HLS Therapeutics Inc.

HLS Therapeutics Announces Q3 2019 Financial Results

- **Revenue of $13.4 million, Adjusted EBITDA of $8.0 million and Cash from Operations of $6.8 million**
- **Paid a quarterly dividend of C$0.05 per outstanding common share**
- **Subsequent to quarter-end, received approval from Health Canada for the CSAN® Pronto™ point-of-care blood testing medical device**

TORONTO, Nov. 7, 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 nine-month periods ended September 30, 2019 ("Q3 2019" and "YTD 2019"). All amounts are in thousands of United States ("U.S.") dollars unless otherwise stated.

Q3 FISCAL 2019 HIGHLIGHTS

- Cash from operations was $6.8 million compared to $6.4 million in Q3 2018;
- Revenue was $13.4 million compared to $15.3 million in Q3 2018;
- Adjusted EBITDA was $8.0 million compared to $10.3 million in Q3 2018;
- Net loss was ($2.0) million, or ($0.06) per common share, compared to net loss of ($19.7) million, or ($0.72) per common share, in Q3 2018;
- Cash and cash equivalents of $51.3 million at the end of Q3 2019;
- Paid a quarterly dividend of C$0.05 per outstanding common share; and
- Subsequent to quarter-end, received a medical device license from Health Canada for the CSAN® Pronto™ point-of-care blood testing device for treatment-resistant schizophrenia patients using Clozaril.

"Q3 was another solid quarter with our business once again generating sequentially stable and consistent Adjusted EBITDA and cash flow," said Greg Gubitz, CEO of HLS Therapeutics. "As expected, we had a strong July with a boost from the Canadian-based Clozaril sales that came in on the last day of Q2 and were delivered in Q3; however, through August and September, and to a lesser extent through the first nine months of the year, we saw certain institutional clients draw-down on their inventory, which impacted overall sales volumes. Nevertheless, the outlook for Clozaril remains strong. The number of Clozaril patients in Canada continues to trend higher, up approximately 2% year-over-year, and subsequent to quarter-end Health Canada granted us a medical device license for the CSAN Pronto device. These two factors give us strong confidence in the growth potential of the product in Canada."

"Having received the medical device license from Health Canada in mid-October, the roll-out for CSAN Pronto is now underway. We have expanded our product portfolio with this device to address the number one barrier to the use of Clozapine-based medications. These products are underutilized in Canada compared to some industrialized countries where they are prescribed at rates up to three times greater. We believe that CSAN Pronto has the potential to reduce barriers and improve access to Clozaril, a proven treatment for treatment-resistant schizophrenia, and in doing so, to enhance the lives of patients who must contend with this challenging condition."

"Looking toward year-end, Q4 is expected to be an exciting period for HLS. Health Canada's priority review of Vascepa® remains underway and we expect to receive their response around the end of December. As we've said previously, we believe Vascepa has the potential to transform our business and have conservatively estimated its potential peak revenue range at C$150-250 million per year, should it achieve regulatory approval. Other potential milestones in 2019 include the filing with Health Canada of two more products from our portfolio. We expect to submit filings for both Trinomia® (indicated for the secondary prevention of cardiovascular events) and PERSERIS® (a once-monthly risperidone long-acting injectable, which is a commercially complementary product to Clozaril). We look forward to reporting updates on these important developments in the coming months."

DIVIDEND

On November 6, 2019, the Company's Board of Directors declared a dividend of C$0.05 per outstanding common share to be paid on March 13, 2020, to shareholders of record as of January 31, 2020.

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 nine-month periods ended September 30, 2019:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Product sales				
Canada	6,851	7,130	20,136	21,661
United States	4,257	5,584	13,027	15,188
	11,108	12,714	33,163	36,849
Royalty revenue	2,318	2,569	7,060	7,905
	13,426	15,283	40,223	44,754

In the Canadian market, during 2019 the number of patients taking Clozaril has grown steadily year-over-year. Despite this increase, Clozaril revenue in Q3 2019 was 4% below Q3 2018 revenue due to changes in provincial purchasing directives for Ontario hospitals, resulting in certain distributors and hospitals drawing down inventories, as well as exchange-rate fluctuations, resulting in lower revenues when results were translated to U.S. dollars. These factors accounted for 3% and 1% of the year-over-year change, respectively. While experiencing fluctuations from quarter-to-quarter in 2019, the Company expects long-term results to positively reflect the stable growth trend in the number of Canadian Clozaril patients as well as the long term impact of the CSAN Pronto medical device, which received approval from Health Canada subsequent to quarter-end.

Year-to-date, branded Clozaril continues to experience modest volume declines in the U.S. market, consistent with management expectations. Product sales in the U.S. declined $1.3 million in Q3 2019 compared to the same period in the prior year, but more than half of this decline is attributable to the discontinuation of the authorized generic supply agreement, which took place in Q4 2018. Product sales in the prior year period also benefited from more favorable gross-to-net adjustments in the prior year. The Company's U.S. pilot program for the Pronto device (known in the U.S. as the Athelas One WBC System), in use together with clozapine, remains ongoing with more than 700 patients utilizing the device. HLS will complete its pilot program and determine its go-forward U.S.-based strategy for the device in early 2020.

Absorica royalty revenue was $2.3 million in Q3 2019 compared to $2.6 million in Q3 2018. After considerable volatility in past years, it appears that Absorica prescription activity in the U.S. market is now relatively stable. 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 September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Cost of product sales	538	887	1,448	2,003
Selling and marketing	1,600	933	4,228	2,943
Medical, regulatory and patient support	1,156	1,131	3,767	3,284
General and administrative	2,087	2,058	6,373	6,619
	5,381	5,009	15,816	14,849

Cost of product sales for Clozaril in 2019 continue to be stable and low relative to revenues, benefiting from economies-of-scale related to Canadian sales volumes and other improved manufacturing costs from the Company's supply chain operations. Higher cost of product sales in the prior year related to Clozaril included the cost of additional product sold under the former authorized generic supply agreement in the U.S.

For both the third quarter of 2019 and the year-to-date period, the year-over-year increases in other operating expenses are driven primarily by the additional activity to prepare and support the planned introductions of Vascepa and CSAN Pronto.

Adjusted EBITDA

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Net loss for the period	(1,998)	(19,736)	(7,332)	(25,175)
Stock-based compensation	659	308	1,727	525
Amortization and depreciation	8,135	8,078	24,356	24,353
Acquisition and transaction costs	31	215	630	748
Finance and related costs, net	1,068	25,217	5,381	34,341
Income tax expense (recovery)	150	(3,808)	(355)	(4,887)
Adjusted EBITDA	8,045	10,274	24,407	29,905

For the quarter and year-to-date periods, the decrease in Adjusted EBITDA reflects the decrease in Clozaril product sales, lower Absorica royalty revenues, and the increase in pre-commercialization selling and marketing costs tied to preparations for the introduction of Vascepa and CSAN Pronto.

Interest Expense and Debt

Interest on the senior secured term loan in Q3 2019 was $1.4 million compared to $2.7 million in Q3 2018. For the YTD 2019 period, interest expense was $4.5 million compared to $10.8 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 September 30, 2019, the principal debt balance outstanding under the new senior secured term facility was $95.0 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 loan balance at the end of Q2 2018 just prior to the Company restructuring its debt.

Net Loss

Net loss in Q3 2019 was ($2.0) million, or ($0.06) per share, compared to a net loss of ($19.7) million, or ($0.72) per share in Q3 2018. For the YTD 2019 period, net loss was ($7.3) million, or ($0.25) per share, compared to ($25.2) million, or ($0.94) per share in the same period last year. Net loss improved year-over-year primarily due to costs incurred in Q3 2018 related to the refinancing of the Company's debt as well as lower interest expense paid throughout 2019 resulting from that refinancing.

Cash from Operations and Financial Position

Cash generated from operations was $6.8 million in Q3 2019, compared to $6.4 million in Q3 2018. For the YTD 2019 period, cash generated from operations was $24.1 million compared to $21.6 million in the same period last year.

As at September 30, 2019, the Company had cash and cash equivalents of $51.3 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.

Q3 FISCAL 2019 CONFERENCE CALL

HLS will hold a conference call today at 8:30 am Eastern Time to discuss its Q3 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, November 7, 2019
TIME:	8:30 am ET
DIAL-IN NUMBER:	(888) 231-8191 or (647) 427-7450
WEBCAST LINK:	https://event.on24.com/wcc/r/2113583/D4010441D361BC9EF6D19A5586585E09
TAPED REPLAY:	(855) 859-2056 or (416) 849-0833

REPLAY PASSCODE: 2586435

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 September 30, 2019	As at December 31, 2018
ASSETS		
Current		
Cash and cash equivalents	51,343	10,930
Accounts receivable	9,618	17,509
Inventories	1,835	1,505
Foreign currency forward contract	76	755
Prepaid expenses and other current assets	1,777	919
Total current assets	64,649	31,618
Property, plant and equipment	1,307	363
Intangible assets	254,189	271,153
Restricted assets	2,190	2,290
Deferred income tax asset	1,023	1,001
Total assets	323,358	306,425
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current		
Accounts payable and accrued liabilities	11,907	12,405
Provisions	5,800	6,574
Debt and other financial liabilities	18,300	18,920
Income taxes payable	294	369
Total current liabilities	36,301	38,268
Debt and other financial liabilities	95,167	104,459
Deferred income tax liability	3,347	5,209
Total liabilities	134,815	147,936
Shareholders' equity		
Share capital	245,314	210,360
Contributed surplus	14,434	12,973
Accumulated other comprehensive loss	(3,135)	(7,455)
Deficit	(68,070)	(57,389)
Total shareholders' equity	188,543	158,489
Total liabilities and shareholders' equity	323,358	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 September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Revenue	13,426	15,283	40,223	44,754
Expenses				
Cost of product sales	538	887	1,448	2,003
Selling and marketing	1,600	933	4,228	2,943
Medical, regulatory and patient support	1,156	1,131	3,767	3,284
General and administrative	2,087	2,058	6,373	6,619
Stock-based compensation	659	308	1,727	525
Amortization and depreciation	8,135	8,078	24,356	24,353
Operating income (loss)	(749)	1,888	(1,676)	5,027
Acquisition and transaction costs	31	215	630	748
Finance and related costs, net	1,068	25,217	5,381	34,341

Loss before income taxes	(1,848)	(23,544)	(7,687)	(30,062)
Income tax expense (recovery)	150	(3,808)	(355)	(4,887)
Net loss for the period	(1,998)	(19,736)	(7,332)	(25,175)
Net loss per share:				
Basic and diluted	$(0.06)	$(0.72)	$(0.25)	$(0.94)

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Net loss for the period	(1,998)	(19,736)	(7,332)	(25,175)
Item that may be reclassified subsequently to net loss				
Unrealized foreign currency translation adjustment	(1,848)	2,770	4,320	(5,418)
Comprehensive loss for the period	(3,846)	(16,966)	(3,012)	(30,593)

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
Stock options exercised	1	—	—	—	1
Warrants granted	—	470	—	—	470
Stock option expense	—	991	—	—	991
Net loss for the period	—	—	—	(7,332)	(7,332)
Dividends declared	—	—	—	(3,349)	(3,349)
Unrealized foreign currency translation adjustment	—	—	4,320	—	4,320
Balance, September 30, 2019	245,314	14,434	(3,135)	(68,070)	188,543
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	(1,036)	—	—	112	(924)
Stock option expense	—	395	—	—	395
Net loss for the period	—	—	—	(25,175)	(25,175)
Dividends declared	—	—	—	(1,047)	(1,047)
Unrealized foreign currency translation adjustment	—	—	(5,418)	—	(5,418)
Balance, September 30, 2018	210,360	12,725	523	(56,742)	166,866

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
OPERATING ACTIVITIES				
Net loss for the period	(1,998)	(19,736)	(7,332)	(25,175)
Adjustments to reconcile net loss to cash provided by operating activities				
Stock option expense	478	178	991	395
Amortization and depreciation	8,135	8,078	24,356	24,353
Debt refinancing costs		18,951	—	18,951
Accreted interest	456	1,050	1,554	4,282
Fair value adjustment on financial assets and liabilities	(788)	2,535	655	(140)
Listing expense	—	—	—	435
Deferred income taxes	(218)	(4,029)	(1,322)	(5,697)
Net change in non-cash working capital balances related to operations	760	(623)	5,161	4,187
Cash provided by operating activities	6,825	6,404	24,063	21,591
INVESTING ACTIVITIES				
Additions to property, plant and equipment	(45)	(2)	(139)	(92)
Deferred purchase obligation payments	(2,825)	(2,825)	(7,475)	(9,475)
Other additions to intangible assets	(1,975)	(107)	(2,663)	(319)
Cash used in investing activities	(4,845)	(2,934)	(10,277)	(9,886)
FINANCING ACTIVITIES				
Common shares issued	—	—	37,329	19,470
Common share issuance costs	(302)	—	(2,579)	(1,699)
Stock options exercised	1	—	1	—
Warrants exercised	—	—	35	—
Common shares repurchased	—	(686)	—	(924)
Dividends paid	(1,166)	—	(3,189)	—
Repayment of senior secured term loan	(1,250)	(137,890)	(3,750)	(151,271)
Drawdown of senior secured term loan	—	100,000	—	100,000
Cash portion of debt refinancing costs	—	(8,453)	(1,000)	(8,453)
Decrease in restricted cash	—	8,055	—	5,555
Lease payments	(98)	—	(321)	—
Lender royalty payment	—	—	—	(237)
Cash provided by (used in) financing activities	(2,815)	(38,974)	26,526	(37,559)
Net increase (decrease) in cash and cash equivalents during the period	(835)	(35,504)	40,312	(25,854)
Foreign exchange	(130)	174	101	(458)
Cash and cash equivalents, beginning of period	52,308	45,237	10,930	36,219
Cash and cash equivalents, end of period	51,343	9,907	51,343	9,907

SOURCE HLS Therapeutics Inc.

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