

HLS Therapeutics Announces Q4 and Fiscal 2022 Financial Results

TORONTO, March 16, 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 twelve-month periods ended December 31, 2022. All amounts are in thousands of United States ("U.S.") dollars unless otherwise stated.

Q4 & FISCAL 2022 FINANCIAL HIGHLIGHTS

- 2022 revenue of \$61.5 million, Adjusted EBITDA of \$23.8 million and cash-flow from operations of \$16.9 million.
- Q4 2022 revenue was \$15.7 million, up 4% to \$16.4 million measured in constant currency.
- 2022 revenue was \$61.5 million, up 5% to \$63.0 million measured in constant currency.
- Q4 2022 Vascepa net revenue was C\$3.6 million compared to C\$2.4 million in Q4 2021, up 51%. In the near-term, Vascepa net revenue growth will trail growth in prescriptions as net pricing adjusts to additional public sector volumes.
- 2022 Vascepa net revenue was C\$12.3 million compared to C\$7.4 million in 2021; up 67%.
- Q4 2022 Adjusted EBITDA was \$5.3 million compared to \$6.2 million in Q4 2021.
- 2022 Adjusted EBITDA was \$23.8 million compared to \$26.3 million in 2021.
- Q4 2022 net loss was (\$6.4) million, compared to net loss of (\$4.2) million in Q4 2021.
- 2022 net loss was (\$23.6) million, compared to net loss of (\$13.1) million in 2021.
- Renewed the Company's Normal Course Issuer Bid ("NCIB"). Share repurchases in 2022 totaled \$1.0 million.
- Extended and updated certain terms of the credit facility to provide additional capital flexibility.

Q4 & FISCAL 2022 OPERATIONAL HIGHLIGHTS

- 2022 total Vascepa prescription volumes ("TRx") grew 85% year-over-year and grew 22% sequentially in Q4 2022.
- 3,300 physicians have prescribed Vascepa, up 92% year-over-year.
- New Prescriptions ("NRx") increased 124% in Quebec and 67% in Ontario in Q4 2022 following recent public reimbursement listings.
- Expanded access to Vascepa by adding public reimbursement for more than 70% of publicly covered lives in Canada.
- Vascepa remains the fastest growing product amongst its competitive set on a monthly, quarterly and trailing twelve-month basis.

"In 2022, HLS delivered revenue growth with reliable cash flows and Adjusted EBITDA, while increasing investment in sales activities related to Vascepa," said Gilbert Godin, CEO of HLS. "On a constant currency basis, consolidated revenue for 2022 increased 5%, reflecting Vascepa's growing top-line contribution. Vascepa's net revenue grew 67% in 2022, also on a constant currency basis."

"We continue to see growing adoption rates for Vascepa which are reflected in the greater number of physicians and patients who are new to the product, particularly in Quebec and Ontario where Q4 NRx growth rates were 124% and 67%, respectively."

"While claims processing by the Quebec drug plan continues to improve resulting in a higher Vascepa growth rate, prescribers in Ontario are reporting a more burdensome public authorization process. We are working with the province to facilitate and simplify the onboarding of new public plan patients. We are confident this will further improve access for those who are at risk of cardiovascular disease."

"Vascepa is well-positioned with public and private reimbursement in place, standard-of-care endorsements from Canadian medical societies, greater access to physicians and fully operational field personnel. Our focus today is on maximizing access and physician interactions. The steady level of field activity in Q4 lays the groundwork for future adoption as increasing the frequency of calls to relevant physicians is essential to generate trial and adoption."

Mr. Godin continued: "Regarding other products in the portfolio, we have successfully maintained our leadership position for Clozaril in Canada at a time when the mental health settings of care have been under pressure. During this period, Clozaril has continued to generate steady and reliable financial results. In 2022, Clozaril revenue in Canada was essentially level year-over-year (on a constant currency basis) as the market continues to recover from the effect that the pandemic had on access to, and initiation of, refractory schizophrenic treatments. We continued the roll-out of CSAN Pronto and believe it will further strengthen our leadership position with Clozaril."

"And finally, we have met with Health Canada to discuss the positive results of the recent Spanish SECURE trial for Trinomia and expect to refile the product in the second half of this year. Trinomia combines three common medications in one daily pill for patients who have experienced a cardiac event. A polypill such as Trinomia can help improve medication compliance, which is important for reducing the likelihood of a subsequent cardiac event in such patients as evidenced in the Spanish trial."

VASCEPA OUTLOOK

In 2023, HLS expects Vascepa's net revenue to be in a range of C\$22-28 million, starting with expected year over year growth of approximately 40-50% in Q1 2023. Growth rates for Vascepa are expected to increase as the year progresses as the frequency of contact with physicians continues and in-line with customary seasonality factors.

DIVIDEND

On March 15, 2023, the Company's Board of Directors declared a dividend of C\$0.05 per outstanding common share to be paid on June 15, 2023, to shareholders of record as of April 28, 2023.

These dividends paid on the Company's common shares are designated to be "eligible dividends" for purposes of section 89(1) of the *Income Tax Act* (Canada).

Q4 & FISCAL 2022 FINANCIAL REVIEW

The Company's Management's Discussion and Analysis and Consolidated Financial Statements for the three- and twelve-month periods ended December 31, 2022 are available at the [Company's website](#) and at its profile at [SEDAR](#).

Revenue	Three months ended December 31,		Year ended December 31,	
	2022	2021	2022	2021
Product sales				
Canada	9,442	9,245	36,942	34,609
United States	3,991	4,003	14,742	16,013
	13,433	13,248	51,684	50,622
Royalty revenue	2,242	2,442	9,783	9,387
	15,675	15,690	61,467	60,009

Product sales

2022 product sales in Canada grew 11% in local currency (7% growth in reported U.S. dollars), led by increased sales of Vascepa, which grew 67% (also in local currency) compared to 2021.

In Canada, Clozaril continues to be the leading medication for treatment-resistant schizophrenia with the number of active patients growing modestly during 2022 in a relatively flat market. On a constant currency and reported basis, revenues in 2022 were relatively flat to 2021 as the market continues its recovery from the impact the pandemic had on patient access to treatment and new patient enrollment. In the US, Clozaril net sales decreased 8% in 2022 reflecting several one-time benefits in 2021 as well as a modest erosion of patients, offset, in part, by favorable trends in pricing, expired returns and government rebates.

Royalty revenues

Royalty revenues were \$9.8 million in 2022, an increase of 4% from 2021. Commercialization for the product underlying the fourth royalty interest in the portfolio started in 2022 following approvals in the US, Japan and Europe earlier in the year.

Operating expenses	Three months ended December 31,		Year ended December 31,	
	2022	2021	2022	2021
Cost of product sales	1,517	1,122	4,981	3,972
Selling and marketing	5,169	4,407	17,846	14,660
Medical, regulatory and patient support	1,606	1,508	5,727	5,679
General and administrative	2,046	2,471	9,086	9,364
	10,338	9,508	37,640	33,675

Operating expenses in 2022 increased 12% from 2021. Cost of product sales increased due to the year-over-year growth in Vascepa sales. Higher selling and marketing expenses were due primarily to an increase in sales activities related to Vascepa, which included expansion of the primary care salesforce, marketing support costs following the achievement of public market access and greater physician interaction following removal of public health restrictions in late Q1 2022. Medical, regulatory and patient support costs were flat year-over-year and general and administrative costs decreased modestly year-over-year.

Adjusted EBITDA¹	Three months ended December 31,		Year ended December 31,	
	2022	2021	2022	2021
Net loss for the period	(6,429)	(4,188)	(23,598)	(13,117)
Stock-based compensation	752	529	2,922	2,354
Amortization and depreciation	8,692	8,045	34,402	30,264
Finance and related costs, net	2,188	1,048	5,040	5,355
Transaction and other costs	229	77	5,185	169
Income tax expense (recovery)	(95)	671	(124)	1,309
Adjusted EBITDA	5,337	(4,188)	23,827	26,334

Adjusted EBITDA in 2022 was 10% lower year-over-year due primarily to the increased selling and marketing expense and increased cost of product sales related to the growth in sales of Vascepa.

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

Net Loss

Net loss for 2022 was (\$23.6 million), or (\$0.73) per share, compared to a net loss of (\$13.1 million), or (\$0.41) per share, in 2021. Net loss increased as revenue growth was offset by higher cost of product sales and selling and marketing expense related to the expansion of Vascepa, as well as higher amortization and depreciation, and transactions and other costs.

Cash from Operations and Financial Position

Cash generated from operations was \$16.9 million in 2022, compared to \$16.4 million in 2021. Cash and cash equivalents were \$20.7 million at December 31, 2022 compared to \$21.2 million at December 31, 2021. In 2022, HLS made dividend payments totaling \$5.0 million, share buybacks under the NCIB of \$1.0 million and \$9.8 million in repayments on the senior secured term loan.

In September 2022, HLS updated its credit agreement and senior secured term loan with its existing syndicate of lenders. The updates extended the maturity of the loan by one year and increased the financial flexibility for the Company as it executes on its strategic priorities. Total borrowing and unused borrowing capacity remain unchanged.

As at December 31, 2022, HLS has a strong financial position with \$20.7 million of cash and cash equivalents, \$26.0 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.

Q4 & FISCAL 2022 CONFERENCE CALL

HLS will hold a conference call today at 8:30 am Eastern Time to discuss its Q4 and 2022 financial results. The call will be hosted by Mr. Gilbert Godin, Chief Executive Officer and Mr. Tim Hendrickson, Chief Financial Officer.

To view the slides that accompany management's discussion, please use the webcast link.

CONFERENCE ID: 87818126

DATE: Thursday, March 16, 2023

TIME: 8:30 a.m. ET

WEBCAST LINK: <https://app.webinar.net/njRg4QKpA0E>

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

NUMBER:

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://bit.ly/3kl1DLy>

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

REPLAY CODE: 818126#

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) "transaction costs and other charges", (iv) "finance and related 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.

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 March 15, 2023, both of which have been filed on SEDAR and can be accessed at www.sedar.com. Accordingly, readers should not place undue reliance on any forward-looking statements or information. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made and HLS undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

HLS THERAPEUTICS INC.
INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
Unaudited

[in thousands of U.S. dollars]

	As at December 31, 2022	As at December 31, 2021
ASSETS		
Current		
Cash	20,723	21,179
Accounts receivable	10,999	11,511
Inventories	8,902	8,925
Income taxes recoverable	195	—
Other current assets	3,555	2,136
Total current assets	44,374	43,751
Property, plant and equipment	1,127	1,569
Intangible assets	195,018	229,181
Deferred tax asset	465	690
Other non-current assets	668	714
Total assets	241,652	275,905
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current		
Accounts payable and accrued liabilities	12,785	10,596
Provisions	2,934	3,472
Debt and other liabilities	15,471	13,507
Income taxes payable	—	97
Total current liabilities	31,190	27,672
Debt and other liabilities	84,578	86,844
Deferred tax liability	566	653
Total liabilities	116,334	115,169
Shareholders' equity		
Share capital	265,206	265,917
Contributed surplus	13,821	11,717
Accumulated other comprehensive income (loss)	(5,260)	2,959
Deficit	(148,449)	(119,857)
Total shareholders' equity	125,318	160,736
Total liabilities and shareholders' equity	241,652	275,905

HLS THERAPEUTICS INC.
INTERIM CONSOLIDATED STATEMENTS OF LOSS
Unaudited

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

	Three months ended December 31, 2022 2021		Year months ended December 31, 2022 2021	
Revenue	15,675	15,690	61,467	60,009
Expenses				
Cost of product sales	1,517	1,122	4,981	3,972
Selling and marketing	5,169	4,407	17,846	14,660
Medical, regulatory and patient support	1,606	1,508	5,727	5,679
General and administrative	2,046	2,471	9,086	9,364
Stock-based compensation	752	529	2,922	2,354

Amortization and depreciation	8,692	8,045	34,402	30,264
Finance and related costs, net	2,188	1,048	5,040	5,355
Transaction and other costs	229	77	5,185	169
Loss before income taxes	(6,524)	(3,517)	(23,722)	(11,808)
Income tax expense (recovery)	(95)	671	(124)	1,309
Net loss for the period	(6,429)	(4,188)	(23,598)	(13,117)

Net loss per share:

Basic and diluted	\$(0.20)	\$(0.13)	\$(0.73)	\$(0.41)
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**HLS THERAPEUTICS INC.
INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

Unaudited

[in thousands of U.S. dollars]

	Three months ended December 31,		Nine months ended December 31,	
	2022	2021	2022	2021
Net loss for the period	(6,429)	(4,188)	(23,598)	(13,117)
Item that may be reclassified subsequently to net loss				
Unrealized foreign currency translation adjustment	1,345	798	(8,219)	939
Comprehensive loss for the period	(5,084)	(3,390)	(31,817)	(12,178)

**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, 2020	257,411	11,393	2,020	(101,575)	169,249
Warrants exercised	3,203	(192)	—	—	3,011
Stock options exercised	5,332	(1,410)	—	—	3,922
Shares repurchased	(29)	—	—	(18)	(47)
Stock option expense	—	1,926	—	—	1,926
Net loss for the year	—	—	—	(13,117)	(13,117)
Dividends declared	—	—	—	(5,147)	(5,147)
Unrealized foreign currency translation adjustment	—	—	939	—	939
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

HLS THERAPEUTICS INC.
INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS
Unaudited

[in thousands of U.S. dollars]

	Three months ended December 31,		Year ended December 31,	
	2022	2021	2022	2021
OPERATING ACTIVITIES				
Net loss for the period	(6,429)	(4,188)	(23,598)	(13,117)
Adjustments to reconcile net loss to cash provided by operating activities				
Stock-based compensation	752	529	2,922	2,354
Amortization and depreciation	8,692	8,045	34,402	30,264
Impairment charge	—	—	3,051	—
Accreted interest	198	206	810	783
Fair value adjustment on financial assets and liabilities	237	(797)	(2,330)	(1,970)
Deferred income taxes	(95)	617	138	1,136
Net change in non-cash working capital balances related to operations	166	(434)	1,547	(3,021)
Cash provided by operating activities	3,521	3,978	16,942	16,429
INVESTING ACTIVITIES				
Additions to property, plant and equipment	(9)	(22)	(45)	(47)
Royalty milestone payment	—	—	(10,000)	—
Rights acquisitions	—	—	—	(3,820)
Other additions to intangible assets	(11)	(400)	(103)	(643)
Cash used in investing activities	(20)	(422)	(10,148)	(4,510)
FINANCING ACTIVITIES				
Stock options exercised	—	260	184	3,922
Warrants exercised	—	—	—	986
Shares repurchased	(350)	—	(998)	(47)
Dividends paid	(1,193)	(1,269)	(4,962)	(5,122)
Drawdown under credit agreement	—	—	10,000	—
Repayment of credit agreement borrowing	(2,389)	(3,000)	(9,778)	(10,500)
Debt costs	—	—	(639)	—
Lease payments	(162)	(161)	(663)	(637)
Cash used in financing activities	(4,094)	(4,170)	(6,856)	(11,398)
Net increase (decrease) in cash during the period	(593)	(614)	(62)	521
Foreign currency translation	37	57	(394)	46
Cash, beginning of period	21,279	21,736	21,179	20,612
Cash, end of period	20,723	21,179	20,723	21,179

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/2023-03-16-HLS-Therapeutics-Announces-Q4-and-Fiscal-2022-Financial-Results>