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# HELIX BIOPHARMA CORP. ANNOUNCES FISCAL 2017 YEAR-END RESULTS AND PROVIDES RESEARCH AND DEVELOPMENT PROGRAM UPDATE

(Richmond Hill, Ontario) – Helix BioPharma Corp. (TSX, FSE: "HBP"), an immuno-oncology company developing drug candidates for the prevention and treatment of cancer, today announced its financial results for the year ended July 31, 2017 and an update on the Company's research and development programs.

## RESEARCH AND DEVELOPMENT UPDATE

#### DOS47 Platform

To-date, the Company's proprietary technology platform, DOS47 has yielded two new drug product candidates, L-DOS47 and V-DOS47. L-DOS47 is currently under clinical study for the treatment of non-small cell lung cancer ("NSCLC") while V-DOS47 is in early pre-clinical testing.

# L-DOS47

- Following the review of clinical data collected to date, L-DOS47 continues to be well tolerated. The data also suggests that L-DOS47 may provide a clinical benefit for certain patients.
- Nine (9) patients in two dosing cohorts have been dosed in study LDOS001. Four (4) patients have had a confirmed partial response (as defined by RECIST v1.1) following treatment of L-DOS47 in combination with pemetrexed/carboplatin. To address patient enrollment issues, the Company received an approval from the FDA, to reduce the number of patients required to complete the study. Furthermore, in the next fiscal year, the Company plans to open additional sites. Enrolment is currently open to the third dosing cohort (1.5 micrograms of L-DOS47 per kilogram of patient body weight in combination with pemetrexed/carboplatin).
- ➤ Enrolment in the first stage of the Phase II component of study LDOS002 (n=21) has been completed. A Trial Steering Committee Meeting will be organized before the end of the year to review safety and efficacy data and determine if the second stage of the study will be open to enrolment.
- The Company has initiated study LDOS003, a Phase IIb trial in the treatment of Stage IV lung adenocarcinoma patients to determine the possible chemo-enhancing properties of L-DOS47 in combination with vinorelbine/cisplatin. Once the MTD of the combination is determined, initiation of the randomization component of the study is anticipated in the second of 2018. The Company has insufficient supply of L-DOS47 to complete the LDOS003 study. As a result, the Company plans to manufacture another batch of drug product in the next fiscal year to support the completion of the study and other planned studies. Completion of the study will depend on the successful release and availability of new drug product.
- Pre-clinical data generated suggests that L-DOS47 may be able to reverse the potential mechanism of resistance resulting from an acidic tumour microenvironment that protects cancer cells from the effects of immunotherapy. As previously announced by the Company, to further investigate the potential combination of L-DOS47 with immunotherapy, the Company has entered into a collaboration with Moffitt Cancer Center to perform basic research studies.

#### V-DOS47

➤ V-DOS47 is Helix's second DOS47 development candidate following L-DOS47, which is currently in preclinical testing for the treatment of triple negative breast cancer and is partially subsidized by the Polish National Centre for Research and Development ("PNCRD").

#### CAR-T Platform

On September 2016 the Company announced that it was developing a novel Chimeric Antigen Receptor T-Cell (CAR-T) therapeutic. The Company has completed two pre-clinical proof-of-principle studies using CEACAM6 and VEGFR2 as target antigens for CAR-T therapy.

# **CAR-T CEACAM6**

The Company presented the first pre-clinical proof-of-principle study applying camelid single domain antibody in making CAR-T Cells. The data showed that CAR-T cells generated against the CEACAM6 antigen significantly reduce the growth of the BxPC3 pancreatic carcinoma in vivo both when used in a preventative tumor model and in a model where treatment is initiated after the tumor is established.

# **CAR-T VEGFR2**

The Company presented preliminary data from a second study in applying camelid single domain antibody in making CAR-T cells to target cancer cells that harbour the vascular epithelial growth factor receptor 2 (VEGFR2) protein. The two camelid anti-VEGFR2 antibodies studied had approximately a 10-fold higher affinity for VEGFR2 than the two human anti-VEGFR2 antibodies.

## **FINANCIAL REVIEW**

The Company recorded a net loss and total comprehensive loss of \$10.059,000 and \$9,665,000 (a loss per common share of \$0.11 and \$0.11) for the fiscal years ended July 31, 2017 and 2016 respectively.

# Research and development

Research and development expenses totalled \$7,055,000 and \$5,821,000, respectively for the twelve-month periods ended July 31, 2017 and July 31, 2016.

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

	2017	2016
L-DOS47	\$5,496,000	\$5,017,000
V-DOS47	894,000	159,000
CAR-T	259,000	_
Corporate research and development expenses	474,000	431,000
Trademark and patent related expenses	361,000	244,000
Stock-based compensation expense	24,000	27,000
Depreciation expense	112,000	118,000
Research and development investment tax credit	(230,000)	(175,000)
Polish government grant subsidy (V-DOS47)	(335,000)	
	\$7,055,000	\$5,821,000

L-DOS47 research and development expenses for fiscal 2017 and 2016 totalled \$5,496,000 and \$5,017,000, respectively. L-DOS47 research and development expenditures relate primarily to the Company's LDOS002 European Phase I/II clinical study in Poland and the LDOS001 U.S. Phase I clinical study in the U.S.

V-DOS47 research and development expenses for fiscal 2017 and 2016 totalled \$894,000 and \$159,000, respectively. In fiscal 2016 the Company established a wholly-owned subsidiary in Poland and entered into a grant funding agreement with the PNCRD for research and development expenditures associated with V-DOS47. The Company's subsidiary received \$335,000 and \$nil in fiscal 2017 and 2016, respectively, from the PNCRD.

CAR-T research and development expenses for fiscal 2017 and 2016 totalled \$259,000 and \$nil, respectively. During the current fiscal year, the Company commenced development of novel CAR-T therapeutics and new antibody based technologies for cell-based therapies.

Corporate research and development expenses were relatively flat for fiscal 2017 and 2016 and totalled \$474,000 and \$431,000, respectively.

Trademark and patent related expenses for fiscal 2017 and 2016 totalled \$361,000 and \$244,000, respectively. The Company continues to ensure it works to adequately protect its intellectual property.

# Operating, general and administration

Operating, general and administration expenses totalled \$3,207,000 and \$3,836,000, respectively for the years ended July 31, 2017 and July 31, 2016. The decrease in operating, general and administration expenses reflects various cost cutting initiatives and is mainly due primarily to lower travel related expenses, director fees, and various terminated consulting service agreements.

# LIQUIDITY AND CAPITAL RESOURCES

As at July 31, 2017 the Company had a working capital deficiency of \$504,000, shareholders' deficiency of \$17,000 and a deficit of \$155,380,000. As at July 31, 2016 the Company had working capital of \$2,929,000, shareholders' equity of \$3,164,000 and a deficit of \$145,321,000.

The Company's cash reserves of \$897,000, as at July 31, 2017, are insufficient to meet anticipated cash needs for working capital and capital expenditures through the next twelve months, nor are they sufficient to see the current research and development initiatives through to completion. Subsequent to the Company's fiscal year ending July 31, 2017, the Company closed two additional private placements for gross proceeds of \$5,221,000. Though the funds raised have assisted the Company in dealing with the working capital deficiency, additional funds are required to advance the various clinical and preclinical programs and pay for the Company's overhead costs. 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 as at July 31, 2017 and July 31, 2016 is summarized below.

Consolidated Statement of Financial Position (thousand \$)			
	31-Jul-17	31-Jul-16	
Non current assets	487	235	
Current assets:			
Prepaids	173	90	
Accounts receivable	630	489	
Cash	897	3,654	
	1,700	4,233	
Total assets	2,187	4,468	
Shareholders' equity / (deficiency)	(17)	3,164	
Current liabilities:			
Deferred government grant	44	-	
Accrued liabilities	722	589	
Accounts payable	1,438	715	
	2,204	1,304	
Total liabilities & shareholders equity	2,187	4,468	

The Company's Consolidated Statement of Net Loss and Comprehensive Loss and Consolidated Statement of Cash Flow for fiscal 2017 and 2016 are summarized below:

Consolidated Statements of Net Loss and Comprehensive Loss				
(thousand \$, except for per share data)				
	For the year ended			
	Jul-31	Jul-31		
	2017	2016		
Expenses:				
Research and development	7,055	5,821		
Operating, general, administration	3,207	3,836		
Gain on sale property, plant, equipment	(168)	· -		
Results from operating activities before finance items	(10,094)	(9,657)		
Finance items	35	(8)		
Loss and total comprehensive loss	(10,059)	(9,665)		
Loss per share * Figures are for both basic and fully diluted	-\$ 0.11 -	\$ 0.11		

Consolidated Statements of Cash Flows		
(thousand \$)		
	For the year ended	
	Jul-31	Jul-31
	2017	2016
Cash provided by (used in):		
Net loss and total comprehensive loss	(10,059)	(9,665)
Harry and Smith Survey by		
Items not involving cash:  Depreciation	130	134
Stock-based compensation	159	230
Foreign exchange loss (gain)	(33)	17
Gain on sale property, plant, equipment	(168)	- '
Common property, praint, equipment	88	381
Changes in non-cash working capital	676	431
Operating activities	(9,295)	(8,853)
Financing activities	6,719	5,772
Investing activities	(214)	(40)
Exchange rate changes on cash	33	(17)
Net increase (decrease) in cash	(2,757)	(3,138)
Cash beginning of the period	3,654	6,792
Cash end of the period	897	3,654

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 <a href="www.sedar.com">www.sedar.com</a>, as well as on the Company's website at <a href="www.helixbiopharma.com">www.helixbiopharma.com</a>.

# 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 and FSE 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, 2017 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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