



Clementia Reports Third Quarter 2018 Operating Results and Pipeline Updates

November 7, 2018

Recent FDA Meeting Identifies Path Towards NDA Submission in the Second Half of 2019

Financing Raises \$75 million to Support a Potential Commercial Launch

MONTREAL, Nov. 07, 2018 (GLOBE NEWSWIRE) -- [Clementia Pharmaceuticals Inc.](#) (NASDAQ: CMTA), a clinical-stage biopharmaceutical company innovating treatments for people with ultra-rare bone disorders and other diseases, today reported financial results for the third quarter ended September 30, 2018 and provided an update on recent progress and upcoming milestones.

“This has been a transformational year for Clementia, with our lead product candidate, palovarotene, advancing towards an NDA submission in the second half of 2019, which if approved, could be the first available treatment indicated for FOP,” said Clarissa Desjardins, Ph.D., president and chief executive officer of Clementia. “Over the next 12 months we also expect to complete enrollment in our MO-Ped Trial, the first-ever clinical trial to test a potential treatment for Multiple Osteochondromas (MO), to reach the first two interim analyses from our MOVE Trial, and to report the results of our Phase 1 study of our palovarotene eye drop formulation for dry eye disease. With our recently completed financing we now have the resources to bring palovarotene to market upon approval, while advancing our other clinical programs to key value inflection points.”

Recent Pipeline Progress and Upcoming Milestones

- On October 23, 2018 Clementia announced that it plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) requesting marketing authorization of palovarotene for the treatment of fibrodysplasia ossificans progressiva (FOP), with an anticipated submission in the second half of 2019. The FDA has agreed, and the meeting minutes confirm, that available data from the completed Phase 2 clinical program would support the filing of an NDA for palovarotene for the prevention of heterotopic ossification (HO) associated with flare up symptoms in patients with FOP.
- On October 2, 2018 the company announced the initiation of a Phase 1 clinical trial evaluating an eye drop formulation of palovarotene in healthy volunteers. Data from this trial are expected in the first quarter of 2019 and will be utilized to inform the design of a proof of concept trial evaluating palovarotene in dry eye disease, which is expected to begin in 2019.
- In September 2018, Clementia reported updated 12-week flare-up imaging data from the open label extension (“Part B”) of its ongoing Phase 2 clinical trial of palovarotene in fibrodysplasia ossificans progressiva (FOP) at ASBMR 2018. The data demonstrated a greater than 70 percent reduction in new HO across three different dosing regimens.
- On August 16, 2018 the company announced the early completion of enrollment in the MOVE Trial, Clementia’s Phase 3 study evaluating the safety and efficacy of a chronic 5 mg daily dose in addition to the episodic 20/10 mg dosing regimen at the time of a flare-up for the potential treatment of individuals with FOP. If successful, this study would add a new dosing regimen for patients with FOP. The company expects two interim analyses in 2019, with a third interim and final results in 2020.

Recent Business Updates

- On October 30, 2018 the company filed a prospectus for a follow-on offering of 5,300,000 common shares, and the underwriters exercised their option to purchase an additional 795,000 common shares, resulting in the issue of 6,095,000 shares for net proceeds of \$75 million, after underwriting discounts and commissions and the estimated offering expenses payable by the company. The proceeds of this financing, together with Clementia's existing cash and investments balance, results in approximately \$180 million as of the closing of the offering.

Third Quarter 2018 Financial Results (all amounts are presented in U.S. dollars)

- **Cash:** As of September 30, 2018, Clementia had cash and investments of \$107.1 million.
- **Research and development (R&D) expenses:** R&D expenses were \$10.7 million and \$29.1 million for the three and nine months ended September 30, 2018, compared to \$7.1 million and \$16.8 million for the same periods in 2017. Increases in R&D expenses were primarily due to increases in: clinical studies and CRO related activities as a result of patient enrollment in the MOVE and MO-Ped Trials; manufacturing activities to meet clinical supply requirements of the MOVE and MO-Ped studies; pre-clinical research activities to support ocular studies and other potential indications; and personnel related expenses in support of increased development activities.
- **General and administrative (G&A) expenses:** G&A expenses were \$4.4 million and \$11.2 million for the three and nine months ended September 30, 2018, compared to \$2.8 million and \$6.9 million for the same periods in 2017. Increases in G&A expenses were primarily due to higher pre-commercial marketing activities, higher personnel and related costs to support the continued growth of the company and higher operating expenses.
- **Net Loss:** Clementia reported net losses for the three and nine months ended September 30, 2018 of \$14.8 million (\$0.46 per share) and \$38.8 million (\$1.22 per share), compared to \$39.0 million (\$1.83 per share) and \$103.7 million (\$11.81 per share) for the same periods in 2017. The decreases in net losses period over period were largely driven by non-cash financial expenses primarily due to the re-measurement at fair value of the preferred shares embedded derivative in 2017 as compared to 2018. With the successful completion of the company's IPO in August 2017, all classes of preferred shares were converted into common shares and as such, gains or losses on the re-measurement of embedded derivatives at fair value and the accretion expenses ended in the third quarter of 2017.

About Clementia Pharmaceuticals Inc.

Clementia is a clinical-stage company innovating treatments for people with ultra-rare bone disorders and other diseases with high medical need. The company is preparing for a 2019 NDA submission to the FDA to seek approval of its lead product candidate, palovarotene, a novel RAR γ agonist, for the prevention of heterotopic ossification (HO) associated with flare up symptoms in patients with fibrodysplasia ossificans progressiva (FOP). The ongoing Phase 3 MOVE Trial is evaluating an additional dosing regimen of palovarotene which includes a chronic 5 mg daily dose in addition to the episodic 20/10 mg dosing regimen at the time of a flare-up. Palovarotene is also in a Phase 2 trial, the MO-Ped Trial, for the treatment of multiple osteochondromas (MO, also known as multiple hereditary exostoses, or MHE). In addition, Clementia has commenced a Phase 1 trial for an eye drop formulation of palovarotene for the potential treatment of dry eye disease and is also investigating other conditions that may benefit from RAR γ therapy. For more information, please visit www.clementiapharma.com and connect with us on Twitter @ClementiaPharma.

Cautionary Note Regarding Forward-Looking Statements

This press release may include "forward-looking statements" within the meaning of the applicable securities laws, including with respect to the proposed timing of submission of the NDA for palovarotene. Each forward-looking statement contained in this press release is subject to known and unknown risks and

uncertainties and other unknown factors that could cause actual results to differ materially from historical results and those expressed or implied by such statement. In addition to statements which explicitly describe such risks and uncertainties, readers are urged to consider statements labeled with the terms “believes,” “belief,” “expects,” “intends,” “anticipates,” “will,” or “plans” to be uncertain and forward-looking. Applicable risks and uncertainties include, among others, the company’s ability to successfully complete in a timely manner the studies required to be completed in order to submit the NDA; the company’s ability to generate revenue and become profitable; the risks related to its heavy reliance on palovarotene, its only current product candidate; the risks associated with the development of palovarotene and any future product candidate, including the demonstration of efficacy and safety; its dependence on licensed intellectual property, including the ability to source and maintain licenses from third-party owners; as well as the risks identified under the heading “Risk Factors” in the company’s Annual Report on Form 20-F filed with the Securities and Exchange Commission (“SEC”), as well as the other information it files with the SEC or on SEDAR. Clementia cautions investors not to rely on the forward-looking statements contained in this press release when making an investment decision in its securities. Investors are encouraged to read the company’s filings with the SEC or on SEDAR, available at www.sec.gov or www.sedar.com, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this press release, and the company undertakes no obligation to update or revise any of these statements, whether as a result of new information, future events or otherwise, except as required by law.

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Clementia Pharmaceuticals Inc.

Interim Condensed Consolidated Statements of Financial Position (unaudited)

As at (in US dollars)	September 30, 2018	December 31, 2017
Assets		
Current assets		
Cash	\$12,056,908	\$36,230,343
Short-term investments	70,000,000	30,000,000
Interest receivable	181,407	575,499
Sales tax and other receivables	168,459	94,497
Income tax and tax credits receivable	1,044,285	977,901
Prepaid expenses	4,609,489	3,023,125
Total current assets	88,060,548	70,901,365
Non-current assets		
Long-term investments	25,000,000	75,000,000
Long-term prepaid expenses	733,058	775,757
Property and equipment	18,987	33,084
Intangible assets	1,570,486	1,715,192

Total non-current assets	27,322,531	77,524,033
Total assets	\$115,383,079	\$148,425,398
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	\$8,792,166	\$6,718,666
Total liabilities	8,792,166	6,718,666
Equity		
Common shares	230,659,692	230,659,692
Contributed surplus	6,319,484	2,659,348
Deficit	(130,388,263)	(91,612,308)
Total equity	106,590,913	141,706,732
Total equity and liabilities	\$115,383,079	\$148,425,398

Clementia Pharmaceuticals Inc.

Interim Condensed Consolidated Statements of Net Loss and Comprehensive Loss (unaudited)

(in US dollars)	Three-month periods ended		Nine-month periods ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Expenses				
Research and development expenses	\$10,691,399	\$7,073,872	\$29,124,117	\$16,813,902
Investment tax credits	(363,232)	(91,484)	(718,187)	(211,524)
	10,328,167	6,982,388	28,405,930	16,602,378
General and administrative expenses	4,447,953	2,816,980	11,204,722	6,878,786
Interest income	(531,479)	(316,081)	(1,622,109)	(503,915)
Financial expenses	3,776	29,415,957	71,541	80,440,739
Net loss before income taxes	14,248,417	38,899,244	38,060,084	103,417,988
Income tax expense	528,694	106,310	715,871	248,338
Net loss and comprehensive loss	(\$ 14,777,111)	(\$39,005,554)	(\$ 38,775,955)	(\$103,666,326)
Basic and diluted loss per share	(\$0.46)	(\$1.83)	(\$1.22)	(\$11.81)
Weighted average number of outstanding basic and diluted shares	31,717,584	21,317,604	31,717,584	8,778,602

Clementia Pharmaceuticals Inc.**Interim Condensed Consolidated Statements of Cash Flows (unaudited)**

	Three-month periods ended September 30,		Nine-month periods ended September 30,	
(in US dollars)	2018	2017	2018	2017
Operating activities				
Net loss	(\$14,777,111)	(\$39,005,554)	(\$38,775,955)	(\$103,666,326)
Adjusting items				
Interest income recognized in net loss	(531,479)	(316,081)	(1,622,109)	(503,915)
Depreciation of property and equipment	4,733	6,063	14,097	19,855
Amortization of intangible assets	48,765	48,673	144,706	130,718
Transaction costs recognized in net loss	-	-	-	35,175
Embedded derivative loss recognized in net loss	-	29,007,078	-	77,902,663
Accretion of preferred shares	-	393,425	-	2,479,161
Share-based compensation	1,656,408	795,806	3,660,136	1,478,082
Net foreign exchange gain	(16,729)	(32,634)	37,884	(48,026)
Income tax expense recognized in net loss	528,694	106,310	715,871	248,338
Income taxes paid	(4,375)	(42,500)	(64,068)	(130,589)
Tax credits	(248,641)	-	(409,638)	-
Net changes in working capital				
Sales tax and other receivables	(95,768)	(49,860)	(75,846)	(74,884)
Investment tax credits receivable	(114,591)	(91,484)	(308,549)	(211,524)
Deferred financing costs	(18,165)	275,784	(18,165)	-
Prepaid expenses	583,103	(3,727,642)	(1,525,500)	(3,807,706)
Accounts payable and accrued liabilities	330,564	457,938	2,078,396	1,835,789
Net operating cash flows	(12,654,592)	(12,174,678)	(36,148,740)	(24,313,189)
Investing activities				
Interest income received	1,752,656	184,040	2,016,201	551,412
Acquisition of short and long-term investments	(15,000,000)	(109,000,000)	(20,000,000)	(134,000,000)
Maturity of short-term investments	25,000,000	19,000,000	30,000,000	49,000,000
Acquisition of property and equipment	-	(4,194)	-	(17,022)
Acquisition of intellectual property	-	-	-	(1,000,000)
Net investing cash flows	11,752,656	(89,820,154)	12,016,201	(85,465,610)
Financing activities				
Issuance of common shares	-	-	-	31,588
Issuance of common shares upon public offering	-	137,865,000	-	137,865,000
Share issuance costs	-	(10,236,593)	-	(10,236,593)
Issuance of preferred shares	-	-	-	10,000,080

Issue costs of preferred shares	-	-	-	(129,520)
Net financing cash flows	-	127,628,407	-	137,530,555
Net (decrease) increase in cash	(901,936)	25,633,575	(24,132,539)	27,751,756
Cash at beginning of period	12,937,235	11,584,221	36,230,343	9,434,495
Effect of exchange rate fluctuations on cash held	21,609	20,400	(40,896)	51,945
Cash at end of period	12,056,908	\$37,238,196	12,056,908	\$37,238,196



Source: Clementia Pharmaceuticals Inc.