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Press Release

HELIX BIOPHARMA CORP. ANNOUNCES FISCAL 2021 YEAR-END 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 financial results for the 2021 fiscal year ended July 31, 2021.

OVERVIEW

The Company reported a net loss and total comprehensive loss of $8,038,000 or $0.06 loss per common share for fiscal 2021 (2020 - $8,985,000 or $0.07 loss per common share).

Clinical development

- Phase I combination therapy study in lung cancer (LDOS001):
  - Final clinical study report expected to be completed in 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):
  - Two dose limiting toxicity events (each, a "DLT") have been reported in the first cohort ("Cohort 1") of the trial. As a result of an amended protocol, an additional three (3) patients are required for this trial, bringing the total number of patients required to complete Cohort 1 to nine (9) patients. The Company currently continues to enroll patients in Cohort 1;
  - If another DLT is observed in Cohort 1, the Company will not be able to complete the currently planned dose escalation plan, but instead will be required to design a protocol revision;
  - 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 and had targeted a possible submission to the FDA by December 2021. 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 a biotechnology consulting firm 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 December 2021.

Corporate development

- On September 3, 2020, Helix Immuno-Oncology S.A., the Company's former wholly-owned subsidiary ("HIO"), completed a direct financing with an arm's length party, CAIAC Fund Management AG ("CAIAC"), as designated trustee of an alternative investment fund to be established, resulting in a further dilution of the Company's holding in HIO from approximately 42.51% to 29.89% and a loss of the Company's control in HIO. On December 22, 2020, the Company disposed of its remaining interest in HIO to CAIAC for gross proceeds of CDN$2,308,000 ($2,020,000 net of transaction costs).

- Effective October 21, 2020, the financial advisory services agreement dated July 2, 2018 between the Company and ACM Consulting Management AG and the investor relations and advisory services agreement dated July 2, 2018 between the Company and ACM Consulting Management Est. ("ACMest") were terminated by mutual agreement of the parties.

- On December 4 and 30, 2020, 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. See *Liquidity and Capital Resources* below.

- In February 2021, BDO Canada LLP resigned as the Company's auditors. The Company appointed Marcum LLP as its new auditors on June 24, 2021.

- 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.

- In the fourth quarter of fiscal 2021, the Company decided to defer its application to the Nasdaq Stock Market (the "NASDAQ") as a result of no longer being able to qualify for an accelerated cross border qualifying financing under the Multijurisdictional Disclosure System ("MJDS").

- 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. Chaor 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 and development expenses for fiscal 2021 totalled $5,880,000 (2020 - $5,868,000).

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:

	2021	2020
Research and development programs, excluding the below items	$ 4,514,000	$ 4,497,000
Salaries and benefits	1,270,000	1,191,000
Stock-based compensation expense	1,000	117,000
Amortization of property, plant and equipment	41,000	54,000
Amortization of right of use assets	129,000	129,000
Research and development investment tax credits	(75,000)	(120,000)
	$ 5,880,000	$ 5,868,000

Research and development expenditures in fiscal 2021, when compared to fiscal 2020, were higher by $12,000. Higher collaborative research activity totaling $1,023,000 and salaries of $79,000 were offset by lower clinical study expenditures of $476,000, lower intellectual property patent expenses of $303,000, lower manufacturing and stability assay expenses of $136,000 and a reduction in stock-based compensation expense of $116,000.

The increase in collaborative research spend in fiscal 2021 compared to fiscal 2020 is related to the Company's sub-licensing agreement with HIO, whereby the Company was responsible to fund pre-clinical activity in exchange for future royalties and milestones. As part of the sub-licensing agreement, HIO is responsible for certain intellectual property expenditures. In addition, the Company also incurred collaborative research spend in fiscal 2021 related to research activities with Moffitt Cancer Centre.

Lower clinical operations spend in fiscal 2021 compared to fiscal 2020 are related to the Company's LDOS003 Phase II clinical study in Poland and Ukraine as a result of enrollment being halted in the previous fiscal year, causing no further expenditures incurred in the current fiscal year. The Company intends to finalize reporting by March 2022 provided the Company's disagreement over billings by the clinical research organization overseeing the program are resolved. The Company also incurred lower expenditures associated with its LDOS001 clinical study in the current fiscal year and is now finalizing the clinical study report which is expected to be completed by December 2021. The Company's LDOS006 Phase Ib/II pancreatic clinical study in the U.S. commenced enrollment in December 2019 during the early days of the coronavirus pandemic (COVID-19) which delayed the clinical trial patient enrollment. In early 2021, the Company added two additional new sites in an effort to increase the rate of patient enrollment and advance the study. The study is currently still in the first cohort.

The decrease in intellectual property spend in fiscal 2021 compared to fiscal 2020 includes an amount totaling $135,000 which the Company invoiced to HIO as passthrough costs for reimbursement associated with the sub-licensing agreement. This amount is included in receivables at July 31, 2021.

The decrease in manufacturing and stability assay spend in fiscal 2021 compared to fiscal 2020 of $136,000 mainly reflects the timing of manufacturing expenses related to the repolishing of older drug substance and the resulting lyophilization of new drug product where the expenses overlapped both fiscal years.

Operating, general and administration

Operating, general and administration expenses for fiscal 2021 totalled $3,251,000 (2020 - $2,748,000).

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

	2021	2020
Wages and benefits	$ 407,000	$ 434,000
Director fees	229,000	174,000
Investor relations	386,000	736,000
Other general and administrative	1,563,000	1,022,000
Stock-based compensation expense	663,000	353,000
Amortization of property plant and equipment	3,000	3,000
Amortization of right of use assets	–	26,000
	$ 3,251,000	$2,748,000

The increase in operating, general and administration expenses of $503,000 in fiscal 2021 compared to fiscal 2020 reflects higher stock-based compensation expense, and higher expenses associated with various third-party advisory services such as legal, accounting, business development and investment banking services in an attempt to raise additional capital as part of a qualifying transaction to list the common shares in the capital of the Company ("Common Shares") on the NASDAQ or other United States stock exchange. Several factors materialized that resulted in the Company eventually abandoning its plans to up-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 MJDS, and the resignation of the Company's previous auditors.

Stock based compensation expense for fiscal 2021 totaled $663,000 (2020 - $353,000). The increase represents the expense associated with the vesting of stock options granted to directors, over their vesting period.

The reduction in investor relations expense for fiscal 2021 compared to fiscal 2020 mainly reflects the termination of the investor relations and advisory services agreement with ACMest.

LIQUIDITY AND CAPITAL RESOURCES

As at July 31, 2021 the Company had working capital of $144,000 (2020 - $2,735,000), shareholders' deficiency of $1,393,000 (2020 – shareholders' equity of 2,981,000) and a deficit of $188,554,000 (2020 - $180,516,000).

On December 22, 2020, the Company disposed of its remaining interest in HIO for net proceeds of $2,020,000. See *Corporate developments* above.

On December 4 and 30, 2020, the Company completed two private placements resulting in the issuance of 8,200,000 Units at a price of $0.50 per Unit for aggregate gross proceeds of $4,100,000 ($3,561,000 net of transaction costs). The sale of the Units resulted in the issuance of an aggregate of 8,200,000 Common Shares and 8,2000,000 Common Share purchase warrants ("Warrants"). Each Warrant entitles 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.

On May 11, 2021, the Company entered into the Lind Agreement and on May 13, 2021, closed the First Tranche for gross proceeds of $3,500,000. In connection with the closing of the First Tranche, the Company issued a convertible security (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. The Convertible Security issued under the First Tranche accrues a simple interest rate obligation of 8.75% per annum on the amount funded, being $3,500,000, which interest is prepaid and attributed to the face value of the Convertible Security. The Lind Agreement also contemplates the issuance of a second Convertible Security upon the mutual agreement of the Company and Lind for gross proceeds to the Company of up to $6,500,000. Lind is entitled to convert the Convertible Securities issued under the terms of the Lind Agreement into Common Shares over their term, subject to certain limitations, at a conversion price equal to 85% of the five-day volume-weighted average trading price ("VWAP") of the Common Shares prior to the date a notice of conversion is provided to the Company by Lind. The Lind Agreement includes certain restrictions on the maximum face value of each of the Convertible Securities that may be converted in any particular month. In addition, the Company has the option to buy-back 66.7% of the Convertible Securities in cash at any time with no penalty, subject to the option of Lind to convert up to 1/3 of the face value of the Convertible Security into Common Shares at the time of such buy-back. The Lind Agreement is subject to covenant requirements. In the event of default Lind may declare, by notice to the Company, effective immediately, all outstanding obligations by the Company under the Funding Agreement to be immediately due and payable in immediately available funds and terminate the agreement. No such declaration has been made at time of filing of these annual consolidated financial statements.

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 projects an average monthly fixed overhead spend of approximately $275,000. 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 one clinical study enrolling patients in LDOS006. Due to slow enrollment, the Company stopped LDOS001 enrollment and continues to work on finalizing the clinical study report. The Company is forecasting a cost of approximately $4,826,000 through to October 2023 to complete both the Phase Ib and Phase II portion of the study. Certain conditions need to be achieved in order for the Company to be able to progress through to the Phase II portion of the study. Of the forecasted $4,826,000, the portion attributable to Phase II is approximately $2,603,000 and is forecasted to begin sometime in May 2023.

The Company is forecasting approximately $256,00 and $456,000, respectively to fully complete and report on both the LDOS001 and LDOS003 studies which are forecasted for December 2021 and March 2022, respectively.

The Company is forecasting manufacturing expenditures of approximately $1,243,000 through to the end of fiscal 2023 in support of the Company's clinical program. The Company previous forecasted a manufacturing technology transfer to a new manufacturer with a scaled-up production in anticipation of having sufficient supply for a contemplated pivotal trial and a new clinical study of L-DOS47 in combination with an immune-oncology drug. The Company has since produced a new batch of drug product from previous drug substance providing additionally sufficient supply for the Company's current clinical program, provided stability assays continue to meet protocol standards.

The Company is currently not forecasting any collaborative research expenditures.

The Company's cash reserves of $3,565,000 as at July 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. Though the funds raised during this fiscal year have assisted the Company in dealing with its immediate working capital requirements, additional funds are required to advance the Company's clinical and preclinical programs and deal with future working capital requirements. 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's Statement of Financial Position and Statement of Net Loss and Comprehensive Loss for fiscal 2021 and 2020 are summarized below:

Consolidated Statement of Financial Position

	FY2021	FY2020
	$	$
Current assets:		
Cash	3,565,000	4,235,000
Accounts receivable	353,000	180,000
Prepaids	100,000	90,000
Assets held for sale	-	155,000
	4,018,000	4,660,000
Non current assets		
Property, plant & equipment	47,000	91,000
Right of use assets	-	155,000
	47,000	246,000
Total assets	4,065,000	4,906,000
Current liabilities:		
Accounts payable	1,466,000	1,416,000
Accrued liabilities	380,000	301,000
Convertible note payable	2,028,000	-
Lease liabilities	-	159,000
Liabilities held for sale assets	-	49,000
	3,874,000	1,925,000
Non-current liabilities:		
Convertible note payable	1,584,000	-
Shareholders' equity / (deficiency)		
Attributable to Helix	(1,393,000)	2,394,000
Non-controlling interest	-	587,000
	(1,393,000)	2,981,000
Total liabilities & Shareholders' equity / (deficiency)	4,065,000	4,906,000

Consolidated Statements of Net Loss and Comprehensive Loss

	FY2021	FY2020
	$	$
Expenses:		
Research and development	5,880,000	5,868,000
Operating, general & administration	3,251,000	2,748,000
Results from operating activities before finance items	(9,131,000)	(8,616,000)
Finance items:		
Finance transaction costs	(338,000)	-
Convertible note FV adjustment	(142,000)	-
Finance income	-	25,000
Finance expense	(15,000)	(25,000)
Foreign exchange gain (loss)	52,000	55,000
	(443,000)	55,000
Loss from continuing operations	(9,574,000)	(8,561,000)
Gain (loss) from discontinued operations	1,536,000	(613,000)
Net loss & total comprehensive loss	(8,038,000)	(9,174,000)
Attributable to non-controlling interest	-	(189,000)
Attributable to Helix BioPharma Corp	(8,038,000)	(8,985,000)
Loss per share	(0.06)	(0.07)

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; (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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