HELIXBIOPHARMA

December 14, 2022
Press Release

2704 - 401 Bay Street
Toronto, Ontario
M5H 2Y4
Tel: 905-841-2300
www.helixbiopharma.com

HELIX BIOPHARMA CORP. ANNOUNCES FISCAL 2023 FIRST QUARTER RESULTS

(Toronto, Ontario) – Helix BioPharma Corp. (TSX: "HBP"), ("**Helix**" or the "**Company**"), a clinical-stage biopharmaceutical company developing unique therapies in the field of immuno-oncology based on its proprietary technological platform DOS47, today announced financial results for the fiscal 2023 first quarter results for the three-month period ending October 31, 2022.

OVERVIEW

The Company reported a net loss and total comprehensive loss of $1,606,000 or $0.01 loss per common share for the three-month period ended October 31, 2022 (2021 - $1,813,000 or $0.01 loss per common share).

Clinical development

LDOS47 in lung cancer

- The Phase I study combination therapy in lung cancer (LDOS001) was completed and the final clinical trial report issued in December 2021. A manuscript was accepted for publication in *Journal of Thoracic Oncology Clinical and Research Reports* on September 2nd, 2022.
- The Phase II study of combination therapy in lung cancer (LDOS003) was halted in the dose escalation portion of the study in 2020 at the height of pandemic lockdown and the final abbreviated clinical trial report has been further delayed amidst war in Ukraine where all subjects were recruited. A final effort is being made in an attempt to retrieve any data that is salvageable and conclude the study.
- Another important aspect of the development of the LDOS47 platform is the combination with chemo- and/or immuno-therapy, that may boost the utility of the platform. The Company has engaged several key opinion leaders to evaluate the feasibility of such combinations and aims to develop a roadmap by the second quarter of 2023.

LDOS47 in pancreatic cancer

The Company's Phase Ib/II combination trial in pancreatic cancer (LDSOS006) continues to recruit patients, as the Company remains committed to this study. The second dosing cohort was successfully completed in November 2022 without any safety concerns and enrolment into the third dosing cohort (9 μg/kg) has now opened.

Corporate development

- On August 9, 2022, the Company announced that it has entered into a two-year scientific collaboration agreement ("Agreement") with University Hospital Tubingen (Germany) to assess the therapeutic response of L-DOS47 in several cancer models expressing CEACAM6, with advanced preclinical metabolic imaging.

- On August 30, 2022, the Company announced that it had completed the buyback of the outstanding amount of the convertible security funding agreement with Lind Global Macro Fund, LP. The Company entered into the Agreement with Lind in May 2021 and closed the first tranche under the Agreement for gross proceeds of $3,500,000 shortly thereafter. The Company has now bought back the amount

outstanding of the Convertible Security under the Agreement, which is C$2,061,875.

- On September 1, 2022, the Company announced the appointment of Dr. Gabrielle M Siegers, MA, Ph.D., as the Head of R&D based out of the Company's lab in Edmonton.

- On September 12, 2022, the Company applied to the TSX to price protect a proposed $5 million financing of common shares at a price of $0.18 per share. The TSX granted a price protection letter on September 14, 2022, and the conditional approval of the placement on September 26, 2022. As of October 31, 2022, the Company has received a total of $4,629,020 in subscription receipts related to this financing with insiders subscribing for $270,000. On November 3, 2022, the Company announced that it had closed a private placement financing for net proceeds of CAD $4,629,020 from the issuance of 25,716,777 common shares at a price of $0.18 per common share. The common shares issued pursuant to the Private Placement are subject to a statutory hold period of four months and one day ending on March 4, 2023, in accordance with applicable securities law. In connection with the closing, the Company paid a cash fee of 10% of gross proceeds raised to an eligible finder.

- On October 3, 2022, the Company announced the appointment of Dr. Frank Gary Renshaw, as the Chief Medical Officer.

- On December 8, 2022, the Company announced the appointment of Mr. Jacek Antas as the CEO of Helix replacing Mr. Artur Gabor who had resigned as the CEO and as a director of the Company. Furthermore, Ms. Malgorzata Laube was appointed to the Board of Directors of the Company with immediate effect.

Research and development

Research & development expenses for the three-month period ended October 31, 2022, totalled $1,300,000 (October 31, 2021– $1,249,000).

The following table outlines research and development costs expensed for the following periods:

		2022	2021
Research and development programs, excluding the below items	$	863,000	$ 839,000
Salaries and benefits		267,000	264,000
Business development		153,000	143,000
Stock-based compensation expense		14,000	nil
Amortization of property plant and equipment		3,000	3,000
	$	1,300,000	

Research and development expenditures for the three-month period ended October 31, 2022, when compared to the three-month period ended October 31, 2021, were higher by $51,000. The increase in spending is mainly the result of higher expenditures associated with research and development activities by 3% as well as a 7% increase in business development cost. When compared to the three-month period ended October 31, 2021, the Company also spent more on salaries and benefits by $3,000 or 1%.

Operating, general and administration

Operating, general and administration expenses for the three-month period ended October 31, 2022, totalled $ 285,000 (October 31, 2021 – $ 447,000).

The following table outlines operating, general and administration expenses for the following periods:

		2022		2021
Operating, general and administration (excluding below items)	$	235,000	$	223,000
Wages and benefits		37,000		97,000
Directors' fees and investor relations		11,000		104,000
Stock-based compensation expense		2,000		23,000
	$	285,000	$	447,000

Operating, general and administration expenditures for the three-month period ended October 31, 2022, when compared to the three-month period ended October 31, 2021, were lower by $162,000 or 36%.

Since May 2022, the Company has made significant efforts to control and reduce its overheads expenditures. This included closing its headquarters at Richmond Hill Ontario and moving it to Grove Corporate Services offices "(Grove") in downtown Toronto. The Company hired Grove to perform accounting and corporate secretarial services following the resignation of its previous CFO in May 2022. The savings apply to various activities including salaries, rent, legal, and other operational expenditures. Further measures are being taken which will result in more reductions in the current year.

Wages and benefits were decreased by $60,000 or 61%. This is due to the fact that the CFO position is now handled by the Grove Corporate Services contract which covers accounting, administration and corporate secretarial services. Directors fees and investor relations were decreased by $93,000 or 91% which is due to the fact that the Company opted to restrict compensation to the directors to only stock-based compensation

LIQUIDITY AND CAPITAL RESOURCES

The Company reported a net loss and total comprehensive loss for the three-month periods ended October 31, 2022 of $1,606,000 (October 31, 2021- $1,813,000). As at October 31, 2022 the Company had working capital deficiency of $903,000, shareholders' equity deficiency of $865,000 and a deficit of $196,72,000. As at July 31, 2022, the Company had working capital of $283,000, shareholders' equity $319,000 and a deficit of $195,117,000**.**

On September 12, 2022, the Company applied to the TSX to price protect a proposed $5 million financing of common shares at a price of $0.18 per share. The TSX granted a price protection letter on September 14, 2022, and the conditional approval of the placement on September 26, 2022. As of October 31, 2022, the Company has received a total of $4,629,020 in subscription receipts related to this financing with insiders subscribing for $270,000. On November 3, 2022, the Company announced that it had closed a private placement financing for net proceeds of CAD $4,629,020 from the issuance of 25,716,777 common shares at a price of $0.18 per common share. The common shares issued pursuant to the Private Placement are subject to a statutory hold period of four months and one day ending on March 4, 2023, in accordance with applicable securities law. In connection with the closing, the Company paid a cash fee of 10% of gross proceeds raised to an eligible finder.

During the three-month period ended October 31, 2021, the Company completed two private placements resulting in the issuance of 8,200,000 units ("Units") at a price of $0.50 per Unit for aggregate gross proceeds of $4,100,000 ($3,561,000 net of issue costs). The sale of the Units resulted in the issuance of an aggregate of 8,200,000 Common shares and 8,200,000 Warrants, with each such Warrant entitling the holder thereof to purchase one Common Share at an exercise price of $0.70 for a period of five years from the date of issuance.

In order for the Company to advance the currently planned preclinical and clinical research and development activities, its collaborative scientific research programs and pay for its overhead costs, the Company will need to raise approximately $11,000,000 through to the end of fiscal 2024. The Company projects an average monthly fixed overhead spend of approximately $250,000. This amount does not include the costs related to any of the Company's third-party activities such as clinical studies, collaborative research activities and contract manufacturing.

The Company currently has three clinical studies (see *Research and Development Activities* above for additional information) in various stages. The Company has completed the clinical study report for LDOS001 and submitted a final annual report to the FDA in April 2022 and update the result into the www.clinicaltrials.gov portal in June 2022.

The Company received IND approval by the FDA to conduct a Phase I-b/II study (LDOS006) in the U.S., L-DOS47 in combination with doxorubicin, for previously treated advanced pancreatic cancer. Patient enrollment commenced December 2019. COVID-19 impacted patient enrollment resulting in the Company adding two additional clinical sites this year. The Company is forecasting a cost of approximately $4,650,000 through to December 2024 to complete both the Phase I-b and Phase II portion of the trial. Certain conditions need to be achieved in order for the Company to be able to progress through to the Phase II portion of the trial. Of the forecasted $4,650,000, the portion attributable to the Phase II is estimated to be approximately $2,600,000.

The Company is also forecasting $1,600,000 towards pre-clinical studies which are to be carried out in cooperation with its partners at Tubingen University and H. Lee Moffitt Cancer Center and Research Institute Inc.

The Company's Statement of Financial Position and Statement of Net Loss and Comprehensive Loss for the three-month periods ended October 31, 2022 and 2021 are summarized below:

Statements of Financial Position		
As of October 31,	2023	2022
	$	$
Current assets:		
Cash	4,397,000	3,252,000
Accounts receivable	111,000	279,000
Prepaid expenses	254,000	164,000
	4,762,000	3,695,000
Non-current assets		
Property, plant & equipment	39,000	36,000
Right of use assets	-	-
	39,000	36,000
Total assets	4,801,000	3,730,000
Current liabilities:		
Accounts payable	660,000	599,000
Accrued liabilities	377,000	345,000
Convertible note payable	-	2,468,000
Subscription receipts	4,629,000	-
Liabilities held for sale assets	-	-
	5,666,000	3,411,000
Shareholders' equity / (deficiency)	(865,000)	319,000
Total liabilities & Shareholders' equity / (deficiency)	4,801,000	3,730,000

Statements of Net Loss and Comprehensive Loss		
Three months ended October 31,	2023	2022
	$	$
Expenses:		
Research and development	1,300,000	1,249,000
Operating, general & administration	285,000	447,000
Results from operating activities before finance items	(1,585,000)	(1,696,000)
Finance items:		
Convertible note FV adjustment	-	(117,000)
Finance income	10,000	-
Finance expense	(4,000)	(3,000)
Foreign exchange gain (loss)	(27,000)	3,000
	(21,000)	(117,000)
Net loss & total comprehensive loss	(1,606,000)	(1,813,000)
Loss per share	(0.01)	(0.01)

The Company's financial statements, management's discussion and analysis and annual information form will be filed under the Company's profile on SEDAR at www.sedar.com, as well as on the Company's website at www.helixbiopharma.com.

About Helix BioPharma Corp.

Helix BioPharma Corp. is a clinical-stage biopharmaceutical company developing unique therapies in the field of immune-oncology for the prevention and treatment of cancer based on our proprietary technological platform DOS47. Helix is listed on the Toronto Stock Exchange under the symbol "HBP".

Company Contact:

Helix BioPharma Corp.
401 Bay Street, suite 2704
Toronto, Ontario, M5H 2Y4
Tel: 905-841-2300
namrata@grovecorp.ca

Forward-Looking Statements and Risks and Uncertainties

This news release contains forward-looking statements and information (collectively, "forward-looking statements") within the meaning of applicable Canadian securities laws. Forward-looking statements are statements and information that are not historical facts but instead include financial projections and estimates, statements regarding plans, goals, objectives, intentions and expectations with respect to the Company's future business, operations, research and development, including the focus of the Company's primary drug product candidate L-DOS47 and other information relating to future periods.

Forward-looking statements include, without limitation, statements concerning (i) the Company's ability to operate on a going concern being dependent mainly on obtaining additional financing; (ii) the Company's priority continuing

to be L-DOS47; (ii) the Company's development programs, clinical studies, trials and reports for DOS-47 and L-DOS47; (iii) the Company's development programs for DOS47 and L-DOS47; (iv) future expenditures, the insufficiency of the Company's current cash resources and the need for financing; (v) future financing requirements, and the seeking of additional funding, and (vi) forecasts and future projections regarding development programs and expenditures. Forward-looking statements can further be identified by the use of forward-looking terminology such as "ongoing", "estimates", "expects", or the negative thereof or any other variations thereon or comparable terminology referring to future events or results, or that events or conditions "will", "may", "could", or "should" occur or be achieved, or comparable terminology referring to future events or results.

Forward-looking statements are statements about the future and are inherently uncertain and are necessarily based upon a number of estimates and assumptions that are also uncertain. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, such statements involve risks and uncertainties, and undue reliance should not be placed on such statements. Forward-looking statements, including financial outlooks, are intended to provide information about management's current plans and expectations regarding future operations, including without limitation, future financing requirements, and may not be appropriate for other purposes. Certain material factors, estimates or assumptions have been applied in making forward-looking statements in this news release, including, but not limited to, the safety and efficacy of L-DOS47; that sufficient financing will be obtained in a timely manner to allow the Company to continue operations and implement its clinical trials in the manner and on the timelines anticipated; the timely provision of services and supplies or other performance of contracts by third parties; future costs; the absence of any material changes in business strategy or plans; and the timely receipt of required regulatory approvals and strategic partner support.

The Company's actual results could differ materially from those anticipated in the forward-looking statements contained in this news release as a result of numerous known and unknown risks and uncertainties, including without limitation, the risk that the Company's assumptions may prove to be incorrect; the risk that additional financing may not be obtainable in a timely manner, or at all, and that clinical trials may not commence or complete within anticipated timelines or the anticipated budget or may fail; third party suppliers of necessary services or of drug product and other materials may fail to perform or be unwilling or unable to supply the Company, which could cause delay or cancellation of the Company's research and development activities; necessary regulatory approvals may not be granted or may be withdrawn; the Company may not be able to secure necessary strategic partner support; general economic conditions, intellectual property and insurance risks; changes in business strategy or plans; and other risks and uncertainties referred to elsewhere in this news release, any of which could cause actual results to vary materially from current results or the Company's anticipated future results. Certain of these risks and uncertainties, and others affecting the Company, are more fully described in the Company's interim management's discussion and analysis for the three-month period ended October 31, 2022 under the heading "Risks and Uncertainty" and Helix's Annual Information Form, in particular under the headings "Forward-looking Statements" and "Risk Factors", and other reports filed under the Company's profile on SEDAR at www.sedar.com from time to time. Forward-looking statements and information are based on the beliefs, assumptions, opinions and expectations of Helix's management on the date of this new release, and the Company does not assume any obligation to update any forward-looking statement or information should those beliefs, assumptions, opinions or expectations, or other circumstances change, except as required by law.

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