HLS Therapeutics Inc.

HLS Therapeutics Announces Q1 2019 Financial Results

- **Revenue of $13.2 million, Adjusted EBITDA of $8.3 million and Cash from Operations of $8.3 million**
- **Granted priority review status for Vascepa™ by Health Canada, which could reduce the review period for the drug by up to four-and-a-half months. Announced the filing of the New Drug Submission ("NDS") for Vascepa with Health Canada on April 29, 2019**
- **Announced the in-licensing of the exclusive Canadian rights for CSAN® *Pronto*™, a point-of-care medical device intended to simplify the blood monitoring process for patients that are prescribed Clozaril®**
- **Subsequent to quarter-end, entered into a license for the Canadian rights to PERSERIS™, a novel long-acting injectable risperidone product for the treatment of schizophrenia**

TORONTO, May 9, 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-month period ended March 31, 2019 ("Q1 2019"). All amounts are in thousands of United States ("U.S.") dollars unless otherwise stated.

Q1 FISCAL 2019 HIGHLIGHTS

- Revenue was $13.2 million compared to $13.2 million in Q1 2018;
- Adjusted EBITDA was $8.3 million compared to $8.6 million in Q1 2018;
- Cash from operations was $8.3 million compared to $13.5 million in Q1 2018;
- Net loss of $(3.7) million, or $(0.14) per common share, compared to net loss of $(4.9) million, or $(0.19) per common share, in Q1 2018;
- Granted priority review status for Vascepa by Health Canada, which could reduce the review period for the drug by up to four-and-a-half months. Announced the filing of the NDS for Vascepa with Health Canada on April 29, 2019;
- Amarin released new data showing that Vascepa™ provided a statistically significant 30% risk reduction in total (first and subsequent) cardiovascular events compared to placebo in the statin-treated patient population studied in REDUCE-IT;
- Announced the in-licensing of the exclusive Canadian rights for CSAN® *Pronto*™, a point-of-care medical device that may help to simplify the mandatory blood safety monitoring process for patients that are prescribed Clozaril®. The device was accepted for review by Health Canada on March 13, 2019;
- Appointed experienced healthcare executive Laura A. Brege to the Board of Directors and Audit Committee;
- Graduated to the Toronto Stock Exchange;
- Paid a dividend of C$0.05 per outstanding common share on March 15, 2019, and declared a dividend of C$0.05 per outstanding common share on March 20, 2019, payable on June 14, 2019 to shareholders of record on April 30, 2019; and
- Subsequent to quarter-end, acquired a license for the Canadian rights to PERSERIS™, a novel long-acting injectable risperidone product for the treatment of schizophrenia.

"Q1 was a solid start to the year with good financial performance from our foundational products, positive new developments with Vascepa and the promising expansion of our product portfolio," said Greg Gubitz, CEO of HLS. "Regarding Vascepa, we were granted priority review status by Health Canada, which could significantly reduce the timeline to bring this innovative therapy to Canadians. Subsequent to quarter-end, on April 29, 2019, we announced that we had filed our NDS for Vascepa with Health Canada."

"Also, during Q1, Amarin released new data from the REDUCE-IT™ trial, indicating that Vascepa reduced total major adverse cardiac events—first and subsequent—by 30% compared to placebo over a five-year period, which further demonstrates significant risk reduction with the product. In addition, in March, the American Diabetes Association issued updates to their Standards of Medical Care in Diabetes for 2019 stating that for patients with diabetes and atherosclerotic cardiovascular disease or other cardiac risk factors that are on a statin with controlled low-density cholesterol (LDL-C), but elevated triglycerides (135-499), the addition of icosapent ethyl (Vascepa) should be considered to reduce cardiovascular risk. We are excited with the prospects for Vascepa and we believe that, if approved, it could ultimately generate revenue in Canada in a range of CDN $150-250 million per year. We believe this a conservative view and these new developments give us greater confidence in our outlook."

"While we are focused on execution and excited with the prospects for Vascepa, we continue to pursue opportunities to expand our product portfolio. In Q1 we in-licensed the exclusive Canadian rights for CSAN Pronto, which is designed to help simplify the mandatory safety blood-monitoring process for patients that are

prescribed Clozaril, or clozapine. The conventional blood-monitoring process has been cited as a major barrier leading to the under-utilization of clozapine. By providing a less invasive safety monitoring procedure that uses just a single drop of blood from a finger prick at the point-of-care and that produces results on the spot, we believe the technology can benefit both patients and the medical practitioners who treat them and could improve access to a proven treatment."

"Today, we are also announcing that we have acquired 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. With PERSERIS, we see an opportunity to help improve treatment adherence for schizophrenia patients in Canada with a clinically meaningful registration-stage psychiatric product that would be complementary to Clozaril. In our view, this product could bring a treatment option to patients and practitioners contending with a very difficult disease state and extends our presence in CNS, one of our two core markets."

DIVIDEND

On May 8, 2019, the Company's Board of Directors declared a dividend of C$0.05 per outstanding common share to be paid on September 13, 2019, to shareholders of record as of July 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-month period ended March 31, 2019:

	Three months ended March 31,	
	2019	**2018**
Product sales		
Canada	6,387	6,759
United States	4,275	4,872
	10,662	11,631
Royalty revenue	2,510	1,535
	13,172	13,166

In the Canadian market, Clozaril is actively managed by a team of HLS employees who support a growing number of patients. The first quarter tends to be a seasonally slow quarter for Clozaril. Clozaril results in Q1 2019 were in-line with expectations following a very strong Q4 2018 and essentially flat compared to a year ago in Canadian dollar terms. As a result of fluctuations in exchange rates, Clozaril product sales decreased by 5.5% for the quarter when the results were translated to U.S. dollars.

Clozaril continued to experience modest volume declines in the U.S. market, mitigated by a nominal price increase, resulting in a modest increase in Clozaril gross revenues in Q1 2019 compared to Q1 2018. However, overall product sales in the U.S. market decreased in Q1 2019, as the comparison period benefitted from an adjustment to government rebate accruals and there were no authorized generic supplies in the current period; this was partially off-set by lower than projected returns for expired products.

Royalty revenues increased by $1.0 million in Q1 2019 compared to Q1 2018. This increase reflects the inventory drawdown that occurred in early 2018 following the end of the 2017 promotional campaign undertaken by the distributor of Absorica in the U.S.

Operating Expenses

	Three months ended March 31,	
	2019	**2018**
Cost of product sales	387	580
Selling and marketing	1,193	964

Medical, regulatory and patient support	1,213	977
General and administrative	2,122	2,053
	4,915	4,574

Cost of product sales decreased in the first quarter of 2019 in-line with reduced authorized generic supplies and improved manufacturing costs as a result of the completion of the manufacturing transition for the U.S. market.

The year-over-year increase in other operating expenses was driven primarily by higher patient registry program costs, following a temporary reduction in these costs in the earlier period, additional commercial activity to prepare and support the planned introductions of Vascepa and CSAN Pronto to the Canadian market, and additional public company costs.

Adjusted EBITDA

	Three months ended March 31,	
	2019	**2018**
Net loss for the period	(3,703)	(4,876)
Stock-based compensation	597	94
Amortization and depreciation	8,118	8,141
Acquisition and transaction costs	421	435
Finance and related costs	3,217	5,567
Income tax recovery	(393)	(769)
Adjusted EBITDA	8,257	8,592

The year-over-year decrease in Adjusted EBITDA is due to higher selling and marketing, and medical, regulatory and patient-support costs related primarily to the Company's growth initiatives, partially off-set by lower cost of product sales. Adjusted EBITDA is a non-IFRS measure and is defined below.

Interest Expense and Debt

Interest on the senior secured term loan was $1.6 million compared to $4.1 million in Q1 2018. 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 March 31, 2019, the principal debt balance outstanding under the new senior secured term facility was $97.5 million compared to $98.75 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 Q1 2019 was $(3.7) million, or $(0.14) per share, compared to a net loss of $(4.9) million, or $(0.19) per share in Q1 2018. Net loss improved year-over-year due primarily to the $2.5 million decrease in interest expense resulting from the debt refinancing completed in August 2018, offset in part by an increase in operating expenses related primarily to the Company's growth initiatives.

Cash from Operations and Financial Position

Cash generated from operations was $8.3 million in Q1 2019, compared to $13.5 million in Q1 2018. Cash generated from operations in Q1 2018 benefited from collections related to Absorica royalty revenue generated in Q4 2017 during the distributor-led promotional campaign for the product. The promotional campaign was completed in 2017.

As at March 31, 2019, the Company had cash and cash equivalents of $12.8 million, up from $10.9 million at December 31, 2018.

Q1 FISCAL 2019 CONFERENCE CALL

HLS will hold a conference call today at 8:30 am Eastern Time to discuss their Q1 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, May 9, 2019
TIME:	8:30 am ET
DIAL-IN NUMBER:	(888) 231-8191 or (647) 427-7450
WEBCAST LINK:	https://event.on24.com/wcc/r/1987816/76C621B2E222AE96A4EE50B4350FECB5
TAPED REPLAY:	(855) 859-2056 or (416) 849-0833
REPLAY PASSCODE:	1739143

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.

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 March 31, 2019	As at December 31, 2018
ASSETS		
Current		
Cash and cash equivalents	12,812	10,930
Accounts receivable	13,344	17,509
Inventories	1,560	1,505
Foreign currency forward contract	401	755
Prepaid expenses and other current assets	856	919
Total current assets	28,973	31,618
Property, plant and equipment	1,288	363
Intangible assets	266,343	271,153
Restricted assets	2,258	2,290
Deferred tax asset	958	1,001
Total assets	299,820	306,425
Current		
Accounts payable and accrued liabilities	10,591	12,405
Provisions	6,739	6,574
Debt and other financial liabilities	19,190	18,920
Income taxes payable	251	369
Total current liabilities	36,771	38,268
Debt and other financial liabilities	101,476	104,459
Deferred tax liability	4,617	5,209
Total liabilities	142,864	147,936
Shareholders' equity		
Share capital	210,360	210,360
Contributed surplus	13,207	12,973
Accumulated other comprehensive loss	(4,497)	(7,455)
Deficit	(62,114)	(57,389)
Total shareholders' equity	156,956	158,489
Total liabilities and shareholders' equity	299,820	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 March 31, 2019	March 31, 2018
Revenues	13,172	13,166
Expenses		
Cost of product sales	387	580
Selling and marketing	1,193	964
Medical, regulatory and patient support	1,213	977

General and administrative	2,122	2,053
Stock-based compensation	597	94
Amortization and depreciation	8,118	8,141
Operating income (loss)	(458)	357
Acquisition and transaction costs	421	435
Finance and related costs, net	3,217	5,567
Loss before income taxes	(4,096)	(5,645)
Income tax recovery	(393)	(769)
Net loss for the period	(3,703)	(4,876)
Net loss per share:		
Basic and diluted	$(0.14)	$(0.19)

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

	Three months ended	
	March 31, 2019	**March 31, 2018**
Net loss for the period	(3,703)	(4,876)
Item that may be reclassified subsequently to net loss		
Unrealized foreign currency translation adjustment	2,958	(4,620)
Comprehensive loss for the period	(745)	(9,496)

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
Stock option expense	—	234	—	—	234
Net loss for the period	—	—	—	(3,703)	(3,703)
Dividends declared	—	—	—	(1,022)	(1,022)
Unrealized foreign currency translation adjustment	—	—	2,958	—	2,958
Balance, March 31, 2019	210,360	13,207	(4,497)	(62,114)	156,956
Balance, December 31, 2017	192,743	12,330	5,941	(30,632)	180,382
Common shares issued	19,905	—	—	—	19,905
Share issuance costs	(1,166)	—	—	—	(1,166)
Stock option expense	—	94	—	—	94
Net loss for the period	—	—	—	(4,876)	(4,876)
Unrealized foreign currency translation adjustment	—	—	(4,620)	—	(4,620)
Balance, March 31, 2018	211,482	12,424	1,321	(35,508)	189,719

HLS THERAPEUTICS INC.

CONDENSED INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS
Unaudited

[in thousands of U.S. dollars]

	Three months ended March 31,	
	2019	**2018**
OPERATING ACTIVITIES		
Net loss for the period	(3,703)	(4,876)
Adjustments to reconcile net loss to cash provided by operating activities		
Stock option expense	234	94
Amortization and depreciation	8,118	8,141
Accreted interest	568	1,629
Fair value adjustment on financial assets and liabilities	1,273	(450)
Listing expense	—	435
Deferred income taxes	(655)	(889)
Net change in non-cash working capital balances related to operations	2,447	9,416
Cash provided by operating activities	8,282	13,500
INVESTING ACTIVITIES		
Additions to property, plant and equipment	(37)	(24)
Acquisitions	(2,825)	(4,325)
Other additions to intangible assets	(213)	—
Cash used in investing activities	(3,075)	(4,349)
FINANCING ACTIVITIES		
Common shares issued	—	19,470
Share issuance costs	—	(1,576)
Dividends paid	(1,001)	—
Repayment of senior secured term loan	(1,250)	(7,104)
Cash portion of debt refinancing costs	(1,000)	—
Increase in restricted cash	—	(2,000)
Lease payments	(113)	—
Lender royalty payment	—	(112)
Cash provided by (used in) financing activities	(3,364)	8,678
Net increase in cash and cash equivalents during the period	1,843	17,829
Foreign exchange	39	(223)
Cash and cash equivalents, beginning of period	10,930	36,219
Cash and cash equivalents, end of period	12,812	53,825

SOURCE HLS Therapeutics Inc.

For further information: HLS CONTACT INFORMATION: Dave Mason, Investor Relations, HLS Therapeutics Inc., (416) 247-9652, dave.mason@loderockadvisors.com; Gilbert Godin, President and Chief Operating Officer, HLS Therapeutics Inc., (484) 232-3400 ext101, g.godin@hlstherapeutics.com

https://hlstherapeutics.investorroom.com/2019-05-09-HLS-Therapeutics-Announces-Q1-2019-Financial-Results