

HLS Therapeutics Announces Fourth Quarter and Fiscal 2020 Financial Results

- **Fourth quarter revenue of \$16.5 million, Adjusted EBITDA of \$8.7 million and cash from operations of \$5.8 million**
- **Produced strong Vascepa® prescription growth amid COVID-19 challenges: more than 2,000 patients and more than 550 prescribers at end of Q4, which are increases of more than 70% and 55%, respectively, from the end of Q3**
- **As of March 18, 2021, reached agreement with private insurers in Canada, representing > 90% of privately covered lives, to provide reimbursement coverage for Vascepa**

TORONTO, March 18, 2021 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX: HLS), a specialty pharmaceutical company focusing on central nervous system ("CNS") and cardiovascular markets, announces its financial results for the three- and twelve-month periods ended December 31, 2020. All amounts are in thousands of United States ("U.S.") dollars unless otherwise stated.

Q4 & FISCAL 2020 FINANCIAL HIGHLIGHTS

- Q4 2020 revenue was \$16.5 million compared to \$13.9 million in Q4 2019; Fiscal 2020 revenue was \$56.1 million compared to \$54.2 million in 2019.
- Q4 2020 Adjusted EBITDA was \$8.7 million compared to \$7.2 million in Q4 2019; Fiscal 2020 Adjusted EBITDA was \$24.1 million compared to \$31.6 million in 2019, which reflects investment in the launch of Vascepa.
- Q4 2020 net loss was (\$7.3) million, or (\$0.23) per common share, compared to net loss of (\$12.2) million, or (\$0.40) per common share, in Q4 2019; Fiscal 2020 net loss was (\$15.3) million, or (\$0.48) per common share, compared to net loss of (\$19.6) million, or (\$0.67) per common share, in 2019.
- Q4 2020 cash generated from operations was \$5.8 million compared to \$2.3 million in Q4 2019; Fiscal 2020 cash generated from operations was \$9.3 million compared to \$26.4 million in 2019, which reflects investment in the launch of Vascepa.
- Cash and cash equivalents were \$20.6 million as at December 31, 2020 compared to \$47.1 million at December 31, 2019.

Q4 & FISCAL 2020 BUSINESS HIGHLIGHTS

- Vascepa was added to Health Canada's Register of Innovative Drugs and as a result the product will benefit from data protection for a term of eight years.
- Launched Vascepa in the Canadian market.
- CADTH recommended Vascepa be reimbursed for patients with established cardiovascular disease.
- PMPRB notified HLS that Vascepa's introductory price submission is compliant.
- Increased the peak-year sales estimate for Vascepa to C\$275-325 million, from C\$150-250 million.
- Launched CSAN Pronto in the Canadian market.
- Acquired a portfolio of four royalty interests that is forecasted to generate average annual Adjusted EBITDA of \$11.0 million per year for a ten-year period.
- Health Canada approved the use of PERSERIS®, a novel long-acting injectable of risperidone, for the treatment of schizophrenia in adults.
- Health Canada approved MyCare™ Psychiatry Lab Assays for use in diagnostic lab settings to measure blood levels in patients prescribed six of the most common antipsychotic drugs.
- Co-founder Gilbert Godin succeeded retiring CEO and co-founder Greg Gubitz.
- Announced a Normal Course Issuer Bid to purchase up to 5% of the Company's issued and outstanding Common Shares.

"Q4 was a strong finish to a year in which we made progress on launching significant growth drivers for the business, despite the challenges posed by the COVID-19 pandemic, as exemplified by multiple lockdowns across Canada, including in the two largest provinces during November and December," said Gilbert Godin, CEO of HLS. "Our financial results reflect the resilience and strength of Clozaril as well as our new royalty portfolio, which together serve as our foundational products. The reliable cash flow received from these products enables us to invest in the expansion of our product portfolio and in the significant organic growth potential of transformational products, such as Vascepa."

"In February, we launched Vascepa and during the year we achieved a number of important milestones that help provide greater visibility towards reaching our peak-year sales estimate for the product. Among those milestones, Vascepa was granted data protection for eight years, it received a favorable reimbursement recommendation from CADTH, a favorable notification from the PMPRB on pricing and, as of today, we have reached agreements with private insurers representing more than 90% of privately covered lives in Canada to reimburse Vascepa for patients in-label."

"While COVID-19 has had an impact on our launch efforts - restricting face-to-face interactions with practitioners and broadly limiting patient visits to doctors' offices - we are still making undeniable progress as evidenced by the growing number of prescribers and patients, and overall, the number of prescriptions that have been written. Cardiovascular disease remains the number one killer worldwide, indicating that there is strong need for a product like Vascepa that has shown 25-30% relative risk reduction of a major adverse cardiac event, including death¹."

"We also made progress in 2020 adding other products to our portfolio and advancing them towards commercialization."

PERSERIS and the MyCare Psychiatry Lab Assays are products in the CNS therapeutic market, and both were approved by Health Canada in Q4. Both products are novel treatment options for practitioners and can leverage our existing commercial infrastructure, relationships and reach in the Canadian psychiatric market. We expect to have both in the market in the second half of 2021. With Trinomia, Health Canada advised they would wait for results of an ongoing clinical trial involving the product, which is expected to finish at the end of this year. Following completion of that trial, we will be in a better position to determine the regulatory path forward for the product. Finally, we added a diversified portfolio of royalty interests on the global sales of four significant products that are already contributing meaningfully to our results."

DIVIDEND

On March 17, 2021, the Company's Board of Directors declared a dividend of C\$0.05 per outstanding common share to be paid on June 15, 2021, to shareholders of record as of April 30, 2021.

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).

Q4 & FISCAL 2020 FINANCIAL REVIEW

The Company's Management's Discussion and Analysis and Consolidated Financial Statements for the three- and twelve-month periods ended December 31, 2020 are available at the [Company's website](#) and at its profile at [SEDAR](#).

Revenue

The following table provides revenue segmentation by revenue type for the three- and twelve-month periods ended December 31, 2020:

	Three months ended		Year ended	
	December 31,	December 31,	December 31,	December 31,
	2020	2019	2020	2019
Product sales				
Canada	7,656	7,023	29,393	27,159
United States	4,198	4,406	16,265	17,433
	11,854	11,429	45,658	44,592
Royalty revenue	4,631	2,508	10,451	9,568
	16,485	13,937	56,109	54,160

Product Sales

The Company's product sales grew by 2% in fiscal 2020, led by 8% growth in product sales in Canada, despite the continued impact of the COVID-19 pandemic. These results reflect the resiliency of the Company's Clozaril franchises in Canada and the U.S. as well as the introduction of Vascepa in Canada.

Despite additional pandemic-related restrictions in major markets within Canada in Q4 2020, the number of Clozaril patients in Canada grew approximately 2% year-over-year. Q4 2020 Clozaril product sales in Canada were essentially flat compared to Q4 2019. Excluding the impact of trade inventory adjustments and the impact of the timing of deliveries around the year-end holidays on revenue recognition, Clozaril revenue growth in the quarter would have been consistent with the steady growth in patients. Steady growth in the number of Canadian physicians prescribing Vascepa as well as in the number of patients taking the medication has resulted in an increase to Vascepa product sales, which grew 42% sequentially in Q4 2020 compared to Q3 2020.

Royalty revenues

Absorica royalty revenue was \$8.1 million for fiscal 2020, down \$1.5 million from \$9.6 million in fiscal 2019. HLS terminated its ownership of these marketing rights effective December 31, 2020, in line with its previously disclosed intention to do so.

On September 30, 2020, HLS acquired a diversified portfolio of royalty interests on global sales of four different products. The portfolio generated royalty revenues of \$2.3 million in Q4 2020 and HLS realized a gain of \$0.5 million as actual royalties received for Q3 2020 were in excess of the estimated acquired royalty receivable. Initial results are tracking ahead of the Company's expectations as total royalties received or receivable by HLS for the six-month period from July 1, 2020 to December 31, 2020 were \$4.8 million, of which \$2.3 million has been included in royalty revenues.

Operating Expenses

	Three months ended		Year ended	
	December 31,	December 31,	December 31,	December 31,
	2020	2019	2020	2019
Cost of product sales	1,311	484	3,625	1,932
Selling and marketing	3,260	2,028	12,900	6,256
Medical, regulatory and patient support	1,284	1,520	5,467	5,287

General and administrative	2,403	2,669	10,487	9,042
	8,258	6,701	32,479	22,517

The cost of product sales increased in fiscal 2020 as a result of the introduction of Vascepa and CSAN Pronto in Canada. Selling and marketing activities increased by \$6.6 million in fiscal 2020 relative to last year, reflecting the additional costs related to the introduction of Vascepa in Canada, which included the salesforce expansion at the start of the year, as well as the roll-out of CSAN Pronto. The \$1.5 million increase in general and administrative costs included \$1.3 million of expense associated with the retirement of the Company's founding CEO. For Q4 2020, operating expenses increased by \$1.6 million compared to Q4 2019. Increases in selling and marketing costs primarily related to the introduction of Vascepa accounted for \$1.2 million of this increase.

Adjusted EBITDA²

	Three months ended December 31,		Year ended December 31,	
	2020	2019	2020	2019
Net loss for the period	(7,278)	(12,220)	(15,331)	(19,552)
Stock-based compensation	2,420	2,034	2,531	3,761
Amortization and depreciation	9,513	8,154	33,186	32,510
Acquisition and transaction costs	152	327	709	957
Finance and related costs	3,372	9,497	4,012	14,878
Income tax expense (recovery)	557	(556)	(968)	(911)
Adjusted EBITDA	8,736	7,236	24,139	31,643

Adjusted EBITDA for fiscal 2020 decreased by \$7.5 million compared to the prior year due to the \$10.0 million increase in operating expenses, which were primarily the result of the increase in the selling and marketing costs to support the Vascepa launch in Canada. The financial contribution in fiscal 2020 from the growth of Clozaril and Vascepa product sales in Canada and the addition of the acquired portfolio of royalty interests were more than sufficient to off-set the impact on Adjusted EBITDA of the erosion of Clozaril product sales in the US market and the decline in the final year of the Absorica royalty revenues.

Adjusted EBITDA for Q4 2020 increased by \$1.5 million from Q4 2019. The increase was primarily due to \$2.3 million of revenue from the acquisition of the portfolio of royalty interests, growth in Canadian product sales and the realized gain of \$0.5 million on the acquired royalty receivable, offset in part by the \$1.6 million increase in operating expenses.

(2) See "Cautionary Note Regarding Non-IFRS Measures" section of this press release.

Net Loss

Net loss for the Q4 2020 and fiscal 2020 periods was (\$7.3) million, or (\$0.23) per share, and (\$15.3) million, or (\$0.48) per share, compared to (\$12.2) million, or (\$0.40) per share, and (\$19.6) million, or (\$0.67) per share, in the prior year periods. Net loss decreased in 2020, primarily due to higher revenue and lower finance and related costs, offset in part by higher operating expenses to support the launch of Vascepa and CSAN Pronto.

Cash from Operations and Financial Position

Cash generated from operations was \$5.8 million in Q4 2020, compared to cash generated from operations of \$2.3 million in Q4 2019. For fiscal 2020, cash generated from operations was \$9.3 million compared to \$26.4 million in the same period last year. The decrease in the 2020 periods is attributable to the expenditures associated with the launch of Vascepa, including the purchase of inventory, and the launch of CSAN Pronto.

As at December 31, 2020, the Company had cash and cash equivalents of \$20.6 million compared to \$47.1 million at December 31, 2019. Factors impacting the change in cash balance since the end of 2019 include increased selling and marketing costs related to Vascepa's launch, initial inventory purchases for the product, the purchase of the royalty portfolio announced on September 30, 2020 and a \$3.75 million milestone payment made to Amarin when Vascepa received confirmation of eight years of data protection in Canada.

HLS has a strong financial position with \$20.6 million of cash and cash equivalents, a \$35.0 million revolving facility that was undrawn at December 31, 2020, and the Company may also request to be provided with incremental loans, up to a maximum amount of \$70.0 million, to support acquisitions and other growth opportunities. In addition, earlier this year, the Company filed a preliminary short-form base shelf prospectus with the securities commissions in each of the provinces and territories of Canada, other than Quebec, to raise up to C\$250.0 million over a period of 25 months should an appropriate strategic opportunity emerge.

Q4 & FISCAL 2020 CONFERENCE CALL

HLS will hold a conference call today at 8:30 am Eastern Time to discuss its Q4 & FISCAL 2020 financial results. The call will be hosted by Mr. Gilbert Godin, Chief Executive Officer and Mr. Tim Hendrickson, Chief Financial Officer. **To view the slides that accompany management's discussion, please use the webcast link.**

CONFERENCE ID: 39965985

DATE: Thursday, March 18, 2021

TIME: 8:30 a.m. Eastern Standard Time

DIAL-IN NUMBER: 1-888-664-6392 or 416-764-8659

WEBCAST LINK: https://produceredition.webcasts.com/starthere.jsp?ei=1425876&tp_key=3150153748

TAPED REPLAY: 1-888-390-0541 or 416-764-8677

REPLAY CODE: 965985

The taped replay will be available for 14 days and the archived webcast will be available for 365 days.

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.

REFERENCES

¹Bhatt DL, Steg PG, Miller M, Brinton EA, Jacobson TA, Ketchum SB, Doyle RT, Juliano RA, Jiao L, Granowitz C, Tardif JC, Ballantyne CM. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. N Engl J Med 2019;380:11-22.

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

²CAUTIONARY 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 income (loss) for the period with Adjusted EBITDA, each of (i) "stock-based compensation", (ii) "amortization and depreciation", (iii) "acquisition and transaction costs", (iv) "finance and related costs", and (v) "income tax recovery" appearing in the Consolidated Statement of Net Income (Loss) are added to net income (loss) for the period 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, expectations regarding financial performance, and the NCIB and ASPP. 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 March 17, 2021 and Management's Discussion and Analysis dated March 17, 2021, both of which have 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
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

[in thousands of U.S. dollars]

	As at December 31, 2020	As at December 31, 2019
ASSETS		
Current		
Cash and cash equivalents	20,612	47,078
Accounts receivable	12,497	11,858
Inventories	10,630	2,055
Derivative financial instruments	—	271
Prepaid expenses and other current assets	2,172	1,838
Total current assets	45,911	63,100
Property, plant and equipment	1,384	1,276
Intangible assets	253,404	252,050
Restricted assets	2,034	2,188
Deferred tax asset	1,173	1,057
Total assets	303,906	319,671
Current		
Accounts payable and accrued liabilities	14,223	13,466
Provisions	4,516	5,471
Debt and other financial liabilities	16,358	27,855
Income taxes payable	545	347
Total current liabilities	35,642	47,139
Debt and other financial liabilities	99,015	91,822
Deferred tax liability	—	2,511
Total liabilities	134,657	141,472
Shareholders' equity		
Share capital	257,411	248,687
Contributed surplus	11,393	11,517
Accumulated other comprehensive income (loss)	2,020	(537)
Deficit	(101,575)	(81,468)
Total shareholders' equity	169,249	178,199
Total liabilities and shareholders' equity	303,906	319,671

HLS THERAPEUTICS INC
CONSOLIDATED STATEMENTS OF NET LOSS

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

	Three months ended December 31, 2020 2019		Year ended December 31, 2020 2019	
Revenues	16,485	13,937	56,109	54,160
Expenses				
Cost of product sales	1,311	484	3,625	1,932
Selling and marketing	3,260	2,028	12,900	6,256
Medical, regulatory and patient support	1,284	1,520	5,467	5,287
General and administrative	2,403	2,669	10,487	9,042
Stock-based compensation	2,420	2,034	2,531	3,761
Amortization and depreciation	9,513	8,154	33,186	32,510
Operating loss	(3,706)	(2,952)	(12,087)	(4,628)
Realized gain on acquired royalty receivable	(509)	—	(509)	—
Acquisition and transaction costs	152	327	709	957
Finance and related costs, net	3,372	9,497	4,012	14,878
Loss before income taxes	(6,721)	(12,776)	(16,299)	(20,463)

Income tax expense (recovery)	557	(556)	(968)	(911)
Net loss for the period	(7,278)	(12,220)	(15,331)	(19,552)

Net loss per share:

Basic and diluted	\$(0.23)	\$(0.40)	\$(0.48)	\$(0.67)
-------------------	----------	----------	----------	----------

HLS THERAPEUTICS INC

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

[in thousands of U.S. dollars]

	Three months ended December 31,		Year ended December 31,	
	2020	2019	2020	2019
Net loss for the period	(7,278)	(12,220)	(15,331)	(19,552)
Item that may be reclassified subsequently to net loss				
Unrealized foreign currency translation adjustment	7,385	2,598	2,557	6,918
Comprehensive income (loss) for the period	107	(9,622)	(12,774)	(12,634)

HLS THERAPEUTICS INC

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

[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	3,395	(3,358)	—	—	37
Stock options exercised	14	—	—	—	14
Warrants granted	—	470	—	—	470
Stock option expense	—	1,432	—	—	1,432
Net loss for the year	—	—	—	(19,552)	(19,552)
Dividends declared	—	—	—	(4,527)	(4,527)
Unrealized foreign currency translation adjustment	—	—	6,918	—	6,918
Balance, December 31, 2019	248,687	11,517	(537)	(81,468)	178,199
Warrants exercised	8,663	(1,652)	—	—	7,011
Stock options exercised	61	(16)	—	—	45
Stock option expense	—	1,544	—	—	1,544
Net loss for the year	—	—	—	(15,331)	(15,331)
Dividends declared	—	—	—	(4,776)	(4,776)
Unrealized foreign currency translation adjustment	—	—	2,557	—	2,557
Balance, December 31, 2020	257,411	11,393	2,020	(101,575)	169,249

HLS THERAPEUTICS INC

CONSOLIDATED STATEMENTS OF CASH FLOWS

[in thousands of U.S. dollars]

	Three months ended December 31,		Year ended December 31,	
	2020	2019	2020	2019
OPERATING ACTIVITIES				
Net loss for the period	(7,278)	(12,220)	(15,331)	(19,552)
Adjustments to reconcile net loss to cash provided by operating activities				
Stock-based compensation	2,420	2,034	2,531	3,761
Amortization and depreciation	9,513	8,154	33,186	32,510
Accreted interest	261	425	1,173	1,979
Fair value adjustment on financial assets and liabilities	1,642	8,729	(2,243)	9,384
Unrealized foreign exchange	—	(982)	176	(982)
Deferred income taxes	(131)	(919)	(2,483)	(2,241)
Net change in non-cash working capital balances related to operations	(581)	(2,876)	(7,665)	1,549

Cash provided by operating activities	5,846	2,345	9,344	26,408
INVESTING ACTIVITIES				
Additions to property, plant and equipment	(4)	(60)	(36)	(199)
Royalty acquisition	(855)	—	(31,692)	—
Rights acquisitions	(1,825)	(4,325)	(12,050)	(12,800)
Other additions to intangible assets	(138)	(697)	(899)	(2,360)
Cash used in investing activities	(2,822)	(5,082)	(44,677)	(15,359)
FINANCING ACTIVITIES				
Common shares issued	—	—	—	37,329
Common share issuance costs	—	(69)	—	(2,648)
Stock options exercised	—	13	45	14
Warrants exercised	—	2	1,590	37
Dividends paid	(1,238)	(1,143)	(4,749)	(4,332)
Drawdown of senior secured term loan	—	—	20,000	—
Repayment of senior secured term loan	(2,250)	(1,250)	(6,132)	(5,000)
Debt costs	—	—	(658)	(1,000)
Lease payments	(158)	(132)	(532)	(453)
Cash provided by (used in) financing activities	(3,646)	(2,579)	9,564	23,947
Net increase (decrease) in cash and cash equivalents during the period	(622)	(5,316)	(25,769)	34,996
Foreign exchange on cash and cash equivalents	344	1,051	(697)	1,152
Cash and cash equivalents, beginning of period	20,890	51,343	47,078	10,930
Cash and cash equivalents, end of period	20,612	47,078	20,612	47,078

SOURCE HLS Therapeutics Inc.

For further information: HLS CONTACT INFORMATION : Dave Mason, Investor Relations, HLS Therapeutics Inc., (416) 247-9652, d.mason@hlstherapeutics.com

<https://hlstherapeutics.investorroom.com/2021-03-18-HLS-Therapeutics-Announces-Fourth-Quarter-and-Fiscal-2020-Financial-Results>