HLS Therapeutics®

Q2 Fiscal 2024 Conference Call
August 8, 2024

Craig Millian, CEO
John Hanna, Interim CFO



Forward-Looking Statements

HLS Therapeutics®

Certain statements in this presentation are “forward-looking statements”. Any statements that express or involve discussions with respect to predictions, expectations, beliefs, plans, projections, objectives, assumptions or future events or performance (often, but not always using words or phrases such as “project”, “forecast”, “target”, “expect”, “seek”, “endeavour”, “anticipate”, “plan”, “estimate”, “believe”, “intend”, or stating that certain actions, events or results may, could, should, would, might or will occur or be taken, or achieved) are not statements of historical fact and may be “forward-looking statements”. Forward-looking statements are based on expectations, estimates and projections at the time the statements are made that involve a number of known and unknown risks and uncertainties which would cause actual results or events to differ materially from those presently anticipated. A number of factors could cause actual results, performance or achievements to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements. Should one or more of these risks or uncertainties materialize, or should assumptions underlying the forward-looking statements prove incorrect, actual results, performance or achievements could vary materially from those expressed or implied by the forward-looking statements contained in this presentation. These factors should be considered carefully and prospective investors should not place undue reliance on these forward-looking statements. Although the forward-looking statements contained in this presentation are based upon what HLS currently believes to be reasonable assumptions, HLS cannot assure prospective investors that actual results, performance or achievements will be consistent with these forward-looking statements. Except as required by law, HLS does not have any obligation to advise any person if it becomes aware of any inaccuracy in or omission from any forward-looking statement, nor does it intend, or assume any obligation, to update or revise these forward-looking statements to reflect new events or circumstances.

All figures in USD unless otherwise noted.

Historical financials are per HLS filed quarterly and annual statements

Forward-looking financial estimates are converted at an exchange rate of 1 USD = 1.35 CAD

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Q2 2024: Financial Highlights

HLS Therapeutics®

Revenue:
$14.5M

Adjusted EBITDA:
$4.3M

Cash from operations:
$2.5M

11% ↑ HLS Canadian product sales

86% ↑ Adjusted EBITDA excluding royalties

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CLOZARIL®
Clozapine

Life-changing medicine for Treatment Resistant Schizophrenia

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Solid Q2 Performance with Momentum Heading into 2H'24

CLOZARIL® Clozapine

US$10.1M
Q2 revenue

US$7.6M
Q2 direct contribution to Adjusted EBITDA

Canadian Q2 revenue up 5% YoY*

U.S. Q2 revenue up 9% YoY

*in Canadian dollars



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Research Article

The Impact of Pharmaceutical Support Programs on Persistence: Clinical, Human and Economic Impact of Clozapine Support Programs in Quebec, Canada

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Abstract

Objective: Though clozapine products have the same clinical benefits, Patient Support Programs (PSPs) may have an impact on treatment persistence. This study aimed to evaluate the impact of clozapine PSPs on treatment persistence, from the Quebec perspective.

Methods and analysis: An 18-month persistence study was conducted using data from the Régie de l' Assurance Maladie du Québec (RAMQ) for patients who initiated clozapine. The persistence rate on clozapine was compared with and without PSPs, which were used to model potential hospitalization, suicide attempts, emergency room consultations, physician visits, and clozapine withdrawal symptoms and their respective costs as well as drug acquisition. Mean annual per-patient costs (2023 Canadian dollars) for clozapine were calculated, considering persistence rates and healthcare resource utilization with and without clozapine from literature. The one-year economic impact was calculated based on the estimated prevalence of TRS patients on clozapine in Quebec.

Results: Persistence rates were better when clozapine was paired with a PSP, and there was a statistical difference in persistence rates between products. The persistence rates of 122 patients on CSAN and GenCAN, two PSPs in Quebec, were 69% and 55% (p=0.040), respectively, as opposed to the 25% reported persistence rate. Despite higher annual treatment costs based on list prices (+$2,097 per patient), the improved persistence on CSAN compared to GenCAN translates into annual savings of $3,324 per patient or $23.4 million for the Quebec healthcare system.

Conclusion: PSPs offer an important advantage in improving clozapine persistence, and there are significant differences in clozapine persistence between PSPs.

Keywords: Persistence; Schizophrenia; Canada; Clozapine; Patient support program; Adherence; Burden; Cost

Abbreviations

CSAN: Clozaril Support and Assistance Network; ER: Emergency Room; PSP: Patient Support Program; RAMQ: Régie de l'Assurance Maladie du Québec; SCZ: Schizophrenia; TRS: Treatment-Resistant Schizophrenia

Introduction

Schizophrenia (SCZ) is a complex, chronic psychiatric disorder characterized by a myriad of symptoms, including delusions, hallucinations, disorganized speech or behavior, and impaired cognitive ability [1]. Although SCZ only affects around 1% of the population it imposes a disproportionate burden on society and the health care system [1,2]. The most recent Canadian study on this topic estimated that, in 2004, the total economic burden attributed to SCZ, including both direct and indirect costs was 6.85 billion dollars [3]. Despite significant improvements in the past decades in pharmacological SCZ treatments, about 30% of patients have Treatment-Resistant SCZ (TRS), usually defined as treatment failure despite adequate trials with at least 2 different antipsychotic medications other than clozapine [4,5]. Clozapine is the only treatment approved for these patients in Canada [5,6] however of those who initiate clozapine a substantial proportion (some estimates suggesting almost 75%, in the first year) discontinue therapy for various reasons such as adverse events, or low compliance challenges [7]. Since clozapine is the only approved treatment in Canada for treatment-resistant schizophrenia, and there is a high relapse rate when patients stop taking medication, non-persistence to clozapine is detrimental since it is associated with increased hospitalizations, mortality, suicide, delayed remission, poorer prognosis, worsening psychiatric symptoms, unemployment, and poor quality of life [8-11].

Canada is among the five countries (with the United States, United Kingdom, Australia, New Zealand, and Japan) that require that each manufacturer of clozapine implement a Patient Support Program (PSP) that includes a patient registry that assures compliance with laboratory monitoring for agranulocytosis. While various clozapine brands may offer the same clinical benefits from an ingredient perspective, proprietary differences in the PSP's operations and offerings may have an impact on treatment persistence, having a substantial economic impact on the health care system. Indeed, the positive impact of PSPs has been seen in other therapeutic areas as

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Goal is to grow North American Clozaril sales 1-2% annually, on average

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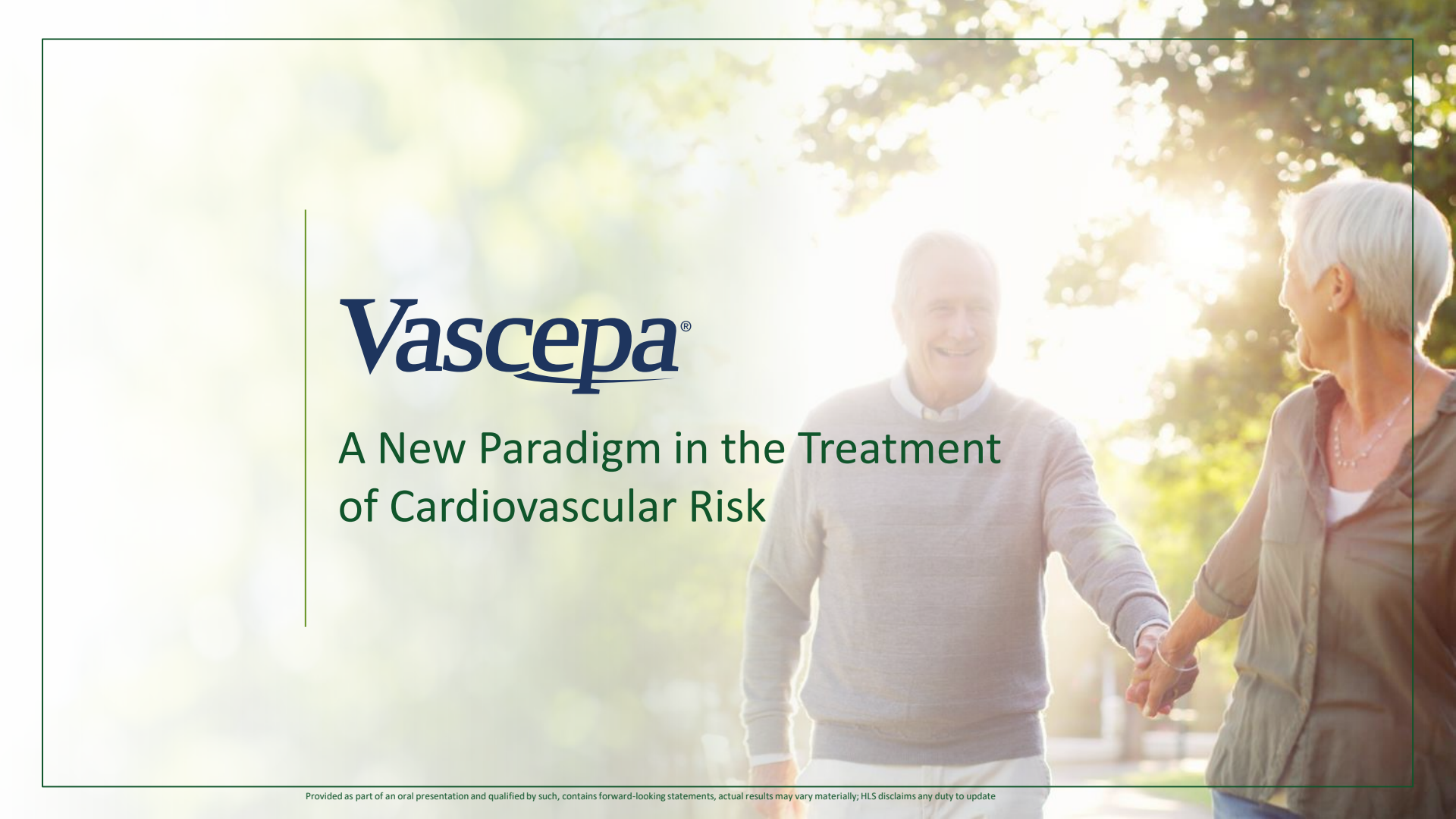

Vascepa®

A New Paradigm in the Treatment of Cardiovascular Risk

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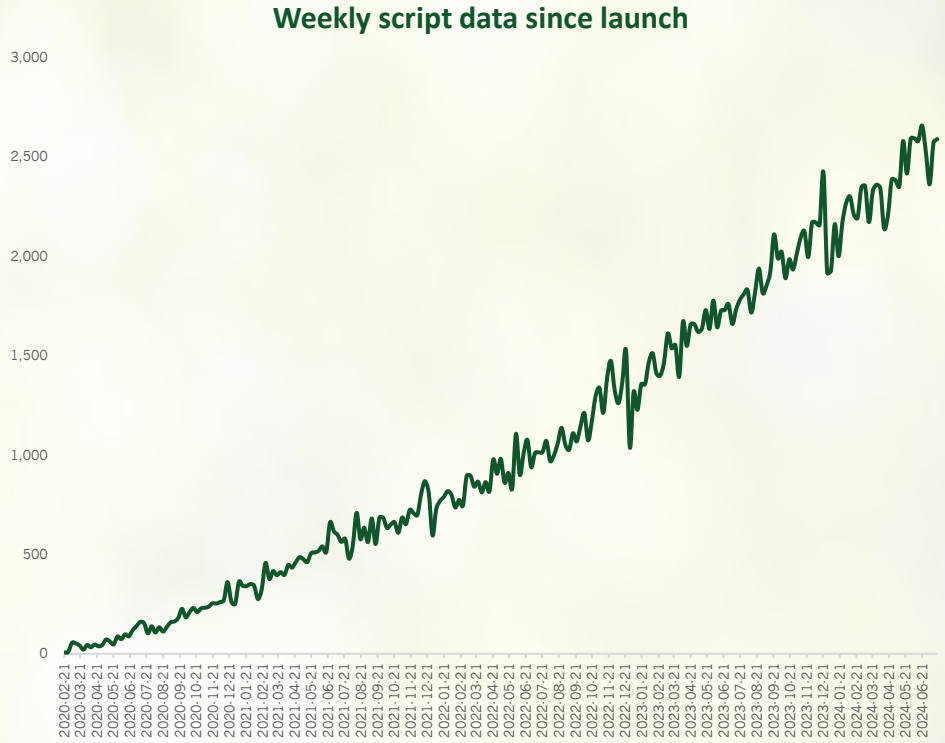
Continued Growth in Prescribing

Vascepa®



76% increase
in consistent prescribers*

45% increase
in unit demand*

21% increase
in revenue (in C$)*

*Q2 2024 compared to Q2 2023

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Vascepa Catalysts for 2H'24

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Bringing Primary Care Sales In-house

Significant cost savings

Increased ownership and accountability

Improving Reimbursement

>90% national coverage for eligible private & public plan patients (recent PLA in Alberta)

Reduced Ontario authorization backlog (from >50 days to <5)

Growing the private payer segment

Enhanced financial assistance program launched in May

25% growth in program participants in recent three-month period

Long period of Vascepa exclusivity into late 2030s

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Royalty Portfolio

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Sold Xenpozyme Royalty Interest Valued at up to $45.75M

$13.25M upfront in cash

$14.0M in potential sales-based milestone payments

$18.5M potential milestone payment obligations assumed by DRI

Accelerates de-leveraging

Strengthens balance sheet

Reduces annual interest expense by $1.5M

Places focus on marketed products

Provides greater flexibility for future capital allocation

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2024 Guidance

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2024 Guidance

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Consolidated revenue: $58.5-59.7M

Clozaril revenue: ~$40M

Vascepa revenue: $17-$18M
(C$22.5-$24.5M)

Royalty revenue: $1.5-1.7M

Adjusted EBITDA: $15.5-16.7M

Vascepa goal: positive contribution to Adjusted EBITDA in Q4 2024

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Financial Review: Solid Foundation to support our growth

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Q2 2024: Financial Review

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Revenue: $14.5M

- ↑ 9% Excluding royalties
- ↑ 11% Canadian product sales*
- ↑ 21% Vascepa
- ↑ 5% Clozaril Canada
- ↑ 9% Clozaril U.S.

Operating Expenses

- ↓ 11% OPEX excluding cost of sales
- ↓ 14% Selling & marketing
- ↓ 17% General & admin

Adjusted EBITDA: $4.3M

- ↑ 86% AEBITDA excluding royalties
- $7.6M Direct to brand contribution from Clozaril
- ($1.6)M Direct to brand contribution from Vascepa

*in Canadian dollars

OPEX savings from the new primary care sales model for Vascepa to begin in Q4

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Strong Balance Sheet

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Summary Balance Sheet & Capitalization

(US$ millions)	At Dec 31, 2023	At Jun 30, 2024
Cash and Cash Equivalents	22.0	**32.5**
Senior Secured Term Loan and Revolver	88.5	**84.9**
Net Debt (Term Loan less Cash)	66.5	**52.4**

	At Dec 31, 2023	At Jun 30, 2024
Shares Outstanding (‘000’s)	31,980	**31,793**

Subsequent to quarter-end

Made $14M debt payment

Reduced term loan to ~ $71M

Q2 2024 Cash Flow From Operations $2.5M

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Q2 Summary

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1. Solid growth from promoted products Clozaril and Vascepa
2. Delivering on our promise to reduce costs
3. Monetized Xenpozyme asset: strengthens financials and increases flexibility
4. Actions set HLS up for future growth and profitability

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