### **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 2, 2017

### 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)
heck 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 al 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)
Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
r check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of ies Exchange Act of 1934 (§240.12b-2 of this chapter).

I

Emerging growth company  $\boxtimes$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ⊠

### 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

### **Exhibit No. Description**

99.1 <u>Presentation of Aptevo Therapeutics Inc. dated November 2017 (filed herewith).</u>

### 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.

APTEVO THERAPEUTICS INC.

Date: November 2, 2017

By: /s/ Shawnte Mitchell

Shawnte Mitchell, Secretary, Vice President and General Counsel



January 2017

## **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 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 our 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.

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## Leadership in Bispecific Antibody Development



- Aptevo Today
- ADAPTIR Differentiated Bispecific Platform
- Summary



## Aptevo: At a Glance



Focus	Oncology/Hematology				
Commercial Products	4				
Product Pipeline	Clinical: 2 Preclinical: Multiple				
Platform Technologies	ADAPTIR™				
Employees	~150				
Headquarters	Seattle, WA				
2016 Revenue (9/30/16)	\$27.5M				
2015 Revenue	\$33.6M				
Cash Position	\$54M 12/31/2016 (approx.) \$20M Emergent payment (1/5/17) \$15M MidCap 2 <sup>nd</sup> tranche option				



### Leading Oncology Platform

 Innovative ADAPTIR platform technology utilizing a promising approach in the highly attractive immuno-oncology field

### Leveraging Technology

 Targeted investments in bispecific ADAPTIR therapeutics

### Strong IP Estate

 Intend to own or exclusively license patent rights for entire product portfolio

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### **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 Strategy**



- Advance novel ADAPTIR product candidates, primarily in immuno-oncology
- 2 Expand collaborations and partnerships
- Maximize cash flow from commercial portfolio to support R&D funding



### **Robust and Diversified Product Portfolio**





RTCC - Redirected T-Cell Cytotoxicity

\* Partnered with MorphoSys AG

## Commercial Portfolio - Hyperimmune Platform





### WINRHO'SDE

US: [Rh<sub>o</sub> (D) Immune Globulin Intravenous (Human)] Canada: (Rh<sub>o</sub>(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

- Mature, well established products
- · Serve niche or ultra niche markets
- Provide stable, dependable revenue base
  - Mitigate cash burn
  - Support R&D spend
  - \$25-30M annually (approx.)
  - \$10M annual cash flow (approx.)
- Modest opportunity for ex-US growth



### VARIZIG\*

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

Post-exposure prophylaxis of varicella zoster in high risk individuals

## Commercial Portfolio - Recombinant Platform





- Strong growth opportunity
- · WW rights owned by Aptevo
- U.S. launch mid-2015
- Target market:
  - Hemophilia B
  - Young, active adults (individuals 12+ years)
- Good acceptance in the market
- Opportunity to explore ex-US launch with partner
- Bulk drug substance manufacturing challenge resolved
- Anticipate Q1 2017 stock out followed by market re-entry in Q2 2017

## Leadership in Bispecific Antibody Development



- Aptevo Today
- ADAPTIR Differentiated Bispecific Platform
- Summary



## ADAPTIR – A Differentiated Bispecific Antibody Platform Technology



### MODULAR AND FLEXIBLE

- Monospecific and bispecific formats
- Flexible design supports reproducible generation of bispecifics with potent activity

## MULTIPLE MECHANISMS OF ACTION

- Redirected T-Cell Cytotoxicity (RTCC)
- Target receptors that stimulate or inhibit immunes responses
- Target cytokines to modify the immune environment

### **EXCELLENT MANUFACTURING PROPERTIES**

- Single chain facilitates ease of CHO cell production
- Antibody backbone increases stability
- Standard manufacturing process with high yields and purity

### ANTIBODY-LIKE HALF LIFE

Half-life up to 12 days

## Expertise in Bispecific Antibodies Facilitates Rapid Development from Concept to Clinic



### **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

### 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 Research /Ops

- · Regulatory Affairs
- Medical Affairs
- Pharmacovigilence

### **Clinical Manufacturing**

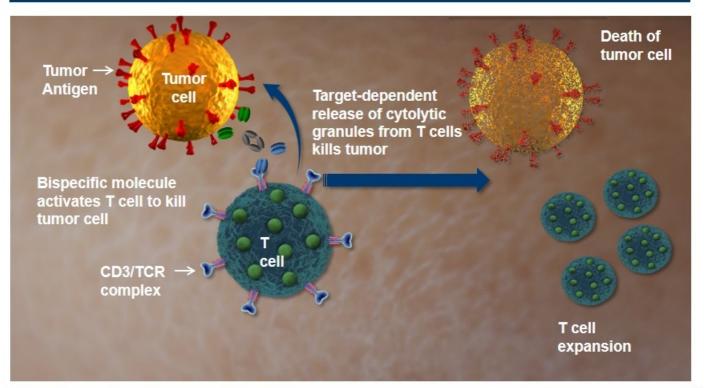
- GMP process validation, scale-up and tech transfer; QA/QC
- · Supply chain management
- · CMO oversight



## **ADAPTIR RTCC Mechanism of Action**



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



# ADAPTIR RTCC Therapeutics Key Advantages vs Other RTCC Bispecifics



Highly potent

Potent target-dependent cytotoxicity in preclinical studies demonstrated for numerous tumor antigens

Longer Half Life

Antibody-like half-life obtained in preclinical studies; up to 12 days

Reduced Toxicity Low levels of cytokines produced after engagement of target cells shown in preclinical studies

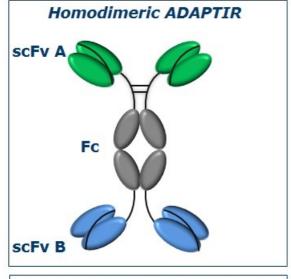
Improved Convenience

"Off the shelf" technology vs "cell-based" therapies Better COGS, ability to control dose

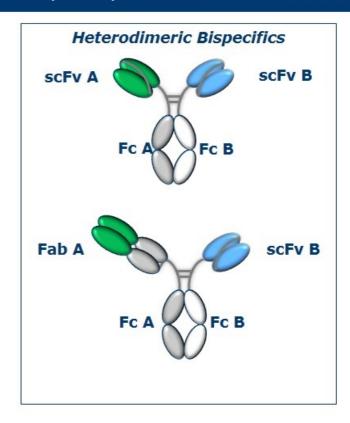
# ADAPTIR RTCC Bispecifics are Differentiated From Other Bispecific Formats



ADAPTIR™ RTCC molecules are more potent in preclinical studies compared to other bispecific platforms







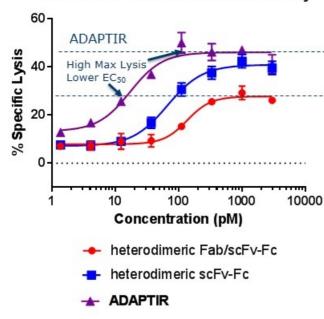
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## ADAPTIR RTCC - More Potent than Bispecifics in Heterodimer Format Targeting the Same Antigen



Redirected T-cell Tumor Lysis assay using unstimulated T cells (20 hr Cr-51 Release Assay)

### 20 hr Chromium-51 Release Assay



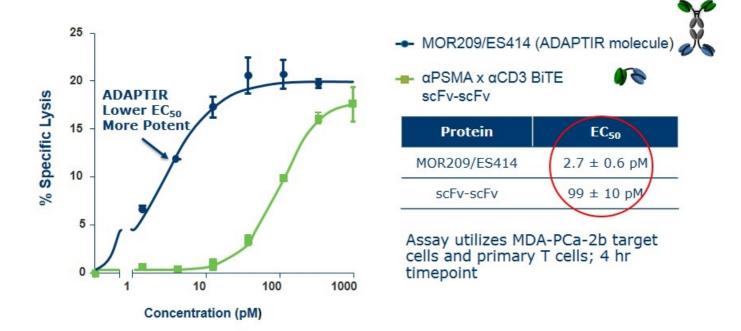
### ADAPTIR Bispecifics Are More Potent Compared to Heterodimeric Antibody Formats

- Higher levels of maximal specific lysis of tumor cells
- Lower EC<sub>50</sub> values

Protein	EC <sub>50</sub>
ADAPTIR	17.2 pM
het scFv-Fc	66.8 pM
Het Fab/scFv-Fc	136 pM

# MOR209/ES414 - More Potent Than BiTE® (scFv-scFv Format)<sup>1</sup>





1. Same amino acid sequence as AMG212/BAY2010112/pasotuxizumab (WHO Drug Information, Vol. 28, No. 2, 2014, pg 251-252)

## **ADAPTIR Clinical Pipeline**



Product	Technology Ind	Indication	Pre-Clinical	Clinical Development Stage			Milestones
Candidate		Indication	rie-Gillicai	Phase I	Phase II	Phase III	Highlights
Otlertuzumab	ADAPTIR Monospecific	CLL				*	Executing Phase 1b combination study
MOR209/ES414*	ADAPTIR Bispecific RTCC	mCRPC Immuno- oncology					Executing Phase 1 clinical trial

RTCC - Redirected T-Cell Cytotoxicity

<sup>\*</sup> Partnered with MorphoSys AG



## Clinical Candidate – otlertuzumab (CLL)





αCD37 scFv



Human IgG₁ Fc

### Description

- · Humanized monospecific protein therapeutic
- Targets CD37 and its signaling pathway involved in B-cell malignancies
- Built on ADAPTIR (modular protein therapeutic) platform
- Demonstrated anti-tumor activity
- · Prolonged serum half-life (mouse /NHP) vs antibody fragments

### **Partnering**

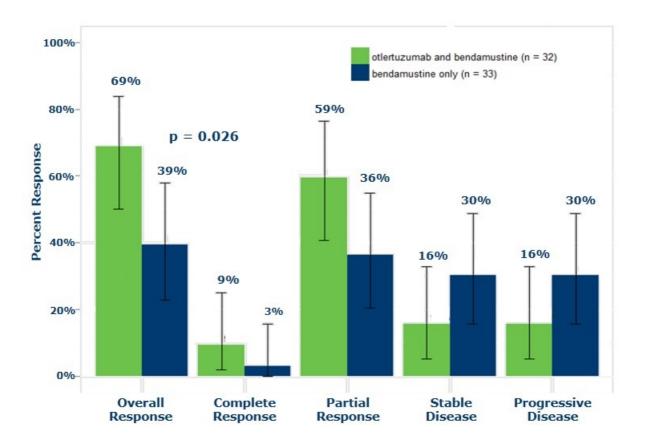
- 100% owned by Aptevo
- · Actively pursuing potential partnership opportunities

### **Development Status**

- · 253 subjects treated to date; appears safe and well tolerated
- Ongoing: Phase 2 study for chronic lymphocytic leukemia (CLL)
  - · Combination with ibrutinib
  - Preliminary data read-out anticipated in H2 2017
- · Multiple clinical trial data published, establishing clinical proof-of-concept
  - PHASE 2 STUDY (16201): Combination of otlertuzumab and bendamustine in patients with relapsed CLL produced significantly higher response rates and longer progression free survival than bendamustine alone
  - PHASE 1b STUDY (16009): Combination of otlertuzumab and rituximab in patients with previously untreated CLL was active and well tolerated 19

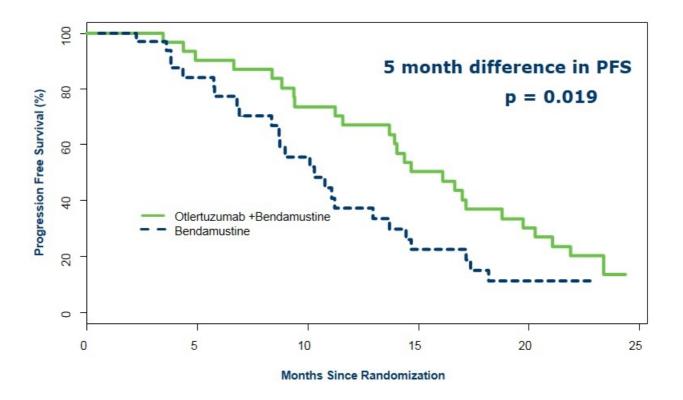
# Otlertuzumab + Bendamustine Significantly Increased Overall Response Rate





# Otlertuzumab + Bendamustine Significantly Increased Progression Free Survival



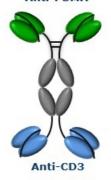


## Clinical Candidate - MOR209/ES414 (mCRPC)





Anti-PSMA



### Description

- · Humanized bispecific protein therapeutic
- · Targets 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**

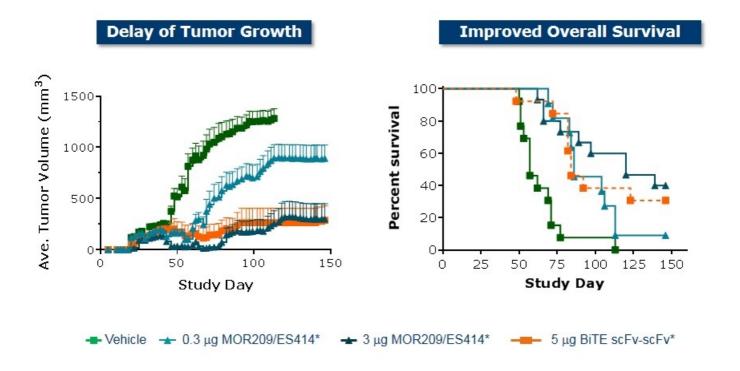
 Co-development/Co-commercialization partnership with MorphoSys AG established August 2014

### **Development Status**

- · Open-label Phase 1 continuous infusion study underway (U.S. & Australia)
- · Safety, tolerability, and clinical activity endpoints
- In patients with metastatic castration-resistant 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
- Preliminary data read-out anticipated mid-2017

# MOR209/ES414 Delays Tumor Growth and Improves Survival (Subcutaneous Xenograft Model)





\*P<0.01; †P<0.001 MOR209/ES414 was dosed on days 0, 4, 8; scFv-scFv molecule dosed daily on days 0-9

## **ADAPTIR - Novel Preclinical 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

	Target Antigen Type	Target Indication(s)	Development Activity					
Molecule			Design	in vitro 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
  - CLL and MCL and subset of ALL (with t-1418 translocation)
- Ability to establish rapid clinical POC in heme-onc. Disease and simultaneously test in solid tumors
- Preclinical in vitro and in vivo proof of concept established
- Improved preclinical PK
- Developing lead candidate

## Leadership in Bispecific Antibody Development



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Spin Date: August 1, 2016						
Shares Outstanding	20.2M	9/30/2016				
Cash Position	\$54M (approx.) \$20M	12/31/2016 Emergent Payment – 1/5/2017				
	\$15M	MidCap Financial - 2 <sup>nd</sup> tranche option				
2015 Revenue	\$34M \$28M \$6M	2015 Pro Forma  Total Product Sales Contracts, Grants, Collaborations				
2016 Revenue	\$27M	9/30/2016 YTD Total Product Sales				
2017 Cash Burn	\$53M - \$58M	Estimated cash burn				

### **Key Milestones – 18-24 Months**



### **Development**

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

### Operational/Financial

- Capture increased market share of Hemophilia B market with expanded U.S. 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?



- Established leadership and capabilities in protein-based therapies for cancer
- Proprietary, versatile, differentiated ADAPTIR technology platform
- Broad pipeline of clinical and preclinical development candidates
- Capital efficient model with commercial product portfolio to support R&D funding
- Solid financial position with runway into 2018



January 2017

## **Aptevo Therapeutics**

**Investor Presentation**