



HLS Therapeutics Inc.

News Release

HLS Therapeutics Announces Q3 2024 Financial Results

2024-11-07

TORONTO, Nov. 7, 2024 /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 months ended September 30, 2024. All amounts are in thousands of United States ("U.S.") dollars unless otherwise stated.

KEY HIGHLIGHTS

- Q3 2024 revenue was \$14.1 million, Adjusted EBITDA¹ was \$4.1 million and cash from operations was \$1.5 million, compared to \$16.0 million, \$5.1 million and \$5.4 million, respectively, in Q3 2023.
- Canadian product sales of Vascepa and Clozaril grew 11% in Canadian dollars compared to Q3 2023.
- Operating expenses decreased 15%, excluding cost of product sales, compared to Q3 2023.
- Excluding the royalty portfolio, Q3 2024 Adjusted EBITDA increased 55% to \$3.9 million, compared to \$2.5 million in Q3 2023.
- Paid down \$15 million of the term loan, ending the quarter with net debt of \$52.4 million compared to net debt of approximately \$66.5 million at the end of Q4 2023.
- Named John Hanna permanent CFO and promoted Brian Walsh to Chief Commercial Officer.

"Q3 saw the continued growth of our promoted products in Canada driven by the strongest quarterly growth of the year for Vascepa. In constant currency, our Q3 net sales in Canada grew 11% with Vascepa leading the way with 30% year-over-year growth," said Craig Millian, CEO at HLS. "At the same time, we significantly reduced our operating expenses in the quarter, and we made a substantial debt repayment to strengthen our balance sheet and increase our future cash flows and financial flexibility. These achievements put us in a much stronger financial and

operating position entering 2025 than when we started this year."

Q3 2024 BRAND PERFORMANCE HIGHLIGHTS

- Completed the transition of Vascepa primary care sales responsibilities from Pfizer back to HLS on August 31, 2024.
- Vascepa revenue in Canada increased 30% in constant currency compared to Q3 2023 while the Q3 2024 loss attributed to Vascepa was \$0.6 million, the lowest since product launch and a significant sequential decrease from a loss of \$1.6 million in Q2 2024.
- Vascepa unit demand increased by 45% compared to Q3 2023.
- The number of consistent prescribers² for Vascepa increased 66% compared to Q3 2023.
- Clozaril revenue in Canada increased by 1% in constant currency compared to Q3 2023.
- Clozaril patient growth in Canada was 2% compared to Q3 2023.

2024 and 2025 OUTLOOK

With the release of its Q3 2024 results, the Company is updating its 2024 revenue and Adjusted EBITDA guidance.

HLS is now guiding to a lower revenue range of \$56.5-57.2 million compared to the previous range of \$58.5-59.7 million. The revised guidance is attributable to year-to-date U.S. Clozaril sales being behind plan and from the negative foreign exchange impact on the Company's Canadian business due to the persistent strength of the U.S. dollar relative to the Canadian dollar in 2024.

The underlying demand fundamentals for U.S. Clozaril remain sound. The decline in 2024 U.S. Clozaril net sales is largely due to higher-than-typical wholesaler inventory at the end of 2023, as previously disclosed. Management had anticipated that this impact would be mitigated through a modest mid-year price increase along with new business acquired through expansion of its specialty pharmacy program. However, the full implementation and impact of this program expansion will not be fully realized until 2025.

Based on the positive progress being made in reducing operating costs, the Company is raising the low end of its 2024 full year Adjusted EBITDA guidance to \$16.0-16.7 million compared to the previous range of \$15.5-16.7 million. HLS continues to expect that Vascepa will make a positive brand contribution to Adjusted EBITDA starting in Q4 2024.

Finally, the Company is providing a preliminary outlook for 2025. HLS expects that revenue growth from its promoted product portfolio will be in the high single-digit percentage range while consolidated Adjusted EBITDA growth will be in the mid-20's percentage range. The Company will update its 2025 financial outlook when it releases its 2024 year-end results in March next year.

Added Mr. Millian: "We are making progress in executing our plan, continuing to grow our promoted product portfolio while significantly reducing operating expenses and paying down debt. We believe the changes we are making this year will position HLS for top-line growth and increased profitability in 2025, while also creating greater flexibility for future capital allocation towards share buybacks and portfolio expansion opportunities."

Q3 2024 FINANCIAL REVIEW

The Company's Management's Discussion and Analysis and Consolidated Financial Statements for the three and nine months ended September 30, 2024, are available at the **Company's website** and at its profile at **SEDAR+**.

Revenue

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Product sales				
Canada	11,087	10,153	30,878	28,755
United States	2,803	3,289	8,907	9,680
	13,890	13,442	39,785	38,435
Royalty revenue	195	2,595	1,292	8,776
	14,085	16,037	41,077	47,211

Revenue for the three and nine months ended September 30, 2024, decreased 12% and 13%, respectively, due to lower royalty revenues and was offset, in part, by growth of the Company's marketed products. Excluding royalties, revenue for the Company's marketed products (Vascepa, and Clozaril) for the three and nine months ended September 30, 2024, increased 3% and 4%, respectively, from the prior year periods.

Product sales – Canada

000's of CAD	Three months ended September 30,			Nine months ended September 30,		
	2024	2023	% change	2024	2023	% change
Clozaril	9,013	8,946	0.7 %	26,009	26,029	(0.1) %
Vascepa	6,077	4,665	30.3 %	15,955	12,661	26.0 %
Other	27	16		54	16	
	15,117	13,627	10.9 %	42,018	38,706	8.6 %

Canadian product sales of Vascepa and Clozaril in Q3 2024 increased 11% in local currency, compared to Q3 2023, driven primarily by the 30% growth of Vascepa. For the nine months ended September 30, 2024, Canadian product sales of Vascepa and Clozaril increased 9% in local currency, compared to the same period in 2023.

Product Sales – United States

In the U.S. market, Clozaril revenue for the three and nine months ended September 30, 2024, decreased 15% and 8%, respectively, compared to the same periods in 2023. Results have been impacted by wholesaler purchasing patterns including a high level of wholesaler inventory at the start of the year and a key customer wholesaler transition that took place during Q3.

Royalty revenues

Royalty revenues for the three and nine months ended September 30, 2024, were down 92% and 85%, respectively, compared to the prior year periods as the term for Emblem, the largest royalty in the portfolio, came to an end midway through Q4 2023. Following the sale of the Xenpozyme royalty interest in Q2 2024, HLS has one remaining royalty interest which generated \$0.2 million in revenue in Q3 2024.

Operating Expenses

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Cost of product sales	2,235	1,870	6,312	5,091
Selling and marketing	4,208	5,048	13,295	15,180
Medical, regulatory and patient support	1,439	1,675	4,124	4,188
General and administrative	2,077	2,316	6,255	7,040
	9,959	10,909	29,986	31,499

Cost of product sales was up for the three and nine months ended September 30, 2024, due primarily to higher Vascepa sales volumes.

Excluding cost of product sales, operational expenses for the three and nine months ended September 30, 2024, decreased 15% and 10%, respectively, compared to the prior year periods. This was due to the Company's focus on cost management while continuing to support the growth potential of its marketed products. Sales and marketing expenses were lower in Q3 2024 in large part due to the discontinuation of co-promotional activities with the Company's marketing partner at the end of August 2024.

Adjusted EBITDA¹

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Net loss for the period	(4,844)	(6,901)	(16,632)	(22,130)
Stock-based compensation	511	(19)	1,194	63
Amortization and depreciation	5,508	8,207	17,283	24,892
Finance and related costs, net	2,389	4,223	7,998	9,128
Other costs (income)	621	42	(2,740)	4,106
Income tax expense (recovery)	(59)	(424)	3,988	(347)
Adjusted EBITDA	4,126	5,128	11,091	15,712

Adjusted EBITDA for the three and nine months ended September 30, 2024, decreased due to the decline in royalty revenue and was offset in part by growth in the Company's marketed products. Excluding royalty revenue, Adjusted EBITDA for the three and nine months ended September 30, 2024, would have been approximately \$3.9 million and \$9.8 million, respectively, compared to \$2.5 million and \$6.9 million in the prior year periods, representing increases of 55% and 41%.

The Company recorded Other Costs in Q3 2024 of approximately \$0.6 million related to exiting its co-promotional agreement.

For Q3 2024, the direct brand contribution from Clozaril to Adjusted EBITDA was \$6.8 million, while the direct brand contribution from Vascepa to Adjusted EBITDA was a loss of \$0.6 million. For the 2024 year-to-date period, the direct brand contribution from Clozaril to Adjusted EBITDA was \$20.4 million, while the direct brand contribution from Vascepa to Adjusted EBITDA was a loss of \$3.8 million.

Net Loss

Net loss for the three months ended September 30, 2024, was (\$4.8) million, or (\$0.15) per share, compared to a net loss of (\$6.9) million, or (\$0.21) per share, in Q3 2023. Net loss for the nine months ended September 30, 2024, was (\$16.6) million, or (\$0.52) per share, compared to a net loss of (\$22.1) million, or (\$0.68) per share, in the same period last year. Net loss improved in the year-over-year periods due primarily to lower operating expenses and lower amortization and depreciation expenses, which were offset, in part, by lower royalty revenue.

Cash from Operations and Financial Position

Cash generated from operations for the three and nine months ended September 30, 2024, was \$1.5 million and \$4.8 million, respectively, compared to \$5.4 million and \$12.1 million in the prior year periods. Cash was \$17.5 million at September 30, 2024 compared to \$22.0 million at December 31, 2023.

Total borrowings under the credit agreement at September 30, 2024, were \$70 million compared to \$88.5 million at

December 31, 2023. During the quarter, HLS made principal payments on its term loan totaling \$15 million, which will save the Company an estimated \$1.5 million annually in interest expense.

Q3 2024 CONFERENCE CALL

HLS will hold a conference call today at 8:30 am Eastern Time to discuss its Q3 2024 financial results. The call will be hosted by Mr. Craig Millian, CEO, Mr. John Hanna, CFO and Mr. Brian Walsh, CCO. To view the slides that accompany management's discussion, please use the webcast link.

CONFERENCE ID: 84749

DATE: Thursday, November 7, 2024

TIME: 8:30 a.m. ET

WEBCAST LINK: <https://app.webinar.net/pK7MRDbWv52>

TRADITIONAL DIAL-IN NUMBER: 1-888-699-1199 or 1-416-945-7677

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/4eQL014>

TAPED REPLAY: 1-888-660-6345 or 1-289-819-1450

REPLAY CODE: 84749#

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 before the conference call to ensure enough time for any software download 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 (income)", 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 13, 2024, and Management's Discussion and Analysis dated November 6, 2024, 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]

	September 30, 2024	As at December 31, 2023	As at
ASSETS			
Current			
Cash	17,540		21,952
Accounts receivable	10,487		10,608
Inventories	7,683		9,534
Income taxes recoverable	98		86
Other current assets	1,766		1,915
Total current assets	37,574		44,095
Property, plant and equipment	897		965
Intangible assets	132,043		162,344
Deferred tax asset	619		1,037
Other non-current assets	607		619
Total assets	171,740		209,060
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current			
Accounts payable and accrued liabilities	13,482		14,107
Provisions	5,649		5,424
Debt and other liabilities	4,811		6,876
Income taxes payable	149		281
Total current liabilities	24,091		26,688
Debt and other liabilities	64,543		84,233
Deferred tax liability	3,777		442
Total liabilities	92,411		111,363
Shareholders' equity			
Share capital	260,595		262,127
Contributed surplus	14,907		13,865
Accumulated other comprehensive loss	(5,016)		(2,838)
Deficit	(191,157)		(175,457)
Total shareholders' equity	79,329		97,697
Total liabilities and shareholders' equity	171,740		209,060

HLS THERAPEUTICS INC.
INTERIM CONSOLIDATED STATEMENTS OF LOSS

Unaudited

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Revenue	14,085	16,037	41,077	47,211
Expenses				
Cost of product sales	2,235	1,870	6,312	5,091
Selling and marketing	4,208	5,048	13,295	15,180
Medical, regulatory and patient support	1,439	1,675	4,124	4,188
General and administrative	2,077	2,316	6,255	7,040
Stock-based compensation	511	(19)	1,194	63
Amortization and depreciation	5,508	8,207	17,283	24,892
Finance and related costs, net	2,389	4,223	7,998	9,128
Other costs (income)	621	42	(2,740)	4,106
Loss before income taxes	(4,903)	(7,325)	(12,644)	(22,477)
Income tax expense (recovery)	(59)	(424)	3,988	(347)
Net loss for the period	(4,844)	(6,901)	(16,632)	(22,130)
Net loss per share:				
Basic and diluted	\$(0.15)	\$(0.21)	\$(0.52)	\$(0.68)

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,	
	2024	2023	2024	2023
Net loss for the period	(4,844)	(6,901)	(16,632)	(22,130)
Item that may be reclassified subsequently to net loss				
Unrealized foreign currency translation adjustment	1,158	(2,154)	(2,178)	236
Comprehensive loss for the period	(3,686)	(9,055)	(18,810)	(21,894)

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 loss	Deficit	Total
Balance, December 31, 2023	262,127	13,865	(2,838)	(175,457)	97,697
Shares repurchased	(1,532)	—	—	932	(600)
Share purchase obligation	—	300	—	—	300
Stock option expense	—	742	—	—	742

Net loss for the period	—	—	—	(16,632)	(16,632)
Unrealized foreign currency translation adjustment	—	—	(2,178)	—	(2,178)
Balance, September 30, 2024	260,595	14,907	(5,016)	(191,157)	79,329
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

HLS THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

Unaudited

[in thousands of U.S. dollars]

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
OPERATING ACTIVITIES				
Net loss for the period	(4,844)	(6,901)	(16,632)	(22,130)
Adjustments to reconcile net loss to cash provided by operating activities				
Stock-based compensation	511	(19)	1,194	63
Amortization and depreciation	5,508	8,207	17,283	24,892
Gain on royalty sale	—	—	(3,381)	—
Impairment charge	—	—	—	2,352
Accreted interest	353	199	912	580
Fair value adjustment on financial assets and liabilities	18	2,030	523	3,151
Deferred income taxes	(47)	(541)	3,753	(803)
Net change in non-cash working capital balances related to operations	2	2,392	1,146	3,950
Cash provided by operating activities	1,501	5,367	4,798	12,055
INVESTING ACTIVITIES				
Proceeds from royalty sale	—	—	13,250	—
Payment of purchase consideration	(1,500)	—	(1,500)	—
Additions to property, plant and equipment	—	—	(2)	(27)
Additions to intangible assets	—	(40)	—	(148)
Cash provided by (used in) investing activities	(1,500)	(40)	11,748	(175)
FINANCING ACTIVITIES				
Stock options exercised	—	—	—	134
Shares repurchased	—	(603)	(600)	(972)
Dividends paid	—	—	—	(2,398)
Repayment of borrowing under credit agreement	(14,965)	(2,173)	(18,533)	(5,683)
Debt costs	—	(1,360)	(1,191)	(1,360)
Lease payments	(131)	(155)	(386)	(474)
Cash used in financing activities	(15,096)	(4,291)	(20,710)	(10,753)
Net increase (decrease) in cash during the period	(15,095)	1,036	(4,164)	1,127
Foreign exchange on cash	120	(160)	(248)	(42)
Cash, beginning of period	32,515	20,932	21,952	20,723
Cash, end of period	17,540	21,808	17,540	21,808

SOURCE HLS Therapeutics Inc.