

**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 14, 2018

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))

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.

Item. 2.02 Results of Operations and Financial Condition.

On November 14, 2018, Aptevo Therapeutics Inc. (the “*Company*”) issued a press release announcing its financial results for the period ended September 30, 2018. 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 Exchange 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

Exhibit Number	Description
99.1	Press Release dated November 14, 2018

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 14, 2018

By: /s/ Shawnte Mitchell
Shawnte Mitchell, Secretary, Senior Vice
President and General Counsel



For Immediate Release

**APTEVO THERAPEUTICS REPORTS
THIRD QUARTER 2018 FINANCIAL RESULTS**

Achieves 132% Increase in IXINITY® Quarterly Net Revenue Year-Over-Year

*More than Doubles Year-to-Date IXINITY Net Revenue
from \$8.1 Million to \$16.7 Million*

*Advances Bispecifics APVO436 and APVO210;
On Track to Commence Patient Dosing Q4 2018 and Q1 2019*

*Discontinues Clinical Development of APVO414 and Otlertuzumab;
Sharpens Focus on Next-Generation ADAPTIR Pipeline*

SEATTLE, WA – November 14, 2018 -- Aptevo Therapeutics Inc. (Nasdaq: APVO), a biotechnology company focused on developing novel oncology and hematology therapeutics, today provided a business review and reported its financial results for the third quarter ended September 30, 2018.

“Our IXINITY sales performance continues to excel as we focus on ramping up efforts to onboard new patients on IXINITY therapy,” said Marvin L. White, President and Chief Executive Officer. “In each of the past three quarters Aptevo achieved year-over-year growth in net revenue for IXINITY demonstrating an increase of 93%, 94%, and 132%, respectively. Year-to-date we have more than doubled our IXINITY net revenue and believe there is still plenty of opportunity ahead.”

In addition to efforts to grow top-line IXINITY net revenue, Aptevo also continued to focus on improving the overall contribution of its IXINITY business, demonstrated by the successful implementation of a new third-party logistics and packaging solution, completed in the third quarter, which is expected to drive significant cost savings and improve operational efficiency.

With U.S. sales growing, Aptevo is implementing new initiatives to further expand the market opportunity for IXINITY in the U.S. and internationally, including: seeking a pediatric label expansion, introducing a more convenient 3000 IU assay for patients, and pursuing ex-US licensing and partnership opportunities.

During the third quarter Aptevo made very good progress advancing its next-generation ADAPTIR platform and is on track to shortly commence dosing of APVO436, its lead, next-generation CD3xCD123 bispecific antibody being evaluated in a Phase 1 clinical study for the treatment of

acute myeloid leukemia (AML) and high-grade myelodysplastic syndrome (MDS). The Phase 1/1b open-label clinical study will evaluate escalating doses of APVO436 to determine the safety profile, maximum tolerated dose, and clinical activity of APVO436 in AML and MDS patients.

“We are especially excited to explore the clinical potential of APVO436 as we have made a number of enhancements to our next-generation platform and during the year presented preclinical data at the American Association for Cancer Research (AACR) annual meeting suggesting that APVO436 may have best-in-class potential among CD123-targeting bispecific antibodies,” continued Mr. White.

Preclinical data presented by Aptevo show that APVO436 is a potent T-cell engager and can stimulate effective T-cell directed tumor killing with reduced cytokine production. Cytokine release syndrome (CRS) is a significant concern with T-cell activating therapies and has been associated with severe complications in clinical trials. Data presented by Aptevo at AACR showed that, compared to an Aptevo-generated version of Macrogenics’ CD123 x CD3 dual-affinity re-targeting (DART) molecule, MGD006, APVO436 induced lower levels of several key T-cell cytokines including IFN γ , IL-2, IL-6, and TNF α , suggesting a potential safety advantage with APVO436. Aptevo believes that an improved cytokine release profile could improve the therapeutic index for APVO436 and other next-generation ADAPTIR bispecific candidates.

Aptevo is also progressing plans to advance a second candidate, APVO210, into the clinic in the first quarter of 2019. Preclinical data for APVO210 show that it has a unique mechanism of action as a novel immunosuppressive therapy. Unlike other cytokine-activating autoimmune therapies, APVO210 is designed to modify the effects of IL-10 to retain its immunosuppressive function without producing any undesired proinflammatory effects.

“We are very pleased with the progress we have made this year advancing both APVO210 and APVO436 towards clinical development and look forward to reporting preliminary top-line data from these programs in 2019,” said Dr. Scott Stromatt, Chief Medical Officer for Aptevo. “With the encouraging preclinical data that is being generated in our next-generation ADAPTIR programs, and both APVO436 and APVO210 poised to begin clinical testing, we have made the decision to focus our resources on our next-generation candidates, which we consider to be the most promising opportunities in our pipeline, and discontinue further development of our first-generation ADAPTIR candidates, otlertuzumab and APVO414. Going forward we will close the otlertuzumab and APVO414 clinical studies to further enrollment but will continue to monitor patients remaining on therapy.”

“By streamlining our portfolio we will focus on the discovery and development of higher-value, next-generation ADAPTIR assets that have the greatest potential for value creation,” continued Dr. Stromatt. “Aptevo’s next-generation ADAPTIR technology may potentially overcome many of the challenges encountered with bispecific antibody development. Our next-generation technology incorporates enhancements that enable us to engineer well-characterized molecules with more traditional antibody-like features that potentially have decreased immunogenicity, increased stability, improved potency, extended half-life, and excellent manufacturing characteristics, including the potential for an improved cytokine release profile, evidenced with our APVO436 candidate. Recent clinical data have been presented this year validating prostate

specific membrane antigen (PSMA) as a target for prostate cancer, so we are excited to continue development of a PSMA/CD3 ADAPTIR candidate based on our next-generation platform.”

Third Quarter 2018 Highlights

- Achieved 132% increase year-over-year in IXINITY net revenue for third quarter 2018
- Continued to expand the patient base for IXINITY, bringing additional new Hemophilia B patients onto IXINITY therapy during the quarter
- Selected new third-party logistics providers for IXINITY improving supply chain and cost efficiencies
- Increased Aptevo’s available cash by approximately \$18 million; executed a new term loan agreement with MidCap Financial extending the interest only repayment period to February 1, 2020 with an opportunity for further deferral through August 1, 2020
- Commenced site activation for the APVO436 Phase 1/1b open-label clinical study; anticipate patient dosing to commence shortly
- Furthered plans to commence a Phase 1 clinical study of APVO210 in the first quarter of 2019 in healthy volunteers
- Completed process development activities for ALG.APV-527 and signed an agreement with a CMO for production of Phase 1 clinical trial material; anticipate filing a clinical trial authorization (CTA) in 2019

Third Quarter 2018 Financial Results

Cash Position: Aptevo had cash, cash equivalents, restricted cash, and short-term investments as of September 30, 2018 totaling \$45.5 million.

IXINITY Revenue: Product sales of IXINITY increased by \$3.3 million, or 132%, to \$5.8 million for the three months ended September 30, 2018, compared to \$2.5 million for the same period in 2017. The increase was due to the expansion of Aptevo’s distribution channel and continuing expansion of the Hemophilia B patient base.

Cost of Product Sales: Cost of product sales increased by \$0.6 million, or 30% for the three months ended September 30, 2018 to \$2.4 million from \$1.9 million for the three months ended September 30, 2017. The 30% increase is significantly lower than the 132% increase in product sales due mainly to the sale of lower cost inventory paid for without any cash costs being incurred due to product being received in settlement against an outstanding inventory credit.

Research and Development Expenses: Research and development expenses increased by \$1.4 million, to \$8.6 million for the three months ended September 30, 2018, compared to \$7.2 million for the corresponding period in 2017. The increase was primarily attributable to increased expenses related to manufacturing and clinical start-up costs for APVO436 and APVO210, as well as ongoing research and discovery efforts related to Aptevo’s ADAPTIR bispecific candidates.

Selling, General and Administrative Expenses: Selling, general and administrative expenses decreased by \$0.5 million, or 7%, to \$7.0 million for the three months ended September 30, 2018,

compared to \$7.5 million for the same period in 2017. The decrease in SG&A expenses in the third quarter of 2018 was primarily due to reduced personnel and professional services costs.

Net Income (Loss): Aptevo's net loss for the three months ended September 30, 2018 was \$12.6 million or (\$0.56) per share, compared to net income of \$37.9 million or \$1.77 per share for the corresponding period in 2017. The difference in net income (loss) between the periods is primarily the result of the gain on the sale of Aptevo's hyperimmune business recorded as discontinued operations in the third quarter of 2017.

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

ASSETS	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Current assets:		
Cash and cash equivalents	\$ 28,447	\$ 7,095
Short-term investments	9,192	73,688
Accounts receivable	6,202	2,141
Inventories	3,969	1,028
Prepaid expenses	5,195	4,022
Other current assets	6,990	6,710
Restricted cash	400	400
Total current assets	<u>60,395</u>	<u>95,084</u>
Restricted cash, net of current portion	7,448	10,000
Property and equipment, net	5,608	5,843
Intangible assets, net	5,458	6,080
Other assets	25	—
Total assets	<u>\$ 78,934</u>	<u>\$ 117,007</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 9,808	\$ 7,350
Accrued compensation	3,875	4,626
Sales rebates and discounts payable	936	623
Current portion of long-term debt	—	3,333
Other short-term liabilities	823	2,578
Total current liabilities	<u>15,442</u>	<u>18,510</u>
Long-term debt, net	19,143	15,728
Other liabilities	349	734
Total liabilities	<u>34,934</u>	<u>34,972</u>
Stockholders' equity:		
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; 22,677,270 and 21,605,716 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	23	22
Additional paid-in capital	157,258	155,837
Accumulated other comprehensive loss	(2)	(105)
Accumulated deficit	<u>(113,279)</u>	<u>(73,719)</u>
Total stockholders' equity	44,000	82,035
Total liabilities and stockholders' equity	<u>\$ 78,934</u>	<u>\$ 117,007</u>

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product sales	\$ 5,824	\$ 2,506	\$ 16,721	\$ 8,131
Collaborations	—	3,666	—	3,709
Total revenues	5,824	6,172	16,721	11,840
Costs and expenses:				
Cost of product sales	2,437	1,872	6,752	3,114
Research and development	8,574	7,175	26,486	19,835
Selling, general and administrative	6,940	7,473	21,556	26,019
Loss from operations	(12,127)	(10,348)	(38,073)	(37,128)
Other expense from continuing operations	(474)	(436)	(1,592)	(1,356)
Loss before income taxes	(12,601)	(10,784)	(39,665)	(38,484)
Benefit from income taxes	—	13,768	—	15,587
Net (loss) income from continuing operations	(12,601)	2,984	(39,665)	(22,897)
Discontinued operations (Note 2):				
Income from discontinued operations, before income taxes	39	56,140	104	62,706
Income tax expense	—	(21,257)	—	(23,076)
Income from discontinued operations	39	34,883	104	39,630
Net (loss) income	\$ (12,562)	\$ 37,867	\$ (39,561)	\$ 16,733
Basic net (loss) income per share:				
Net (loss) income from continuing operations	\$ (0.56)	\$ 0.14	\$ (1.77)	\$ (1.08)
Net income from discontinued operations	\$ —	\$ 1.63	\$ —	\$ 1.87
Net (loss) income per basic share	\$ (0.56)	\$ 1.77	\$ (1.77)	\$ 0.79
Weighted-average shares used to compute per share calculations	22,672,721	21,385,381	22,431,146	21,138,332
Diluted net (loss) income per share:				
Net (loss) income from continuing operations	\$ (0.56)	\$ 0.14	\$ (1.77)	\$ (1.08)
Net income from discontinued operations	\$ —	\$ 1.61	\$ —	\$ 1.87
Net (loss) income per diluted share	\$ (0.56)	\$ 1.75	\$ (1.77)	\$ 0.79
Weighted-average shares used to compute per share calculations	22,672,721	21,672,269	22,431,146	21,138,332

About the APVO414 mCRPC Clinical Study

APVO414 is a first-generation bispecific antibody that that was built on Aptevo's ADAPTIR modular protein therapeutic platform and is designed to simultaneously target prostate specific membrane antigen (PSMA) on prostate cancer cells, and CD3 on T-cells. It functions by redirecting cytotoxic T cell activity towards PSMA-expressing tumor cells.

The Phase 1 clinical study of APVO414 was designed to determine the safety, tolerability and clinical activity of escalating doses of APVO414 delivered by continuous infusion in patients with metastatic castration resistant prostate cancer (mCRPC). A total of 23 patients were treated with continuous infusion, including 3 patients currently enrolled in Cohort 9, where patients are being dosed with 50 mcg/day for 1 week and then dose escalated to 300 mcg/day. To date, no dose limiting toxicities have been reported with continuous infusion. Evidence of pharmacodynamic activity was observed with an increase in activation markers and redistribution of peripheral blood T cells but clinical responses were not obtained at the doses tested. Aptevo has elected to close the study to further enrollment and will continue to monitor patients remaining on therapy.

About the Otlertuzumab PTCL Clinical Study

Otlertuzumab is a first-generation, monospecific antibody targeting CD37 that was built on Aptevo's ADAPTIR modular protein therapeutic platform. CD37 is a member of the tetraspanin superfamily of molecules and is expressed on the surface of normal and transformed B cells, and also recently discovered to be present on the surface of T-cell lymphomas.

The pilot Phase 2 study of otlertuzumab was designed to evaluate otlertuzumab combined with bendamustine for the treatment of patients with peripheral T cell lymphoma (PTCL). A total of 9 patients were enrolled in the study and the combination of otlertuzumab and bendamustine was well tolerated. Evidence of tumor regression (43% in primary tumor) was observed in one patient, however, there was no evidence of an early response in the remaining patients.

Preliminary immunohistochemistry analysis has revealed that the number of patients with tumors expressing CD37, and the degree of CD37 expression within the tumors, is much lower than that found on tissue panels of PTCL patient samples that were tested prior to the initiation of the pilot study. Based on the uncertainty of CD37 tumor expression and the limited efficacy signal, Aptevo elected to close the study to further enrollment and will continue to monitor patients remaining on therapy.

Otlertuzumab has previously been evaluated in over 250 patients with evidence of clinical activity and a manageable safety profile. Clinical proof-of-concept data from a randomized Phase 2 study of otlertuzumab demonstrated the efficacy and tolerability of otlertuzumab in combination with bendamustine in the treatment of relapsed chronic lymphocytic lymphoma (CLL). In this Phase 2 study there was a significant increase in median progression free survival, from approximately 10 months to 16 months in patients receiving the combination of otlertuzumab and bendamustine.

About Aptevo Therapeutics Inc.

Aptevo Therapeutics Inc. is a clinical-stage biotechnology company focused on novel oncology 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. For more information, please visit 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; challenges in sales and marketing efforts; 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 13, 2018 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:

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