

HLS Therapeutics Announces Q2 Fiscal 2023 Financial Results

TORONTO, Aug. 10, 2023 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX: HLS), a pharmaceutical company focusing on central nervous system ("CNS") and cardiovascular markets, announces its financial results for the three- and six-month periods ended June 30, 2023. All amounts are in thousands of United States ("U.S.") dollars unless otherwise stated.

KEY HIGHLIGHTS

- Q2 2023 revenue was \$16.4 million and Adjusted EBITDA¹ was \$5.5 million, compared to \$15.5 million and \$6.2 million, respectively, in Q2 2022.
- New leadership with the appointment of Craig Millian as CEO and Brian Walsh as Senior Vice President, Commercial.
- Board changes with John Welborn named Chair; Christian Roy, Craig Millian and John Hanna joining the board; and a reduction in the size of the board from ten to eight members.

"Q2 revenue and Adjusted EBITDA results were largely in line with expectations with topline growth driven by the increase in Canadian product revenue and strong royalty revenue," said Craig Millian, CEO of HLS. "The quarter was one of significant transition for HLS. We made important structural and leadership changes to drive our company forward and ensure strong alignment with shareholders. We are making necessary adjustments to our operating model to build a solid foundation for sustainable and profitable growth moving forward."

Q2 & YEAR-TO-DATE ("YTD") 2023 FINANCIAL & OPERATIONAL HIGHLIGHTS

- Q2 2023 Vascepa net revenue was C\$4.5 million, up 49% compared to C\$3.0 million in Q2 2022.
- Vascepa total prescriptions in Q2 2023 increased by 91% year-over-year from Q2 2022.
- Vascepa prescribers in Q2 2023 increased by 20% sequentially from Q1 2023 and 96% year-over-year from Q2 2022.
- Vascepa consistent prescribers² in Q2 2023 increased by 30% sequentially from Q1 2023 and 139% year-over-year from Q2 2022.
- Clozaril YTD 2023 Canadian net revenue was C\$17.1 million, down 1.5% compared to C\$17.3 million in the same period last year.
- Clozaril's YTD 2023 patient growth rate was 1%.

"Vascepa generated 49% year-over-year net sales growth in Q2 with 91% growth in prescribing driven by increases in new prescribers, new patients, and more prescribing by current writers," Millian added. "We are excited about the continued adoption of Vascepa and opportunities for future growth, while also acknowledging that the current growth trajectory is not as rapid as originally projected. Our goal moving forward is to invest where we can drive continued growth but with an accelerated timeframe to brand profitability."

Due to payer mix dynamics, public plan reimbursement delays, and slower than expected uptake with general practitioners, HLS is guiding to a 2023 Vascepa revenue range of C\$18-20 million compared to the low end of its previously issued C\$22-28 million revenue range. The Company remains confident in the potential for Vascepa and is putting plans in place so that Vascepa begins to make a positive contribution to Adjusted EBITDA in the second half of 2024.

Q2 & YTD 2023 FINANCIAL REVIEW

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

Revenue

	Three months ended		Six months ended	
	June 30,		June 30,	
			2023	2022
Product sales				
Canada	9,791	9,527	18,602	17,930
United States	3,179	3,718	6,391	7,161
	12,970	13,245	24,993	25,091
Royalty revenue	3,447	2,287	6,181	4,997
	16,417	15,532	31,174	30,088

Q2 2023 revenue increased 6% compared to Q2 2022. Q2 2023 revenue increased 9% in constant currency terms, compared to Q2 2022, as the decline in the Canadian dollar had an impact on the reported values, which are in U.S. dollars.

Q2 2023 product sales in Canada increased 3% compared to Q2 2022. Q2 2023 product sales in Canada grew 8% in constant currency, compared to Q2 2022, led by increased sales of Vascepa, which grew 49% in Q2 2023 in constant currency compared to Q2 2022, and grew by C\$1.0 million, or 28% sequentially, from Q1 2023. 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 5% in Q2 2023 in constant currency, compared to Q2 2022, impacted by the timing of wholesaler ordering. For the six-month period ended June 30, 2023, the number of patients taking Clozaril increased 1% while revenue decreased 1.5% compared to the same period in the prior year. The variance between the increase in patients and decrease in revenue is due to the order timing issues mentioned above. Clozaril continues to be the leading medication for treatment-resistant schizophrenia in Canada.

In the U.S., Q2 2023 Clozaril net sales decreased \$0.5 million compared to Q2 2022. While gross sales remain steady year-over-year, the decrease was primarily due to a \$0.5 million benefit in Q2 2022 related to expired product returns while public rebates and co-pay assistance programs have increased moderately in the current year.

Royalty revenues

Royalty revenues were \$3.4 million in Q2 2023, up 51% from Q2 2022, reflecting contribution from all four products in the portfolio. \$0.5 million of the year-over-year increase is due to receipt of a one-time milestone payment related to the approval of Xenpozyme.

Operating Expenses

	Three months ended June 30,		Six months ended June 30,	
			2023	2022
Cost of product sales	1,777	1,154	3,221	2,107
Selling and marketing	5,325	4,542	10,132	8,371
Medical, regulatory and patient support	1,437	1,347	2,513	2,623
General and administrative	2,373	2,331	4,724	4,513
	10,912	9,374	20,590	17,614

Q2 2023 operating expenses increased 16% compared to Q2 2022, which was driven by an increase in cost of sales due to the growth in shipments and sales of Vascepa, and an increase in selling and marketing costs for Vascepa related to increased selling activity in primary care. Selling and marketing costs are expected to remain steady for the remainder of 2023 and then to decrease in 2024 as we drive towards profitability for Vascepa in the second half of 2024.

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

Adjusted EBITDA¹

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Net loss for the period	(9,437)	(9,143)	(15,229)	(12,759)
Stock-based compensation	137	1,230	82	2,045
Amortization and depreciation	8,366	8,489	16,685	16,876
Finance and related costs, net	2,471	1,043	4,905	1,363
Other costs	3,851	4,542	4,064	4,887
Income tax expense (recovery)	117	(3)	77	62
Adjusted EBITDA	5,505	6,158	10,584	12,474

Q2 2023 Adjusted EBITDA was \$5.5 million compared to \$6.2 million in Q2 2022. The decrease is due primarily to the increase in operating expenses for Vascepa. Clozaril and royalty revenues continue to generate strong Adjusted EBITDA and cash flow for the business.

For the six-month period ended June 30, 2023, the direct contribution to Adjusted EBITDA from the Clozaril franchise was \$14.4 million, while the direct contribution of Vascepa and other products was a loss of \$4.7 million and \$0.4 million, respectively.

¹ See "Cautionary Note Regarding Non-IFRS Measures" section of this press release.

Net Loss

Net loss for Q2 2023 was (\$9.4) million, or (\$0.29) per share, compared to a net loss of (\$9.1) million, or (\$0.28) per share, in Q2 2022. Net loss increased as revenue growth was offset by higher cost of product sales and selling and marketing expenses related to the expansion of Vascepa, and Q2 2023 had Other costs of \$3.9 million which included \$2.4 million related to the discontinuation of PERSERIS and \$1.5 million of reorganization costs.

Cash from Operations and Financial Position

Cash generated from operations was \$2.7 million in Q2 2023, compared to \$3.5 million in Q2 2022. Cash was \$20.9 million at June 30, 2023 up from \$20.7 million at December 31, 2022.

As at June 30, 2023, HLS has a strong financial position with \$20.9 million of cash, \$26.5 million of undrawn revolving facility, 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.

Q2 FISCAL 2023 CONFERENCE CALL

HLS will hold a conference call today at 8:30 am Eastern Time to discuss its Q2 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, August 10, 2023

TIME: 8:30 a.m. ET

WEBCAST LINK: <https://app.webinar.net/Yd576N3ZzeW>

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/3ND4vyc>

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

REPLAY CODE: 567994#

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", (iv) "other costs", and (v) "income tax expense (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 August 9, 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	As at
	June 30, 2023	December 31, 2022
ASSETS		
Current		
Cash	20,932	20,723
Accounts receivable	11,950	10,999
Inventories	9,965	8,902
Income taxes recoverable	118	195
Other current assets	2,700	3,555

Total current assets	45,665	44,374
Property, plant and equipment	1,099	1,127
Intangible assets	178,802	195,018
Deferred tax asset	624	465
Other non-current assets	668	668
Total assets	226,818	241,652

LIABILITIES AND SHAREHOLDERS' EQUITY

Current

Accounts payable and accrued liabilities	12,925	12,785
Provisions	5,367	2,934
Debt and other liabilities	13,009	15,471
Income taxes payable	232	—
Total current liabilities	31,533	31,190
Debt and other liabilities	83,386	84,578
Deferred tax liability	463	566
Total liabilities	115,382	116,334

Shareholders' equity

Share capital	264,761	265,206
Contributed surplus	14,151	13,821
Accumulated other comprehensive loss	(2,870)	(5,260)
Deficit	(164,606)	(148,449)
Total shareholders' equity	111,436	125,318
Total liabilities and shareholders' equity	226,818	241,652

HLS THERAPEUTICS INC.

INTERIM CONSOLIDATED STATEMENTS OF LOSS

Unaudited

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

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Revenue	16,417	15,532	31,174	30,088
Expenses				
Cost of product sales	1,777	1,154	3,221	2,107
Selling and marketing	5,325	4,542	10,132	8,371
Medical, regulatory and patient support	1,437	1,347	2,513	2,623
General and administrative	2,373	2,331	4,724	4,513
Stock-based compensation	137	1,230	82	2,045
Amortization and depreciation	8,366	8,489	16,685	16,876
Finance and related costs, net	2,471	1,043	4,905	1,363
Other costs	3,851	4,542	4,064	4,887
Loss before income taxes	(9,320)	(9,146)	(15,152)	(12,697)
Income tax expense (recovery)	117	(3)	77	62
Net loss for the period	(9,437)	(9,143)	(15,229)	(12,759)
Net loss per share:				
Basic and diluted	\$(0.29)	\$(0.28)	\$(0.47)	\$(0.39)

HLS THERAPEUTICS INC.

INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Unaudited

[in thousands of U.S. dollars]

	Three months ended June 30, 2022		Six months ended June 30, 2022	
Net loss for the period	(9,437)	(9,143)	(15,229)	(12,759)
Item that may be reclassified subsequently to net loss				
Unrealized foreign currency translation adjustment	2,297	(4,424)	2,390	(1,986)
Comprehensive loss for the period	(7,140)	(13,567)	(12,839)	(14,745)

HLS THERAPEUTICS INC.

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, 2022	265,206	13,821	(5,260)	(148,449)	125,318
Stock options exercised	178	(44)	—	—	134
Shares repurchased	(623)	—	—	254	(369)
Share purchase obligation	—	(305)	—	—	(305)
Stock option expense	—	679	—	—	679
Net loss for the period	—	—	—	(15,229)	(15,229)
Dividends declared	—	—	—	(1,182)	(1,182)
Unrealized foreign currency translation adjustment	—	—	2,390	—	2,390
Balance, June 30, 2023	264,761	14,151	(2,870)	(164,606)	111,436
Balance, December 31, 2021	265,917	11,717	2,959	(119,857)	160,736
Stock options exercised	236	(64)	—	—	172
Shares repurchased	(146)	(191)	—	(41)	(378)
Share purchase obligation	—	(272)	—	—	(272)
Stock option expense	—	1,435	—	—	1,435
Net loss for the period	—	—	—	(12,759)	(12,759)
Dividends declared	—	—	—	(2,549)	(2,549)
Unrealized foreign currency translation adjustment	—	—	(1,986)	—	(1,986)
Balance, June 30, 2022	266,007	12,625	973	(135,206)	144,399

HLS THERAPEUTICS INC.

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

Unaudited

[in thousands of U.S. dollars]

	Three months ended June 30, 2022		Six months ended June 30, 2022	
OPERATING ACTIVITIES	(9,437)	(9,143)	(15,229)	(12,759)
Net loss for the period				
Adjustments to reconcile net loss to cash provided by operating activities				
Stock-based compensation	137	1,230	82	2,045
Amortization and depreciation	8,366	8,489	16,685	16,876
Impairment	2,352	3,051	2,352	3,051
Accreted interest	190	205	381	412
Fair value adjustment on financial assets and liabilities	570	(696)	1,121	(2,170)

Deferred income taxes	(85)	20	(262)	429
Net change in non-cash working capital balances related to operations	575	356	1,558	1,386
Cash provided by operating activities	2,668	3,512	6,688	9,270
INVESTING ACTIVITIES				
Additions to property, plant and equipment	(27)	(15)	(27)	(24)
Additions to intangible assets	(108)	(66)	(108)	(92)
Cash used in investing activities	(135)	(81)	(135)	(116)
FINANCING ACTIVITIES				
Stock options exercised	—	7	134	172
Shares repurchased	(185)	(357)	(369)	(378)
Dividends paid	(1,216)	(1,267)	(2,398)	(2,549)
Repayment of credit agreement borrowing	(1,389)	(3,000)	(3,510)	(6,000)
Lease payments	(158)	(180)	(319)	(339)
Cash used in financing activities	(2,948)	(4,797)	(6,462)	(9,094)
Net increase (decrease) in cash during the period	(415)	(1,366)	91	60
Foreign currency translation	133	(138)	118	(79)
Cash, beginning of period	21,214	22,664	20,723	21,179
Cash, end of period	20,932	21,160	20,932	21,160

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/2023-08-10-HLS-Therapeutics-Announces-Q2-Fiscal-2023-Financial-Results>