

# VBI-2901: Pan-Coronavirus Vaccine Candidate Overview

NASDAQ: VBIV

MAY 2020

## **Forward-Looking Statements**

Certain statements in this presentation that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and are forward-looking information within the meaning of Canadian securities laws (collectively "forward-looking statements"). The company cautions that such statements involve risks and uncertainties that may materially affect the company's results of operations. Such forward-looking statements are based on the beliefs of management as well as assumptions made by and information currently available to management. Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors, including but not limited to the ability to establish that potential products are efficacious or safe in preclinical or clinical trials; the ability to establish or maintain collaborations on the development of therapeutic candidates; the ability to obtain appropriate or necessary governmental approvals to market potential products, including the approval of Sci-B-Vac<sup>®</sup> in the U.S., Europe, and Canada following the completion of its recent Phase 3 studies; the ability to obtain future funding for developmental products and working capital and to obtain such funding on commercially reasonable terms; the company's ability to manufacture product candidates on a commercial scale or in collaborations with third parties; changes in the size and nature of competitors; the ability to retain key executives and scientists; and the ability to secure and enforce legal rights related to the company's products, including patent protection. A discussion of these and other factors, including risks and uncertainties with respect to the company, is set forth in the Company's filings with the Securities and Exchange Commission and the Canadian securities authorities, including its Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 5, 2020, and filed with the Canadian security authorities at sedar.com on March 5, 2020, and may be supplemented or amended by the Company's Quarterly Reports on Form 10-Q. The company disclaims any intention or obligation to revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.



## **Overview of VBI Vaccines**

- Leveraging significant immunology expertise to address unmet medical needs in both INFECTIOUS DISEASE and IMMUNO-ONCOLOGY
- Advancing prevention and treatment of **HEPATITIS B**:
  - Sci-B-Vac<sup>®</sup> : Only tri-antigenic Hepatitis B vaccine; recently completed a Phase III program in the U.S., Europe, and Canada; approved and marketed in Israel
  - *VBI-2601* : Immuno-therapeutic in development in a collaboration with Brii Biosciences for a functional cure for chronic Hepatitis B
- Leveraging a proprietary enveloped virus-like particle (eVLP) platform technology to develop next-generation vaccines:
  - *VBI-1901* : **GLIOBLASTOMA** (GBM) vaccine immunotherapeutic candidate (currently in Phase I/IIa study)
  - *VBI-2901* : **PAN-CORONAVIRUS** (COVID-19, SARS, MERS) vaccine candidate in development in a collaboration with the National Research Council of Canada
  - *VBI-1501* : Prophylactic **CMV** vaccine candidate (positive topline Phase I data announced in May 2018)

## **VBI Vaccines Pipeline**

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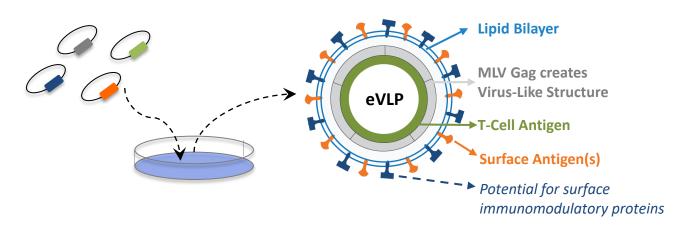
		PRE- CLINICAL	PHASE I	PHASE II	PHASE III	APPROVED	STATUS
INFECTIOUS DISEASE	_						
Hepatitis B —	Sci-B-Vac®						Approved for use and commercially-available in Israel
Prophylaxis	VLP						<ul> <li>Regulatory submissions in U.S., Europe, and Canada expected to begin Q4 2020</li> </ul>
Hepatitis B – Therapeutic	<b>VBI-2601</b> VLP						<ul> <li>License &amp; collaboration agreement with Brii Biosciences</li> <li>Initial Phase Ib/IIa data expected H2 2020</li> </ul>
Cytomegalovirus (CMV)	<b>VBI-1501</b> <i>eVLP</i>						<ul> <li>Positive Phase I data announced May 2018</li> </ul>
Pan-Coronavirus (COVID-19, SARS, MERS)	<b>VBI-2901</b> <i>eVLP</i>						<ul> <li>Development collaboration with NRC announced March 2020</li> </ul>
Zika	<b>VBI-2501</b> <i>eVLP</i>						<ul> <li>Candidate selected from NRC collaboration</li> </ul>
IMMUNO-ONCOLOGY							
Glioblastoma (GBM)	<b>VBI-1901</b> eVLP						<ul> <li>Ongoing Phase I/IIa</li> <li>Expanded immunologic data expected mid-year 2020 and Q4 2020</li> </ul>
Other CMV+ Tumors	<b>VBI-1901</b> <i>eVLP</i>						Preclinical work ongoing

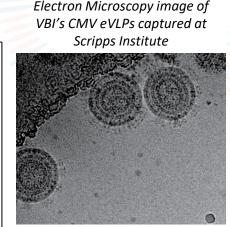
### Vaccine Platforms Targeting COVID-19

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Name	COVID-19	Live Virus or Vector		Recombinant Protein		Virus Like Particle	DNA	mRNA
Class	RNA Virus	Live or Live Attenuated		Subunit - simple		Subunit - complex	Nucleic Acid	Nucleic Acid
Key Structural Features	"Enveloped" with "Spike" Protein	Replicating virus, with COVID swapped in		Focuses on Spike protein		Virus-mimic including Spike protein	None, code injected & proteins produced internally	None, code injected & proteins produced internally
Pros	Similar to SARS & MERS	Looks like a virus to immune system		Cheap, scalable, safe		Safe, Looks like a virus to immune system, Spike adopts native	Cheap, fast to clinic, good T-cell responses	Cheap, fast to clinic
Cons	Highly infectious, virulent, mutating?	Those in use not structurally similar to COVID19		Less immunogenic, proteins adopt different shape		shape Timelines similar to Virus or Recombinant	Limited antibodies, No approved products since 1987	Limited data available, product is produced inside body (or not)
	The Enemy		-[	Approved Produ	cts		L – – No Approved	Products



## Advantages of the Enveloped Virus-Like Particle (eVLP) Technology Platform





**Highly Immunogenic:** Because of their structural similarity to viruses found in nature, vaccination with a target protein expressed in an eVLP is capable of imparting greater immunity than vaccination with the same recombinant target protein alone

**Customizable:** eVLPs are highly-customizable, which allows VBI to rationally design preventative or therapeutic vaccine candidates by controlling the expression of both surface and internal target proteins of interest

**Safe:** eVLPs do not contain any infectious genetic machinery and have proven to be safe and well tolerated in clinical studies, with no vaccine-related safety signals observed

Commercially Viable: eVLPs are manufactured and purified using highly-scalable methods

# Multiple eVLP Candidates have Clinical & Preclinical Proof-of-Concept

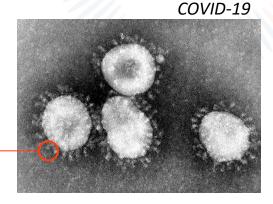
	Infectiou	s Disease	Immuno-Oncology			
	Prophylactic CMV (VBI-1501)	Prophylactic Zika (VBI-2501)	Therapeutic CMV+ Tumors (VBI-1901)	Immuno-Oncology (VBI-2701)		
Schematic						
Construct Design	<i>Monovalent:</i> Modified gB-G	<i>Bivalent:</i> Modified-E / NS1	<i>Bivalent:</i> gB / pp65 (major CD4, CD8 & Ab epitopes)	<i>Bivalent</i> with Immuno- modulatory protein		
Adjuvant	Alum	Alum	GM-CSF	Self Adjuvanted		
Most Advanced Development Stage	Ph I complete	Preclinical	Ph I/II ongoing	Preclinical		
Key Features	<ul> <li>Modified gB elicits fibroblast &amp; epithelial cell neutralization</li> <li>Qualitatively enhanced neutralizing response</li> </ul>	<ul> <li>Modified-E enhances neutralizing responses</li> <li>NS1 T cell response enhances antibody response &amp; protection</li> </ul>	<ul> <li>Internal antigen expression elicits T cell immunity</li> <li>Stimulates innate immunity</li> </ul>	<ul> <li>Immunomodulatory proteins can enhance antigen-specific Th1 immunity</li> </ul>		

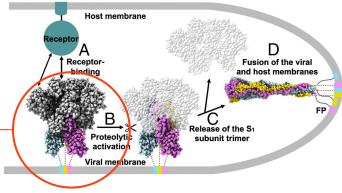


# eVLP Approach to a Pan-Coronavirus Vaccine

#### Coronaviruses are members of the "enveloped" class of viruses

- Morphology:
  - Enveloped RNA virus with a predominant S1/S2 spike
  - RNA viruses are prone to genetic drift/shift (though coronaviruses seem to be more stable than most)
- Key Target Antigen:
  - Based on knowledge of SARS and MERS, it is anticipated that the spike protein (S1/S2) is likely a neutralizing determinant and an ideal target for inclusion in a vaccine
  - The spike protein is trimeric eVLPs encourage trimerization and expression of native conformation of proteins

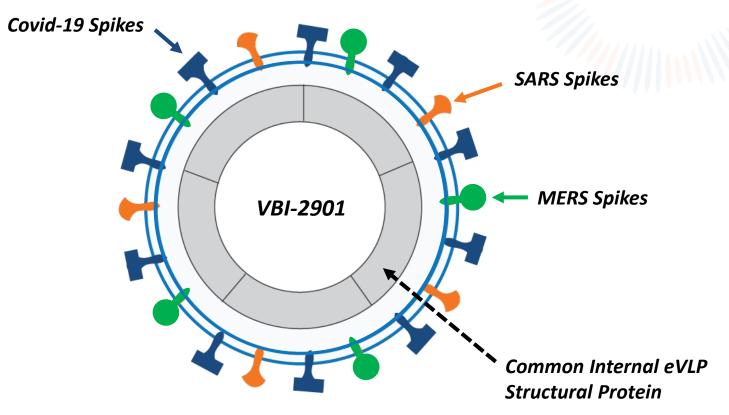




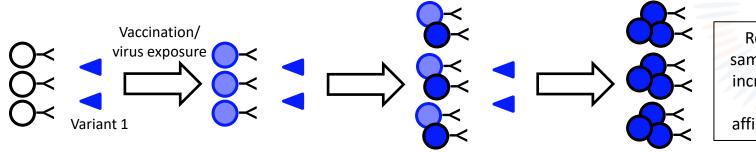
• Based on past experience with the eVLP platform, VBI expects that a multivalent eVLP vaccine candidate, coexpressing SARS-CoV-2, SARS-CoV, and MERS-CoV spike proteins on the same particle, will be possible

#### NASDAQ: VBIV

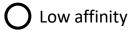
### eVLP Pan-Coronavirus Trivalent Construct



#### How trivalent eVLP vaccination may enrich for highly potent crossreactive immunity



Repeat exposure to the same viral variant gradually increases the 1) frequency, 2) specificity, and 3) affinity/potency over time.



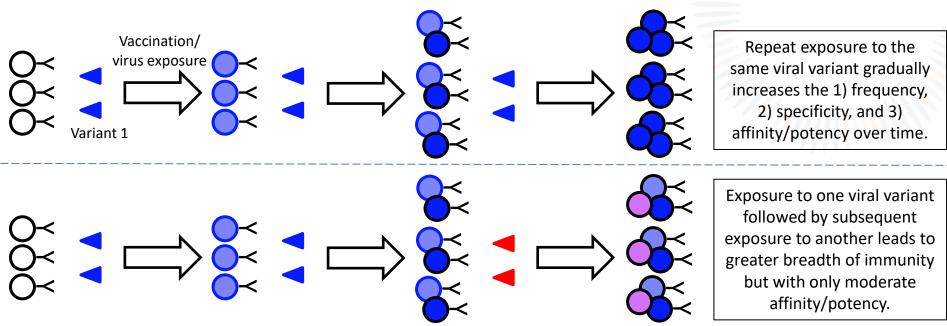
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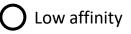


Intermediate affinity



#### How trivalent eVLP vaccination may enrich for highly potent crossreactive immunity

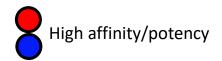




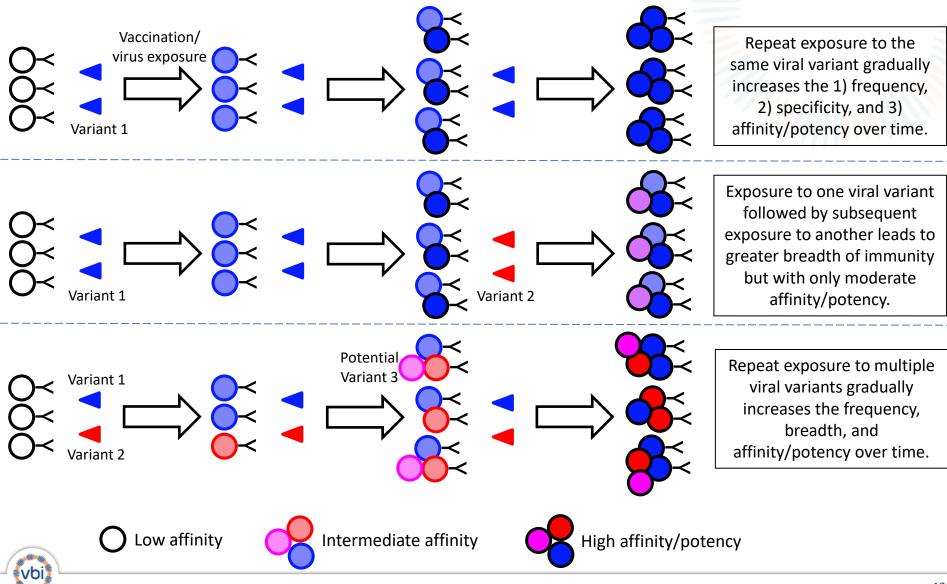
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Intermediate affinity



#### How trivalent eVLP vaccination may enrich for highly potent crossreactive immunity



## **VBI-2901 (Pan-Coronavirus) : Program Milestones**

- March 2020 : Announcement of collaboration with the National Research Council of Canada (NRC) to develop a pan-coronavirus vaccine candidate targeting COVID-19, severe acute respiratory syndrome (SARS), and Middle East respiratory syndrome (MERS)
  - Collaboration will combine VBI's viral vaccine expertise, eVLP technology platform, and coronavirus antigens with the NRC's uniquely-designed COVID-19 antigens and assay development capabilities
  - IND-enabling pre-clinical studies will be conducted at both the NRC core facilities and at VBI's research facility in Ottawa, Canada
- **Q4 2020** : Clinical study materials expected to be available for human clinical studies





## **Summary**





## Summary

#### ANTICIPATED CATALYSTS THROUGH 2020 YEAR-END:



Sci-B-Vac®: Hepatitis B Prophylactic Vaccine

- *Q2 2020* Pre-BLA discussions expected with FDA
- Beginning Q4 2020 Submissions of applications for regulatory approvals in the U.S., Europe, and Canada expected to begin



VBI-1901: GBM Vaccine Immunotherapeutic (Immuno-Oncology)

- Mid-year 2020 Expanded immunologic and tumor response data as well as potentially-predictive biomarker data expected from VBI-1901 + GM-CSF Phase IIa (Part B) study arm
- Q4 2020 Initial immunologic data expected from VBI-1901 + AS01<sub>B</sub> Phase IIa (Part B) study arm



VBI-2601: Hepatitis B Immunotherapeutic

H2 2020 – Initial human proof-of-concept Phase Ib/IIa data readout expected



VBI-2901: Pan-Coronavirus Prophylactic Vaccine

• Q4 2020 – Clinical study materials expected to be available

## **VBI Vaccines Leadership**

#### - MANAGEMENT -

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#### **BOARD OF DIRECTORS**



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## **VBI Vaccines Global Footprint**



#### HEADQUARTERS - CAMBRIDGE, MA

- 7 FTEs (Incl. CEO, CSO, CFO, CBO)
- Central location in biotechnology hub

#### **RESEARCH OPERATIONS - OTTAWA, CANADA**

- ~35 FTEs (Incl. CMO)
- R&D team and facility

#### MANUFACTURING FACILITY - REHOVOT, ISRAEL

- ~80 FTEs
- GMP manufacturing facility for the production of Sci-B-Vac<sup>®</sup>





#### **VBI Vaccines Inc.**

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