

**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): August 9, 2019

**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)
- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	APVO	The Nasdaq Stock Market LLC

Indicate by 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 the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

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.

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**Item. 2.02 Results of Operations and Financial Condition.**

On August 9, 2019, Aptevo Therapeutics Inc. (the “**Company**”) issued a press release announcing its financial results for the period ended June 30, 2019. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this report, including the exhibit hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission (the “**SEC**”) made by the Company, whether made before, on or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release dated August 9, 2019.</a>

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**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: August 9, 2019

By: /s/ Marvin L. White  
Marvin L. White  
President and Chief Executive Officer



**For Immediate Release**

**APTEVO THERAPEUTICS REPORTS SECOND QUARTER 2019 FINANCIAL RESULTS**

*Reports Positive Preliminary Top-Line Safety Data for APVO210  
Phase 1 Single Ascending Dose (SAD) Clinical Study*

*Advances APVO210 into Phase 1 Multiple Ascending Dose (MAD) Study*

*Commences Dosing in Cohort 4 of APVO436 Phase 1 AML/MDS Clinical Trial*

*Achieves 32% Increase in First Half 2019 Year-Over-Year IXINITY® Net Revenue;  
Launches New 3,000 IU IXINITY Assay for Enhanced IXINITY User Experience & Convenience*

*Receives \$4.3 Million Milestone Payment from Saol Therapeutics;  
Reconfirms \$36-\$40 Million 2019 Cash Burn Guidance*

**SEATTLE, WA – August 9, 2019** -- Aptevo Therapeutics Inc. (Nasdaq: APVO), a biotechnology company focused on developing novel oncology, autoimmune and hematology therapeutics, today provided a business review and reported its financial results for the second quarter ended June 30, 2019.

“We expect 2019 will be an important year for Aptevo from a clinical safety data perspective,” said Marvin L. White, President and Chief Executive Officer. “With both our APVO210 and APVO436 programs making important progress in the clinic this year, we anticipate robust news flow over the next several quarters. Preliminary clinical trial updates began from both programs in July 2019 and will continue over the next several quarters.”

“We recently announced the first segment of clinical data from our APVO210 program, which is a potential first-in-class autoimmune-focused bispecific antibody. Dosing was completed in 64 healthy volunteers in a single ascending dose Phase 1 study of APVO210. Preliminary data showed that APVO210 appears to be safe and well-tolerated at single intravenous doses up to 320 mcg/kg – well above doses which have generated clinical effects with previous competitor IL-10 investigational therapeutics. No adverse events of concern or dose-limiting toxicities were noted, and most importantly, no evidence of anti-drug antibodies (ADA) was observed, based on patient samples to date. We are excited to begin the second phase of the study, evaluating multiple ascending doses of APVO210. We anticipate results from this study will read out in the first quarter of 2020 and we will also provide an update on clinical results to date at the end of the year.”

“Our second bispecific candidate in clinical development, APVO436, is currently being evaluated in a Phase 1/1b study in patients with Acute Myeloid Leukemia (AML) and High-Grade Myelodysplastic Syndrome (MDS). This study continues to progress on schedule with dosing in Cohort 4 now underway. There are currently seven U.S. clinical sites actively enrolling patients. Importantly, we are reaching a critical point in the study whereby we believe, based on our analysis of competitors’ clinical data and our preclinical *in vitro* and *in vivo* data for APVO436, that we will be achieving predicted dose levels needed to see potential clinical activity of APVO436. We look forward to reporting preliminary top line data from this study later this year, and to providing updates as additional data becomes available.”

“Finally, we are also pleased with our commercial endeavors, as revenue for IXINITY increased 32% in the first half of 2019 compared to the same period in 2018. We anticipate that new growth initiatives being implemented this year will continue to drive future conversions to IXINITY. The first of these initiatives, a new 3,000 IU assay for IXINITY, was launched in the U.S market at the end of the second quarter. This diversity in our assay offerings is highly desirable for patients and our channel partners as it provides enhanced convenience and functionality. We’ve already had our first new patient convert to IXINITY therapy due to availability of the larger assay. Later this year, we will also commence a pediatric label expansion study of IXINITY. In summary, I am extremely excited about the progress we are making on several fronts to unlock value for Aptevo and our shareholders and look forward to reporting on our continued progress throughout the year,” said Mr. White.

Jeff Lamothe, Chief Financial Officer for Aptevo, continued, “We are also pleased to reaffirm our 2019 cash burn guidance of \$36–40 million. The first half of the year included planned significant expenditure related to a multi-batch IXINITY manufacturing campaign and clinical trial initiation costs, including preparatory work for the upcoming IXINITY pediatric trial. The second half of the year will see our burn rate moderate significantly.”

### **Second Quarter 2019 Highlights**

- Achieved 32% increase in year-over-year IXINITY net revenue in the first half of 2019 through continued expansion of the patient base for IXINITY
- Launched a new, more desirable 3,000 IU assay for IXINITY providing advantages for Hemophilia B patients and our channel partners
- Completed dosing in a Phase 1 clinical trial of APVO210 designed to evaluate single ascending doses (SAD) in healthy volunteers
- Announced preliminary top-line safety data from the APVO210 SAD study showing that APVO210 did not cause any adverse events of concern or dose-limiting toxicities in doses up to 320 mcg/kg; no evidence of anti-drug antibodies (ADA) were observed based on patient samples obtained to date; anticipate reporting more comprehensive data from the SAD study in Q4 2019
- Commenced a multiple ascending dose (MAD) Phase 1 clinical study of APVO210 evaluating repeat administrations of APVO210 (5 doses over 29 days at 4 different dose levels) administered by intravenous injection; anticipate preliminary data read-out from the MAD study in Q1 2020

- Continued enrollment in a dose escalation Phase 1/1b open-label clinical study of APVO436 in patients with Acute Myeloid Leukemia (AML) and High-Grade Myelodysplastic Syndrome (MDS); dosing in Cohort 4 currently underway; anticipate reporting preliminary Phase 1 safety data in the fourth quarter of 2019
- Presented new preclinical data for APVO436 and ALG.APV-527 at the American Association for Cancer Research (AACR) 2019 annual meeting; demonstrated in preclinical studies the ability of APVO436 to promote T cell differentiation into effector cells; showed that ALG.APV-527 was well-tolerated in a dose-range finding pilot toxicology study
- Continued preparations to file a Clinical Trial Authorization (CTA) in Q4 2019 for ALG.APV-527, Aptevo's 4-1BB x 5T4 bispecific antibody candidate partnered with Alligator Bioscience

## Second Quarter 2019 Financial Results

**Cash Position:** Aptevo had cash, cash equivalents, and marketable securities as of June 30, 2019 totaling \$28.5 million, including \$7.5 million in restricted cash.

**IXINITY Revenue:** Product sales of IXINITY increased by \$0.5 million, or 8%, to \$7.4 million for the three months ended June 30, 2019, compared to \$6.8 million for the same period in 2018. The increase in IXINITY sales in the quarter was primarily related to the continuing expansion of the Hemophilia B patient base for IXINITY and a price increase which went into effect on January 1, 2019.

**Cost of Product Sales:** Cost of product sales for the three months ended June 30, 2019 increased by \$3.5 million, or 136% to \$6.0 million compared to \$2.5 million for the three months ended June 30, 2018. The increase in cost of product sales is primarily due to a volume-driven increase in IUs sold in the second quarter of 2019. In addition, included in the cost of sales for the second quarter of 2019 is approximately \$0.9 million in costs related to testing and stability work associated with the initial commercial production of the new 3,000 IU assay, launched at the end of June 2019, and \$0.5 million related to certain inventory write-offs.

**Research and Development Expenses:** Research and development expenses decreased by \$2.0 million, to \$7.7 million for the three months ended June 30, 2019, compared to \$9.7 million for the corresponding period in 2018. The decrease was primarily attributable to a decrease in expenses related to the APVO436 and APVO210 clinical programs, primarily due to the timing of certain manufacturing and clinical trial activities, offset by an increase in expenses related to Aptevo's preclinical programs and general research and development efforts, and an increase in R&D expense for IXINITY related to start-up costs associated with the pediatric clinical study expected to commence in 2019.

**Selling, General and Administrative Expenses:** Selling, general and administrative expenses decreased by \$0.5 million, or approximately 7%, to \$6.5 million for the three months ended June 30, 2019, compared to \$7.0 million for the same period in 2018. The decrease in SG&A expenses in the second quarter of 2019 was primarily due to reduced personnel and professional services costs.

**Net Loss:** Aptevo's net loss for the three months ended June 30, 2019 was (\$13.3) million or (\$0.30) per share, compared to (\$13.1) million or (\$0.58) per share for the three months ended June 30, 2018.

Financial Statements Follow

**Aptevo Therapeutics Inc.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share and per share amounts, unaudited)

<b>ASSETS</b>	<b>June 30, 2019</b>	<b>December 31, 2018</b>
<b>Current assets:</b>		
Cash and cash equivalents	\$ 20,957	\$ 30,635
Accounts receivable	7,378	5,220
Inventories	6,967	1,785
Prepaid expenses	5,200	6,907
Other current assets	3,170	4,142
Total current assets	43,672	48,689
Restricted cash	7,498	7,448
Property and equipment, net	4,610	5,202
Intangible assets, net	4,835	5,250
Operating lease right-of-use asset	4,264	—
Other assets	1,248	905
Total assets	<u>\$ 66,127</u>	<u>\$ 67,494</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 11,904	\$ 11,671
Accrued compensation	2,535	3,898
Sales rebates and discounts payable	894	1,245
Other short-term liabilities	1,265	796
Total current liabilities	16,598	17,610
Long-term debt, net	19,558	19,278
Operating lease liability, net of current portion	3,759	—
Other liabilities	13	200
Total liabilities	<u>39,928</u>	<u>37,088</u>
<b>Stockholders' equity:</b>		
Preferred stock: \$0.001 par value; 15,000,000 shares authorized, zero shares issued or outstanding	—	—
Common stock: \$0.001 par value; 500,000,000 shares authorized; 45,098,823 and 22,808,416 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	45	23
Additional paid-in capital	178,912	157,791
Accumulated deficit	(152,758)	(127,408)
Total stockholders' equity	<u>26,199</u>	<u>30,406</u>
Total liabilities and stockholders' equity	<u>\$ 66,127</u>	<u>\$ 67,494</u>



**Aptevo Therapeutics Inc.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share amounts, unaudited)

	<u>For the Three Months Ended June 30,</u>		<u>For the Six Months Ended June 30,</u>	
	2019	2018	2019	2018
Revenues:				
Product sales	\$ 7,360	\$ 6,826	\$ 14,382	\$ 10,897
Costs and expenses:				
Cost of product sales	5,985	2,534	9,832	4,315
Research and development	7,733	9,713	15,018	17,912
Selling, general and administrative	6,538	7,023	13,868	14,616
Loss from operations	<u>(12,896)</u>	<u>(12,444)</u>	<u>(24,336)</u>	<u>(25,946)</u>
Other expense, net	(436)	(700)	(1,014)	(1,053)
Net loss	<u>\$ (13,332)</u>	<u>\$ (13,144)</u>	<u>\$ (25,350)</u>	<u>\$ (26,999)</u>
Basic and diluted net loss per basic share	<u>\$ (0.30)</u>	<u>\$ (0.58)</u>	<u>\$ (0.70)</u>	<u>\$ (1.21)</u>
Weighted-average shares used to compute per share calculations	<u>45,095,041</u>	<u>22,588,334</u>	<u>36,379,731</u>	<u>22,308,356</u>

### About Aptevo Therapeutics Inc.

Aptevo Therapeutics Inc. is a clinical-stage biotechnology company focused on developing novel oncology, autoimmune and hematology therapeutics to meaningfully improve patients' lives. Aptevo has a commercial product, IXINITY® coagulation factor IX (recombinant), approved and marketed in the United States for the treatment of Hemophilia B, and a versatile core technology – the ADAPTIR™ modular protein technology platform capable of generating highly-differentiated bispecific antibodies with unique mechanisms of action to treat cancer and autoimmune diseases. Aptevo has a broad pipeline of novel investigational-stage bispecific antibody candidates focused in immuno-oncology and autoimmune disease and inflammation. For more information, please visit [www.aptevotherapeutics.com](http://www.aptevotherapeutics.com)

### Safe Harbor Statement

This press release 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, without limitation, statements regarding potential milestone payments, Aptevo's outlook, financial performance or financial condition, Aptevo's technology and related pipeline, collaboration and partnership opportunities, commercial portfolio, milestones, and any other statements containing the words "believes," "expects," "anticipates," "intends," "plans," "forecasts," "estimates," "will" and similar expressions are forward-looking statements. These forward-looking statements are based on Aptevo's current intentions, beliefs and expectations regarding future events. Aptevo 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 Aptevo's 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 press release, and, except as required by law, Aptevo does 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 a deterioration in Aptevo's business or prospects; adverse developments in research and development; adverse developments in the U.S. or global capital markets, credit markets or economies generally; 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 its most recent Annual Report on Form 10-K, as filed on March 18, 2019 and its subsequent reports on Form 10-Q and current reports on Form 8-K. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Aptevo's expectations in any forward-looking statement.

**Source:**

Aptevo Therapeutics

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