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December 15, 2021
Press Release

HELIX BIOPHARMA CORP. ANNOUNCES FISCAL 2022 FIRST QUARTER RESULTS

(Richmond Hill, 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 fiscal 2022 first quarter results for the period ending October 31, 2021.

OVERVIEW

The Company reported a net loss and total comprehensive loss for the three-month period ended October 31, 2021, of $1,813,000 (2020 - $222,000). Net loss and comprehensive loss for the three-month period ending October 31, 2020, included a gain from loss of control in Helix Immuno-Oncology S.A. ("HIO") of $2,162,000.

Clinical development

- Phase I combination therapy study in lung cancer (LDOS001):
  - Final clinical study report expected to be completed by the end of December 2021;
- Phase II combination therapy trial in lung cancer (LDOS003):
  - Final clinical study report expected to be completed in March 2022 provided the Company settles a contractual disagreement with the clinical research organization engaged to oversee the study.
  - The Company ceased patient enrolment into the trial in 2020 and proceeded to data analysis.
  - As previously announced, the Company will not be advancing the randomized portion of the study without third-party partner funding. To date, no third-party partner has been identified.
- Phase Ib/II combination trial in pancreatic cancer (LDSOS006):
  - On November 15, 2021, the Company applied for a revision to the clinical protocol to the U.S. Food and Drug Administration ("FDA").
- L-DOS47 immunotherapy chemo combination study in lung cancer:
  - The Company engaged key opinion leaders on the feasibility and design of a possible immunotherapy chemo combination clinical study. The Company is not currently in a position to make a submission to the FDA regarding the potential clinical study.
- Clinical drug product strategic review:
  - The Company hired biotechnology consults 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. This engagement includes input from key opinion leaders on the positioning of possible combination therapies and the prioritization of current and/or any additional clinical indications. The Company expects the consulting firm's report to be finalized by the end of December 2021.

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 Dr. Heman Chao as CEO, CSO and as a member of the Board. Mr. Chao's resignation became effective on September 1, 2021 and assumed the position of Chair of the Company's Scientific Advisory Board on the same date.

- On September 20, 2021, the Company announced the appointment of the company's Chairman, Dr. Slawomir Majewski, as Interim Chief Executive Officer to hold office while the Board worked to identify and evaluate potential candidates as permanent CEO.

Research and development

Research & development expenses for the three-month period ended October 31, 2021, totalled $1,249,000 (2020 – $1,084,000).

Components of research and development expenses for the three-month periods ended October 31:

	2021	2020
Research and development programs, excluding the below ítems	$ 982,000	$ 689,000
Salaries and benefits	264,000	315,000
Stock-based compensation expense	–	4,000
Amortization of property, plant and equipment	3,000	17,000
Amortization of right of use assets	–	32,000
Research and development investment tax credits	–	27,000
	$ 1,249,000	$ 1,084,000

Research and development expenditures in the three-month period ended October 31, 2021, when compared to the three-month period ended October 31, 2020, were higher by $165,000. The increase is mainly the result of higher third-party research and development consulting services of $163,000 in addition to higher contact manufacturing services of $267,000 which were offset by lower clinical operations spend of $213,000.

The Company hired biotechnology consults 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. This engagement includes broad clinical development key opinion leader input on the positioning of possible combination therapies and the prioritization of current and/or any additional clinical indications. The Company expects the consulting firm's report to be finalized by the end of December 2021.

The increase in manufacturing spend is the result of new production lot of Polysorbate 80 and increased stability and assay activity from recently repolished old drug substance and lyophilization of new drug product.

Lower clinical operations spend is mainly the result of analytical method development spend incurred in the comparative prior year's quarter related to LDOS006, the Company's Phase Ib/II combination trial for pancreatic cancer.

Operating, general and administration

Operating, general and administration expenses for the three-month period ended October 31, 2021, totalled $447,000 (2020 - $1,303,000).

Components of operating, general and administration expenses for the three-month periods ended October 31:

	2021	2020
Operating, general and administration, excluding the below items	$ 223,000	$ 394,000
Salaries and benefits	97,000	107,000
Directors' fees	65,000	62,000
Investor relations	39,000	319,000
Stock-based compensation expense	23,000	421,000
	$ 447,000	$ 1,303,000

Operating, general and administration expenditures in the three-month period ended October 31, 2021, when compared to the three-month period ended October 31, 2020, were lower by $856,000. The decrease is mainly the result of expenses associated with various third-party advisory services such as legal, accounting and investment banking of $210,00 incurred in the comparative prior year's quarter related to the Company's attempt to raise additional capital as part of a qualifying transaction to list on the Nasdaq; lower investor relations spend of $287,000 as a result of the termination of the agreement on October 21, 2020 the Company had in place with ACM Alpha Consulting Management EST ("ACMest"); and lower stock-based compensation expense of options granted to directors of the Company over their vesting period of $355,000.

LIQUIDITY AND CAPITAL RESOURCES

The Company reported a net loss and total comprehensive loss for the three-month period ended October 31, 2021, of $1,813,000 (2020 - $222,000). As at October 31, 2021 the Company had working capital deficiency of $1,493,000, shareholders' deficiency of $2,730,000 and a deficit of $190,367,000. As at July 31, 2021, the Company had working capital of $144,000, shareholders' deficiency of $1,393,000, a deficit of $188,554,000.

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 $15,000,000 through to the end of fiscal 2023.

The Company's cash reserves of $1,873,000 as at October 31, 2021 are insufficient to meet anticipated cash needs for working capital and capital expenditures through the next twelve months, nor are they sufficient to see planned research and development initiatives through to completion. To the extent that the Company does not believe it has sufficient liquidity to meet its current obligations, management considers securing additional funds, preferably through the issuance of equity securities of the Company, to be critical for its development needs. The Company may also consider other forms of raising funds, such as the issuance of debt which may or may not include a conversion of equity in the Company.

The Company's long-term liquidity depends on its ability to raise funds from various sources, which depends substantially on the success of its ongoing research and development programs, economic conditions and the state of the biotech industry.

The Company's Statements of Financial Position as at October 31, 2021 and July 31, 2021 in addition to the Statements of Net Loss and Comprehensive Loss for the three-month periods ended October 31, 2021 and 2020 are summarized below:

Statements of Financial Position

	31-Oct-21	31-Jul-21
	$	$
Current assets:		
Cash	1,873,000	3,565,000
Accounts receivable	309,000	353,000
Prepaids	87,000	100,000
	2,269,000	4,018,000
Non current assets		
Property, plant & equipment	44,000	47,000
Total assets	2,313,000	4,065,000
Current liabilities:		
Accounts payable	1,416,000	1,466,000
Accrued liabilities	309,000	380,000
Convertible note payable	2,037,000	2,028,000
	3,762,000	3,874,000
Non-current liabilities:		
Convertible note payable	1,281,000	1,584,000
Total Liabilities	5,043,000	5,458,000
Shareholders' deficiency	(2,730,000)	(1,393,000)
Total liabilities & shareholders' deficiency	2,313,000	4,065,000

Statements of Net Loss and Comprehensive Loss

	31-Oct-21	31-Oct-20
	$	$
Expenses:		
Research and development	1,249,000	1,084,000
Operating, general & administration	447,000	1,303,000
Results from operating activities before finance items	(1,696,000)	(2,387,000)
Finance items:		
Convertible note FV adjustment	(117,000)	-
Finance income	-	1,000
Finance expense	(3,000)	(4,000)
Foreign exchange gain (loss)	3,000	6,000
	(117,000)	3,000
Loss from continuing operations	(1,813,000)	(2,384,000)
Gain (loss) from discontinued operations	-	2,162,000
Net loss & total comprehensive loss	(1,813,000)	(222,000)
Loss per share	(0.01)	-

The Company's Interim Condensed Financial Statements and Management's Discussion and Analysis 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; (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 annual management’s discussion and analysis for the year ended July 31, 2021 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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