic and diluted	18,759	18,609	18,731	18,575
Cost of product sales reconciliation:				
GAAP cost of product sales	$ 15,703	$ 14,277	$ 29,208	$ 30,722
Amortization of acquired intangible assets	(6,274)	(6,273)	(12,548)	(12,504)
Inventory fair value step-up	(2,032)	(3,097)	(3,736)	(8,206)
Non-GAAP cost of product sales	$ 7,397	$ 4,907	$ 12,924	$ 10,012
Selling, general and administrative expense reconciliation:				
GAAP selling, general and administrative expenses	$ 23,735	$ 26,514	$ 47,424	$ 50,965
Stock-based compensation	(746)	(980)	(1,514)	(2,104)
Inventory fair value step-up	(1,283)	(479)	(2,580)	(822)
Non-GAAP selling, general and administrative expenses	$ 21,706	$ 25,055	$ 43,330	$ 48,039
Research and development expense reconciliation:				
GAAP research and development expenses	$ 10,360	$ 10,824	$ 22,126	$ 20,124
Stock-based compensation	(190)	(114)	(328)	(389)
Non-GAAP research and development expenses	$ 10,170	$ 10,710	$ 21,798	$ 19,735

Primary Logo

Source: Novelion Therapeutics, Inc.