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HELIX BIOPHARMA CORP. ANNOUNCES FISCAL 2020 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 its financial results for the 2020 fiscal year ended July 31, 2020.

OVERVIEW

The Company reported a consolidated net loss and total comprehensive loss of \$9,174,000 or \$0.07 loss per common share for fiscal 2020 (2019 - \$7,526,000 or \$0.07 loss per common share). This includes a net loss from discontinued operations in fiscal 2020 of \$613,000 (2019 - \$719,000) related to the Company’s planned divestiture of Helix Immuno-Oncology S.A. (“HIO”).

The Company began the year with a working capital deficiency of \$3,534,000 until August 21, 2019 when the Company closed a series of private placements in fiscal 2020 for total gross proceeds of approximately \$16,000,000. A portion of these private placement financings included the disposition of a 49.0% stake in HIO. On July 8, 2020 HIO completed a direct Series B private placement which resulted in a dilution of the Company’s holding in HIO down to 42.51% as at July 31, 2020 and subsequently on September 3, 2020, HIO closed a direct Series C private placement which further diluted the Company’s holding in HIO down to 29.89%.

On June 26, 2020, the Company announced that it had entered into agreements with HIO, pursuant to which the Company cancelled an aggregate amount of approximately \$2,700,000 of intercompany debt owed to the Company by HIO. As a result, all transferred assets related to Biphaxis and V-DOS47 have been automatically reassigned and transferred from HIO back to the Company without any formality. In addition, the Company also ceased financing HIO with immediate effect.

Also, on June 26, 2020, the Company announced the receipt of a non-binding offer for PLN6,700,000 from CAIAC Fund Management AG (“CAIAC”) to purchase the Company’s remaining shares in HIO. The transaction was initially expected to close no later than August 31, 2020 but has since been deferred to the end of October 30, 2020, subject to the satisfaction of certain conditions. As of the filing date of this press release the Company has not yet closed the transaction with CAIAC though both parties continue to work through the process to finalize and close the transaction.

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. were terminated by mutual agreement of the parties.

As previously disclosed, the Company has also been in discussions, during the year, with various capital market firms, both in the U.S. and Canada, with the goal of raising additional sufficient capital to qualify for a NASDAQ listing and further advance the Company’s clinical development programs.

At present, the only clinical program enrolling patients is the Company’s U.S. Phase Ib/II LDOS006 study (L-DOS47 in combination with doxorubicin) in the treatment of patients with metastatic pancreatic cancer who have progresses

on at least two prior treatment regimens. COVID-19 had impacted patient enrollment and as a result, the Company is in the process of adding two additional clinical trial sites in other U.S. jurisdictions.

The Company's clinical studies in non-small cell lung cancer patients, a U.S. Phase I LDOS001 study (L-DOS47 in combination with pemetrexed and carboplatin) and a European Phase II LDOS003 study (L-DOS47 in combination with vinorelbine and cisplatin), have completed patient enrolment.

For LDOS001, the Company is working through the process of completing the anti-drug antibody assays, which from a timing perspective, have been hampered by COVID-19. Once the analysis is complete, the clinical study database lock will be initiated with the goal of finalizing the clinical study report by April 2021.

As for LDOS003, the Company previous disclosed that the first stage of the study related to dose escalation would be concluded and that any progression to the second stage would only proceed if a third-party was willing to partner with the Company on the study. The Company is in a contractual dispute with the CRO that is managing the clinical study. Until such time the dispute is resolved, the Company expects a delay in completing final monitoring, close out activities and finalizing the clinical study report. The Company is currently in discussion with the CRO in order to resolve the matter.

Research and development

Research and development expenses for fiscal 2020 totalled \$5,868,000 (2019 - \$4,948,000).

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:

	2020	2019
L-DOS47	\$ 4,715,000	\$ 3,530,000
CAR-T	64,000	333,000
Corporate research and development expenses	393,000	531,000
Trademark and patent related expenses	516,000	435,000
Stock-based compensation expense	117,000	197,000
Amortization of property, plant and equipment	54,000	48,000
Amortization of right of use assets	129,000	-
Research and development investment tax credit	(120,000)	(126,000)
	\$ 5,868,000	\$ 4,948,000

L-DOS47 research and development expenses for fiscal 2020 totalled \$4,715,000 (2019 - \$3,530,000). L-DOS47 research and development expenditures relate primarily to the Company's LDOS001 Phase I clinical study in the U.S., the LDOS003 Phase II clinical study in Poland and the Ukraine and the Company's new LDOS006 Phase Ib/II pancreatic clinical study in the U.S.

For fiscal 2020 when compared to fiscal 2019 the increase in spending mainly reflects drug substance manufacturing spend of \$590,000, costs associated with the new LDOS006 pancreatic trial in the U.S. of \$1,144,000 and costs associated with finalizing and reporting on LDOS001 of \$168,000. Offsetting the increased spend was a reduction in spending of \$354,000 related to the Company's LDOS003 and a further reduction of \$278,000 related to the Moffitt Cancer Centre research collaboration.

CAR-T research and development expenses for fiscal 2020 totalled \$64,000 (2019 - \$333,000). The Company's collaboration with ProMab Biotechnologies Inc. has been impacted by the Coronavirus pandemic and as such certain planned activities have been deferred.

Trademark and patent related expenses for fiscal 2020 totalled \$516,000 (2019 - \$435,000). The Company continues to ensure it adequately protects its intellectual property.

Stock based compensation expense for fiscal 2020 totalled \$117,000 (2019 - \$197,000). The amount represents the expense associated with the vesting of stock options that were granted, over their vesting period.

Operating, general and administration

Operating, general and administration expenses for fiscal 2020 totalled \$2,748,000 (2019 - \$1,827,000).

The increase is mainly the result of higher expenses associated with various third-party advisor services such as investor and media relations, legal, business development activities and investment banking services. During the year, the Company has been in discussions with various capital market firms, both in the U.S. and Canada, with the goal of raising additional capital to qualify the Company for a listing on a U.S. stock exchange such as NASDAQ.

Stock based compensation expense for fiscal 2020 totalled \$353,000 (2019 - \$164,000). The amount represents the expense associated with the vesting of stock options that were granted, over their vesting period.

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

	2020	2019
Wages and benefits	\$ 434,000	\$ 493,000
Director fees	174,000	162,000
Third-party advisors	1,424,000	762,000
Other general and administrative	360,000	239,000
Stock-based compensation expense	353,000	164,000
Amortization of property plant and equipment	3,000	7,000
Amortization of right of use assets	26,000	-
	\$ 2,748,000	\$ 1,827,000

LIQUIDITY AND CAPITAL RESOURCES

The Company reported a consolidated net loss and total comprehensive loss of \$9,174,000 for the fiscal year ended July 31, 2020 (July 31, 2019 - \$7,526,000). As at July 31, 2020 the Company had working capital of \$2,735,000, shareholders' equity of \$2,981,000, a deficit of \$180,516,000. As at July 31, 2019 the Company had a working capital deficiency of \$3,534,000, shareholders' deficiency of \$3,281,000 and a deficit of \$171,531,000.

The Company experienced a working capital deficiency throughout fiscal 2018 and 2019 until August 21, 2019 when the Company closed the first of a series of private placements for total gross proceeds of approximately \$16,000,000. A portion of the private placement financings included the total disposition of a 49.0% stake in HIO. On July 8, 2020 HIO completed a direct Series B private placement which resulted in a dilution of the Company's holding in HIO down to 42.51% as at July 31, 2020 and subsequently on September 3, 2020, HIO closed a direct Series C private placement which further diluted the Company's holding in HIO down to 29.89%.

On June 26, 2020, the Company announced the receipt of a non-binding offer from CAIAC, as designated trustee of an alternative investment fund to be established, to purchase the Company's remaining shares in HIO. The transaction was initially expected to close no later than August 31, 2020 but has since been deferred to the end of October 30, 2020, subject to the satisfaction of certain conditions, including, but not limited to, the negotiation of binding documentation, the receipt of a minimum of PLN7,300,000 by CAIAC pursuant to a financing, and the receipt of all required regulatory approvals. As of the filing of this press release, the Company had not yet closed the transaction with CAIAC though both parties continue to work through the process to finalize and close the transaction. There can be no assurance that the closing of the divestment will occur on the terms set out herein or at all.

In addition, the Company has been in discussions, during the year, with various capital market firms, both in the U.S. and Canada, with the goal of raising additional sufficient capital (\$15,000,000 to \$20,000,000) in order to qualify for a NASDAQ listing and further advance the Company's clinical development programs.

The Company's group cash reserves of \$4,235,000 as at July 31, 2020 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 have assisted the Company in dealing with its working capital deficiency, additional funds are required to advance the Company's clinical and preclinical programs and deal with 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, primarily through the issuance of equity securities of the Company, to be critical for its development needs.

The Company's Consolidated Statement of Financial Position and Consolidated Statement of Net Loss and Comprehensive Loss for fiscal 2020 and 2019 are summarized below:

<i>Consolidated Statement of Financial Position</i>			<i>Consolidated Statements of Net Loss and Comprehensive Loss</i>		
	FY2020	FY2019		FY2020	FY2019
Current assets:			Expenses:		
Cash	4,235,000	206,000	Research and development	5,868,000	4,948,000
Accounts receivable	180,000	290,000	Operating, general & administration	2,748,000	1,827,000
Prepays	90,000	191,000			
Assets held for sale	155,000	-	Results from operating activities		
	4,660,000	687,000	before finance items	(8,616,000)	(6,775,000)
Non current assets			Finance items:		
PPE's	91,000	253,000	Finance income	25,000	3,000
Right of use assets	155,000	-	Finance expense	(25,000)	(13,000)
	246,000	253,000	Foreign exchange (loss) / gain	55,000	(22,000)
Total assets	4,906,000	940,000		55,000	(32,000)
Current liabilities:			Net loss from continuing operations	(8,561,000)	(6,807,000)
Accounts payable	1,416,000	3,040,000	Net loss from discontinued operations	(613,000)	(719,000)
Accrued liabilities	301,000	1,057,000	Net loss & total comprehensive loss	(9,174,000)	(7,526,000)
Deferred government grant	-	124,000			
Lease liabilities	159,000	-	Attributable to non-controlling interest	(189,000)	-
Liabilities held for sale assets	49,000	-	Attributable to Helix BioPharma Corp	(8,985,000)	(7,526,000)
	1,925,000	4,221,000	Loss per share	-\$ 0.07	-\$ 0.07
Shareholders' equity / (deficiency)					
Attributable to Helix	2,394,000	(3,281,000)			
Non-controlling interest	587,000	-			
	2,981,000	(3,281,000)			
Total liabilities & Shareholders' equity / (deficiency)	4,906,000	940,000			

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 Company’s activities relating to DOS47, and other information in 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 for DOS47, L-DOS47, V-DOS47 and CAR-T; (iv) future expenditures, the insufficiency of the Company’s current cash resources and the need for financing; and (v) future financing requirements and the seeking of additional funding. 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, 2020 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.
