

November 12, 2020



# IMV Inc. Announces Third Quarter 2020 Financial Results and Provides Clinical Update

- *Identification of PD-L1 as a potential Biomarker with 86% of clinical responses in patients with r/r DLBCL in our combination trial with Merck's Keytruda®*
- *Cash and cash equivalents of \$54.7M as of September 30<sup>th</sup>, 2020*
- *Expanded Board of Directors and strengthened management team*
- *Reviewing data presented at SITC on 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, announces financial results for the third quarter ended September 30, 2020 and provides an update on its clinical and operational progress.

"Biomarkers predictive of responses can be game-changing in the development of new treatments for cancer. We are extremely happy to share our success this week in finding a potential predictive biomarker that is associated with a very high level of clinical efficacy in patients with relapsed/refractory DLBCL. The PD-L1 biomarker is well recognized and already approved for multiple cancer indications and this finding brings us closer to an accelerated path to market for DPX-Survivac in this high unmet medical need patient population."

"In addition to this significant milestone, we continued to make progress across our pipeline and corporate development objectives steadily advancing development in other cancer indications as well as our vaccine against COVID-19," said Fred Ors, Chief Executive Officer at IMV.

## **Third quarter 2020 and Recent Operational Highlights:**

### **DPX-Survivac**

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

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.

As of October 30, 2020, 24 patients have been enrolled across six clinical sites in Canada.

As reported in May 2020, the study has already met its primary efficacy endpoint.

On November 11, 2020, Dr. Berinstein delivered a poster presentation at *The Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting*. As of the data cut-off date of this presentation, 18 pre-treatment samples from 18 patients enrolled in the SPiReL study were available for biomarker analysis and thirty-nine percent (7/18) of these patients had pre-treatment tumors that were classified as PD-L1 positive.

Key findings for this population include:

- 6/7 subjects demonstrated a partial response (PR) or complete response (CR), resulting in an Objective Response Rate (ORR) of 86% (3 CR and 3 PR) and no clinical response (PR or CR) has been observed in the PD-L1 negative population (n=11); and
- Observed 100% Disease Control Rate (DCR) defined as Stable Disease, PR or CR.

On the strength of these results, IMV is working on the design of the next clinical study in r/r DLBCL. The Company plans to engage with the U.S. Food and Drug Administration (FDA) as soon as possible to identify the best path toward registration.

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

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

IMV intends to present top line data during a virtual key opinion leader meeting on December 3, 2020 at 8:00 am ET.

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

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.

As of October 30, 2020, a total of 106 patients out of the planned 184 patients have been 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 verification from this study. The Company intends to report results in the first quarter of 2021 to coincide with seasonal healthcare industry conferences.

### **DPX-COVID-19**

In October 2020, IMV announced that in consultation with Health Canada, it intends to combine its original Phase 1 and 2 studies into a single trial with the potential to accelerate the clinical development and the timeline of the overall project. The design of this study will incorporate the same two-age strata cohorts (18-55 years old and over 55 years old) as originally planned.

Subject to the approval of Health Canada and after the completion and submission of the preclinical safety, GLP toxicology and challenge studies, the Phase 1/2 trial is expected to be approved and initiated before the end of 2020.

### Additional funding and Increased Manufacturing Capacity

In October 2020, IMV announced that the [National Research Council of Canada Industrial Research Assistance Program \(NRC IRAP\)](#) will provide advisory services and up to \$5.4 million in funding to support the continuation of clinical trials for its DPX-COVID-19 vaccine candidate. This funding is milestone based and will be dependent upon the achievement of certain objectives. To date, IMV has secured more than \$10 million to fund its DPX-COVID-19 development efforts and other non-dilutive funding requests are ongoing.

To increase its current manufacturing capacity, IMV has entered a collaboration with a global manufacturing partner and initiated transfer and scale-up activities of DPX-COVID-19. This collaboration has the potential to bring two additional production sites in India and Europe with capacity to produce several hundred million doses of DPX-COVID-19.

### Corporate Update

On November 10, 2020, Andrew Hall joined IMV as Chief Business Officer. Mr. Hall was previously Executive Director, Business Development and Global Alliances at Celgene.

In July 2020, Michael P. Bailey was appointed to the board of directors. Mr. Bailey currently serves as President and Chief Executive Officer and a member of the board of directors at AVEO Oncology.

### Upcoming Milestones

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

- DPX-Survivac
  - Additional Phase 2 clinical results from the DLBCL combination at the American Society of Hematology (ASH) annual meeting to be held virtually on December 6, 2020
  - Top line Phase 2 clinical results from the ovarian cancer trial on December 3, 2020
  - Updated Phase 2 clinical results from the basket trial in Q1 2021
- DPX-COVID-19
  - Initiation of Phase 1/2 clinical trial with DPX-COVID-19 in 2020
  - Preliminary Phase 1/2 results in Q1 2021

### Overview of Third quarter 2020 Financial Results

On September 30, 2020, the Company had cash and cash equivalents of \$54,700,000 and working capital of \$55,875,000, compared with \$14,066,000 and \$13,199,000, respectively at December 31, 2019. This primarily reflects proceeds from the \$25,100,000 private placement completed on May 7<sup>th</sup>, the 6,841,773 common shares issued for gross proceeds of US\$30 million (CAD\$40.8 million) under its March and June At-The-Market facilities and

\$2,276,000 from the exercise of 611,888 common share warrants. Based on its current operating 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 \$889,000 during the quarter ended September 30, 2020, compared to Q3 2019. These increases are mainly due to pre-clinical development for DPX-COVID-19, which is offset 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, DPX-SurMAGE preclinical development 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 \$1,064,000 for the quarter ended September 30, 2020 compared to Q3 2019. This increase is explained by an increase in insurance premium and to a lesser extent is also attributable to an increase in foreign exchange loss. This increase is partly offset by a decrease of \$223,000 in legal and professional fees and a decrease of \$170,000 in travel due to COVID-19 travel restrictions.

The net loss and comprehensive loss of \$8,327,000 (\$0.13 per share) for the quarter ended September 30, 2020 was \$431,000 higher than the net loss and comprehensive loss of \$7,896,000 (\$0.16 per share) for the quarter ended September 30, 2019.

For the nine-month period ended September 30, 2020, the net loss and comprehensive loss of \$25,259,000 was \$6,369,000 higher than the net loss and comprehensive loss for the nine-month period ended September 30, 2019. This relates mainly to a \$5,161,000 increase in R&D expenses and a \$3,000,000 increase in general and administrative expenses partly compensated by a \$1,556,000 increase in government assistance mainly towards COVID-19 vaccine development.

For the nine months ended September 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 \$23,566,000.

As of November 11, 2020, the number of issued and outstanding common shares was 67,093,547 and a total of 4,490,791 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 September 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, November 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# 6146758. Other interested parties will be able to access the live audio webcast at this [link](#).

## 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-targeted immunotherapies and vaccines based on the Company's proprietary delivery platform (DPX). This patented technology leverages a novel mechanism of action that enables the activation 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 novel cancer target: survivin. IMV is currently assessing DPX-Survivac in advanced ovarian cancer, as well as a combination therapy in multiple clinical studies with Merck. IMV is also developing a DPX-based vaccine to fight against COVID-19. 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 for share and per share amounts)

	Three-months ended		Nine-months ended	
	September 30		September 30	
	2020	2019	2020	2019
	\$	\$	\$	\$
<b>Income</b>				
Subcontract revenue	3	13	3	26
Interest Income	85	151	209	405
Total income	88	164	212	431
<b>Expenses</b>				
Research and development	6,541	5,652	18,628	13,467
General and administrative	3,699	2,635	9,778	6,778
Government assistance	(1,684)	(606)	(3,649)	(2,093)
Accreted interest and valuation adjustments	(141)	379	714	1,169
Total operating expenses	8,415	8,060	25,471	19,321
<b>Net loss and comprehensive loss</b>	(8,327)	(7,896)	(25,259)	(18,890)
<b>Basic and diluted loss per share</b>	(0.13)	(0.16)	(0.44)	(0.38)
Weighted-average shares outstanding	65,970,269	50,615,488	58,025,986	49,324,232

IMV INC.

Unaudited Interim Condensed Consolidated Statements of Financial Position

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

	September 30,	December
	2020	31,
		2019
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 54,700	\$ 14,066
Accounts receivable	1,663	845
Prepaid expenses	7,191	3,032

Investment tax credits receivable	1,588	1,661
Total current assets	65,142	19,604
Property and equipment	2,833	2,830
Total assets	<u>\$ 67,975</u>	<u>\$ 22,434</u>

### **Liabilities and Equity**

#### Current liabilities

Accounts payable, accrued and other liabilities	\$ 8,236	\$ 6,157
Amounts due to directors	62	60
Current portion of long-term debt	843	88
Current portion of lease obligations	126	100
Total current liabilities	<u>9,267</u>	<u>6,405</u>
Lease obligation	1,234	1,208
Long-term debt	8,670	8,373
Total liabilities	<u>19,171</u>	<u>15,986</u>
Equity	48,804	6,448
Total liabilities and equity	<u>\$ 67,975</u>	<u>\$ 22,434</u>

View source version on businesswire.com:

<https://www.businesswire.com/news/home/2020112005180/en/>

### **Investor Relations**

#### **Marc Jasmin, Senior Director, Investor Relations, IMV**

O: (902) 492-1819, ext: 1042

M: (514) 617-9481

E: [mjasmin@imv-inc.com](mailto:mjasmin@imv-inc.com)

#### **Irina Koffler, Managing Director, LifeSci Advisors**

O: (646) 970-4681

M: (917) 734-7387

E: [ikoffler@lifesciadvisors.com](mailto:ikoffler@lifesciadvisors.com)

### **Media**

#### **Delphine Davan, Director of Communications, IMV**

M: (514) 968-1046

E: [ddavan@imv-inc.com](mailto:ddavan@imv-inc.com)

Source: IMV Inc.