

HLS Therapeutics Announces Q3 Fiscal 2023 Financial Results and Renewal of Normal Course Issuer Bid

TORONTO, Nov. 9, 2023 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX: HLS), a pharmaceutical company focused on addressing unmet needs in the treatment of psychiatric disorders and cardiovascular disease, announces its financial results for the three- and nine-month periods ended September 30, 2023. All amounts are in thousands of United States ("U.S.") dollars unless otherwise stated.

RECENT HIGHLIGHTS

- Q3 2023 revenue was \$16.0 million, Adjusted EBITDA¹ was \$5.1 million and cash from operations was \$5.4 million, compared to \$15.7 million, \$6.0 million and \$4.2 million, respectively, in Q3 2022.
- Updated the Vascepa promotional services agreement with Pfizer which should increase salesforce productivity in primary care and reduce costs starting in 2024.
- Re-entered discussions with British Columbia on a path forward to a Vascepa Product Listing Agreement. HLS is currently working through coverage implementation with the province.
- Amended credit agreement to extend term and increase borrowing capacity.

"Growth from Vascepa and ongoing consistent performance from Clozaril drove product sales of \$13.4 million in Q3, which is the most ever for HLS in a quarter," said Craig Millian, CEO of HLS. "We also made significant progress on our key commercial imperatives to drive greater salesforce effectiveness and to improve access and reimbursement. We recently amended our promotional services agreement with Pfizer and will implement by year-end what we believe is an improved primary care go-to-market model for Vascepa. In addition, we are seeing some improvement with access and reimbursement in Ontario as well as making progress in finalizing a product listing agreement for British Columbia."

Q3 & YEAR-TO-DATE ("YTD") 2023 FINANCIAL & OPERATIONAL HIGHLIGHTS

- Q3 2023 Vascepa net revenue was C\$4.7 million, up 44% compared to C\$3.2 million in Q3 2022.
- Vascepa total prescriptions in Q3 2023 increased by 89% year-over-year from Q3 2022.
- Vascepa prescribers in Q3 2023 increased 86% year-over-year from Q3 2022.
- Vascepa consistent prescribers² in Q3 2023 increased by 97% year-over-year from Q3 2022.
- Clozaril YTD 2023 Canadian net revenue was C\$26.0 million, down 2% compared to C\$26.6 million in the same period last year.
- Clozaril's YTD 2023 patient growth rate was 1%.

Mr. Millian added: "We continue to see strong growth in Vascepa prescribing along with an increase in the base of total prescribers and consistent prescribers. While Q3 includes some seasonality during the slower summer months, we saw a strong uptick in new and total prescriptions in September - reaching 2,000 prescriptions per week for the first time."

OUTLOOK

Vascepa

Supported by progress against its key commercial imperatives and positive prescribing trends, HLS believes that it is on track to achieve its fiscal 2023 revenue guidance for Vascepa of C\$18-20 million. The Company is also taking necessary actions to achieve the goal of Vascepa making a positive contribution to Adjusted EBITDA starting in the second half of 2024.

Royalty Portfolio

The royalties related to Boston Scientific's Emblem S-ICD, currently the largest royalty interest in the Company's portfolio, will complete its contracted term during Q4 2023. This impact will be partially offset by the expected growth of royalties from Sanofi's Xenpozyme, which had its commercial launch in the second half of 2022. The net effect of the transition from four to three products is that revenue from the royalty portfolio will be lower in fiscal 2024. The Company expects royalty revenue to grow in subsequent years.

Q3 & YTD 2023 FINANCIAL REVIEW

The Company's Management's Discussion and Analysis and Consolidated Financial Statements for the three- and nine-month periods ended September 30, 2023 are available at the [Company's website](#) and at its profile at [SEDAR+](#).

Revenue	Three months ended		Nine months ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Product sales				
Canada	10,153	9,570	28,755	27,500
United States	3,289	3,590	9,680	10,751
	13,442	13,160	38,435	38,251
Royalty revenue	2,595	2,544	8,776	7,541

16,037 15,704 47,211 45,792

Q3 2023 revenue increased 2% compared to Q3 2022. Q3 2023 revenue increased 4% in constant currency terms, compared to Q3 2022, as the decline in the Canadian dollar had an impact on the reported values, which are in U.S. dollars.

Product sales – Canada

000's of CAD	Three months ended September 30,			Nine months ended. September 30,		
	2023	2022	% change	2023	2022	% change
Clozaril	8,946	9,244	(3.2) %	26,029	26,581	(2.1) %
Vascepa	4,665	3,247	43.7 %	12,661	8,720	45.2 %
Other	16	—	—	16	—	—
	13,627	12,491	9.1 %	38,706	35,301	9.6 %

Q3 2023 product sales in Canada increased 9% in Canadian dollars, compared to Q3 2022, led by increased sales of Vascepa, which grew 44% in Q3 2023 in Canadian dollars compared to Q3 2022. The Vascepa net revenue growth rate trails the growth rate in prescriptions as net pricing adjusts to increased public sector volumes.

Clozaril revenue in Canada declined 3% in Q3 2023 in Canadian dollars, compared to Q3 2022, but increased 3% sequentially from Q2 2023. Clozaril remains the leading medication for treatment resistant schizophrenia in Canada and for the nine-month period ended September 30, 2023, the number of patients taking Clozaril increased 1%.

In the U.S., Q3 2023 Clozaril net sales increased 3% sequentially from Q2 2023 but decreased \$0.3 million compared to Q3 2022. The year-over-year decline in unit volumes was partially offset by small annual price increases.

Royalty revenues

Royalty revenues were \$2.6 million in Q3 2023, up 2% from Q3 2022, reflecting contribution from all four products in the portfolio. The year-to-date results include a one-time milestone receipt of \$0.6 million included in Q2 2023 related to the approval of Xenpozyme in 2022.

Operating Expenses	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Cost of product sales	1,870	1,357	5,091	3,464
Selling and marketing	5,048	4,306	15,180	12,677
Medical, regulatory and patient support	1,675	1,498	4,188	4,121
General and administrative	2,316	2,527	7,040	7,040
	10,909	9,688	31,499	27,302

Q3 2023 operating expenses increased 13% compared to Q3 2022. This was driven by an increase in cost of product sales due to the growth in shipments and sales of Vascepa, as well as higher selling and marketing costs for Vascepa related to increased selling activity in primary care. General and administrative expenses decreased 8% in Q3 2023 compared to Q3 2022 as the Company maintains prudent management of expenses.

Support costs and strong gross margins remain stable across the Company's key Clozaril franchises in Canada and the United States.

Adjusted EBITDA ¹	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Net loss for the period	(6,901)	(4,410)	(22,130)	(17,169)
Stock-based compensation	(19)	125	63	2,170
Amortization and depreciation	8,207	8,834	24,892	25,710
Finance and related costs, net	4,223	1,489	9,128	2,852
Other costs	42	69	4,106	4,956
Income tax recovery	(424)	(91)	(347)	(29)
Adjusted EBITDA	5,128	6,016	15,712	18,490

Q3 2023 Adjusted EBITDA was \$5.1 million compared to \$6.0 million in Q3 2022. The decrease was due primarily to the increase in operating expenses for Vascepa and was partially offset by the growth in sales of Vascepa. Clozaril and royalty revenues continue to generate strong Adjusted EBITDA and cash flow for the business.

For the nine-month period ended September 30, 2023, the direct contribution to Adjusted EBITDA from the Clozaril

franchise was \$21.7 million, while the direct contribution of Vascepa to Adjusted EBITDA was a loss of \$7.0 million.

Net Loss

Net loss for Q3 2023 was (\$6.9) million, or (\$0.21) per share, compared to a net loss of (\$4.4) million, or (\$0.14) per share, in Q3 2022. Revenue growth was offset by the increase in cost of product sales and selling and marketing expenses related to the selling and marketing of Vascepa, and higher finance and related costs, net, including fair value adjustments on financial instruments and the effect of higher interest rates, including fair value adjustments on the interest rate swap, resulting in higher net loss for the quarter and year-to-date period.

Cash from Operations and Financial Position

Cash generated from operations was \$5.4 million in Q3 2023, compared to \$4.2 million in Q3 2022. Cash was \$21.8 million at September 30, 2023 up from \$20.7 million at December 31, 2022.

Credit Agreement Amendment

On August 14, 2023, HLS announced an extension to its credit agreement, which comprises a senior secured term loan, a revolver facility and an expansion facility, (the "Amended Agreement") with a syndicate of bank lenders led by JPMorgan Chase Bank, N.A.

Under the terms of the Amended Agreement, the maturity date has been extended to August 11, 2026. The balance on the revolver facility at the time of the amendment was combined with the principal amount remaining on the existing senior secured term loan for a new senior secured term loan balance of \$93.8 million. In addition, there is a new revolving facility of \$30.0 million and an expansion facility of up to \$70.0 million to support acquisitions and other growth opportunities.

As a result, at September 30, 2023 HLS had a strong financial position consisting of \$21.8 million in cash, a \$30.0 million undrawn revolving facility and a \$70.0 million expansion facility. The principal amount of the senior secured term loan outstanding at September 30, 2023 was \$91.7 million.

RENEWAL OF NORMAL COURSE ISSUER BID

HLS has filed with the Toronto Stock Exchange (the "TSX"), and the TSX has accepted, the Company's notice of intention to renew its Normal Course Issuer Bid (the "NCIB") for its issued and outstanding common shares (each a "Common Share"). Pursuant to the NCIB, HLS may, if considered advisable, purchase for cancellation through the facilities of the TSX and/or alternative Canadian trading systems, from time to time over the next 12 months, up to an aggregate of 1,607,892 Common Shares, representing 5% of the 32,157,854 issued and outstanding Common Shares as of October 31, 2023.

HLS may commence purchases of Common Shares under the NCIB on November 14, 2023, and the NCIB will remain in effect until the earliest of: (i) the close of trading on November 13, 2024, (ii) the date upon which HLS acquires the maximum number of Common Shares permitted under the NCIB, and (iii) the date upon which HLS provides written notice of termination of the NCIB to the TSX. Daily purchases pursuant to the NCIB will be limited to 5,307 Common Shares, other than purchases made pursuant to the block purchase exception, based on the applicable average daily trading volume on the TSX for six months ending October 31, 2023 of 21,229 Common Shares.

Purchases of Common Shares under the NCIB will be made by Haywood Securities Inc. ("Haywood") based on the parameters prescribed by the TSX, the provisions of the Company's credit agreement and applicable Canadian securities laws at a price per Common Share equal to the market price at the time of acquisition. All Common Shares acquired by the Company under the NCIB will be cancelled.

The Company also intends to renew the automatic share purchase plan (the "**ASPP**") with Haywood to allow for the purchase of Common Shares under the NCIB at times when the Company would ordinarily not be permitted to purchase shares due to regulatory restrictions or self-imposed blackout periods.

HLS believes that any purchases pursuant to the NCIB, if considered advisable, will be in the best interests of the Company and will be a desirable use of corporate funds. HLS previously sought and received approval of the TSX to purchase up to 1,620,365 Common Shares in a normal course issuer bid (the "Previous Bid") that commenced on November 14, 2022 and will expire on November 13, 2023. As of October 31, 2023, HLS had purchased 334,869 Common Shares on the open market at an average purchase price of C\$5.96 per Common Share under the Previous Bid.

Q3 FISCAL 2023 CONFERENCE CALL

HLS will hold a conference call today at 8:30 am Eastern Time to discuss its Q3 2023 financial results. The call will be hosted by Mr. Craig Millian, CEO, and Mr. Tim Hendrickson, CFO. **To view the slides that accompany management's discussion, please use the webcast link.**

CONFERENCE ID: 52567994

DATE: Thursday, November 9, 2023

TIME: 8:30 a.m. ET

WEBCAST LINK: <https://app.webinar.net/a9kpB2jB7nW>

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

RAPIDCONNECT: To instantly join the conference call by phone, please use the following URL to easily register and be connected into the conference call automatically: <https://emportal.ink/3ZK16TS>

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

REPLAY CODE: 864357#

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.

ABOUT HLS THERAPEUTICS INC.

Formed in 2015, HLS is a 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

¹CAUTIONARY 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) "finance and related costs, net", (iv) "other 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.

²CONSISTENT PRESCRIBER

A consistent prescriber is a physician that has prescribed Vascepa in at least 4 of the past 5 weeks.

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 15, 2023, and Management's Discussion and Analysis dated November 8, 2023, both of which have been filed on SEDAR and can be accessed at www.sedarplus.ca. 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.

INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

Unaudited

[in thousands of U.S. dollars]

	As at September 30, 2023	As at December 31, 2022
ASSETS		
Current		
Cash	21,808	20,723
Accounts receivable	10,625	10,999
Inventories	8,753	8,902
Income taxes recoverable	93	195
Other current assets	2,174	3,555
Total current assets	43,453	44,374
Property, plant and equipment	1,101	1,127
Intangible assets	168,867	195,018
Deferred tax asset	1,152	465
Other non-current assets	655	668
Total assets	215,228	241,652
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current		
Accounts payable and accrued liabilities	14,011	12,785
Provisions	3,867	2,934
Debt and other liabilities	7,101	15,471
Income taxes payable	324	—
Total current liabilities	25,303	31,190
Debt and other liabilities	87,673	84,578
Deferred tax liability	450	566
Total liabilities	113,426	116,334
Shareholders' equity		
Share capital	263,586	265,206
Contributed surplus	14,175	13,821
Accumulated other comprehensive loss	(5,024)	(5,260)
Deficit	(170,935)	(148,449)
Total shareholders' equity	101,802	125,318
Total liabilities and shareholders' equity	215,228	241,652

HLS THERAPEUTICS INC.**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,	
	2023	2022	2023	2022
Revenue	16,037	15,704	47,211	45,792
Expenses				
Cost of product sales	1,870	1,357	5,091	3,464
Selling and marketing	5,048	4,306	15,180	12,677
Medical, regulatory and patient support	1,675	1,498	4,188	4,121
General and administrative	2,316	2,527	7,040	7,040
Stock-based compensation	(19)	125	63	2,170
Amortization and depreciation	8,207	8,834	24,892	25,710
Finance and related costs, net	4,223	1,489	9,128	2,852
Other costs	42	69	4,106	4,956
Loss before income taxes	(7,325)	(4,501)	(22,477)	(17,198)

Income tax recovery	(424)	(91)	(347)	(29)
Net loss for the period	(6,901)	(4,410)	(22,130)	(17,169)

Net loss per share:

Basic and diluted	\$(0.21)	\$(0.14)	\$(0.68)	\$(0.53)
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HLS THERAPEUTICS INC.

INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Unaudited

[in thousands of U.S. dollars]

	Three months ended		Nine months ended	
	September 30,	September 30,	September 30,	September 30,
	2023	2022	2023	2022
Net loss for the period	(6,901)	(4,410)	(22,130)	(17,169)
Item that may be reclassified subsequently to net loss				
Unrealized foreign currency translation adjustment	(2,154)	(7,578)	236	(9,564)
Comprehensive loss for the period	(9,055)	(11,988)	(21,894)	(26,733)

HLS THERAPEUTICS INC.

INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

Unaudited

[in thousands of U.S. dollars]

	Share	Contributed	Accumulated other		
	capital	surplus	comprehensive	Deficit	Total
			income (loss)		
Balance, December 31, 2022	265,206	13,821	(5,260)	(148,449)	125,318
Stock options exercised	178	(44)	—	—	134
Shares repurchased	(1,798)	—	—	826	(972)
Share purchase obligation	—	(295)	—	—	(295)
Stock option expense	—	693	—	—	693
Net loss for the period	—	—	—	(22,130)	(22,130)
Dividends declared	—	—	—	(1,182)	(1,182)
Unrealized foreign currency translation adjustment	—	—	236	—	236
Balance, September 30, 2023	263,586	14,175	(5,024)	(170,935)	101,802
Balance, December 31, 2021	265,917	11,717	2,959	(119,857)	160,736
Stock options exercised	251	(67)	—	—	184
Shares repurchased	(539)	—	—	(109)	(648)
Share purchase obligation	—	(255)	—	—	(255)
Stock option expense	—	1,930	—	—	1,930
Net loss for the period	—	—	—	(17,169)	(17,169)
Dividends declared	—	—	—	(3,768)	(3,768)
Unrealized foreign currency translation adjustment	—	—	(9,564)	—	(9,564)
Balance, September 30, 2022	265,629	13,325	(6,605)	(140,903)	131,446

HLS THERAPEUTICS INC.

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

Unaudited

[in thousands of U.S. dollars]

	Three months ended		Nine months ended	
	September 30,	September 30,	September 30,	September 30,
	2023	2022	2023	2022

OPERATING ACTIVITIES

Net loss for the period	(6,901)	(4,410)	(22,130)	(17,169)
Adjustments to reconcile net loss to cash provided by operating activities				
Stock-based compensation	(19)	125	63	2,170
Amortization and depreciation	8,207	8,834	24,892	25,710
Impairment charge	—	—	2,352	3,051
Accreted interest	199	200	580	612
Fair value adjustment on financial assets and liabilities	2,030	(397)	3,151	(2,567)
Deferred income taxes	(541)	(196)	(803)	233
Net change in non-cash working capital balances related to operations	2,392	(5)	3,950	1,381
Cash provided by operating activities	5,367	4,151	12,055	13,421

INVESTING ACTIVITIES

Additions to property, plant and equipment	—	(12)	(27)	(36)
Royalty milestone payment	—	(10,000)	—	(10,000)
Additions to intangible assets	(40)	—	(148)	(92)
Cash used in investing activities	(40)	(10,012)	(175)	(10,128)

FINANCING ACTIVITIES

Stock options exercised	—	12	134	184
Shares repurchased	(603)	(270)	(972)	(648)
Dividends paid	—	(1,220)	(2,398)	(3,769)
Repayment of credit agreement borrowing	(2,173)	(1,389)	(5,683)	(7,389)
Drawdown under credit agreement	—	10,000	—	10,000
Debt costs	(1,360)	(639)	(1,360)	(639)
Lease payments	(155)	(162)	(474)	(501)
Cash provided by (used in) financing activities	(4,291)	6,332	(10,753)	(2,762)

Net increase in cash during the period	1,036	471	1,127	531
Foreign currency translation	(160)	(352)	(42)	(431)
Cash, beginning of period	20,932	21,160	20,723	21,179
Cash, end of period	21,808	21,279	21,808	21,279

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/2023-11-09-HLS-Therapeutics-Announces-Q3-Fiscal-2023-Financial-Results-and-Renewal-of-Normal-Course-Issuer-Bid>