

August 12, 2020



## IMV Inc. Announces Second Quarter 2020 Financial Results

- *Rapidly progressing DPX-COVID-19, including Health Canada agreement on Phase 1 clinical study design protocol, with preliminary results expected in fall 2020*
- *Confirmed \$4.75M of non-dilutive fund supporting Phase 1 clinical development of DPX-COVID-19*
- *Updated data from Phase 2 DeCidE1 study with a 26% clinical response rate highlighting the potential of DPX-Survivac to improve the standard of care in advanced ovarian cancer*
- *Pro-forma cash and cash equivalents of \$61.8M on June 30<sup>th</sup>, 2020*
- *Management to host a conference call and webcast today at 8:00 a.m. ET*

DARTMOUTH, Nova Scotia--(BUSINESS WIRE)-- IMV Inc. (the "Company" or "IMV") (TSX: IMV; NASDAQ: IMV), a clinical-stage biopharmaceutical company pioneering a novel class of cancer immunotherapies and vaccines against infectious diseases, today announced financial results for the second quarter ended June 30, 2020 and provided an update on its clinical and operational progress.

"This quarter, we greatly strengthened our financial position and made continued progress across our portfolio with the rapid advancement of our vaccine program against SARS-CoV-2. This includes the selection of our clinical candidate, DPX-COVID-19, which demonstrated strong immunogenicity including its binding on target to the spike protein and viral neutralization in preclinical studies. In addition, Health Canada agreed with the design of our Phase 1 study, that will enroll across two clinical sites including in elderly subjects. We also confirmed non-dilutive government funding, expected to cover development costs through Phase 1.

We believe the DPX technology, combined with the thoughtful selection of non-overlapping, immunogenic peptides, offers meaningful clinical potential and we look forward to reporting preliminary Phase 1 results later this fall for DPX-COVID-19," stated Frederic Ors, Chief Executive Officer at IMV. "In parallel, we continue to advance DPX-Survivac, our lead program, currently being evaluated in multiple phase 2 studies. On the heels of our recent announcement that SPiReL, a Phase 2 study of a DPX-Survivac combination regimen in patients with r/r DLBCL, met its primary efficacy endpoint, we presented data demonstrating deepening responses in ovarian cancer at ASCO 2020. We look forward to reporting updated data from both studies later this year, and to engaging with regulators on the path forward for DPX-Survivac."

### **Second Quarter 2020 and Recent Operational Highlights:**

## **DPX-COVID-19**

IMV continues to rapidly advance its vaccine candidate for COVID-19. A summary of recent progress is outlined below:

- In May 2020, IMV announced the selection of DPX-COVID-19 as its clinical candidate for COVID-19. DPX-COVID-19 is formulated within the Company's DPX delivery platform, with four complementary peptide antigens selected for their high immunogenicity and ability to bind non-overlapping areas on the virus spike. These four peptides are independent of the 614 gene mutation, which may increase the virus' ability to infect cells in vitro, reduce vaccine-induced immunity and avoid mutation resistance. Additionally, areas on the virus spike identified as potentially responsible for vaccine-enhanced disease have been excluded from target selection to minimize safety risk.
- In July 2020, IMV received agreement with Health Canada on the design of its Phase 1 clinical study. This study is a randomized, controlled study, assessing the safety and immunogenicity of DPX-COVID-19, in 84 healthy adults across two age cohorts: (1) adults age 18-55; and (2) adults age 56 and older. To support the initiation of clinical trials, the Company completed the current good manufacturing practice (cGMP) formulation and manufacturing process development for DPX-COVID-19 and multiple batches have been successfully produced. Two dose levels of DPX-COVID-19 will be tested across both cohorts (25µg or 50µg). IMV anticipates preliminary results of the Phase 1 clinical study in the fall of 2020.
- In August 2020, the Company confirmed that it will receive non-dilutive funding of \$4.75 M from the [National Research Council of Canada Industrial Research Assistance Program \(NRC IRAP\)](#), the [Innovation Assistance Program \(NRC IAP\)](#), the [Atlantic Canada Opportunities Agency \(ACOA\)](#), and from [Next Generation Manufacturing Canada \(NGen\)](#) to support upcoming clinical trials and the rapid scale-up of DPX-COVID-19. This provides sufficient capital to fund clinical development through a Phase 1 study of DPX-COVID-19.

## **DPX-Survivac**

### **Phase 2 SPiReL Study in Recurrent / Refractory Diffuse Large B-Cell Lymphoma (r/r DLBCL)**

In March 2020, the Company announced that the study had met its primary efficacy endpoint with 64% (7/11) of evaluable patients demonstrating a clinical response so far. The study remains ongoing and IMV anticipates presenting topline data at a scientific conference later in 2020.

Additionally, the Company plans to engage with the U.S. Food and Drug Administration (FDA) later this year, to identify the path forward in r/r DLBCL.

As of August 3, 2020, 22 patients have been enrolled across five different clinical sites in Canada.

SPiReL is an investigator-initiated Phase 2 study evaluating DPX-Survivac/CPA in

combination with Keytruda® (pembrolizumab) in r/r DLBCL. The study is led by Dr. Neil Berinstein, MD, FFCP®, ABIM, hematologist-oncologist at the Odette Cancer Centre at Sunnybrook Health Sciences Centre in Toronto, Ontario.

## **Phase 2 DeCidE1 Study in Advanced Recurrent Ovarian Cancer**

In May 2020, IMV presented a poster as part of the American Society of Clinical Oncology (ASCO) [Virtual Scientific Program](#). Results from the ongoing study showed prolonged durable clinical responses, continued favorable tolerability and strong translational data linking the observed clinical benefit with DPX-Survivac's mechanism of action.

As of the data cut-off date on May 2, 2020, 19 patients were evaluable for efficacy with four patients (21%) still receiving treatment. 5/19 patients (26%) achieved a partial regression (PR) on target lesions with tumor regression >30% on target lesions. These results compare favorably to with historical data with single agent chemotherapy standard of care (12% clinical response rate) and warrant further clinical development.

Translational analyses link observed clinical benefit and survivin-specific T cells, showing treatment generated a survivin-specific CD8+ T cell response in PBMC samples of 14/16 (87%) evaluable patients and induced an immune response with survivin-specific T cell clones infiltrating tumors as early as day 56 following treatment. More data, including the poster, are available [here](#).

DeCidE1 is a Phase 2 multicenter, randomized, open-label study to evaluate the safety and efficacy of DPX-Survivac with intermittent low dose cyclophosphamide (CPA). This Phase 2 arm enrolled 22 patients with recurrent, advanced platinum-sensitive and/or resistant ovarian cancer.

## **Phase 2 Basket Trial in Multiple Advanced Metastatic Solid Tumors**

As of August 3, 2020, a total of 100 patients out of the planned 184 patients were enrolled across all five indications at 19 clinical sites in Canada and the US.

As noted previously, the COVID-19 pandemic has impacted data collection and validation processes from this study. However, the Company remains on track to report updated results from this study in the second half of 2020.

The Basket Trial is an open label, multi-center Phase 2 study, evaluating the safety and efficacy of DPX-Survivac/CPA in combination with Keytruda® across five cohorts of patients with bladder cancer, liver cancer (hepatocellular carcinoma), ovarian cancer (with and without CPA), NSCLC and tumors shown to be positive for the microsatellite instability high (MSI-H) biomarker.

## **Upcoming Milestones**

Over the course of upcoming quarters, the Company expects to deliver the following milestones:

- DPX-COVID-19
  - Initiation of Phase 1 Clinical trial with DPX-COVID-19 in summer 2020
  - Preliminary Phase 1 results in fall 2020

- DPX-Survivac
  - Top line Phase 2 clinical results from the DLBCL combination trial in 2020
  - Top line Phase 2 clinical results from the ovarian monotherapy trial in 2020
  - Updated Phase 2 clinical results from the basket trial in 2020

## **Overview of Second Quarter 2020 Financial Results**

At June 30, 2020, the Company had cash and cash equivalents of \$28,251,000 and working capital of \$29,501,000, compared with \$14,066,000 and \$13,199,000, respectively at December 31, 2019. This primarily reflects proceeds from the CDN \$25,100,000 private placement completed on May 7<sup>th</sup>. Subsequent to June 30<sup>th</sup>, the Company sold 4,770,890 common shares for gross proceeds of US\$24.5 million (CAD\$33.5 million) under its At-The-Market facility resulting in pro-forma cash and cash equivalents of \$61,751,000 as of June 30, 2020. Based on its current plan, IMV expects its current cash position will be sufficient to fund operations for more than the next 12 months.

Research and development expenses increased by \$1,457,000 during the quarter ended June 30, 2020, compared to Q2 2019. These increases are mainly due to increased enrollment for the ongoing basket trial prior to the onset of the pandemic, pre-clinical development for DPX-COVID-19, which is offset fully by an increase in government assistance, and to a lesser extent, also attributable to personnel costs due to an increase in headcount. The increase in research and development expenses is partly offset by a decrease in travel and costs related to the DeCidE1 Phase 2 study of DPX-Survivac/CPA, in patients with advanced recurrent ovarian cancer.

General and administrative expenses increased by \$863,000 for the quarter ended June 30, 2020 compared to Q2 2019. This increase is explained by an increase in insurance premium and is also attributable to non-cash DSU compensation caused by share price fluctuation and legal and professional fees. The Company expects reduced comparative volatility in the DSU compensation expense from Q3 2020 onward as a result of electing to settle all future DSU redemptions in shares effective August 8, 2019. This increase is partly offset by a decrease of \$180,000 in travel due to COVID-19 travel restrictions.

The net loss and comprehensive loss of \$7,268,000 (\$0.13 per share) the quarter ended June 30, 2020 was \$2,217,000 higher than the net loss and comprehensive loss for the quarter ended June 30, 2019.

For the six-month period ended June 30, 2020, the net loss and comprehensive loss of \$16,936,000 was \$5,942,000 higher than the net loss and comprehensive loss for the six-month period ended June 30, 2019. This relates mainly to a \$4,269,000 increase in R&D expenses and a \$1,938,000 increase in general and administrative expenses partly compensated by a \$476,000 increase in government assistance during the six-month period ended June 30, 2020.

For the six months ended June 30, 2020, IMV's cash burn rate, defined as net loss for the period adjusted for operations not involving cash (interest on lease obligation, depreciation, accretion of long-term debt, stock-based compensation and DSU compensation), was \$15,047,000. IMV expects the cash burn for the remainder of 2020 to be approximately \$6,000,000 per quarter.

As of August 11, 2020, the number of issued and outstanding common shares was 66,481,659 and a total of 5,037,425 stock options, deferred share units and warrants were outstanding.

The Company's unaudited interim condensed consolidated results of operations, financial condition and cash flows for the quarter ended June 30, 2020 and the related management's discussion and analysis (MD&A) are available on SEDAR at [www.sedar.com](http://www.sedar.com) and on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar).

### **Conference Call and Webcast Information**

Management will host a conference call and webcast today, August 12, 2020, at 8:00 a.m. ET. Financial analysts are invited to join the conference call by dialing (866) 211-3204 (U.S. and Canada) or (647) 689-6600 (international) using the conference ID# 2593517 Other interested parties will be able to access the live audio webcast at this link: <https://ir.imv-inc.com/events-and-presentations>.

### **About IMV**

IMV Inc. is a clinical stage biopharmaceutical company dedicated to making immunotherapy more effective, more broadly applicable, and more widely available to people facing cancer and other serious diseases. IMV is pioneering a new class of cancer immunotherapies and vaccines against infectious diseases based on the Company's proprietary drug delivery platform, DPX. This patented technology leverages a novel mechanism of action that enables the programming of immune cells *in vivo*, which are aimed at generating powerful new synthetic therapeutic capabilities. IMV's lead candidate, DPX-Survivac, is a T cell-activating immunotherapy that combines the utility of the platform with a target: survivin. IMV is currently assessing DPX-Survivac as a monotherapy in advanced ovarian cancer, as well as a combination therapy in recurrent/refractory diffuse large B cell lymphoma and other indications across multiple clinical studies with Merck. Visit [www.imv-inc.com](http://www.imv-inc.com) and connect with us on [Twitter](#) and [LinkedIn](#).

### **Cautionary Language Regarding Forward-Looking Statements**

*This press release contains forward-looking information under applicable securities law. All information that addresses activities or developments that we expect to occur in the future is forward-looking information. Forward-looking statements are based on the estimates and opinions of management on the date the statements are made. In the press release, such forward-looking statements include, but are not limited to, statements regarding the Company's progress in developing a DPX-based vaccine candidate against COVID-19, the Company's belief that the DPX-based platform creates the opportunity for production of a COVID-19 vaccine, the Company's belief in the potential efficacy of its DPX-based vaccine against COVID-19, the anticipated timing of the Company's preclinical assays, studies and clinical trials related to its DPX-based vaccine against COVID-19 and the expected impact of COVID-19 on the Company's other clinical studies and trials and its operations generally. Such statements should not be regarded as a representation that any of the plans will be achieved. Actual results may differ materially from those set forth in this press release due to risks and uncertainties affecting the Company and its products.*

*The Company assumes no responsibility to update forward-looking statements in this press*

*release except as required by law. These forward-looking statements involve known and unknown risks and uncertainties and those risks and uncertainties include, but are not limited to, the Company's ability to develop a DPX-based vaccine candidate against the COVID-19 through the successful and timely completion of preclinical assays, studies and clinical trials, the receipt of all regulatory approvals by the Company to commence and then continue clinical studies and trials, and, if successful, the commercialization of its proposed vaccine candidate related to COVID-19, the Company's ability to raise sufficient capital, including potentially through grant awards available in Canada, to fund such clinical studies and trials and the production of any COVID-19 vaccine, the ultimate applicability of any third-party research and studies in related coronavirus and SARS studies and sequencing, the Company's ability to enter into agreements with the proposed lead investigators to assist in the clinical development on its vaccine candidate related to COVID-19, the Company's ability to collaborate with governmental authorities with respect to such clinical development, the coverage and applicability of the Company's intellectual property rights to any vaccine candidate related to COVID-19, the ability of the Company to manufacture any vaccine candidate related to COVID-19 rapidly and at scale, the ability for the Company to accurately assess and anticipate the impact of COVID-19 on the Company's other clinical studies and trials and operations generally and other risks detailed from time to time in the Company's ongoing filings and in its annual information form filed with the Canadian regulatory authorities on SEDAR as [www.sedar.com](http://www.sedar.com) and with the United States Securities and Exchange Commission on EDGAR at [www.sec.edgar](http://www.sec.edgar). Investors are cautioned not to rely on these forward-looking statements and are encouraged to read the Company's continuous disclosure documents which are available on SEDAR and on EDGAR.*

IMV INC.

Unaudited Interim Condensed Consolidated Statements of Loss and Comprehensive Loss

(In thousands of Canadian dollars, except shares and per share amounts)

	Three-month end	
	2020	2019
	\$	\$
<b>Income</b>		
Subcontract revenue	—	
Interest Income	55	1
Total income	<u>55</u>	<u>1</u>
<b>Expenses</b>		
Research and development	5,260	3,8
General and administrative	3,047	2,1
Government assistance	(1,406)	(1,14
Accreted interest	422	3
Total operating expenses	<u>7,323</u>	<u>5,2</u>
<b>Net loss and comprehensive loss</b>	<u>(7,268)</u>	<u>(5,04</u>
<b>Basic and diluted loss per share</b>	<u>(0.13)</u>	<u>(0.1</u>

Weighted-average shares outstanding

57,300,903 50,601,8

IMV INC.

Unaudited Interim Condensed Consolidated Statements of Financial Position  
(In thousands of Canadian dollars, except shares and per share amounts)

	June 30, 2020	December 31, 2019
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 28,251	\$ 14,066
Accounts receivable	911	845
Prepaid expenses	7,973	3,032
Investment tax credits receivable	1,442	1,661
Total current assets	<u>38,577</u>	<u>19,604</u>
Property and equipment	2,825	2,830
Total assets	<u>\$ 41,402</u>	<u>\$ 22,434</u>
<b>Liabilities and Equity</b>		
Current liabilities		
Accounts payable, accrued and other liabilities	\$ 8,286	\$ 6,157
Amounts due to directors	75	60
Current portion of long-term debt	592	88
Current portion of lease obligations	123	100
Total current liabilities	<u>9,076</u>	<u>6,405</u>
Lease obligation	1,295	1,208
Long-term debt	8,696	8,373
Total liabilities	<u>19,067</u>	<u>15,986</u>
Equity	22,335	6,448
Total liabilities and equity	<u>\$ 41,402</u>	<u>\$ 22,434</u>

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