

March 16, 2020 Press Release

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# HELIX BIOPHARMA CORP. ANNOUNCES FISCAL SECOND QUARTER 2020 RESULTS

(Richmond Hill, Ontario) – Helix BioPharma Corp. (TSX: "HBP"), a an immuno-oncology company developing drug candidates for the prevention and treatment of cancer, today announced its financial results for the fiscal second quarter ended January 31, 2020.

## OVERVIEW

The Company reported a consolidated net loss and total comprehensive loss, including non-controlling interest of \$2,255,000 (\$0.02 loss per common share) and \$4,466,000 (\$0.04 loss per common share), respectively for the three and six-month period ended January 31, 2020. For the three and six-month periods ended January 31, 2019, consolidated net loss and total comprehensive loss including non-controlling interest totalled \$1,908,000 (\$0.02 loss per common share) and \$3,287,000 (\$0.03 loss per common share), respectively.

To-date in fiscal 2020, the Company has raised gross proceeds totaling approximately \$16,000,000 and as a result, no longer faces a working capital deficiency. In addition, the Company during the fiscal year, to-date has divested a 49% percent stake in its Polish subsidiary and is working on divesting the remaining 51% before the end of the Company's fiscal 2020 year-end while retaining licensing agreements for future royalties and milestones payments.

The Company has also been in discussions with various capital market firms, both in the U.S. and Canada, with the goal of raising additional capital to further advance the Company's clinical development programs and to qualify for a NASDAQ listing.

Patient enrollment and screening commenced on the LDOS006 Phase lb/II clinical study in the U.S. for the treatment of patients with previously treated advanced pancreatic cancer. Two patients have been enrolled to-date. The Phase lb portion of the study involves three dose escalating cohorts enrolling a total of nine (9) patients. The Phase II portion of the study will enroll an additional eleven (11) patients depending on meeting safety and efficacy criteria. The Company's other clinical studies for non-small cell lung cancer are in the following stages of development. LDOS001 clinical study has completed enrollment and the Company is working on finalizing data for reporting while LDOS003 is in the last cohort of the study's dose escalation phase.

#### Research and development

Research and development costs for the three and six-month periods ended January 31, 2020 totalled \$1,588,000 and \$3,099,000, respectively (\$1,330,000 and \$2,344,000 respectively for the three and six-month periods ended January 31, 2019).

The following table outlines research and development expenditures for the Company's significant research and development projects:

	For the three-month periods ended January 31		For the six-month periods ended January 31	
	2020	2019	2020	2019
L-DOS47	\$ 1,332,000	\$ 788,000	\$ 2,453,000	\$1,649,000
V-DOS47	69,000	102,000	180,000	232,000
CAR-T	-	333,000	-	333,000
Corporate research and development expenses	160,000	125,000	260,000	225,000
Trademark and patent related expenses	85,000	43,000	238,000	68,000
Depreciation expense	34,000	26,000	48,000	59,000
Stock-based compensation expense	40,000	_	79,000	· _
Polish government grant subsidy (V-DOS47)	(132,000)	(87,000)	(159,000)	(222,000)
	\$ 1,588,000	\$1,330,000	\$ 3,099,000	\$ 2,344,000

L-DOS47 research and development expenses for the three and six-month periods ended January 31, 2020 totalled \$1,332,000 and \$2,453,000, respectively (January 31, 2019 - \$788,000 and \$1,649,000, respectively). 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 newly approved LDOS006 Phase Ib/II clinical study in the U.S. The increase in L-DOS47 expenditures in Q2 fiscal 2020 when compared to Q2 fiscal 2019 reflects an increase of approximately \$350,000 in L-DOS47 manufacturing activity to produce additional drug substance in addition to increased spend of approximately \$295,000 in the Company's newly launched pancreatic clinical study in the U.S. The Company commenced enrollment in the new pancreatic clinical study in December 2019. For the six-month period ending Q2 2020 when compared to the six-moth period ended Q2 2019 the increase in spending mainly reflects the increase in cost associated with the commencement of the new pancreatic clinical trial in the U.S.

Preclinical V-DOS47 research and development expenses for the three and six-month periods ended January 31, 2020 and 201 totalled \$69,000 and \$180,000, respectively (January 31, 2019 - \$102,000 and \$232,000, respectively). The Company's wholly owned subsidiary in Poland has a grant funding agreement with the Polish National Centre for Research and Development ("PNCRD") for research and development expenditures associated with V-DOS47. In the three and sixmonth period ended January 31, 2020, the Company's Polish subsidiary received grant funding of \$132,000 and \$159,000, respectively (January 31, 2019 - \$87,000 and \$222,000, respectively), from the PNCRD.

CAR-T research and development expenses for both the three and six-month periods ended January 31, 2020 totalled \$nil, respectively (January 31, 2019 - \$333,000, respectively). 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 the three and six-month periods ended January 31, 2020 totalled \$85,000 and \$238,000, respectively (January 31, 2019 - \$43,000 and \$68,000, respectively). The Company continues to ensure it adequately protects its intellectual property.

Stock based compensation expense for the three and six-month periods ended January 31, 2020 totalled \$40,000 and \$79,000, respectively (January 31, 2019 - \$nil and \$nil, respectively). The amount represents the expense associated with the vesting of stock options that were granted in May 2019, over their vesting period.

## Operating, general and administration

Operating, general and administration expenses for the three and six-month periods ended January 31, 2020 totalled \$654,000 and \$1,363,000, respectively (\$533,000 and \$906,000 respectively for the three and six-month periods ended January 31, 2019). 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. The Company has been in discussion with various advisory groups as it pursues a listing on a recognized U.S. stock exchange, like the Nasdaq.

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

	For the three-month periods ended January 31		For the six-month periods ended January 31		
	2020	2019	2020	2019	
Wages and benefits	\$ 145,000	\$ 179,000	\$ 319,000	\$ 334,000	
Director fees	39,000	41,000	81,000	80,000	
Third-party advisors	320,000	210,000	685,000	314,000	
Other general and administrative	114,000	100,000	206,000	172,000	
Depreciation expense	3,000	_	6,000	1,000	
Stock-based compensation expense	33,000	3,000	66,000	5,000	
	\$ 654,000	\$ 533,000	\$ 1,363,000	\$ 906,000	

# LIQUIDITY AND CAPITAL RESOURCES

The Company reported a consolidated net loss and total comprehensive loss including non-controlling interest of \$2,255,000 for the three-month period ended January 31, 2020 (January 31, 2019 - \$1,908,000) and \$4,466,000 for the six-month period ended January 31, 2020 (January 31, 2019 - \$3,287,000). As at January 31, 2020 the Company had working capital of \$873,000, shareholders' equity of \$1,088,000 and a deficit of \$175,938,000. 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 for several fiscal quarters, until August 21, 2019 when the Company closed a private placement financing for gross proceeds of \$7,000,005 which included a disposition of a 25% stake in the Company's Polish subsidiary. Subsequent to the August 21, 2019 private placement and as of March 12, 2020, the Company raised an additional \$9.000,000. To-date in fiscal 2020 the Company has raised a total of \$16,000,000.

As previously disclosed, the Company intends to fully divest its remaining 51.0% interest in its Polish subsidiary to raise additional capital to further fund the Company's clinical development programs for future royalties and milestone payments.

In addition, 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 in order to further advance the Company's clinical development programs.

The Company's cash reserves of \$2,094,000 as at January 31, 2020 in addition to the subsequent private placement the Company closed on March 12, 2020 are insufficient to meet anticipated cash needs for working capital and capital expenditures through the next twelve months, and nor are they sufficient to see planned research and development initiatives through to completion. Though the funds raised have materially 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 condensed unaudited interim consolidated statement of net loss and comprehensive loss for the three and six-month periods ending January 31, 2020 and 2019 and the condensed unaudited interim consolidated statement of cash flows for the six-month periods ending January 31, 2020 and 2019 are summarized below:

Consolidated Statements of Net Loss and	d Compre	hensive L	.oss		Consolidated Statements of Cash Flows	S	
(thousand \$. except for per share data)					(thousand \$)		
	For the	three-	For th	e six-		For the six-	
	months	onths ended months ended		ended		months	ended
	Janua				_	Janua	
	2020	2019	2020	2019	-	2020	2019
Expenses:					Cash provided by (used in):		
Research and development	1,588	1,330	3,099	2,344	Net loss and total comprehensive loss	З,	
Operating, general, administration	654	533	1,363	906	including non-ontrolling interest	(4,466)	(3,287)
Results from operating activities					Adjustments, inclding non-controlling		
before finance items	(2,242)	(1,863)	(4,462)	(3,250)	interest to net cash provided by operations:		
Finance items	(13)	(45)	(4)	(37)	Items not involving cash:		
					Depreciation	54	64
Net loss and total comprehensive loss,					Stock-based compensation	146	2
including non-controlling interest	(2,255)	(1,908)	(4,466)	(3,287)	Foreign exchange loss (gain)	10 210	13 79
Add: Net loss and total comprehensive lo	199					210	79
attributable to non-controlling interest	24	-	59		Changes in non-cash working capital	(2,519)	37
Net loss and total comprehensive loss, attributable to Helix BioPharma Corp.	(2,231)	_	(4,407)	-	Operating activities	(6,775)	(3,171)
	(2,201)		(1,107)		Financing activities	7,657	3,126
Loss per share * Figures are for both basic and fully dilut	-\$ 0.02 ed	-\$ 0.02	-\$ 0.04	-\$ 0.03	Investing activities	1,016	(2)
,					Exchange rate changes on cash	(10)	(13)
					Net increase (decrease) in cash	1,888	(60)
					Cash beginning of the period	206	366
					Cash end of the period	2,094	306

The Company's Consolidated Statement of Financial Position as at January 31, 2020 and July 31, 2019 are summarized below.

Consolidated Statement of Financial Position (thousand \$)				
	31-Jan-20	31-Jul-19		
Non current assets	215	253		
Current assets:				
Prepaids	258	191		
Accounts receivable	172	290		
Cash	2,094	206		
	2,524	687		
Total assets	2,739	940		
Shareholders' equity / (deficiency)	1,088	(3,281)		
Current liabilities:				
Deferred government grant	84	124		
Accrued liabilities	473	1,057		
Accounts payable	1,094	3,040		
	1,651	4,221		
Total liabilities &				
shareholders' equity / (deficiency)	2,739	940		

The Company's condensed unaudited interim consolidated financial statements and management's discussion and analysis will be filed under the Company's profile on SEDAR at <u>www.sedar.com</u>, as well as on the Company's website.

## About Helix BioPharma Corp.

Helix BioPharma Corp. is an immuno-oncology company specializing in the field of cancer therapy. The company is actively developing innovative products for the prevention and treatment of cancer based on its proprietary technologies. Helix's product development initiatives include its novel L-DOS47 new drug candidate. Helix is currently listed on the TSX 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, 2019 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.