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HELIX BIOPHARMA CORP. ANNOUNCES FISCAL 2022 YEAR-END 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 2022 fiscal year ended July 31, 2022.

OVERVIEW

The Company reported a net loss and total comprehensive loss of \$6,563,000 or \$0.04 loss per common share for fiscal 2022 (2021 - \$8,038,000 or \$0.06 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. A pre-print can be found here: [https://www.jtocrr.org/article/S2666-3643\(22\)00132-1/fulltext#relatedArticles](https://www.jtocrr.org/article/S2666-3643(22)00132-1/fulltext#relatedArticles).
- 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 2022.

LDOS47 in pancreatic cancer

The Company's Phase I-b/II combination trial in pancreatic cancer (LDSOS006) continues to recruit patients. We recently applied to the U.S. Food and Drug Administration for a revision to the clinical study protocol to extend the number of treatment cycles for those patients where the benefits outweigh the risks. We remain committed to this study. The first dosing cohort was successfully completed and now the second dosing cohort is also nearing completion.

Corporate development

- On August 19, 2021, the Company announced that Dr. Krzysztof Saczek had been appointed as a member of the board of directors of the Company (the “Board”) effective immediately in connection with the resignation of Mr. Heman Chao as CEO, CSO and as a member of the Board. Mr. Chao's resignation became effective on September 1, 2021 and Mr. Chao assumed the position of Chair of the Company's Scientific Advisory Board on the same date.
- On March 11, 2022, the Company closed a private placement financing for gross proceeds of \$1,001,000 from the issuance of 3,850,000 common share at a price of \$0.26 per common share. On April 21, 2022, the

Company closed a private placement financing for net proceeds of \$2,002,000 from the issuance of 7,700,000 common shares at a price of \$0.26 per common share.

- On April 13, 2022, the Company announced that it has received conditional approval from the Toronto Stock Exchange to extend its previously announced Early Warrant Exercise Incentive Program from April 28, 2022, to May 31, 2022. The Incentive Program is a period during which holders of the Company's eligible common share purchase warrants ("Eligible Warrants") may take advantage of a temporary reduction in the exercise price of the Eligible Warrants to a price of C\$0.26. The Eligible Warrants include an aggregate of 49,806,469 warrants that if exercised at the Incentive Exercise Price will result in the Company receiving gross proceeds of up to \$12,949,682. During the year ended July 31, 2022, 12,346,938 warrants were exercised for a total subscription amount of \$3,210,204.
- On April 18, 2022, the Company announced that Artur Gabor has been appointed as the Company's Chief Executive Officer with immediate effect. The Company also announced the addition of three new members to its Board of Directors: Jerzy Leszczyński, Christopher Maciejewski and Jacek Antas have been appointed to the Board effective immediately.
- On May 11, 2021, the Company entered into a definitive convertible security funding agreement (the "Lind Agreement") with Lind Global Macro Fund, LP, a New York based institutional investment fund managed by The Lind Partners, LLC (collectively "Lind"). The Company closed the first tranche under the Lind Agreement on May 13, 2021 for gross proceeds of \$3,500,000 (the "First Tranche"). See *Liquidity and Capital Resources* section below.
- On May 18, 2022, the Company announced the appointment of Mr. Hatem Kwar as the Company's Chief Financial Officer effective immediately.
- 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, 2021, 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 Sep 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 Sep 14, 2022, and the conditional approval of the placement on Sep 26, 2022. The closing of the private placement is expected by November 1, 2022. As of October 31, 2022, the Company has received a total of \$4,644,000 in subscription receipts related to this financing.
- On October 3, 2022, the Company announced the appointment of Dr. Frank Gary Renshaw, as the Chief Medical Officer.

Research and development

Research and development expenses for fiscal 2022 totalled \$4,544,000 (2021 - \$5,880,000).

The following table outlines research and development costs and investment tax credits for the Company's significant research and development projects for the fiscal years ended July 31:

	2022	2021
Research and development programs, excluding the below items	\$ 3,196,000	\$ 4,514,000
Wages and benefits	\$ 1,075,000	\$ 1,270,000
Stock-based compensation expense	\$ 272,000	\$ 1,000
Amortization of property, plant and equipment	\$ 12,000	\$ 41,000
Amortization of right of use assets	\$ -	\$ 129,000
Research and development investment tax credits	\$ (11,000)	\$ (75,000)
	\$ 4,544,000	\$ 5,880,000

Research and development expenditures for the year ended July 31, 2022, when compared to the year ended July 31, 2021, were lower by \$1,318,000. The decrease in spending is mainly the result of lower expenditures associated with research and development activities by 29% partially offsetting the increases in consulting services and stock-based compensation, which were higher due to expense of stock options granted to consultants. When compared to the year ended July 31, 2021, the Company also spent less on salaries and benefits by \$195,000 or 15% while consulting and stock-based compensation were higher by \$943,000.

The Company hired biotechnology consultants to assess the Company's drug product candidate with a focus on identifying value propositions and positioning strategies that would enable clinical adoption of L-DOS47.

Operating, general and administration

Operating, general and administration expenses for fiscal 2022 totalled \$1,496,000 (2021 - \$3,251,000).

The following table outlines operating, general and administration costs expensed for the fiscal years ended July 31:

	2022	2021
Operating, general and administration (excluding below items)	\$ 901,000	\$ 1,563,000
Wages and benefits	275,000	407,000
Director fees and Investor relations	168,000	616,000
Stock-based compensation	152,000	663,000
Amortization of property, plant and equipment	-	3,000
	\$ 1,496,000	\$ 3,251,000

Operating, general and administration expenditures for the year ended July 31, 2022, when compared to the year ended July 31, 2021, were lower by \$1,756,000 or 54%.

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 next quarter.

Some expenditures in the comparative period relate to the Company's attempt to raise additional capital as part of a qualifying transaction to list its common shares on a U.S. stock exchange, the termination of an investor relations agreement with ACM Alpha Consulting Management EST ("ACMest") and stock-based compensation expenses of stock options granted to directors and consultants.

Several factors materialized that resulted in the Company abandoning its plans to list on a U.S. stock exchange. These include but are not limited to the increase in the percentage ownership of the Common Shares by new insiders; a decline in the price of the Common Shares making it extremely challenging for the Company to leverage the Multijurisdictional Disclosure System; and the resignation of the Company's previous auditors.

LIQUIDITY AND CAPITAL RESOURCES

As at July 31, 2022 the Company had working capital of \$283,000 (2021 - \$144,000), shareholders' equity of \$319,000 (2021 – shareholders' deficit of 1,393,000) and a deficit of \$195,117,000 (2021 - \$188,554,000).

On March 11, 2022, the Company closed a private placement financing for gross proceeds of \$1,001,000 from the issuance of 3,850,000 common share at a price of \$0.26 per common share. On April 21, 2022, the Company closed a private placement financing for net proceeds of \$2,002,000 from the issuance of 7,700,000 common shares at a price of \$0.26 per common share.

On April 13, 2022, the Company announced that it has received conditional approval from the Toronto Stock Exchange to extend its previously announced Early Warrant Exercise Incentive Program from April 28, 2022, to May 31, 2022. The Incentive Program is a period during which holders of the Company's eligible common share purchase warrants ("Eligible Warrants") may take advantage of a temporary reduction in the exercise price of the Eligible Warrants to a price of C\$0.26. The Eligible Warrants include an aggregate of 49,806,469 warrants that if exercised at the Incentive Exercise Price will result in the Company receiving gross proceeds of up to \$12,949,682. During the year ended July 31, 2022, 12,346,938 warrants were exercised for a total subscription amount of \$3,210,204.

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 at a cost of C\$2,061,875. In May 2021, the Company initially issued a convertible security with a two-year term and a face value of \$4,112,500 and issued an aggregate of 1,957,056 warrants exercisable into Common Shares for a period of 48 months at an exercise price of \$1.0283 per Common Share. As of July 31, 2022, Lind has converted an aggregate of \$1,233,750 of the face value of the Convertible Security issued under the first tranche into an aggregate of 4,345,087 common of the Company at an average deemed price of \$0.243 per common share. In August 2022, Lind further converted \$405,625 of face value into an aggregate 2,507,329 shares at an average deemed price of \$0.1618 per common share.

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 \$4,644,000 in subscription receipts related to this financing.

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 is forecasting approximately \$10,000 to finalize reporting.

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 Tübingen 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 fiscal 2022 and 2021 are summarized below:

<i>Consolidated Statements of Financial Position</i>			<i>Consolidated Statements of Net Loss and Comprehensive Loss</i>		
	FY2022	FY2021		FY2022	FY2021
	\$	\$		\$	\$
Current assets:			Expenses:		
Cash	3,252,000	3,565,000	Research and development	4,544,000	5,880,000
Accounts receivable	279,000	353,000	Operating, general & administration	1,496,000	3,251,000
Prepays	164,000	100,000			
Assets held for sale	-	-	Results from operating activities		
	3,695,000	4,018,000	before finance items	(6,041,000)	(9,131,000)
Non current assets			Finance items:		
Property, plant & equipment	36,000	47,000	Finance transaction costs	-	(338,000)
Right of use assets	-	-	Convertible note FV adjustment	(501,000)	(142,000)
	36,000	47,000	Finance income	4,000	-
Total assets	3,730,000	4,065,000	Finance expense	(18,000)	(15,000)
Current liabilities:			Foreign exchange gain (loss)	(9,000)	52,000
Accounts payable	599,000	1,466,000		(523,000)	(443,000)
Accrued liabilities	345,000	380,000	Loss from continuing operations	(6,563,000)	(9,574,000)
Convertible note payable	2,468,000	2,028,000	Gain (loss) from discontinued operations	-	1,536,000
Lease liabilities	-	-	Net loss & total comprehensive loss	(6,563,000)	(8,038,000)
Liabilities held for sale assets	-	-			
	3,411,000	3,874,000	Attributable to non-controlling interest	-	-
Non-current liabilities:			Attributable to Helix BioPharma Corp	(6,563,000)	(8,038,000)
Convertible note payable	-	1,584,000	Loss per share	(0.04)	(0.06)
Shareholders' equity / (deficiency)					
Attributable to Helix	319,000	(1,393,000)			
Non-controlling interest	-	-			
	319,000	(1,393,000)			
Total liabilities & Shareholders' equity / (deficiency)	3,730,000	4,065,000			

The Company's consolidated 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".

Investor Relations

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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; (iii) the Company’s development programs, clinical studies, trials and reports for DOS-47 and L-DOS47; (iv) the Company’s development programs for DOS47 and L-DOS47; (v) future expenditures, the insufficiency of the Company’s current cash resources and the need for financing; (vi) future financing requirements, and the seeking of additional funding, and (vii) 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 annual management’s discussion and analysis for the year ended July 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.
