

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): March 18, 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))

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 March 18, 2019, Aptevo Therapeutics Inc. (the “*Company*”) issued a press release announcing its financial results for the quarter and year ended December 31, 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 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 No.	Description
99.1	Press Release dated March 18, 2019.

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: March 18, 2019

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



For Immediate Release

**APTEVO THERAPEUTICS REPORTS 2018 FINANCIAL RESULTS
AND PROVIDES BUSINESS UPDATE**

*Achieves Record Annual IXINITY® Net Revenue of \$23.1 Million
Representing 111% Increase Over 2017*

*Advances APVO436 Into Phase 1/1b Clinical Trial for Treatment of
Acute Myeloid Leukemia and High-Grade Myelodysplastic Syndrome*

*Receives Authorization to Commence Dosing in Phase 1 Clinical Trial of APVO210;
Dosing Scheduled to Begin March 2019*

*Progresses Novel 4-1BB/5T4 Bispecific Antibody ALG.APV-527
Towards CTA Filing in Q4 2019*

SEATTLE, WA – March 18, 2019 -- Aptevo Therapeutics Inc. (Nasdaq: APVO), a biotechnology company focused on developing novel oncology, autoimmune and hematology therapeutics, today reported its financial results for the year ended December 31, 2018 and provided an update on its development programs.

“Aptevo continued to make important progress in 2018 in both our pipeline and commercial programs setting up 2019 as a pivotal year for the Company,” said Marvin L. White, President and Chief Executive Officer. “First, we continue to be pleased with the growth trajectory for IXINITY and our success onboarding new patients. Net revenue for IXINITY in 2018 more than doubled to \$23.1 million from \$10.9 million in 2017. New patient on-boarding has continued at a gratifying level thus far in 2019, and therefore we are optimistic about further momentum in our IXINITY business generally, and from the launch of new growth initiatives this year. These include: seeking a pediatric label expansion for IXINITY (as more than a third of patients with Hemophilia B in the U.S. are under the age of 12); introducing a more convenient 3,000 IU assay for patients; and finally, pursuing ex-US licensing and partnership opportunities for IXINITY. We believe these initiatives will allow us to continue to grow our footprint for IXINITY in the U.S. and internationally.

We also reached a key milestone in 2018 – advancing our lead, next-generation ADAPTIR™ bispecific antibody candidate, APVO436, into clinical development. We are particularly excited about this achievement as pre-clinical data for APVO436 has shown promising attributes, specifically by inducing lower levels of several key T cell cytokines compared to a competitor candidate, which have been associated with serious adverse events in clinical studies with other T-

cell engagers. We look forward to evaluating this attribute in our clinical studies, as it would represent an important advantage for our molecule vis-à-vis other bispecific approaches.

With APVO436 solidly on track, we are poised to also begin a Phase 1 study this month of our second ADAPTIR candidate, APVO210 – a novel bispecific antibody intended for the treatment of autoimmune and inflammatory diseases. The Phase 1 study, which is being conducted in Australia, has received authorization to begin dosing of APVO210 in healthy volunteers and will commence imminently. APVO210 has a unique mechanism of action to deliver IL-10 without causing lymphocyte stimulation, which could represent a critical improvement in IL-10 therapies for autoimmune disease.

With two novel ADAPTIR bispecific candidates now advancing in the clinic towards important data read-outs later this year, IXINITY revenues growing, and the proceeds from our equity offering completed in March 2019, we are well-positioned from a cash perspective and anticipate 2019 will potentially be a transformative year for Aptevo,” concluded Mr. White.

2018 Highlights

IXINITY

- Achieved record year-over-year annual IXINITY net revenue of \$23.1 million in 2018, representing a 111% increase compared to revenue of \$10.9 million in 2017
- Continued to expand the patient base for IXINITY bringing additional new Hemophilia B patients onto therapy throughout the year
- Improved supply chain logistics and cost efficiencies for IXINITY by contracting with new third-party logistics providers
- Presented new data from a small retrospective study of IXINITY at the *Thrombosis and Hemostasis 2018 Summit of North America* annual meeting describing patient-reported outcomes data for IXINITY for various clinical and quality of life measures; overall, respondents in this study reported a high level of satisfaction with IXINITY with low annualized bleed rates and a positive impact on quality of life scores
- Introduced new growth initiatives for IXINITY (launch of new 3,000 IU assay; pediatric clinical trial, and pursuit of ex-US distribution and partnership opportunities) commencing in 2019; the initiation of the pediatric trial is required for the pursuit of business in markets such as Europe

ADAPTIR Pipeline (APVO436 / APVO210 / ALG.APV-527)

- Commenced patient dosing in a Phase 1/1b open-label, dose-escalation study of APVO436 in patients with Acute Myeloid Leukemia (AML) and High-Grade Myelodysplastic Syndrome (MDS); anticipate reporting preliminary anti-drug antibody (ADA) read-out in Q3 2019 and reporting preliminary Phase 1 safety data in Q4 2019
- Presented comprehensive new pre-clinical data for APVO436 at the American Association for Cancer Research (AACR) Annual Meeting demonstrating potent T cell-directed tumor killing with reduced cytokine release in pre-clinical studies compared to an Aptevo-generated competitor bispecific construct

- Completed preparations to begin a Phase 1 clinical study of APVO210 evaluating single and multiple ascending doses in healthy volunteers; APVO210 is being developed for the treatment of autoimmune and inflammatory diseases
- Received authorization in Australia to commence dosing in APVO210; Phase 1 clinical trial scheduled to begin March 2019 with initial results for the single dose group cohort anticipated in Q3 2019 and preliminary Phase 1 safety data in Q4 2019
- Published comprehensive pre-clinical data in the journal, *Frontiers in Immunology*, showing that APVO210 has a unique mechanism of action for delivering the cytokine, IL-10, which can generate antigen specific T-regulatory cells, and suppress inflammation and immune activation without stimulating pro-inflammatory cytokines
- Advanced ALG.APV-527 (partnered with Alligator Bioscience) which targets 4-1BB, a co-stimulatory receptor found on activated T cells and 5T4 (a solid tumor antigen) illustrating the capability of the ADAPTIR platform to generate immunotherapeutic antibodies with different mechanisms of immune system engagement. A bispecific candidate targeting 4-1BB and the tumor antigen 5T4 is a novel approach with potential to improve clinical outcomes in several solid tumors; anticipate filing a clinical trial authorization (CTA) in Q4 2019
- Presented new pre-clinical data for ALG.APV-527 at several industry conferences showing that it has the potential to selectively activate and enhance tumor-specific T cell responses at the tumor site without triggering systemic immune activation, supporting the advantages of this novel pathway for tumor immunotherapy
- Focused Aptevo's ADAPTIR portfolio on next-generation ADAPTIR candidates that have the potential to provide increased stability, improved potency and an improved cytokine release profile

Corporate

- Increased Aptevo's available cash by approximately \$18 million through the execution of 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
- Executed a share purchase agreement with Lincoln Park Capital (LPC) establishing a three-year, \$35 million equity line with LPC
- Announced significant reduction in 2019 cash burn rate; estimate 2019 cash burn of between \$36-\$40 million from \$55-\$60 million in 2018
- Completed a public equity offering in March 2019 raising gross proceeds of approximately \$22 million for Aptevo, strengthening the company's balance sheet and providing additional cash runway beyond validating clinical milestones in the APVO436 and APVO210 Phase 1 clinical development programs anticipated in Q3 and Q4 2019

2018 Summary Financial Results

Cash Position: Aptevo had cash, cash equivalents, and short-term investments as of December 31, 2018 totaling \$38.1 million, including \$7.5 million in restricted cash.

Product Revenue: Revenue for IXINITY for the year ended December 31, 2018 increased approximately 111% to \$23.1 million from \$10.9 million for the year ended December 31, 2017.

This increase was primarily related to the continuing expansion of Aptevo's IXINITY Hemophilia B patient base and expansion of the Company's distribution channel for IXINITY.

Collaborations revenue for 2017 was due to a one-time recognition of the remaining deferred revenue related to Aptevo's collaboration with MorphoSys, which was terminated in the third quarter of 2017.

Cost of Product Sales: Cost of product sales increased by \$6.2 million, or 124%, to \$11.2 million for the year ended December 31, 2018 from \$5.0 million for the year ended December 31, 2017. The increase in cost of product sales is mainly due to the increase in product sales, as well as lower cost of inventory in 2017 due to inventory being received in settlement against an outstanding inventory credit.

Research and Development Expenses: Research and development expenses increased by \$6.4 million to \$35.4 million for the year ended December 31, 2018 compared to \$29.0 million for the year ended December 31, 2017. The increase in research and development expenses is primarily related to manufacturing costs for clinical drug product for APVO436 and APVO210, and increased activities around the development of new ADAPTIR pipeline candidates.

Selling, General and Administrative Expenses: Selling, general and administrative expenses decreased by \$6.4 million, or 19%, to \$28.1 million for the year ended December 31, 2018, compared to \$34.5 million for the year ended December 31, 2017. The decrease was primarily due to reduced personnel and professional services costs.

Net Income (Loss): Aptevo's net loss for the year ended December 31, 2018 was (\$53.7) million or \$(2.39) per share, compared to a net income of \$7.0 million or \$0.33 per share for the corresponding period in 2017. Net income in 2017 is due to income from discontinued operations in connection with the sale of the Company's Hyperimmune Business in 2017, and allocation of income tax benefit as required by GAAP, offset by the Company's losses from operations.

Aptevo 2019 Milestones:

March 2019

- Commence Phase 1 clinical trial of APVO210

Mid 2019

- Launch new 3,000 IU IXINITY assay

Q3 2019

- Commence patient dosing in Phase 4 IXINITY study
- Report preliminary ADA read-out for APVO436 in going Phase 1 study
- Report initial results of APVO210 single dose cohorts
- Disclose new ADAPTIR molecule with new MOA

Q4 2019

- Report preliminary Phase 1 safety data for APVO436
- Report preliminary Phase 1 safety data for APVO210
- File CTA submission for Phase 1 study of ALG.APV-527

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

	As of December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 30,635	\$ 7,095
Short-term investments	—	73,688
Accounts receivable	5,220	2,141
Inventories	1,785	1,028
Prepaid expenses	6,907	4,022
Other current assets	4,142	6,710
Restricted cash	—	400
Total current assets	48,689	95,084
Restricted cash, net of current portion	7,448	10,000
Property and equipment, net	5,202	5,843
Intangible assets, net	5,250	6,080
Other assets	905	—
Total assets	\$ 67,494	\$ 117,007
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 11,671	\$ 7,350
Accrued compensation	3,898	4,626
Sales rebates and discounts payable	1,245	623
Current portion of long-term debt	—	3,333
Other current liabilities	796	2,578
Total current liabilities	17,610	18,510
Long-term debt, net	19,278	15,728
Other liabilities	200	734
Total liabilities	37,088	34,972
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; 22,808,416 and 21,605,716 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	23	22
Additional paid-in capital	157,791	155,837
Accumulated other comprehensive loss	—	(105)
Accumulated deficit	(127,408)	(73,719)
Total stockholders' equity	30,406	82,035
Total liabilities and stockholders' equity	\$ 67,494	\$ 117,007

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

	For the Year Ended December 31,	
	2018	2017
Revenues:		
Product sales	\$ 23,067	\$ 10,949
Collaborations	—	3,709
Total revenues	23,067	14,658
Costs and expenses:		
Cost of product sales	11,214	5,010
Research and development	35,385	29,021
Selling, general and administrative	28,133	34,576
Loss from operations	(51,665)	(53,949)
Other expense:		
Other expense, net	(2,024)	(1,944)
Loss before income taxes	(53,689)	(55,893)
Benefit from income taxes	—	23,301
Net loss from continuing operations	(53,689)	(32,592)
Discontinued operations (Note 2):		
Income from discontinued operations, before income taxes	—	62,864
Income tax expense	—	(23,299)
Income from discontinued operations	—	39,565
Net income (loss)	\$ (53,689)	\$ 6,973
Basic and diluted net income (loss) per share:		
Net loss from continuing operations	\$ (2.39)	\$ (1.53)
Net income from discontinued operations	\$ —	\$ 1.86
Net income (loss)	\$ (2.39)	\$ 0.33
Weighted-average shares used to compute per share calculation	22,500,053	21,335,157

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. 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

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:

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