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Helix BioPharma Corp. (HBP.TO - TSX)

One Patient Remains In First Dosing Cohort

Based on our DCF model and a 15% discount rate, Helix is valued at approximately CAD$2.00 per share. Our model applies a 15% probability of ultimate approval and commercialization for L-DOS47 in NSCLC and pancreatic cancer. The model includes contributions from the United States and Europe.

Current Price (8/3/2020)	$0.54
Valuation ($CAD)	**$2.00**

OUTLOOK

Helix is an immuno-oncology company developing an anti-cancer therapeutic platform which acts by modulating the tumor micro-environment pH with an enzyme conjugated to an antibody. Helix's lead candidate, L-DOS47, is being evaluated in clinical trials for NSCLC and pancreatic cancer in combination with other agents. The antibody targets the CEACAM6 antigen in tumor cells allowing the linked urease enzyme to increase surrounding pH by catalyzing urea breakdown into basic ammonia. Additional DOS47 compounds are in the preclinical stage for solid tumors.

Lead candidate L-DOS47 is in Ph2 clinical trials for pancreatic cancer & NSCLC in combination with chemotherapy. We expect pivotal trials to generate registrational data in 2025 for both indications and work with a partner will advance the candidate outside North America.

Our valuation assumes a 2026 approval and launch of L-DOS47 in select markets including the US and Europe, the latter of which will be achieved through the efforts of partners.

SUMMARY DATA

52-Week High	**2.01**
52-Week Low	**0.53**
One-Year Return (%)	**-3.6**
Beta	**-0.03**
Average Daily Volume (sh)	**10,153**
Shares Outstanding (mil)	**132.9**
Market Capitalization ($mil)	**71.8**
Short Interest Ratio (days)	**2.45**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**16.0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**N/A**
P/E using 2021 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of CAD)

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2019	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2020	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2021					$0.0 E
2022					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2019	-$0.01 A	-$0.02 A	-$0.02 A	-$0.02 A	-$0.07 A
2020	-$0.02 A	-$0.02 A	-$0.02 A	-$0.02 E	-$0.07 E
2021					-$0.07 E
2022					-$0.08 E

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WHAT'S NEW

Third Quarter 2019 Operational and Financial Results

Helix BioPharma Corp. (TSX: HBP.TO / OTC: HBPCF) reported third quarter 2020 results and submitted its SEDAR filings on July 30, 2020. During the third quarter, extending from February 1 to April 30, 2020, Helix presented at the Noble Capital Markets conference, raised CAD$6 million in a private placement and updated investors on the impact of COVID-19 on operations. Following the end of the reporting period, the company announced the Phase I lung cancer data presentation at the American Society of Clinical Oncology (ASCO) conference, signaled that it will completely divest of its interest in its Polish subsidiary and entered into an agreement with CAIAC Fund Management to sell its remaining interest in it. Helix also participated in investor events, one of which we summarize in an article here.[1]

Net loss for 3Q:20 was ($2.6) million,[2] which compares with the ($2.1) million loss in 3Q:19. On a per share basis, this was ($0.02). Research and development expense was $1.5 million, up 13% from prior year levels due to expenditure on manufacturing of L-DOS47 for use in clinical trials and expenditure for the Phase Ib/II pancreatic trial. These amounts were partially offset by a reduction in spend related to the L-DOS001 study and lower spending related to the research collaboration with the Moffitt Cancer Center. General and administrative expenses were $862,000, rising 23% on increased expenditures for third party advisory services such as investor and media relations, legal, business development activities and investment banking services.

As of April 30, 2020, the cash balance was $5.0 million compared to $0.2 million at the end of the fiscal year, July 31, 2019. Cash burn in the third quarter was ($2.2) million, compared with prior year levels of ($1.2) million. During the fiscal third quarter, Helix raised CAD$6 million which will continue to fund operations and research and development activities. The company has no debt on its balance sheet.

Helix is sponsoring two active Phase II trials. These include a combination chemotherapy trial for European and Asian markets and a monotherapy trial which has completed data collection and the clinical study report as of June 2020 for non-small cell lung cancer (NSCLC). Phase Ib/II pancreatic cancer trial LDOS006 was recently launched that is expected to read out in 2021. LDOS006 is being conducted in Scottsdale, Arizona with five patients enrolled in the study. Two of the enrollees have successfully completed the cycles and only one patient remains to complete the first cohort. One patient is currently active in the safety evaluation portion. Due to delays anticipated from the COVID-19 pandemic, additional sites are being sought to conduct the trial and additional locations may be added.

Drug Product

Helix recently contracted with a manufacturing organization to produce additional volumes of L-DOS47 for use in ongoing trials. Additional supply is expected before the end of the year. The product has already been manufactured and the polishing and fill and finish steps are now taking place. During the third quarter, approximately $161,000 was spent in this effort.

Polish Subsidiary

On June 26, 2020 Helix announced that it would be divesting its remaining ownership in its Polish subsidiary, Helix Immuno-Oncology S.A. (HIO). At the time of the announcement, Helix held a 51% interest in the entity following the sale earlier in the year of a 15.5% ownership stake. HIO had been developing V-DOS47, an antibody protein conjugate that targets vascular endothelial growth factor 2 receptor (VEGFR2) expressed in many carcinomas and lymphomas. Following the end of the reporting period, Helix cancelled approximately $2.7 million in intercompany debt owed it by HIO and assets related to Biphasix and V-DOS47 were transferred back to Helix. An increase in share capital was approved for HIO, which allowed for 2.2 million shares to be issued raising gross proceeds of approximately 3 million Polish zloty. This action reduced Helix' interest in HIO to 42.5%. The company also accepted a non-binding offer to purchase the remaining 42.5% for 6.7 million Polish zloty, equivalent to CAD$2.3 million. The transaction is scheduled to close on August 31, 2020 and is subject to several conditions.

[1] https://scr.zacks.com/News/Press-Releases/Press-Release-Details/2020/HBPTO-Helix-BioPharma-Pitches-at-Proactives-One2One-Virtual-Forum/default.aspx

[2] Share prices, value references in the text and financial statement items are denominated in Canadian dollars.

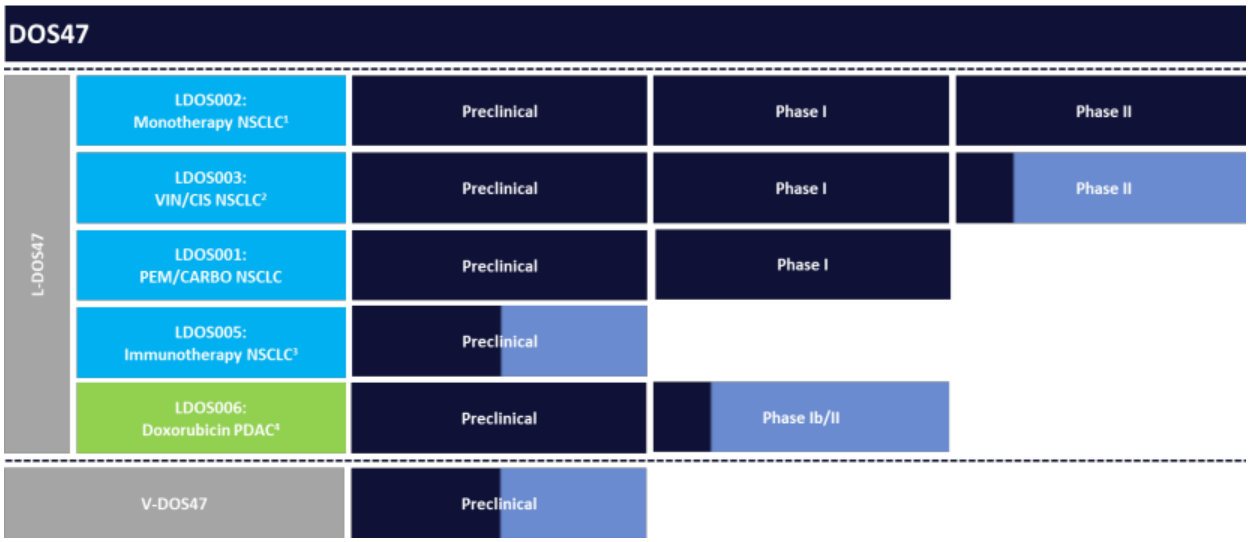
Pipeline

Helix' pancreatic cancer trial, LDOS006, was launched in December and now has enrolled five patients in the Phase Ib portion of the study with only one more patient necessary to complete enrollment in the first cohort. This trial is combining chemotherapy agent doxorubicin with L-DOS47 in a dose escalating study for pancreatic cancer patients who have already undergone prior lines of therapy. The Phase Ib portion is targeting 9 patients for the study and will progress to the 11-patient Phase II segment of the study.

The LDOS003 trial is also underway examining the benefit of L-DOS47 with a combination of vinorelbine and cisplatin for non-small cell lung cancer (NSCLC) patients. This trial has been on hold since 2018 due to a shortage of vinorelbine and as management awaits a partner to advance the work.

The LDOS001 trial is being conducted in the United States using L-DOS47 in combination with carboplatin and pemetrexed for NSCLC. Patient recruitment was closed mid-2019 and the trial has issued a clinical study report. An abstract for trial outcomes has been submitted for presentation at American Society of Clinical Oncology (ASCO) conference this year.

Exhibit I – Product Development Pipeline[3]



Corporate Milestones

Below we list key milestones that have occurred in the last year and anticipated future events.

- IND clearance by FDA for LDOS006 – August 2019
- Launch of LDOS006 – December 2019
- $6.0 million capital raise – March 2020
- Divestiture of 15.5% of Helix Immuno-Oncology (HIO) – March 2020
- LDOS001 abstract submitted – Calendar 1Q:20
- LDOS002 clinical study report completed – June 2020
- Full divestiture of HIO – August 31, 2020
- Availability of additional supply of L-DOS47 – Fall / Winter 2020
- Advancement of LDOS003 to Part II – Dependent on partnership
- Anticipated completion of LDOS006 – year-end 2021

[3] Source: Helix Biopharma February 2020 Corporate Presentation.

Investment Thesis

Helix is focused on modulating the acidic tumor microenvironment through the use of an antibody protein conjugate which links an antibody to a urease enzyme. The urease enzyme is able to catalyze extracellular urea into inert carbon dioxide and basic ammonia which raises the pH of the tumor microenvironment. The ammonia is toxic to cancer cells and also creates an environment that allows weak-base chemotherapies to regain potency. Helix is currently pursuing indications in combination with chemotherapy for non-small cell lung carcinoma (NSCLC) and pancreatic cancer. There may be future opportunities for combination work with checkpoint inhibitors. Below we summarize the key elements supporting our investment thesis. Refer to our initiation report for a detailed discussion of the company.

Key reasons to own Helix shares:

- **Novel mechanism of action that is synergistic with other therapies**
- **CEACAM6 target is specific to tumor cells, especially lung and pancreatic adenocarcinoma**
- **L-DOS47 may reverse acidic extra-cellular conditions favorable to cancer cell survival**
- **L-DOS47 may improve uptake of weak-base chemotherapeutics**
- **L-DOS47 may reduce PD-1 and PD-L1 expression thereby improving immune response**
- **Favorable drug safety profile with no reported drug-related adverse events**
- **Biologic eligible for 12 years of exclusivity in United States and extended protection in other geographies**
- **North American rights to intellectual property**
- **Pursuing multiple indications**
    - **Non small cell lung cancer**
    - **Pancreatic cancer**

Based on our analysis of L-DOS47 and its impact on the tumor microenvironment we see a pathway forward in NSCLC and pancreatic cancer. Our valuation work takes into account commercialization of L-DOS47 in both the United States and Europe assuming a 15% probability of ultimate success. The opportunity for L-DOS47 extends beyond the US and Europe and the company has other programs in development that may ultimately generate value. Fundraising efforts late last year and in the first months of 2020 have provided additional capital through the issuance of additional shares and the cumulative divestiture of 49% of HIO. Following a December launch, Helix is now enrolling its LDOS006 trial for pancreatic cancer, an indication with few successful therapies available. We maintain our current valuation opinion of $2.00 per share.

PROJECTED FINANCIALS

Helix BioPharma Corporation - Income Statement

Helix BioPharma Corp	2019 A	Q1 A	Q2 A	Q3 A	Q4 E	2020 E	2021 E	2022 E
Total Revenues ($CAD)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Research & Development	$5,006	$1,511	$1,588	$1,523	$1,600	$6,222	$8,000	$10,000
Operating, General & Admin	$2,486	$709	$654	$862	$750	$2,975	$3,000	$3,500
Income from operations	($7,492)	($2,220)	($2,242)	($2,385)	($2,350)	($9,197)	($11,000)	($13,500)
Other Income	($33)	$15	($10)	($211)	$0	($206)	$0	$0
Interest Expense	($1)	($6)	($3)	$2	$0	($7)	$0	$0
Pre-Tax Income	($7,526)	($2,211)	($2,255)	($2,594)	($2,350)	($9,410)	($11,000)	($13,500)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($7,526)**	**($2,211)**	**($2,255)**	**($2,594)**	**($2,350)**	**($9,410)**	**($11,000)**	**($13,500)**
Net Margin								
Reported EPS	**($0.07)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.07)**	**($0.07)**	**($0.08)**
YOY Growth								
Basic Shares Outstanding	106,646	121,818	125,526	130,636	132,000	127,495	150,000	180,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Helix BioPharma Corporation – Share Price Chart[4]



[4] Source: Zacks Research System

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