

**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): February 4, 2020

ZIOPHARM Oncology, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33038
(Commission
File Number)

84-1475642
(IRS Employer
Identification No.)

One First Avenue, Parris Building 34, Navy Yard Plaza
Boston, Massachusetts
(Address of Principal Executive Offices)

02129
(Zip Code)

(617) 259-1970
(Registrant's telephone number, including area code)

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	ZIOP	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 (17 CFR 230.405) or Rule 12b-2 of the Exchange Act (17 CFR 240.12b-2).

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 February 4, 2020, Ziopharm Oncology, Inc. (the “**Company**”) filed a preliminary prospectus supplement with the Securities and Exchange Commission (the “**Preliminary Prospectus Supplement**”) in connection with a proposed registered underwritten public offering of common stock (the “**Offering**”), which included the following disclosure:

As of December 31, 2019, we had approximately \$79.7 million of cash and cash equivalents. This amount is unaudited and preliminary, and does not present all information necessary for an understanding of our financial condition as of December 31, 2019. Our internal closing procedures with respect to the period presented above are not complete. Our actual results for the year ended December 31, 2019 will not be finalized until after this offering is completed and may differ materially from the above estimates.

Item 8.01 Other Events.

On February 4, 2020, the Company issued a press release announcing the commencement of the Offering. A copy of the press release is filed herewith as Exhibits 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The Preliminary Prospectus Supplement contains an updated description of certain aspects of the Company’s business. Accordingly, the Company is filing this information with this Current Report on Form 8-K for the purpose of supplementing and updating disclosures contained in the Company’s prior filings with the SEC. The updated disclosures are filed herewith as Exhibit 99.2 and are incorporated herein by reference.

Caution Concerning Forward-Looking Statements

This Current Report on Form 8-K may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can be identified by the use of words such as “may,” “will,” “expect,” “project,” “estimate,” “anticipate,” “plan,” “believe,” “potential,” “should,” “continue” or the negative versions of those words or other comparable words. These forward-looking statements include statements about the Company’s anticipated public offering, clinical development of the Company’s product candidates, expectations regarding future clinical trials, the preliminary financial results as of December 31, 2019 and the Company’s future expectations, plans and prospects. These forward-looking statements are based on information currently available to the Company and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including the uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all. The Company’s forward-looking statements also involve assumptions that, if they prove incorrect, would cause its results to differ materially from those expressed or implied by such forward-looking statements. These and other risks concerning the Company’s business are described in additional detail in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018, the Preliminary Prospectus Supplement and in the Company’s other reports filed with the Securities and Exchange Commission. The Company is under no obligation to, and expressly disclaims any such obligation to, update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated February 4, 2020, titled “Ziopharm Oncology Announces Proposed Public Offering of Common Stock.”
99.2	Updated Company Disclosures.

SIGNATURES

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.

ZIOPHARM ONCOLOGY, INC.

Date: February 4, 2020

By: /s/ Robert Hadfield

Name: Robert Hadfield

Title: General Counsel and Secretary



Ziopharm Oncology Announces Proposed Public Offering of Common Stock

BOSTON, MA Feb. 4, 2020 (GLOBE NEWSWIRE) — Ziopharm Oncology, Inc. (Nasdaq:ZIOP) today announced that it intends to offer and sell shares of its common stock in an underwritten registered public offering. All of the shares in the offering are to be sold by Ziopharm. Ziopharm also intends to grant the underwriters a 30-day option to purchase up to an additional fifteen percent (15%) of the number of shares of common stock offered in the public offering at the public offering price, less underwriting discounts and commissions. The offering is subject to market and other conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

Jefferies is acting as sole book-running manager for this offering and Cantor is acting as lead manager for this offering.

The securities are being offered pursuant to a shelf registration statement on Form S-3ASR, which became automatically effective upon filing with the Securities and Exchange Commission (SEC) on June 21, 2019. The offering will be made only by means of a prospectus supplement and accompanying prospectus that form a part of the registration statement. A preliminary prospectus supplement relating to the offering will be filed with the SEC and will be available on the SEC's website at www.sec.gov. This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

When available, copies of the preliminary prospectus supplement and the accompanying prospectus relating to these securities may be obtained for free from Jefferies LLC, Attention: Equity Syndicate Prospectus Department, 520 Madison Avenue, 2nd Floor, New York, NY 10022, or by telephone at +1 877 821 7388 or by email at Prospectus_Department@Jefferies.com; or Cantor Fitzgerald & Co., Attention: Capital Markets, 499 Park Avenue, 6th Floor, New York, New York 10022, or by email at prospectus@cantor.com.

About Ziopharm Oncology, Inc.

Ziopharm Oncology is an immuno-oncology company focused on developing end-to-end cost-effective solutions using its non-viral Sleeping Beauty platform for T-cell receptor (TCR) and chimeric antigen receptor (CAR) T-cell therapies and immune-stimulating gene therapy with Controlled interleukin 12 (IL-12).

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including statements regarding Ziopharm's expectations regarding the proposed public offering. Words such as "anticipates," "believes," "expects," "intends," "projects," "anticipates," and "future" or similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to the inherent uncertainties in predicting future results and conditions and no assurance can be given that the proposed securities offering discussed above will be consummated on the terms described or at all. Completion of the proposed offering and the terms thereof are subject to numerous factors, many of which are beyond the control of Ziopharm, including, without limitation, market conditions, failure of customary closing conditions and the risk factors and other matters set forth in Ziopharm's Quarterly Report on Form 10-Q for the period ended September 30, 2019 and other filings Ziopharm makes with the SEC from time to time. Ziopharm undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

Contacts for Ziopharm Oncology:

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In the preliminary prospectus supplement filed pursuant to Rule 424(b)(5) in connection with a public offering of common stock by Ziopharm Oncology, Inc. (the "Company"), the Company provided the following overview of the Company's business as updates to the information provided in the Company's previous periodic filings with the Securities and Exchange Commission.

Company Overview

We are a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing next generation immunotherapy platforms that leverage cell- and gene-based therapies to treat patients with cancer. We are developing two immuno-oncology platform technologies that utilize the immune system by employing novel, controlled gene expression and innovative cell engineering technologies designed to deliver safe, effective, and scalable non-viral cell- and viral-based gene therapies for the treatment of multiple cancer types. Our first platform is referred to as *Sleeping Beauty* and is based on the genetic engineering of immune cells using a non-viral transposon/transposase system that is intended to stably reprogram T cells outside of the body for subsequent infusion. Our second platform is termed Controlled IL-12, which is designed to stimulate expression of interleukin 12, or IL-12, a master regulator of the immune system, in a controlled and safe manner to focus the patient's immune system to attack cancer cells. We believe these two platforms have the potential to provide unique and powerful solutions to address the issues associated with (1) treating solid tumors with heterogeneous and unknown antigens, and (2) providing cost-effective scalable manufacturing solutions for T cell receptor T cell, or TCR⁺ T, therapies for solid tumors and chimeric antigen receptor, or CAR T cell, or CAR⁺ T, therapies targeting CD19 on malignant B cells.

Using our *Sleeping Beauty* platform, we are developing TCR⁺ T therapies initially to target solid tumors. Our T cell receptor, or TCR, program designs and manufactures T cells that are intended to target tumor-specific antigens, thereby delivering personalized therapy that can attack an individual patient's cancer. These antigens are referred to as neoantigens as they are only expressed by the tumor, reducing the potential for toxicity upon targeting normal cells. A minority of neoantigens are shared between patients and between classes of tumors and are referred to as "hotspots". The *Sleeping Beauty* system uses DNA plasmids to reprogram T cells to express introduced TCRs on a patient-by-patient basis (addressing inter-tumor heterogeneity) and possibly to express more than one TCR for each patient (addressing intra-tumor heterogeneity). The genetic modification using the *Sleeping Beauty* system of recipient-derived products enables us to target neoantigens in two ways. The first recognizes that most neoantigens are unique to each patient's tumor and we plan to infuse TCR⁺ T cells expressing recipient-derived (autologous) TCRs. The second is based on the finding that some neoantigens in hotspots are shared between patients and we plan to administer TCR⁺ T expressing allogeneic TCRs from a library derived from third parties. We have in-licensed from the National Cancer Institute, or the NCI, multiple allogeneic TCRs derived from third parties that are reactive to mutated KRAS, TP53 and EGFR and we plan to expand our TCR library as part of our commitment to advance clinical development for the treatment of patients whose solid tumors have driver mutations. These TCRs are typically obtained from tumor-infiltrating lymphocytes, or TILs.

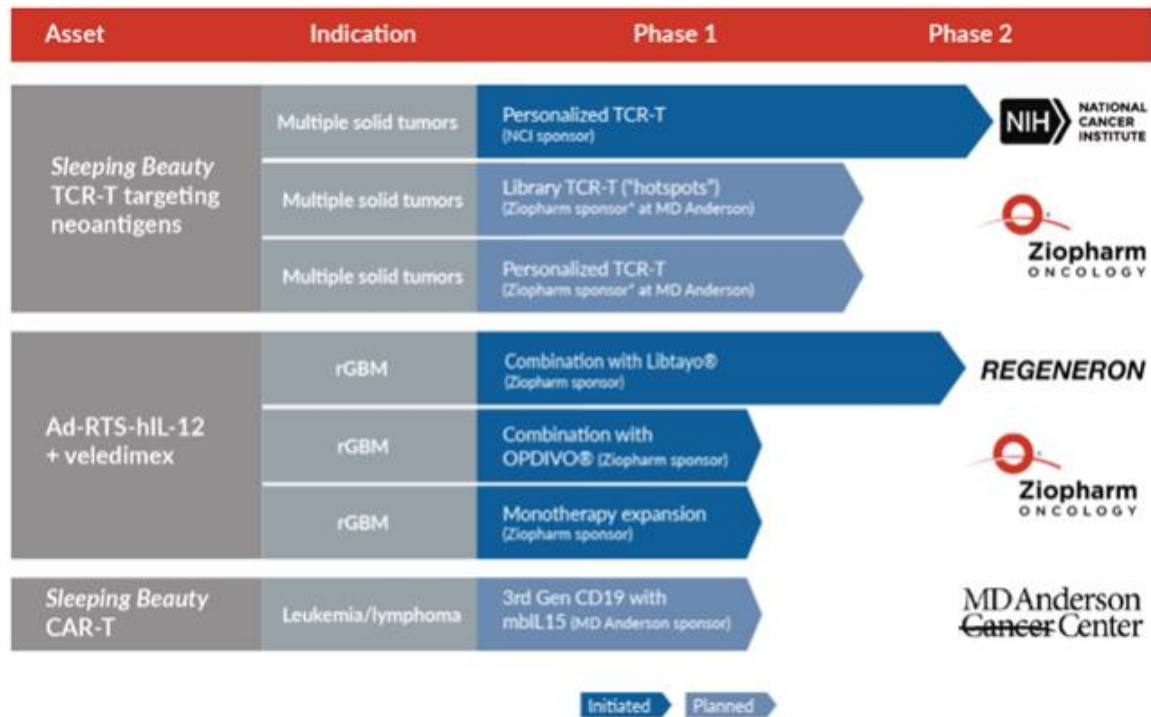
Under our Cooperative Research and Development Agreement, the NCI is conducting a Phase 2 clinical trial to evaluate autologous peripheral blood lymphocytes genetically modified with the *Sleeping Beauty* system to express autologous (personalized) TCRs. The U.S. Food and Drug Administration, or FDA, has cleared the investigational new drug, or IND, application submitted by the NCI for this clinical trial. The trial was initiated in October 2019 and preparations to enable patient enrollment by the NCI are underway. We expect the trial will enroll patients with a broad range of solid tumors over the next several years.

In addition, we are currently planning a clinical program to study our TCR approach with The University of Texas MD Anderson Cancer Center, or MD Anderson. Under this program, we expect to evaluate both our personalized TCR, or autoTCR, approach and our hotspot TCR, or alloTCR, approach. Our autoTCR approach is designed to identify neoantigens and TCRs on a patient-by-patient basis, which we believe should allow it to be broadly applicable to many patients' solid tumors. The advantage of the alloTCR approach is that a subset of patients with solid tumors may be rapidly treated based on screening them for target neoantigens (e.g., in TP53), identifying human leukocyte antigen, and matching these data to the alloTCRs in the library.

We are also developing CAR⁺ T therapies using our *Sleeping Beauty* platform. Our CAR⁺ T program seeks to solve the complex and costly manufacturing limitations that we believe continue to limit the commercial potential of existing CD19-specific CAR⁺ T therapies. We believe using DNA plasmids in the *Sleeping Beauty* system to express a CD19-specific CAR and our proprietary membrane-bound interleukin 15, or mbIL15, in resting T cells obtained from peripheral blood will enable infused T cells to propagate within the patient to target leukemia and lymphoma, thus avoiding the need to numerically expand T cells for weeks in bioreactors before patient administration. The mbIL15 is co-expressed with a “kill switch” or “safety switch” to conditionally eliminate infused T cells. We expect the lower cost of DNA plasmids compared with the virus used by other CAR⁺ T programs, together with the avoidance of lengthy *ex vivo* manufacturing, will reduce the cost and complexity of manufacturing CAR⁺ T cells. These technologies should enable T cells to be infused as soon as the day after gene transfer in a process we refer to as rapid personalized manufacture, or RPM. We are advancing our CAR⁺ T technology in the United States in collaboration with MD Anderson in a Phase 1 clinical trial in the United States infusing CD19-specific CAR⁺ T therapies manufactured using our RPM technology. In this trial, we plan to infuse donor-derived T cells after allogeneic bone marrow transplantation, or BMT, for recipients who have relapsed with CD19⁺ leukemias and lymphomas. We are also advancing our RPM technology including using patient-derived (autologous) T cells in order to treat patients with relapsed or refractory CD19⁺ leukemias and lymphomas. In a joint venture with TriArm Therapeutics, Ltd., or TriArm, we have formed Eden BioCell, Ltd., or Eden BioCell, to lead the clinical development and commercialization of *Sleeping Beauty*-generated CD19-specific RPM CAR-T therapies in the People’s Republic of China, Taiwan and Korea. Eden BioCell is focused on advancing our RPM technology using patient-derived (autologous) T cells in order to treat patients with relapsed or refractory CD19⁺ leukemias and lymphomas. Eden BioCell is owned equally by us and TriArm and the parties share decision-making authority. TriArm has committed up to \$35.0 million, of which \$10.0 million has been paid as of September 30, 2019, to this joint venture and will also manage all clinical development to execute trials in the designated countries.

Our Controlled IL-12 platform uses virotherapy based on an engineered replication-incompetent adenovirus, referred to as Ad-RTS-hIL-12, plus veledimex as a gene delivery system to conditionally produce IL-12, a potent, naturally occurring anti-cancer protein, to treat patients with solid tumors where a specific target is unknown, including brain cancer. Our Controlled IL-12 platform allows us to deliver IL-12 in a tunable dose as the cytokine is under transcriptional control of the rheoSwitch therapeutic system[®] (RTS[®]). We believe the ability regulate production of IL-12 after administration of the virus is critical for the development of this potent cytokine. We are currently studying our Controlled IL-12 Platform as a monotherapy in a Phase 1 clinical trial of patients with recurrent glioblastoma multiforme, or rGBM. Our substudy of this clinical trial is fully enrolled with 36 patients diagnosed with rGBM. The substudy is designed to encourage use of low-dose steroids and 20 mg veledimex to further understand the potential of Controlled IL-12 as a monotherapy. We are also developing our Controlled IL-12 platform in combination with immune checkpoint inhibitors. We are studying Ad-RTS-hIL-12 plus veledimex in combination with OPDIVO[®] (nivolumab) in a Phase 1 dose-escalation clinical trial of patients with rGBM. We have entered into a clinical supply agreement with Regeneron Pharmaceuticals, Inc., or Regeneron, to evaluate Ad-RTS-hIL-12 plus veledimex in combination with Regeneron’s PD-1 antibody Libtayo[®] (cemiplimab-rwlc) for the treatment of patients with rGBM. We have initiated a Phase 2 clinical trial evaluating Controlled IL-12 (Ad-RTS-hIL-12 plus veledimex, Ad+V), in combination with PD-1 antibody Libtayo[®] (cemiplimab-rwlc) for the treatment of recurrent or progressive glioblastoma multiforme in adults. In our clinical trials, we have observed that Controlled IL-12 increases T-cell activity in the tumor microenvironment in patients with rGBM and we may conduct trials of Controlled IL-12 in other tumor types as both a monotherapy and in combination with immune checkpoint inhibitors.

Our Pipeline



* Subject to FDA discussions and feedback regarding the trial phase and design.

Recent Developments

Sleeping Beauty Solid Tumor TCR-T Program

We expect to pursue our TCR⁺T cell therapy program in collaboration with MD Anderson. In October 2019, we entered into the 2019 Research and Development Agreement with MD Anderson where, we will, among other things, collaborate with MD Anderson on programs to expand our TCR library and conduct clinical trials.

As part of our effort to continue expanding our TCR library, in January 2020, we announced an amendment to our license with the NCI to expand our license to include additional TCRs reactive to mutated KRAS and TP53. We also announced in January 2020 that the journal *Clinical Cancer Research* published a paper, co-authored by Drew Deniger, Ph.D., who leads our TCR⁺T cell therapy program. The *Clinical Cancer Research* publication describes how TCRs with specificity to mutations within TP53 present in tumor cells can be obtained from circulating T cells, which may overcome the need to obtain TILs through surgical resection.

Our third generation CAR⁺ T program utilizes our proprietary mbIL15, which enables infused T cells to propagate within the patient, thus avoiding the need to numerically expand T cells for weeks in bioreactors before patient administration. At the American Society of Hematology, or ASH, Annual Meeting in December 2019, we presented pre-clinical data of our RPM technology demonstrating that T cells genetically modified using DNA plasmids from the *Sleeping Beauty* system to express TCRs with mbIL15 exhibit anti-tumor effects.

Controlled IL-12 Platform

In November 2019, we provided an update from two ongoing studies of our Controlled IL-12 platform at the 2019 Society for Neuro-Oncology, or SNO, Annual Meeting.

Monotherapy Expansion Substudy—Interim Results

In a Phase 1 clinical trial of patients with rGBM, referred to as the Main Study, a subset of patients (n=6) with unifocal disease who received single administration of Ad-RTS-hIL-12 with 20 mg daily dosing (15 total planned doses) of veledimex along with low-dose steroids along, achieved 17.8 months median overall survival, or mOS. Thirty-six additional patients with rGBM were recruited into a substudy, referred to as the Expansion Substudy, designed to encourage use of low-dose steroids and 20 mg veledimex to further understand the potential of Controlled IL-12 as a monotherapy. During the 2019 SNO Annual Meeting, we provided an interim update for the Expansion Substudy and announced that:

- We observed a decrease in tumor from baseline resulted in a patient's lesion being too small to measure, assessed as a partial response (per iRANO), with follow up ongoing.
- We provided an analysis of MRI findings of pseudoprogression in subjects with initial increases and subsequent decreases in tumor size, which was consistent with immune-mediated anti-tumor effects.
- We observed that subjects in the Expansion Substudy were comparable to the subjects in the Main Study, except a higher percentage of subjects enrolled in the Expansion Substudy had multifocal disease (as compared with unifocal disease) and fewer previous recurrences of disease.
- Subjects receiving 20 mg of veledimex in both the Main Study and Expansion Substudy (n=20) with unifocal disease at entry, receiving low-dose steroids (defined as <20 mg cumulative dosing of dexamethasone during the time of veledimex dosing) had a mOS of 16.2 months. The mOS for these subjects in the Expansion Substudy alone (n=14) has not been reached at a mean follow up of 9.7 months
- We observed subjects with multifocal disease at initial enrollment that received 20mg of veledimex and low-dose steroids (n=13) had a mOS of 10.1 months. We believe this is consistent with literature, which shows that multifocal glioblastoma is associated with worse prognosis compared to unifocal disease
- Adverse reactions that we observed in the Expansion Substudy as of the data cut-off date were consistent with prior studies of Controlled IL-12 and were predictable, dose-related, and promptly reversible upon discontinuation of veledimex

Combination Study—Interim Results

We are also studying Ad-RTS-hIL-12 plus veledimex in combination with nivolumab, an immune checkpoint inhibitor, in a Phase 1 dose-escalation trial of patients with rGBM. During the 2019 SNO Annual Meeting, we provided an interim update for this trial and announced that:

- We observed a decrease of approximately 64% in a patient's tumor from baseline resulting in a partial response (per iRANO), with follow up ongoing.
- We provided an analysis of MRI findings of pseudoprogression in subjects, which was consistent with immune-mediated anti-tumor effects.
- Active dosing is ongoing in the trial and mOS has not been reached, with a mean follow up for these subjects of 4.8 months.
- No dose limiting toxicities, no serious adverse events that were considered related to the combination with nivolumab and no clinically significant overlapping toxicities have been observed as of the data cut-off date in the trial.
- Drug-related toxicities we have observed as of the data cut-off date were comparable to the Main Study, and have been predictable, dose-related, and promptly reversible upon discontinuation of veledimex. Further, there were no drug-related deaths reported.

Sleeping Beauty Solid Tumor CAR+ T Program

In October 2019, we announced the FDA had cleared an IND application submitted by MD Anderson Cancer Center for a Phase 1 clinical trial to evaluate our third generation CD19-specific CAR-T therapies for patients with relapsed CD19+ leukemias and lymphomas. The clinical trial will evaluate CAR-T therapies prepared using our RPM technology.

In January 2020, we announced that a letter published in the *Blood*, the journal of the American Society of Hematology, discussed long-term outcomes of seven patients with relapsed or refractory B-cell lymphoid malignancies, all of whom had received our second-generation CD19-specific CAR-T cells infused two days following autologous hematopoietic stem-cell transplantation, also referred to as BMT. In this study, four of the seven patients demonstrated sustained persistence of CAR-T (median time of persistence duration was 4.5 years, range 2-5 years). Five-year progression-free survival and overall survival were 71% and 86%, respectively.