### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

### FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 28, 2016

### **APTEVO THERAPEUTICS INC.**

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-37746 (Commission File Number) 81-1567056 (IRS Employer Identification No.)

2401 4th Avenue, Suite 1050 Seattle, Washington (Address of Principal Executive Offices)

98121 (Zip Code)

Registrant's telephone number, including area code: (206) 838-0500

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

D Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 7.01 Regulation FD Disclosure

Aptevo Therapeutics Inc. ("Aptevo") has prepared investor presentation materials with information about Aptevo, which it intends to use as part of investor presentations. A copy of the investor presentation materials to be used by management for presentations is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K, including the attached Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

See Exhibit Index attached hereto.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 28, 2016

#### APTEVO THERAPEUTICS INC.

By: /s/ Shawnte Mitchell

Shawnte Mitchell, Secretary, Vice President and General Counsel

# Exhibit <u>Number</u> Exhibit Description

99.1 Presentation of Aptevo Therapeutics Inc. dated November 28, 2016





November 2016

# **Aptevo Therapeutics**

**Investor Presentation** 

## **Forward-Looking Statements**



This presentation includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including our financial guidance, product portfolio, product sales, capabilities and any other statements containing the words "believes", "expects", "anticipates", "intends", "plans", "forecasts", "estimates" and similar expressions in conjunction with, among other things, discussions of financial performance or financial condition, growth strategy, product sales, manufacturing capabilities, product development, regulatory approvals or expenditures are forward-looking statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this presentation, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause Aptevo's actual results to differ materially from those indicated by such forward-looking statements, including possible negative effects on Aptevo's business operations, assets or financial results as a result of the separation; a deterioration in the business or prospects of Aptevo; adverse developments in Aptevo's customer-base or markets; our ability to enter into and maintain selective collaboration and partnership arrangements; the timing of and our ability to achieve milestones in collaboration and partnership contracts; our ability and the ability of our contractors and suppliers to maintain compliance with cGMP and other regulatory obligations; the results of regulatory inspections; the rate and degree of market acceptance and clinical utility of our products; the success of our ongoing and planned development programs; the timing of and our ability to our ability to obtain and maintain regulatory approvals for our product candidates; and our commercialization, marketing and manufacturing capabilities and strategy and changes in regulatory, social and political conditions. Additional risks and factors that may affect results are set forth in Aptevo's filings with the Securities and Exchange Commission, including Aptevo's most recent Quarterly Report on Form 10-Q, as filed on November 14, 2016.

The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

Aptevo<sup>™</sup>, ADAPTIR<sup>™</sup> and any and all Aptevo Therapeutics Inc. brand, product, service, and feature names, logos, and slogans are trademarks or registered trademarks of Aptevo Therapeutics Inc. or its subsidiaries in the United States or other countries. All rights reserved.

AGENDA Leadership in Bispecific Antibody Development

- Aptevo today
- What sets us apart
- Summary



# Aptevo: At a Glance



Focus	Oncology/Hematology
Commercial Products	4
Product Pipeline	Clinical: 2 Preclinical: Multiple
Platform Technologies	ADAPTIR™
Employees	~130
Headquarters	Seattle, WA
2016 Revenue (9/30/16)	\$27.5M
2015 Revenue	\$33.6M

Cash

\$61M (9/30/16)
\$20M EBS future contribution
\$15M MidCap 2<sup>nd</sup> tranche option



#### Leading Oncology Platform

 Innovative ADAPTIR<sup>™</sup> platform technology utilizing a promising approach in the highly attractive immuno-oncology field

#### Leveraging Technology

- Targeted investments in bispecific ADAPTIR™ therapeutics
- Increased awareness of the RTCC Mechanism of Action

#### Strong IP Estate

- Will own or exclusively license patent rights for entire product portfolio
- Will seek exclusive licenses for supporting technologies

# **Executive Leadership**



#### Senior Management

Marvin White – President & CEO Former Emergent Director; Former CFO, St. Vincent's Health; Former Exec. Director & CFO, Lilly USA

Jeff Lamothe – SVP, CFO Former Emergent VP, Finance; Former CFO, Cangene Corporation

Randy Maddux – SVP, Operations Former VP, Global Mfg & Supply, GSK; Former VP, Mfg Ops & Quality, Human Genome Sciences

Dr. Scott Stromatt – SVP, CMO Former Emergent SVP, CMO; Former CMO, Trubion

**Dr. Jane Gross – SVP, CSO** Emergent VP, Research/Non-Clinical Development; Former VP Immunology Research ZymoGenetics Inc.

Mike Adelman – VP, Commercial Ops. Former Emergent VP, Commercial Operations; Former, VP Commercial Operations, Cangene Corporation

Shawnte Mitchell – VP, Gen'l Counsel/HR Former Emergent VP, Associate General Counsel

#### **Board of Directors**

Marvin White Former Emergent Director; Former CFO, St. Vincent's Health; Former Exec. Director & CFO, Lilly USA

Fuad El-Hibri Founder, Executive Chairman, Emergent BioSolutions

Daniel Abdun-Nabi President & CEO, Emergent BioSolutions

Grady Grant, III Mead Johnson Nutrition; Eli Lilly & Co.

Zsolt Harsanyi, Ph.D. N-Gene Research Labs; Exponential Biotherapies; Porton Int'l

Barbara Lopez Kunz DIA; Battelle; Thermo Fisher Scientific; ICI/Uniqema

John Niederhuber, M.D. Inova Translational Medicine Institute; NCI; Johns Hopkins Univ.

### Deep R&D, Commercial and Financial Expertise and Experience

# **Our Capabilities**



#### **Process Development**

- Generate CHO production cell lines
- Develop platform cell culture and purification processes, optimize as needed
- Produce material for toxicology studies
- · Develop & qualify analytical methods

#### **Protein Engineering**

- Generate new binding domains or take partner's mAbs and convert to ADAPTIR format
- Optimize for:
  - Screening to reduce potential for immunogenicity
  - Binding affinity
  - Activity
  - Expression
  - Manufacturability

#### **Clinical Research /Ops**

- Regulatory Affairs
- Medical Affairs
- Pharmacovigilence
- Biostatistics

#### **Preclinical Development**

- Evaluate new ADAPTIR bispecifics using standard *in vitro* assays to assess function
- Determine PK and *in vivo* activity in mouse models
- Assess NHP PK and tolerability with CRO

#### **Clinical Manufacturing**

- GMP process validation, scale-up and tech transfer; QA/QC
- · Supply chain management
- CMO oversight

### Expertise and Leadership in Bispecific Antibody Development Facilitates Rapid Drug Development from Concept to Clinic

# **Our Strategy**





Advance novel ADAPTIR<sup>™</sup> product candidates, primarily in I/O

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Expand collaborations and partnerships



Maximize cash flow from commercial portfolio to support R&D funding



AGENDA Leadership in Bispecific Antibody Development

- Aptevo today
- What sets us apart
- Summary



# **Robust and Diversified Product Portfolio**



Product/Candidate Technology Indica	Indication	Pre-	Clinical Development Stage					
	Indication	Clinical	Phase I	Phase II Phase III		Marketed	Milestones/Highlights	
IXINITY	Recombinant Protein	Hemophilia B						\$1.0M WW in 2015 \$7.0M (9/30/2016)
WinRho	Hyper Immune	ΙΤΡ		_	_			\$14.2M WW in 2015 \$10.6M (9/30/2016)
HepaGam B	Hyper Immune	HBV						\$10.3M WW in 2015 \$7.1M (9/30/2016)
VARIZIG	Hyper Immune	Varicella						\$2.3M WW in 2015 \$2.8M (9/30/2016)
Otlertuzumab	ADAPTIR Monospecific	CLL						Executing combination clinical trials
MOR209/ES414*	ADAPTIR Bispecific RTCC	mCRPC Immuno-oncology						Executing Phase 1 clinical trial
ROR1	ADAPTIR Bispecific RTCC	Hematological, Solid Tumor Malignancies						Preclinical in vitro and in vivo POC, developing lead candidate
Multiple ADAPTIR Candidates	ADAPTIR Bispecific	Hematological, Solid Tumor Malignancies						Multiple RTCC candidates and ADAPTIR with novel MOA
ES210	ADAPTIR Targeted cytokine	IBD						Preclinical POC in IBD, CHO production cell line
5E3 mAb	Monoclonal Antibody	Alzheimer's Disease						Pursuing partnerships

RTCC – Redirected T-Cell Cytotoxicity

\* Partnered with MorphoSys AG

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# **Commercial Products to Support R&D Funding**







[coagulation factor IX (recombinant)]

An intravenous recombinant human coagulation factor IX therapeutic for use in patients with Hemophilia B





US: [Rh\_ (D) Immune Globulin Intravenous (Human)] Canada: (Rh\_(D) Immune Globulin (Human) for injection)

Immune Thrombocytopenic Purpura (ITP) and suppression of Rhesus (Rh) isoimmunization



# HEPAGAM B

US: [Hepatitis B Immune Globulin Intravenous (Human)] Canada: (Hepatitis B Immune Globulin (Human) Injection)

Prevention of hepatitis B recurrence following liver transplantation in HBsAgpositive patients and post exposure prophylaxis after acute hepatitis B exposure



# VARIZIG

US: VARIZIG<sup>®</sup> [Varicella Zoster Immune Globulin (Human)] Canada: VariZIG<sup>®</sup> (Varicella Zoster Immune Globulin (Human))

Post-exposure prophylaxis of varicella zoster in high risk individuals

# **IXINITY Supply Interruption**



- On November 14, 2016 Aptevo reported that it anticipated experiencing a supply interruption of IXINITY as follows:
  - 1,500 IU dosage form beginning December 2016
  - All remaining dosage forms beginning January 2017
- The supply interruption relates to ongoing challenges associated with the manufacture of bulk drug substance for IXINITY
- Aptevo is continuing to work with its BDS supplier to resolve the IXINITY manufacturing issue
- IXINITY customers (patients, health care providers, specialty pharmacies, advocacy groups) have been notified of the temporary supply interruption
- Aptevo remains committed to supporting our patients and IXINITY as we address the manufacturing challenge



# **ADAPTIR™** – Proprietary Platform Technology



### MODULAR

- New bispecifics readily assembled with potent preclinical activity
- Ultimate flexibility; able to generate candidates with novel MOA
- Single chain format optimized for CHO cell production; avoids issues found with other bispecifics

### VERSATILE

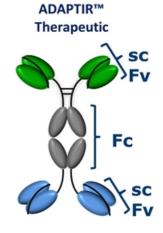
- Redirected T-Cell Cytotoxicity (RTCC)
- Targeted Cytokine Delivery
- Potential for additional MOAs

### ADAPTABLE

 Applicable to a variety of solid and hematologic cancers, i.e.: breast, lung, ovarian, prostate, kidney, melanoma, pancreatic

### SYNERGISTIC

 Potential for single, sequential, or combination immunotherapeutic approaches



Bispecific

## ADAPTIR™ RTCC Key Advantages vs Other Bispecifics

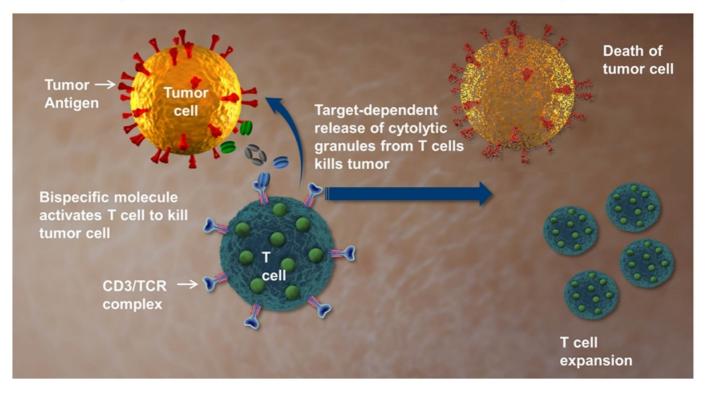


Highly potent	Induce target-dependent cytotoxicity at low concentrations in preclinical studies
Longer Half Life	Longer half-life in preclinical studies supports less frequent administration
Reduced Toxicity	Induce low levels of cytokine engagement of target cells in preclinical studies
Ease of Manufac- turing	Improved stability & physical characteristics GMP manufacturing up to 2000L scale
Improved Economics	mAB-like manufacturing advantages "Off the shelf" technology vs "cell-based" therapies

### ADAPTIR™ – RTCC Mechanism of Action



### ADAPTIR Bispecific Molecules Mediate RTCC: Potent Immunotherapeutic for Cancer



## ADAPTIR™ Clinical Pipeline



Product Taskaslary Indian	Indication	Resting Drs Official	Clinical Development Stage			Milestones	
Candidate	Technology	indication	Pre-Clinical	Phase I	Phase II	Phase III	Highlights
Otlertuzumab	ADAPTIR Monospecific	CLL					Executing combination clinical trials
MOR209/ES414*	ADAPTIR Bispecific RTCC	mCRPC Immuno- oncology					Executing Phase 1 clinical trial

RTCC – Redirected T-Cell Cytotoxicity

\* Partnered with MorphoSys AG



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### ADAPTIR™ Clinical Stage Candidate – otlertuzumab (CLL)





αCD37 scFv



### Description

- · Humanized monospecific protein therapeutic
- Targeting the CD37 signaling pathway involved in B-cell malignancies
- Built on ADAPTIR<sup>™</sup> (modular protein therapeutic) platform
- · Demonstrated anti-tumor activity
- · Prolonged serum half-life (mouse /NHP) vs antibody fragments

#### Partnering

- 100% owned by Aptevo
- Actively pursuing potential partnership opportunities

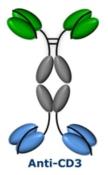
#### **Development Status**

- · Ongoing: Phase 2 Study for chronic lymphocytic leukemia (CLL)
- · Planning: Combination study
- Multiple clinical trial data published at ASH 2013, establishing clinical proof-of-concept
  - PHASE 2 STUDY (16201): Combination of otlertuzumab and bendamustine in patients with relapsed CLL produced higher response rates than bendamustine alone
  - PHASE 1b STUDY (16009): Combination of otlertuzumab and rituximab in patients with previously untreated CLL was active and well tolerated

## ADAPTIR™ Clinical Stage Candidate – MOR209/ES414 (mCRPC) Aptevo



Anti-PSMA



#### Description

- · Humanized bispecific protein therapeutic
- · Targeting PSMA and CD3, a component of the T-cell receptor
- Demonstrated redirection of T-cells to kill tumor cells expressing PSMA in vitro and in vivo
- · Prolonged serum half-life (mouse/NHP) vs antibody fragments

#### Partnering

Co-development/Co-commercialization partnership with MorphoSys AG
 established August 2014

#### **Development Status**

- · Open-label Phase 1 Study underway (U.S. & Australia)
- Safety, tolerability, and clinical activity in patients with metastatic castrationresistant prostate cancer (mCRPC) to be conducted in 2 stages
  - Stage 1: Primary Objective -- identify MTD administered intravenously. Secondary Objectives -- evaluate tolerability, PK, PD, immunogenicity, cytokine response, and clinical activity
  - Stage 2: Primary Objective -- evaluate clinical activity in patients that
     have or have not received prior chemotherapy

### ADAPTIR™ Novel Preclinical Product Pipeline



### Validated Platform Technology:

 Bispecific ADAPTIR molecules can redirect T-cell cytotoxicity against multiple tumor targets in preclinical models

### Modular Bispecific Platform:

 ADAPTIR platform can be used to generate bispecifics with novel MOA in immunooncology and other diseases

Molecule Target Antigen Type	Target	Target	Development Activity					
	Indication(s)	Design	<i>in vitro</i> RTCC	in vivo POC	Tox/IND	Clinical: Phase 1		
αROR1 x αCD3	Tyrosine Kinase (ROR1)	Hematologic malignancies; solid tumors						
RTCC Candidate	Undisclosed target	Hematological malignancies						
Multiple RTCC candidates	Undisclosed targets	Immuno- oncology						
ADAPTIR with Novel MOA	Undisclosed targets	Immuno- oncology						

### ADAPTIR™ RTCC Preclinical Candidate – ROR1



- Targets hematologic malignancies and solid tumors
  - Triple-negative breast cancer
  - Ovarian cancer
  - Non-small cell lung cancer
  - Prostate cancer
  - Kidney cancer
- Preclinical in vitro and in vivo proof of concept established
- Improved preclinical PK
- Developing lead candidate



- Aptevo today
- What sets us apart
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# **Financial Summary**



Spin Date: August 1, 2016					
Shares Outstanding	20.2M	9/30/2016			
Cash	\$61M \$20M* \$15M	9/30/2016 Future Emergent payment MidCap Financial - 2 <sup>nd</sup> tranche option			
2015 Revenue	\$34M \$28M \$6M	2015 Pro Forma Total Product Sales Contracts, Grants, Collaborations			
2016 Revenue	\$27.5M	9/30/2016 YTD Total Product Sales			
Estimated Cash Burn	\$50M-\$55M	2016 Pro Forma			

\*Includes \$20M cash from Emergent Biosolutions to be paid by August 1, 2017

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# Key Milestones – 18-24 Months



### Development

- Complete Phase 1 study of MOR209/ES414 and advance into Phase 2 development in partnership with MorphoSys
- Generate new ADAPTIR-based RTCC candidates
- Expand application of ADAPTIRbased candidates into new MOA
- Advance new preclinical ADAPTIRbased candidates into the clinic

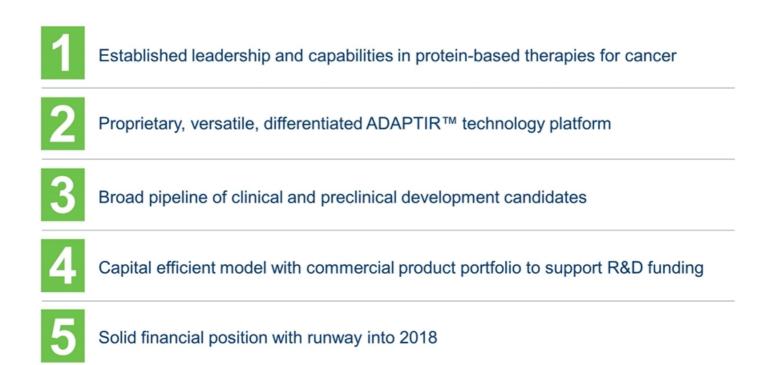
### **Operational/Financial**

- Capture incremental market share of Hemophilia B market with expanded sales of IXINITY
- Expand ex-US commercial market opportunities through new regulatory filings in select foreign jurisdictions
- Continue current and initiate future partnering discussions around product candidates

### Multiple Upcoming Valuation Catalysts

# Why Aptevo?





# Appendix

# **Intellectual Property Estate**



### APTEVO owns or exclusively licenses patent rights protecting

- IXINITY
- ADAPTIR
- otlertuzumab
- MOR209/ES414
- ES210
- ROR1
- 5E3mAb

### **APTEVO'S General Patent Filing and Prosecution Strategy**

- Will seek patent protection on all products and platforms
  - Exception existing hyperimmune products
- Will practice life cycle management
  - File new patent applications as products and related methods evolve
- Will seek broad geographic scope
- Will seek exclusive licenses as available for supporting technologies







#### IXINITY® [coagulation factor IX (recombinant)]

IXINITY<sup>®</sup> is an intravenous recombinant human coagulation factor IX therapeutic for the control and prevention of bleeding episodes and for perioperative management in adults and children,  $\geq$ 12 years of age, with Hemophilia B.

What is Hemophilia B? Hemophilia B is a bleeding disorder caused by a mutation on the factor IX gene resulting in a deficiency of clotting factor IX in the blood, which controls bleeding. The primary aim of care is to prevent and treat bleeding by replacement with the deficient clotting factor.

How does IXINITY work? IXINITY contains recombinant coagulation factor IX (trenonacog alfa) which replaces the deficient clotting factor.

IXINITY was approved by the FDA in April 2015 and launched into the market in June 2015.





# WINRHO

# US: [Rho (D) Immune Globulin Intravenous (Human)] Canada: (Rho (D) Immune Globulin (Human) for injection)

WinRho<sup>®</sup> SDF is a Rh<sub>o</sub>(D) Immune Globulin Intravenous (Human) product indicated for use in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage in the treatment of non-splenectomized, Rh<sub>o</sub>(D)-positive:

- · Children with chronic or acute Immune Thrombocytopenic Purpura (ITP)
- Adults with chronic ITP
- · Children and adults with ITP secondary to HIV infection

What is ITP? Immune Thrombocytopenic Purpura (ITP) is a type of autoimmune bleeding disorder. It occurs because of a reduction in cells (platelets) that normally cause blood to clot. Sometimes, ITP occurs after an infection, especially in children.

How does WinRho SDF work? WinRho is a sterile, liquid gamma globulin (lgG) fraction containing antibodies to the  $Rh_o(D)$  antigen (D antigen). WinRho has been shown to increase platelet counts through the formation of red blood cell complexes which spare antibody coated platelets from removal.

WinRho SDF has been used to treat ITP in the U.S. since 1995.





# HEPAGAM B

### US: [Hepatitis B Immune Globulin Intravenous (Human)] Canada: (Hepatitis B Immune Globulin (Human) Injection)

HepaGam B<sup>®</sup> is the only Hepatitis B Immune Globulin approved by the FDA for the prevention of hepatitis B recurrence following liver transplantation in HBsAg-positive patients. HepaGam B is also approved for post-exposure prophylaxis after acute exposure to the hepatitis B virus (HBV).

What is HBV? HBV causes the liver disease Hepatitis B. The virus interferes with liver functioning and causes pathological damage. A small percentage of infected people cannot get rid of the virus and become chronically infected – these people are at higher risk of death from cirrhosis of the liver and liver cancer.

How does HepaGam B work? HepaGam B is a sterile solution of purified gamma globulin (IgG) fraction of human plasma containing antibodies to hepatitis B surface antigen. HepaGam B provides passive immunization for individuals exposed to the hepatitis B virus, by binding to the surface antigen of the virus and reducing the rate of hepatitis B infection.

HEPAGAM B is the ONLY hepatitis B immune globulin (HBIg) approved by the FDA to both prevent hepatitis B virus (HBV) recurrence following liver transplantation in HBsAg-positive patients and provide post-exposure prophylaxis





# VARIZIG®

#### US: VARIZIG® [Varicella Zoster Immune Globulin (Human)] Canada: VariZIG® (Varicella Zoster Immune Globulin (Human))

VARIZIG<sup>®</sup> is intended for use as post-exposure prophylaxis to reduce the severity of chickenpox infections in high risk patient groups (see respective U.S. and Canadian prescribing information for details).

What is Varicella? Varicella-zoster virus (VZV) causes an illness commonly known as chickenpox. This easily spread disease can be a serious health issue for high risk patient groups. Chickenpox causes a blister-like rash, itching, tiredness, and fever.

How does VARIZIG work? VARIZIG is a sterile lyophilized preparation of purified human immune globulin G (IgG) containing antibodies to VZV that can reduce the severity of varicella infections.

VARIZIG was approved by the FDA in 2012 and is the <u>only approved post exposure</u> treatment for VZV.



November 2016

# **Aptevo Therapeutics**

# **Investor Presentation**