

HLS Therapeutics Announces Q2 2019 Financial Results

- **Revenue of \$13.6 million, Adjusted EBITDA of \$8.1 million and Cash from Operations of \$9.0 million**
- **Filed the New Drug Submission for Vascepa® with Health Canada after having been granted Priority Review status**
- **Completed a C\$50.0 million (US\$37.3 million) bought-deal offering**
- **In - licensed the Canadian rights to PERSERIS™, a novel long-acting injectable risperidone product for the treatment of schizophrenia**
- **Paid a quarterly dividend of C\$0.05 per outstanding common share**

TORONTO, Aug. 8, 2019 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX:HLS), a specialty pharmaceutical company focusing on central nervous system and cardiovascular markets, announces its financial results for the three- and six-month periods ended June 30, 2019 ("Q2 2019" and "YTD 2019"). All amounts are in thousands of United States ("U.S.") dollars unless otherwise stated.

Q2 FISCAL 2019 HIGHLIGHTS

- Filed the New Drug Submission ("NDS") for Vascepa® with Health Canada after having been granted Priority Review status;
- Completed a C\$50.0 million (US\$37.3 million) bought-deal offering, which included the exercise in full of the underwriters' over-allotment option;
- Acquired a license for the Canadian rights to PERSERIS™, a novel long-acting injectable risperidone product for the treatment of schizophrenia;
- Cash from operations was \$9.0 million compared to \$1.7 million in Q2 2018;
- Revenue was \$13.6 million compared to \$16.3 million in Q2 2018;
- Adjusted EBITDA was \$8.1 million compared to \$11.0 million in Q2 2018;
- Net loss was (\$1.6) million, or (\$0.06) per common share, compared to net loss of (\$0.6) million, or (\$0.02) per common share, in Q2 2018; and
- Paid a quarterly dividend of C\$0.05 per outstanding common share.

"Financial results continue to demonstrate steady financial performance and solid cash-flow generation in the business," said Greg Gubitz, CEO of HLS. "Canadian Clozaril results for Q2 were impacted by the timing of approximately \$0.7 million in Clozaril orders, which were received uncharacteristically late in the quarter and were subsequently delivered in Q3. The timing of these orders impacted Q2 revenue but should have a favorable impact in Q3. The Q2 results also reflect Absorica royalty levels that were below expectations and below Q2 2018's level by approximately \$1.6 million. While these two factors had an impact in Q2, overall, the stable financial fundamentals underpinning HLS - namely, attractive margins and reliable cash flows - remained in place in the quarter and, with a number of growth catalysts on the horizon, we achieved several important operational milestones in the period."

"The key operational development in Q2 was the filing with Health Canada of our NDS for Vascepa with Priority Review status. Vascepa seeks to reduce the risk of ischemic cardiovascular events in statin-treated patients with elevated triglycerides and other risk factors. Cardiovascular disease is the world's number one cause of mortality and no therapy is currently approved to treat such residual cardiovascular risk in the population studied in Amarin Corporation's REDUCE-IT trial. We believe Vascepa has the potential to transform our business and have conservatively estimated its potential peak revenue range at C\$150-250 million, should it achieve regulatory approval. With its Priority Review underway, we expect to receive Health Canada's response toward the end of Q4 2019."

"We also expanded our product portfolio in Q2 by acquiring a license for the Canadian rights to PERSERIS, a novel long-acting injectable risperidone product from Indivior PLC that is approved in the U.S. by the FDA for the treatment of schizophrenia. We believe PERSERIS could bring another treatment option to patients and practitioners contending with a difficult disease state, and it is complementary to our CNS business, which also includes Clozaril and once approved, CSAN Pronto. Regarding PERSERIS, we are currently working towards an end-of-year filing and an expected launch in the second half of 2020."

"Finally, in Q2 we completed a C\$50.0 million (US\$37.3 million) bought-deal financing, which included the exercise in full of the underwriters' over-allotment option. We expect the funds raised to be used to strengthen our business development activities and pursue additional growth opportunities. With established products in market, two products filed with Health Canada, two additional products at the pre-filing stage and a growing business development pipeline, we believe we have a busy and exciting road ahead of us."

DIVIDEND

On August 7, 2019, the Company's Board of Directors declared a dividend of C\$0.05 per outstanding common share to be paid on December 13, 2019, to shareholders of record as of October 31, 2019.

These dividends paid on the Company's common shares are designated to be "eligible dividends" for purposes of section 89(1) of the *Income Tax Act* (Canada).

FINANCIAL REVIEW

Revenue

The following table provides revenue segmentation by revenue type and geography for the three- and six-month periods ended June 30, 2019:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Product sales				
Canada	6,898	7,772	13,285	14,531
United States	4,495	4,732	8,770	9,604
	11,393	12,504	22,055	24,135
Royalty revenue	2,232	3,801	4,742	5,336
	13,625	16,305	26,797	29,471

While patient numbers have increased year-to-date, Clozaril financial results in Canada in Q2 2019 were impacted by the timing of several customer orders. An uncharacteristically large number of customer orders representing \$0.7 million in product sales were received and shipped on the last working day of the quarter and were subsequently delivered to customers in Q3. As a result, these orders will be included in Q3 revenue. In addition, a 3.4% reduction in the exchange rate compared to the same period in the prior year reduced product sales by \$0.2 million when revenues for the quarter were translated to U.S. dollars. Despite fluctuations from quarter-to-quarter, the Company expects long-term results to reflect the stable growth trend in the number of Canadian Clozaril patients.

For the YTD 2019 period, Clozaril experienced the lowest erosion rate in the U.S. market since HLS acquired the product in 2015. The 3.3% decrease in Clozaril gross revenues in Q2 2019 and a corresponding 1.4% decrease for the YTD 2019 period compare favorably to the same periods last year. Overall, Clozaril results in the U.S. for the YTD 2019 period are down as the prior year benefitted from favorable gross-to-net adjustments and authorized generic supplies prior to termination of that agreement.

Absorica royalty revenues in Q2 2019 were disappointing at \$2.2 million compared to \$3.8 million in Q2 2018. For the YTD 2019 period, royalty revenues were \$4.7 million compared to \$5.3 million in the same period last year. HLS acquired the U.S. marketing rights to Absorica in 2016 which provides a source of income based on U.S. sales of the product but, unlike the rest of the HLS portfolio, the Company is not involved in the day-to-day operations for Absorica.

Operating Expenses

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Cost of product sales	523	536	910	1,116
Selling and marketing	1,435	1,046	2,628	2,010
Medical, regulatory and patient support	1,398	1,176	2,611	2,153
General and administrative	2,164	2,508	4,286	4,561
	5,520	5,266	10,435	9,840

Cost of product sales for Clozaril continue to be low relative to revenues with the decrease in the current quarter reflecting sales volumes, initial costs to transition manufacturing for the Canadian market and lower manufacturing costs from the Company's supply chain operations.

The year-over-year increase in other operating expenses was driven primarily by additional activity to support the planned introductions of Vascepa and CSAN Pronto to the Canadian market and higher patient registry program costs, notably following a temporary reduction in these costs in the prior year periods, offset in part by lower General and Administrative ("G&A") costs.

Adjusted EBITDA

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Net loss for the period	(1,631)	(563)	(5,334)	(5,439)
Stock-based compensation	471	123	1,068	217
Amortization and depreciation	8,103	8,134	16,221	16,275
Acquisition and transaction costs	178	98	599	533
Finance and related costs, net	1,096	3,557	4,313	9,124
Income tax recovery	(112)	(310)	(505)	(1,079)
Adjusted EBITDA	8,105	11,039	16,362	19,631

The decrease in Adjusted EBITDA for Q2 2019 was driven by the decrease in Absorica royalties and to a lesser extent due to the timing of certain Clozaril orders in Canada. For both Q2 and the YTD 2019 periods, Adjusted EBITDA also reflects the higher levels of selling and marketing costs tied to preparations to commercialize Vascepa and CSAN Pronto and increased costs for medical, regulatory and patient support costs.

Interest Expense and Debt

Interest on the senior secured term loan in Q2 was \$1.5 million compared to \$4.0 million in Q2 2018. For the YTD 2019 period, interest expense was \$3.1 million compared to \$8.1 million in the same period last year. The decrease in interest is primarily due to the refinancing of the Company's debt in August 2018. The Company's current debt structure has both a lower principal amount outstanding and a lower interest rate than its original debt facility.

As at June 30, 2019, the principal debt balance outstanding under the new senior secured term facility was \$96.3 million compared to \$98.8 million at December 31, 2018. This compares with the original senior secured loan borrowing of \$185.0 million at the Company's inception and the \$137.9 million original loan balance at the end of Q2 2018 just prior to the Company restructuring its debt.

Net Loss

Net loss in Q2 2019 was (\$1.6) million, or (\$0.06) per share, compared to a net loss of (\$0.6) million, or (\$0.02) per share in Q2 2018. For the YTD 2019 period, net loss was (\$5.3) million, or (\$0.19) per share, compared to (\$5.4) million, or (\$0.20) per share in the same period last year. Net loss increased in the year-over-year comparison periods due primarily to lower revenue and higher operating expenses to prepare for the introduction of new commercial products, offset in part by lower interest expense.

Cash from Operations and Financial Position

Cash generated from operations was \$9.0 million in Q2 2019, compared to \$1.7 million in Q2 2018. For the YTD 2019 period, cash generated from operations was \$17.2 million compared to \$15.2 million in the same period last year.

As at June 30, 2019, the Company had cash and cash equivalents of \$52.3 million, up from \$10.9 million at December 31, 2018. Cash and cash equivalents have increased due to positive cash generated from operations year-to-date and the C\$50.0 million (US\$37.3 million) bought-deal equity financing completed in Q2 2019. As a result of the financing completed in the quarter, the Company's shares outstanding at June 30, 2019 were 30,741,094.

Q2 FISCAL 2019 CONFERENCE CALL

HLS will hold a conference call today at 8:30 am Eastern Time to discuss its Q2 2019 financial results. The call will be hosted by Mr. Greg Gubitz, Chief Executive Officer, Mr. Gilbert Godin, President and Chief Operating Officer and Mr. Tim Hendrickson, Chief Financial Officer.

DATE: Thursday, August 8, 2019

TIME: 8:30 am ET
DIAL-IN NUMBER: (888) 231-8191 or (647) 427-7450

WEBCAST LINK: <https://event.on24.com/wcc/r/2049475/B8D0B4917900EEDB22FADAE58DB8907>
TAPED REPLAY: (855) 859-2056 or (416) 849-0833
REPLAY PASSCODE: 6390197

A link to the live audio webcast of the conference call will also be available on the events page of the investors section of HLS Therapeutics' website at www.hlstherapeutics.com. Please connect at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be required to hear the webcast. The taped replay will be available for 14 days and the archived webcast will be available for 90 days.

ABOUT HLS THERAPEUTICS INC.

Formed in 2015, HLS is a specialty pharmaceutical company focused on the acquisition and commercialization of late stage development, commercial stage promoted and established branded pharmaceutical products in the North American markets. HLS's focus is on products targeting the central nervous system and cardiovascular therapeutic areas. HLS's management team is composed of seasoned pharmaceutical executives with a strong track record of success in these therapeutic areas and at managing products in each of these lifecycle stages. For more information visit: www.hlstherapeutics.com

CAUTIONARY NOTE REGARDING NON-IFRS MEASURES

This press release refers to certain non-IFRS measures. These measures are not recognized measures under IFRS, do not have a standardized meaning prescribed by IFRS and are therefore unlikely to be comparable to similar measures presented by other companies. Rather, these measures are provided as additional information to complement those IFRS measures by providing further understanding of HLS's results of operations from management's perspective. Accordingly, they should not be considered in isolation nor as a substitute for analysis of HLS's financial information reported under IFRS. HLS uses non-IFRS measures to provide investors with supplemental measures of its operating performance and thus highlight trends in its core business that may not otherwise be apparent when relying solely on IFRS financial measures. HLS also believes that securities analysts, investors and other interested parties frequently use non-IFRS measures in the evaluation of issuers. HLS's management also uses non-IFRS measures in order to facilitate operating performance comparisons from period to period, prepare annual operating budgets and assess HLS's ability to meet its future debt service, capital expenditure and working capital requirements.

In particular, management uses Adjusted EBITDA as a measure of HLS's performance. To reconcile net loss for the year with Adjusted EBITDA, each of (i) "stock-based compensation", (ii) "amortization and depreciation", (iii) "acquisition costs", (iv) "finance and related costs", and (v) "income tax recovery" appearing in the Consolidated Statement of Net Loss are added to net loss for the year to determine Adjusted EBITDA. Adjusted EBITDA does not have any standardized meaning prescribed by IFRS and is not necessarily comparable to similar measures presented by other companies. Adjusted EBITDA should not be considered in isolation or as a substitute for net income (loss) prepared in accordance with IFRS as issued by the IASB.

FORWARD LOOKING INFORMATION

This release includes forward-looking statements regarding HLS and its business. Such statements are based on the current expectations and views of future events of HLS's management. In some cases the forward-looking statements can be identified by words or phrases such as "may", "will", "expect", "plan", "anticipate", "intend", "potential", "estimate", "believe" or the negative of these terms, or other similar expressions intended to identify forward-looking statements, including, among others, statements with respect to HLS's pursuit of additional product and pipeline opportunities in certain therapeutic markets, statements regarding growth opportunities and expectations regarding financial performance. The forward-looking events and circumstances discussed in this release may not occur and could differ materially as a result of known and unknown risk factors and uncertainties affecting HLS, including risks relating to the specialty pharmaceutical industry, risks related to the regulatory approval process, economic factors and many other factors beyond the control of HLS. Forward-looking statements and information by their nature are based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause HLS's actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statement or information. Accordingly, readers should not place undue reliance on any forward-looking statements or information. A discussion of the material risks and assumptions associated with this release can be found in the Company's Annual Information Form dated April 1, 2019, which has been filed on SEDAR and can be accessed at www.sedar.com. Accordingly, readers should not place undue reliance on any forward-looking statements or information. Except as required

by applicable securities laws, forward-looking statements speak only as of the date on which they are made and HLS undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

HLS THERAPEUTICS INC.
CONDENSED INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
Unaudited

[in thousands of U.S. dollars]

	As at June 30, 2019	As at December 31, 2018
ASSETS		
Current		
Cash and cash equivalents	52,308	10,930
Accounts receivable	11,075	17,509
Inventories	1,831	1,505
Foreign currency forward contract	116	755
Prepaid expenses and other current assets	1,529	919
Total current assets	66,859	31,618
Property, plant and equipment	1,210	363
Intangible assets	263,378	271,153
Restricted assets	2,256	2,290
Deferred income tax asset	1,015	1,001
Total assets	334,718	306,425
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current		
Accounts payable and accrued liabilities	13,393	12,405
Provisions	6,533	6,574
Debt and other financial liabilities	19,128	18,920
Income taxes payable	212	369
Total current liabilities	39,266	38,268
Debt and other financial liabilities	98,780	104,459
Deferred income tax liability	3,602	5,209
Total liabilities	141,648	147,936
Shareholders' equity		
Share capital	245,313	210,360
Contributed surplus	13,956	12,973
Accumulated other comprehensive loss	(1,287)	(7,455)
Deficit	(64,912)	(57,389)
Total shareholders' equity	193,070	158,489
Total liabilities and shareholders' equity	334,718	306,425

HLS THERAPEUTICS INC.
CONDENSED INTERIM CONSOLIDATED STATEMENTS OF LOSS
Unaudited

[in thousands of U.S. dollars, except per share amounts]

	Three months ended June 30, 2019		Six months ended June 30, 2019	
	2019	2018	2019	2018
Revenue	13,625	16,305	26,797	29,471
Expenses				
Cost of product sales	523	536	910	1,116

Selling and marketing	1,435	1,046	2,628	2,010
Medical, regulatory and patient support	1,398	1,176	2,611	2,153
General and administrative	2,164	2,508	4,286	4,561
Stock-based compensation	471	123	1,068	217
Amortization and depreciation	8,103	8,134	16,221	16,275
Operating income (loss)	(469)	2,782	(927)	3,139
Acquisition and transaction costs	178	98	599	533
Finance and related costs, net	1,096	3,557	4,313	9,124
Loss before income taxes	(1,743)	(873)	(5,839)	(6,518)
Income tax recovery	(112)	(310)	(505)	(1,079)
Net loss for the period	(1,631)	(563)	(5,334)	(5,439)
Net loss per share:				
Basic and diluted	\$(0.06)	\$(0.02)	\$(0.19)	\$(0.20)

HLS THERAPEUTICS INC.
CONDENSED INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
Unaudited
[in thousands of U.S. dollars]

	Three months ended		Six months ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Net loss for the period	(1,631)	(563)	(5,334)	(5,439)
Item that may be reclassified subsequently to net loss				
Unrealized foreign currency translation adjustment	3,210	(3,568)	6,168	(8,188)
Comprehensive income (loss) for the period	1,579	(4,131)	834	(13,627)

HLS THERAPEUTICS INC.
CONDENSED INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
Unaudited
[in thousands of U.S. dollars]

	Share capital	Contributed surplus	Accumulated other comprehensive income (loss)	Deficit	Total
Balance, December 31, 2018	210,360	12,973	(7,455)	(57,389)	158,489
Common shares issued	37,329	—	—	—	37,329
Share issuance costs	(2,411)	—	—	—	(2,411)
Warrants exercised	35	—	—	—	35
Warrants granted	—	470	—	—	470
Stock option expense	—	513	—	—	513
Net loss for the period	—	—	—	(5,334)	(5,334)
Dividends declared	—	—	—	(2,189)	(2,189)
Unrealized foreign currency translation adjustment	—	—	6,168	—	6,168
Balance, June 30, 2019	245,313	13,956	(1,287)	(64,912)	193,070
Balance, December 31, 2017	192,743	12,330	5,941	(30,632)	180,382
Common shares issued	19,905	—	—	—	19,905
Share issuance costs	(1,252)	—	—	—	(1,252)
Shares repurchased	(248)	—	—	10	(238)
Share purchase obligation	—	(857)	—	—	(857)
Stock option expense	—	217	—	—	217
Net loss for the period	—	—	—	(5,439)	(5,439)

Unrealized foreign currency translation adjustment	—	—	(8,188)	—	(8,188)
Balance, June 30, 2018	211,148	11,690	(2,247)	(36,061)	184,530

HLS THERAPEUTICS INC.
CONDENSED INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS
Unaudited
[in thousands of U.S. dollars]

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
OPERATING ACTIVITIES				
Net loss for the period	(1,631)	(563)	(5,334)	(5,439)
Adjustments to reconcile net loss to cash provided by operating activities				
Stock option expense	279	123	513	217
Amortization and depreciation	8,103	8,134	16,221	16,275
Accreted interest	530	1,603	1,098	3,232
Fair value adjustment on financial assets and liabilities	170	(2,225)	1,443	(2,675)
Listing expense	—	—	—	435
Deferred income taxes	(449)	(779)	(1,104)	(1,668)
Net change in non-cash working capital balances related to operations	1,954	(4,606)	4,401	4,810
Cash provided by operating activities	8,956	1,687	17,238	15,187
INVESTING ACTIVITIES				
Additions to property, plant and equipment	(57)	(66)	(94)	(90)
Acquisitions	(1,825)	(2,325)	(4,650)	(6,650)
Other additions to intangible assets	(475)	(212)	(688)	(212)
Cash used in investing activities	(2,357)	(2,603)	(5,432)	(6,952)
FINANCING ACTIVITIES				
Common shares issued	37,329	—	37,329	19,470
Common share issuance costs	(2,277)	(123)	(2,277)	(1,699)
Warrants exercised	35	—	35	—
Common shares repurchased	—	(238)	—	(238)
Dividends paid	(1,022)	—	(2,023)	—
Repayment of senior secured term loan	(1,250)	(6,277)	(2,500)	(13,381)
Cash portion of debt refinancing costs	—	—	(1,000)	—
Increase in restricted cash	—	(500)	—	(2,500)
Lease payments	(110)	—	(223)	—
Lender royalty payment	—	(125)	—	(237)
Cash provided by (used in) financing activities	32,705	(7,263)	29,341	1,415
Net increase (decrease) in cash and cash equivalents during the period	39,304	(8,179)	41,147	9,650
Foreign currency translation	192	(409)	231	(632)
Cash and cash equivalents, beginning of period	12,812	53,825	10,930	36,219
Cash and cash equivalents, end of period	52,308	45,237	52,308	45,237

SOURCE HLS Therapeutics Inc.

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