

HLS Therapeutics Announces Fiscal 2023 Financial Results

TORONTO, March 14, 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 twelve-month periods ended December 31, 2023. All amounts are in thousands of United States ("U.S.") dollars unless otherwise stated.

KEY HIGHLIGHTS

- Fiscal 2023 revenue was \$63.1 million, Adjusted EBITDA¹ was \$21.1 million and cash from operations was \$15.8 million, compared to \$61.5 million, \$23.8 million and \$16.9 million, respectively, in 2022.
- Q4 2023 revenue was \$15.9 million, Adjusted EBITDA was \$5.3 million and cash from operations was \$3.7 million, compared to \$15.7 million, \$5.3 million and \$3.5 million, respectively, in Q4 2022.
- Q4 2023 and fiscal 2023 product sales in Canada increased 11% and 10%, respectively, in Canadian dollars, compared to the same periods in 2022.
- Introduced the updated Pfizer partnering model in primary care on January 1, 2024.
- Completed a Product Listing Agreement ("PLA") on February 6, 2024, with the province of British Columbia ("BC"), for the listing and public reimbursement of Vascepa.

"2023 was a year of transition for HLS with leadership changes and an increased focus on operational execution that has us entering 2024 well-positioned for our next phase of growth," said Craig Millian, CEO of HLS. "With Vascepa, we made important changes to our commercial strategy that included updating our primary care go-to-market model with Pfizer along with renewed efforts to improve access and reimbursement, primarily in BC and Ontario. In 2024, we have already seen positive developments in each of these areas, which we believe will help us generate accelerated growth and a transition to profitability for Vascepa later this year."

"Clozaril continued to be a consistent performer and generator of cash flow in 2023. The number of patients on Clozaril in Canada grew by 1% for the year reflecting the underlying stability of Clozaril in the market. Along with maintaining strong margins, we think there are opportunities to drive modest growth for the product, and this will also be a focus of ours in 2024."

Q4 & FISCAL 2023 OTHER HIGHLIGHTS

- Craig Millian appointed Chief Executive Officer, Brian T. Walsh appointed Senior Vice President, Commercial and John Hanna appointed Interim Chief Financial Officer.
- Reduced the size of the Board of Directors from ten to eight members; John Welborn appointed Chair.
- Vascepa total prescriptions in fiscal 2023 increased by 86% from 2022.
- Q4 2023 Vascepa net revenue was C\$5.1 million, up 42% compared to C\$3.6 million in Q4 2022.
- The number of patients on Clozaril in Canada increased by more than 1% in 2023, compared to 2022.
- Clozaril sales in Canada in Q4 2023 were essentially flat compared to Q4 2022.

Mr. Millian added: "Vascepa revenue for 2023 was C\$17.8 million, just below the low-end of our revenue target range of C\$18-20 million, but still up significantly over 2022. The uptake in public plans continued to outpace private plan growth in Q4, which was a common theme through much of 2023. While helping to build our growing base of patients and prescribers, this rapid increase in public claims impacted our gross-to-net and therefore impacted net revenue for the quarter and year. On a positive note, this uptick was due in part to a clearing of the backlog in the Ontario public plan, where turnaround times have improved considerably."

"Going forward, we will also provide our outlook for Vascepa in U.S. dollars in order to simplify our guidance presentation as we are now providing a consolidated outlook for the company as well as an outlook by product."

2024 OUTLOOK

HLS is targeting 2024 consolidated revenue of \$63.5-66.5 million, or 1-5% growth. This consists of revenue from its marketed products (Vascepa and Clozaril) of \$60.5-62.5 million, or 15-19% growth, and revenue from its royalty portfolio of \$3-4 million, a 60-70% decline. Top-line growth from the Company's marketed products is therefore expected to more than offset the decline in royalty revenue.

Vascepa revenue is expected to be in a range of \$20.5-22.5 million (C\$27.5-30 million), an increase of 55-70% over 2023, while Clozaril is expected to generate revenue of approximately \$40 million, an increase of 1-2% over 2023. The Company also expects Vascepa to make a positive contribution to Adjusted EBITDA, starting in the fourth quarter of this year.

HLS is targeting 2024 consolidated Adjusted EBITDA that is flat compared to 2023 as product-related Adjusted EBITDA growth is projected to fully offset the significant decline in royalties. The Company will pursue this goal through a combination of top-line growth and cost management. HLS expects non-royalty related Adjusted EBITDA

driven by its marketed products to increase by approximately 60% over 2023. The royalty portfolio is expected to contribute just \$3-4 million to Adjusted EBITDA in 2024 compared to more than \$10 million in 2023.

Mr. Millian added: "Our go-forward optimism for Vascepa is based on recent positive operational and reimbursement catalysts combined with the ongoing strong prescription growth we experienced throughout 2023. We are excited about the projected growth in our promoted products along with their significantly increased contribution to Adjusted EBITDA in 2024. Looking ahead to 2025 and beyond, we expect consolidated revenue and Adjusted EBITDA growth to improve considerably. This is driven by four key factors: (1) we expect to exit 2024 with two profitable products (Vascepa and Clozaril) and both are expected to be profitable for the entirety of 2025; (2) we have scale in our sales and marketing model such that operating margins for Vascepa will improve on a go-forward basis as the top-line grows; (3) the royalty portfolio is expected to grow again starting in 2025; and (4) improved operating performance from our core portfolio and strengthening financials could support bringing in additional synergistic assets down the road."

CREDIT AGREEMENT

Subsequent to year end, the Company amended the terms of its credit agreement to modify certain covenant ratios. This was done to provide the Company with operating flexibility while revenue for Vascepa continues to ramp up in fiscal 2024 and while quarterly royalty revenues are expected to grow sequentially after Q1 2024.

Under the amended agreement, the Company's revolving facility has been reduced to \$25 million from \$30 million. Allowable restricted payments, which include NCIB purchases, are expected to be capped at approximately \$2.5 million in fiscal 2024, providing flexibility this year to go beyond the \$1.5 million returned to shareholders in the form of share buybacks in 2023. Interest on borrowings under the Amended Agreement accrues at a rate per month equal to the sum of the SOFR plus a range of 2.75% to 4.75% depending on the leverage ratio of the Company at the time. The Company's expansion facility of up to \$70 million to support growth opportunities remains in place.

"These amendments provide HLS with added flexibility in the near term during a transition period with the royalty portfolio in 2024," said John Hanna, Interim CFO at HLS. "We continue to view the share buyback as an important and attractive aspect of our capital allocation strategy."

Q4 & FISCAL 2023 FINANCIAL REVIEW

The Company's Management's Discussion and Analysis and Consolidated Financial Statements for the three- and twelve-month periods ended December 31, 2023, are available at the [Company's website](#) and at its profile at [SEDAR+](#).

Revenue

	Three months ended December 31,		Year ended December 31,	
	2023	2022	2023	2022
Product sales				
Canada	10,464	9,442	39,219	36,942
United States	3,835	3,991	13,515	14,742
	14,299	13,433	52,734	51,684
Royalty revenue	1,564	2,242	10,340	9,783
	15,863	15,675	63,074	61,467

Q4 2023 and fiscal 2023 revenue increased 1% and 3%, respectively, compared to the same periods in 2022. Q4 2023 and fiscal 2023 revenue increased 1% and 5%, respectively, in constant currency terms, compared to the same periods in 2022, as the decline in the Canadian dollar had an impact on the reported values, which are in U.S. dollars. Excluding royalties, revenue for the Company's marketed products (Vascepa, and Clozaril) in Q4 2023 was \$14.3 million, up 6% from Q4 2022, and for the year was \$52.7 million, up 2% from 2022.

Product sales – Canada

000's of CAD	Three months ended December 31,			Year ended December 31,		
	2023	2022	% change	2023	2022	% change
Clozaril	9,131	9,195	(0.7) %	35,160	35,776	(1.7) %
Vascepa	5,118	3,605	42.0 %	17,779	12,325	44.3 %
Other	11	6		27	6	
	14,260	12,806	11.4 %	52,966	48,107	10.1 %

Q4 2023 and fiscal 2023 product sales in Canada increased 11% and 10%, respectively, in Canadian dollars, compared to the same periods in 2022. This was led by growth in Canadian dollar sales of Vascepa, which increased 42% in Q4 2023 and 44% in fiscal 2023.

Q4 2023 and fiscal 2023 Clozaril revenue in Canada declined 1% and 2%, respectively, compared to the same periods in 2022. Clozaril revenue in Canada increased 2% sequentially from Q3 2023. Clozaril remains the leading medication for treatment resistant schizophrenia in Canada and for fiscal 2023, the number of patients taking Clozaril increased 1%.

Product Sales – United States

In the U.S., Q4 2023 and fiscal 2023 Clozaril net sales declined 4% and 8%, respectively, compared to the same periods in 2022. Key fundamentals remain in place as the year-over-year revenue declines were due to the release of provisions for expired returns in 2022 of \$0.6 million (Q4 2022) and \$1.3 million (fiscal 2022). Clozaril revenue in the U.S. increased 17% sequentially from Q3 2023.

Royalty revenues

Royalty revenues were \$1.6 million in Q4 2023, down 30% from Q4 2022, as the term for what was the largest royalty in the portfolio came to an end midway through the quarter. Royalty revenue was \$10.3 million for fiscal 2023, up 6% from 2022. The fiscal 2023 increase was primarily due to a one-time milestone receipt of \$0.5 million included in Q2 2023 related to the approval of Xenpozyme.

Operating Expenses

	Three months ended December 31,		Year ended December 31,	
	2023	2022	2023	2022
Cost of product sales	2,533	1,517	7,624	4,981
Selling and marketing	4,716	5,169	19,896	17,846
Medical, regulatory and patient support	1,386	1,606	5,574	5,727
General and administrative	1,888	2,046	8,928	9,086
	10,523	10,338	42,022	37,640

Cost of product sales was up for the year due to higher sales volumes of Vascepa. In addition, Q4 2023 included a provision of \$0.5 million against inventory.

Selling and marketing expenses were up for the year due to increased promotional efforts related to Vascepa. However, selling and marketing expenses were lower in Q4 2023 and medical, regulatory and patient support expenses, as well as general and administrative expenses, were lower for both the quarter and the year due to the Company's ongoing cost management efforts.

Adjusted EBITDA¹

	Three months ended December 31,		Year ended December 31,	
	2023	2022	2023	2022
Net loss for the period	(5,401)	(6,429)	(27,531)	(23,598)
Stock-based compensation	(601)	752	(538)	2,922
Amortization and depreciation	7,047	8,692	31,939	34,402
Finance and related costs, net	2,109	2,188	11,237	5,040
Other costs	2,111	229	6,217	5,185
Income tax expense (recovery)	75	(95)	(272)	(124)
Adjusted EBITDA	5,340	5,337	21,052	23,827

Q4 2023 Adjusted EBITDA was \$5.3 million, which was flat compared to Q4 2022. Fiscal 2023 Adjusted EBITDA was \$21.1 million compared to \$23.8 million in 2022. The decrease for the year 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 generated strong Adjusted EBITDA and cash flow for the business in both Q4 2023 and fiscal 2023.

For fiscal 2023, the direct brand contribution from Clozaril to Adjusted EBITDA was \$29.7 million, while the direct brand contribution from Vascepa to Adjusted EBITDA was a loss of \$9.2 million.

Net Loss

Net loss for Q4 2023 was (\$5.4) million, or (\$0.17) per share, compared to a net loss of (\$6.4) million, or (\$0.20) per share, in Q4 2022. Net loss for fiscal 2023 was (\$27.5) million, or (\$0.85) per share, compared to a net loss of (\$23.6) million, or (\$0.73) per share, in 2022. For fiscal 2023, revenue growth was offset by the increase in cost of product sales and selling and marketing expenses related to Vascepa, and higher finance and related costs, due to higher interest expense, as well as fair value adjustments for the contingent liability for a future milestone payment and an interest rate swap that settled in the year. Other costs in Q4 2023 included a non-cash charge of \$1.5 million related to ceasing commercialization of Trinomia.

Cash from Operations and Financial Position

Cash generated from operations in Q4 2023 and fiscal 2023 was \$3.7 million and \$15.8 million, respectively, compared to \$3.5 million and \$16.9 million in the same periods last year. Cash was \$22.0 million at December 31, 2023, up from \$20.7 million at December 31, 2022.

Total borrowings under the credit agreement at December 31, 2023, was \$88.5 million compared to \$97.3 million at December 31, 2022.

Q4 FISCAL 2023 CONFERENCE CALL

HLS will hold a conference call today at 8:30 am Eastern Time to discuss its Q4 and fiscal 2023 financial results. The call will be hosted by Mr. Craig Millian, CEO, and Mr. John Hanna, Interim CFO. **To view the slides that accompany management's discussion, please use the webcast link.**

CONFERENCE ID: 51683499

DATE: Thursday, March 14, 2024

TIME: 8:30 a.m. ET

WEBCAST LINK: <https://app.webinar.net/1lgp2aPDwy0>

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/3vCiu23>

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

REPLAY CODE: 683499#

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", 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 13, 2024, and Management's Discussion and Analysis dated March 13, 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.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

Unaudited

[in thousands of U.S. dollars]

	As at December 31, 2023	As at December 31, 2022
ASSETS		
Current		
Cash	21,952	20,723
Accounts receivable	10,608	10,999
Inventories	9,534	8,902
Income taxes recoverable	86	195
Other current assets	1,915	3,555
Total current assets	44,095	44,374
Property, plant and equipment	965	1,127
Intangible assets	162,344	195,018
Deferred tax asset	1,037	465
Other non-current assets	619	668
Total assets	209,060	241,652
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current		
Accounts payable and accrued liabilities	14,107	12,785
Provisions	5,424	2,934
Debt and other liabilities	6,876	15,471
Income taxes payable	281	—

Total current liabilities	84,598	84,598
Debt and other liabilities	84,293	84,578
Deferred tax liability	442	566
Total liabilities	111,363	116,334
Shareholders' equity		
Share capital	262,127	265,206
Contributed surplus	13,865	13,821
Accumulated other comprehensive loss	(2,838)	(5,260)
Deficit	(175,457)	(148,449)
Total shareholders' equity	97,697	125,318
Total liabilities and shareholders' equity	209,060	241,652

HLS THERAPEUTICS INC.
INTERIM CONSOLIDATED STATEMENTS OF LOSS
Unaudited

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

	Three months ended		Year ended	
	December 31,		December 31,	
	2023	2022	2023	2022
Revenue	15,863	15,675	63,074	61,467
Expenses				
Cost of product sales	2,533	1,517	7,624	4,981
Selling and marketing	4,716	5,169	19,896	17,846
Medical, regulatory and patient support	1,386	1,606	5,574	5,727
General and administrative	1,888	2,046	8,928	9,086
Stock-based compensation	(601)	752	(538)	2,922
Amortization and depreciation	7,047	8,692	31,939	34,402
Finance and related costs, net	2,109	2,188	11,237	5,040
Other costs	2,111	229	6,217	5,185
Loss before income taxes	(5,326)	(6,524)	(27,803)	(23,722)
Income tax recovery	75	(95)	(272)	(124)
Net loss for the period	(5,401)	(6,429)	(27,531)	(23,598)
Net loss per share:				
Basic and diluted	\$(0.17)	\$(0.20)	\$(0.85)	\$(0.73)

HLS THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
Unaudited

[in thousands of U.S. dollars]

	Three months ended		Year ended	
	December 31,		December 31,	
	2023	2022	2023	2022
Net loss for the period	(5,401)	(6,429)	(27,531)	(23,598)
Item that may be reclassified subsequently to net loss				
Unrealized foreign currency translation adjustment	2,186	1,345	2,422	(8,219)
Comprehensive loss for the period	(3,215)	(5,084)	(25,109)	(31,817)

HLS THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
Unaudited

[in thousands of U.S. dollars]

Accumulated other

	Share capital	Contributed surplus	comprehensive income (loss)	Deficit	Total
Balance, December 31, 2021	265,917	11,717	2,959	(119,857)	160,736
Stock options exercised	251	(67)	—	—	184
Shares repurchased	(962)	—	—	(36)	(998)
Share purchase obligation	—	(185)	—	—	(185)
Stock option expense	—	2,356	—	—	2,356
Net loss for the year	—	—	—	(23,598)	(23,598)
Dividends declared	—	—	—	(4,958)	(4,958)
Unrealized foreign currency translation adjustment	—	—	(8,219)	—	(8,219)
Balance, December 31, 2022	265,206	13,821	(5,260)	(148,449)	125,318
Stock options exercised	178	(44)	—	—	134
Shares repurchased	(3,257)	—	—	1,705	(1,552)
Share purchase obligation	—	(115)	—	—	(115)
Stock option expense	—	203	—	—	203
Net loss for the year	—	—	—	(27,531)	(27,531)
Dividends declared	—	—	—	(1,182)	(1,182)
Unrealized foreign currency translation adjustment	—	—	2,422	—	2,422
Balance, December 31, 2023	262,127	13,865	(2,838)	(175,457)	97,697

HLS THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

Unaudited

[in thousands of U.S. dollars]

	Three months ended December 31,		Year ended December 31,	
	2023	2022	2023	2022
OPERATING ACTIVITIES				
Net loss for the period	(5,401)	(6,429)	(27,531)	(23,598)
Adjustments to reconcile net loss to cash provided by operating activities				
Stock-based compensation	(601)	752	(538)	2,922
Amortization and depreciation	7,047	8,692	31,939	34,402
Impairment charge	1,541	—	3,893	3,051
Accreted interest	217	198	797	810
Fair value adjustment on financial assets and liabilities	(263)	237	2,888	(2,330)
Deferred income taxes	107	(95)	(696)	138
Net change in non-cash working capital balances related to operations	1,087	166	5,037	1,547
Cash provided by operating activities	3,734	3,521	15,789	16,942
INVESTING ACTIVITIES				
Additions to property, plant and equipment	(14)	(9)	(41)	(45)
Royalty milestone payment	—	—	—	(10,000)
Additions to intangible assets	—	(11)	(148)	(103)
Cash used in investing activities	(14)	(20)	(189)	(10,148)
FINANCING ACTIVITIES				
Stock options exercised	—	—	134	184
Shares repurchased	(580)	(350)	(1,552)	(998)
Dividends paid	—	(1,193)	(2,398)	(4,962)
Drawdown under credit agreement	—	—	—	10,000
Repayment of borrowing under credit agreement	(3,172)	(2,389)	(8,855)	(9,778)
Debt costs	—	—	(1,360)	(639)
Lease payments	(134)	(162)	(608)	(663)
Cash used in financing activities	(3,886)	(4,094)	(14,639)	(6,856)
Net increase (decrease) in cash during the period	(166)	(593)	961	(62)

Foreign exchange on cash	310	37	268	(394)
Cash, beginning of period	21,808	21,279	20,723	21,179
Cash, end of period	21,952	20,723	21,952	20,723

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/2024-03-14-HLS-Therapeutics-Announces-Fiscal-2023-Financial-Results>