UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): **June 7, 2019**

Trovagene, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35558**	**27-2004382**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	IRS Employer Identification No.)

11055 Flintkote Avenue
San Diego, CA 92121
(Address of principal executive offices)

Registrant's telephone number, including area code: **(858) 952-7570**

(Former name or former address, if changed since last report)

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	TROV	Nasdaq Capital Market

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:

o Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 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 o

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. o

Item 7.01 Regulation FD Disclosure

On June 7, 2019, Trovagene, Inc. (the "Company") held a Business Update conference call. The script for the conference call ("Script") is attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated into this Item 7.01 by reference.

All statements in this Item 7.01 and the Script, may be deemed to be forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Although the Company believes the expectations expressed in such forward-looking statements are based on reasonable assumptions, such statements are not guarantees of future performance, and actual results or developments may differ materially from those in the forward-looking statements. See the Company's Annual Report on Form 10-K for the year ended December 31, 2018 and the Company's other filings with the Securities and Exchange Commission for a discussion of other risks and uncertainties. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

In accordance with General Instruction B.2 of Form 8-K, the information furnished under this Item 7.01 of this Current Report on Form 8-K and the exhibit attached hereto are deemed to be "furnished" and shall not be deemed "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall such information and exhibit be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit Number	Description
99.1	Business Update Script

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.

Dated: June 7, 2019

TROVAGENE, INC.

By: /s/ Thomas Adams
Thomas Adams
Chief Executive Officer

Exhibit 99.1

Trovagene Company Update

Conference Call Script
Friday, June 7, 2019 - 11:00 a.m. EDT (8:00 a.m. PDT)
Speaker dial-in: (877) 330-2645; Conference ID: 8596214

Debrief with LHA immediately after the call:
877-852-2556; Passcode: 3106917104

Operator

Welcome to the Trovagene conference call. At this time, all participants are in a listen-only mode. Following management's prepared remarks, we will hold a Q&A session.

To ask a question, please press "star" followed by "one" on your touchtone phone. If anyone has difficulty hearing the conference, please press star zero for the operator assistance. As a reminder, this conference is being recorded today, June 7. I would now like to turn the conference over to Vicki Kelemen, Vice President, Investor Relations and Clinical Development. Ms. Kelemen, please go ahead.

Vicki Kelemen

Good morning and thank you all for participating in today's Business Update Conference call.

Joining me are Dr. Thomas Adams, Chief Executive Officer and Chairman of Trovagene, and Dr. Mark Erlander, our Chief Scientific Officer.

During today's call we're going to review the status of our onvansertib clinical development programs; key preliminary data; a recent collaboration announcement and future milestones. At the conclusion of our prepared remarks, we will open the call for questions.

Before we begin, we advise that certain remarks that are made during this call

about the Company's future expectations, plans and prospects constitute forward-looking statements for purposes of the Safe Harbor provisions under the Private Securities Litigation Reform Act of 1995, which provides a Safe Harbor for such forward-looking statements. These forward-looking statements involve material risks and uncertainties.

For a discussion of risk factors, I encourage you to review the Trovagene annual report on Form 10-K and subsequent reports as filed with the Securities and Exchange Commission, which can be accessed at Trovagene.com or sec.gov. Furthermore, the content of this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, June 7, 2019. The Company undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this conference call.

With that, let me turn the call over to Tom Adams. Tom?

Tom Adams

Thanks, Vicki. Good morning everyone, and thank you for joining us. Today Mark and I will be reviewing the status of our clinical development programs, our recent collaboration announcement with Nektar Therapeutics and key upcoming milestones.

Since licensing onvansertib from Nerviano Medical Sciences in March of 2017, I am proud to say we have made significant, and very rapid progress with our clinical development program. We have three active Investigational New Drug, or INDs, in place with the FDA, which enables us to conduct clinical trials in leukemias, lymphomas and solid tumor cancers. Our clinical development program with onvansertib, a first-in-class, third generation Polo-like Kinase 1 (PLK1) inhibitor includes three different cancer indications: acute myeloid leukemia, or AML; metastatic castration-resistant prostate cancer, or mCRPC; and metastatic colorectal cancer, or mCRC. All three of these cancers represent a significant medical need for a new treatment option.

In most cancers, the PLK1 enzyme is over-expressed. And as a master regulator of cell division blocking or inhibiting PLK1 by kinase inhibitors, such as onvansertib, can effectively stem the growth of tumors and induce tumor cell death.

Think of onvansertib as a pipeline within a molecule; a single molecule addressing multiple indications, each with a significant medical need for new treatment options. And combine this with the synergy that results when onvansertib is added to standard-of-care chemotherapies and targeted therapeutics, and you have the cornerstone of precision cancer medicine.

Why this is so important is that many cancers either fail to respond to single targeted therapy from the start of treatment or the tumor acquires resistance after initially responding. Targeted therapies block a specific pathway that is signaling for increased tumor cell division, and with the addition of onvansertib, we are getting a second hit by directly inhibiting this cell division. This two-hit approach by a combination greatly decreases the opportunity for tumors to be resistant and stops tumors from proliferating.

As part of our precision cancer medicine strategy, we are incorporating predictive clinical biomarkers to identify the patients who are most likely to respond to therapy. We believe this is key to the success of our clinical trials and the development of onvansertib, as published reports estimate that there is a nearly seven-fold increase in the probability of success of oncology drug development when biomarkers are incorporated into clinical trials.

To-date in 2019 we have made significant progress with advancing our clinical trials. Earlier this year, we presented data from our mCRPC trial at the Genitourinary Cancers Symposium, followed by presentation of data from both our mCRPC and AML trials at the American Association for Cancer Research. We were pleased to announce that the preliminary data demonstrate the safety and efficacy of onvansertib in combination with standard-of-care therapies.

In our Phase 1b dose-escalation safety trial in AML, we have completed the first five dose escalation cohorts without any dose-limiting toxicities, and a number of patients are remaining on the trial for multiple cycles because they are seeing clinical benefit and tolerating treatment very well.

As we continue to advance our AML trial, I am pleased to announce we will be holding our first Clinical Advisory Board Meeting next week, in conjunction with the European Hematology Association Conference. We have assembled a group of key opinion leaders from leading cancer centers, including MD Anderson,

Cornell, Dana Farber, Johns Hopkins and Yale for this important meeting. Our primary objective for convening this group of AML experts is to obtain their input and guidance to inform our overall clinical development and FDA approval pathway for onvansertib in AML. We look forward to an informative and productive meeting and to sharing the outcome with you.

In mCRPC, the preliminary data also is encouraging with two out of the first six patients achieving early PSA response, as presented at the AACR conference in April. We recently opened a second arm in this trial to explore a shorter dosing schedule, and early indications of treatment response are encouraging. This trial, as you may recall, is being conducted by the prestigious Harvard Medical Cancer Centers. We anticipate having data readouts throughout the second half of the year and presentations at key oncology conferences.

Our third clinical trial in metastatic colorectal cancer is now activated at USC Norris Comprehensive Cancer Center and the Mayo Clinic and patient recruitment is underway.

Mark will further discuss our clinical development programs and the preliminary results demonstrated to date in just a moment.

Before I turn things over to Mark, I want to update you on one of our primary business objectives, which is to establish partnerships with pharma/biotech companies to expand development and establish market opportunities for onvansertib. We have focused our efforts on engaging companies that have complementary oncology therapeutics, either marketed or in clinical development, and with development programs and interest in indications where onvansertib in combination may prove to be clinically beneficial and financially advantageous.

To this end, we recently announced our partnership with multi-billion-dollar company, Nektar Therapeutics, a large biotech and significant player in the oncology arena. While this is our first, of what we believe will be several similar collaborations with major pharma/biotech partners, and a significant milestone achievement for Trovagene, we believe it speaks to the validation of onvansertib and its potential value across numerous indications. There are at least a dozen FDA approved drugs that are currently marketed by large pharma companies with

which we have data demonstrating synergy when onvansertib is added. This is a development strategy that is appealing, and that is generating a great deal of interest, because combining onvansertib with standard-of-care therapies provides a second mechanism of action pathway, and backstop, to tumor growth.

Under the collaboration, our two companies will evaluate the antitumor activity and tolerability of the combination of onvansertib and ONZEALD in two preclinical tumor models of colorectal cancer.

ONZEALD is the first long-acting topoisomerase I-inhibitor (Topo I) designed to enhance the anti-cancer effects of topo I-inhibition, while minimizing its toxicities. In a wide range of human xenograft tumors, including two colorectal models, ONZEALD has shown superior antitumor activity, compared with irinotecan. Onvansertib also has shown strong antitumor activity in preclinical models of colorectal cancers, and demonstrated significant and durable synergistic antitumor activity in combination with irinotecan, greater than that of either drug alone.

Working together with Nektar will enable us to very quickly assess the potential value of the onvansertib/ONZEALD combination.

We continue to pursue a collaboration with a pharma company outside the U.S. to expand the clinical development and market opportunities for onvansertib. We are encouraged by the ongoing interest and discussions to further develop onvansertib in combination with approved drugs to improve efficacy and potentially expand the market, including meetings we had earlier this week at ASCO in Chicago and the BIO International Conference in Philadelphia. We look forward to updating you on any developments in this partnering strategy.

And now, let me turn things over to Mark to provide an update on our three ongoing clinical trials.

Mark Erlander

Thank you, Tom.

Before I review our three ongoing clinical trials, I would like to reiterate that we are very pleased with the advancement of our clinical programs and the safety and preliminary efficacy data demonstrated to date with onvansertib.

Our first clinical study is an open-label Phase 1b/2 trial of onvansertib in combination with either low-dose cytarabine or decitabine in patients with AML. This trial is being conducted at nine sites across the U.S., with two of the lead investigators in AML at MD Anderson and Yale University Cancer Center.

AML is an aggressive hematologic malignancy of immature blood cells with no effective treatments for relapsed or refractory patients. You may recall that we have been granted orphan drug designation for onvansertib in AML, both in the U.S. and in Europe, which affords us greater, and more frequent, access to the respective regulatory agencies, as well as significant financial incentives.

We are continuing with the Phase 1b dose-escalation safety segment of our AML trial to identify the maximum tolerated dose and the recommended dose for use in the Phase 2 continuation segment of this trial. As Tom mentioned, to date, no dose-limiting toxicities have been observed and the treatment has been well tolerated by patients. In terms of preliminary efficacy, the greatest anti-leukemic activity has been observed in the onvansertib/decitabine combination arm, with a complete response achieved in three of the six, or fifty percent, of the evaluable patients to-date. This is particularly encouraging considering that both low-dose cytarabine and decitabine have relatively low response rates of eight percent and fifteen percent, respectively, in this relapsed / refractory patient population. Overall, we are seeing approximately a ninety percent clinical benefit achieved; a combination of complete response, plus partial response, plus stable disease, in patients treated to-date.

Currently, we are enrolling our sixth dose level cohort of patients with onvansertib at 90mg/m^2 in combination with decitabine, and we are wrapping up the 60mg/m^2 dose level with the cytarabine patient cohort. We anticipate reaching the important milestone of identifying our recommended Phase 2 dose shortly, and moving forward with enrollment in the Phase 2 segment of this trial. Because we have nine trial sites conducting this trial, we anticipate fairly rapid enrollment in Phase 2 and having efficacy data to report this year.

Incorporating our precision medicine approach, our predictive clinical biomarker is enabling us to identify subsets of patients who are most likely to respond to treatment. Biomarkers are being measured and correlated with pharmacokinetic drug levels to assess treatment effects by measuring the percent of leukemic blast cells in the blood and bone marrow, inhibition of PLK1 by onvansertib, and correlating underlying tumor genetics with treatment response.

PLK1, the target of onvansertib, drives cell division by activating multiple downstream proteins which then drive specific pathways integral to the process of cell division. One such protein, known as translational control tumor protein, or TCTP is a specific target for PLK1 that is phosphorylated by the enzymatic activity of PLK1. In other words, TCTP is phosphorylated by PLK1. We are observing a significant correlation between the extent of inhibition of TCTP phosphorylation by onvansertib and subsequent patient response to treatment with onvansertib within a subset of AML patients. Approximately thirty to forty percent of patients fall into this category and we plan to incorporate this biomarker strategy to identify patients that are more likely to respond as we advance our clinical development of onvansertib in AML.

Our second clinical study is an open-label, Phase 2 trial of onvansertib in combination with Zytiga, abiraterone and prednisone, in metastatic Castration-Resistant Prostate Cancer, or mCRPC. Zytiga is a standard-of-care hormonal therapy that blocks the production of androgens. Resistance to Zytiga generally occurs within 9 to 16 months following the start of treatment, and currently the only option for these patients is chemotherapy, which has a poor prognosis. Onvansertib has shown significant synergy when combined with Zytiga having the potential to increase the duration of response to treatment.

Metastatic Castration-Resistant Prostate Cancer has a five-year survival rate of only thirty-seven percent. There is a significant need to increase the duration of response to treatment as patients eventually develop resistance. Patients with metastatic prostate cancer will become castrate-resistant, yet the tumor cells will continue utilizing the androgen signaling pathway to drive tumor growth. PLK1 inhibition not only inhibits tumor growth by preventing cell division, but recent data also indicate that blocking PLK1 appears to repress the androgen signaling pathway.

This trial is evaluating the safety and efficacy of onvansertib in combination with daily Zytiga and prednisone, all taken orally, in patients with mCRPC who are showing initial signs of resistance to Zytiga. Prostate-specific antigen, or PSA, is the biomarker with which we are able to measure our primary endpoint of disease stabilization following twelve weeks of treatment, defined as a rise in PSA of no more than twenty-five percent over baseline measured at cycle one, day one. We have two arms running simultaneously, each with a different dosing schedule: patients in Arm A complete a 21-day cycle, and patients in Arm B complete a shorter, 14-day cycle. This trial is being conducted by the three Harvard Medical Cancer centers — Beth Israel Deaconess, Dana Farber, and Mass General — and is being led by Dr. David Einstein, a leading Genitourinary Oncologist at Beth Israel.

At the AACR conference in early April, we announced preliminary data from our Phase 2 trial indicating activity of onvansertib in prostate cancer patients showing initial resistance to anti-androgen therapy. PSA response was observed in two of the six patients that had been treated to-date at that time, both of whom harbor the highly aggressive androgen-receptor variant 7, or AR-V7 mutation. The AR-V7 mutation is found in approximately twenty to twenty-five percent of patients with mCRPC and is known to be resistant to treatment with Zytiga. As a component of our biomarker strategy, we are exploring the AR-V7 status in patients as an opportunity to identify this subset of patients who may benefit most from the addition of onvansertib to their Zytiga daily regimen.

We are, in essence, changing the trajectory of resistance in this setting, an example of how onvansertib works as a backstop when used in combination with Zytiga, when as a single agent it can no longer control the proliferative state of the tumor.

We recently activated our third clinical trial, a Phase 1b/2 dose escalation, safety and preliminary efficacy study in metastatic colorectal cancer, at USC Norris Comprehensive Cancer Center, under the leadership of renowned colorectal cancer expert, Dr. Heinz-Joseph Lenz, and at The Mayo Clinic. In this trial, we will be evaluating the safety and efficacy of onvansertib in combination with standard-of-care FOLFIRI plus Avastin, as second-line treatment for patients who have a KRAS mutation.

Currently, the prognosis for mCRC is poor with the overall survival at five years being only fifteen percent. There is a large unmet need for new therapies in this patient population, particularly in the second-line setting, and for the approximately fifty percent of patients with mCRC who harbor the harmful tumor-promoting KRAS mutation. Up to now, pharma has been unable to develop a drug to treat colon cancer that harbors the KRAS mutation and the efficacy of second-line therapy in terms of prolonging survival and response to treatment remains very limited. FOLFIRI, a chemotherapy regimen of irinotecan, fluorouracil [5-FU], and leucovorin + bevacizumab, in the second-line setting, is the standard treatment in US. The response rate; however, is less than five percent as reported in a large international trial. This represents a large opportunity for Trovagene to bring a much needed new treatment option to patients.

We know that PLK1 inhibition, as we anticipate seeing with onvansertib when added to the standard-of-care regimen, results in impairment of viability of several RAS mutated cell lines. In preclinical models, it's been shown that inhibition of PLK1 affects the growth of KRAS-mutated cell lines and xenografts, which make onvansertib an appealing drug candidate in this setting. Additionally, we have in-vitro and in-vivo preclinical data demonstrating good response to treatment with onvansertib in combination with standard-of-care therapies, including irinotecan — a major component of FOLFIRI — showing inhibition of tumor growth. By integrating our biomarker strategy, we will select for KRAS mutated patients to be enrolled in the trial, and secondly, we will be able to measure changes in the KRAS mutation burden in real-time by a blood test to see very quickly how patients are responding to the combination of FOLFIRI plus onvansertib. Given that response to FOLFIRI in this patient population is approximately five percent, we anticipate an increase in objective response with the combination.

To summarize, we believe that combining onvansertib with standard-of-care drugs may effectively put the brakes on the development of resistance, extend the duration of response and enhance the efficacy of numerous regimens across a wide array of cancer types and indications.

With that overview of our clinical programs and progress, I will turn things back over to Tom to review our key upcoming milestones. Tom?

Tom Adams

Thanks, Mark. We anticipate seeing a number of catalysts in the balance of the year and into early 2020 with our clinical programs and partnering initiatives, including the following:

In our AML trial:

- We look forward to a productive clinical advisory board meeting and to obtaining input and guidance from key opinion leaders on the clinical development and FDA approval pathway for onvansertib in this indication;

- We anticipate reaching our recommended Phase 2 dose by completing the Phase 1b dose-escalation and to initiating and completing enrollment in the Phase 2 continuation segment of our ongoing trial; and

- We look forward to providing efficacy and safety data readouts throughout the year at various industry conferences including the European Society for Medical Oncology, or ESMO, in September, the European School of Hematology Conference in October, and the American Society of Hematology, or ASH, Conference in December.

In our prostate cancer trial:

- We will continue enrolling both arms of this trial and anticipate reporting safety and efficacy results in the coming months at key conferences, including the Asian Pacific Prostate Cancer Conference in August, ESMO in September, the European Multidisciplinary Congress on Urological Cancers in November, and at the ASCO-Genitourinary Cancers Symposium next February.

And in our colorectal cancer trial:

- We expect enrollment of the first three patients in the initial dose-level cohort of the Phase 1b dose-escalation segment of this trial within the next couple of months; and to having early safety and efficacy data to present before the end of the year.

- We anticipate presenting our first data in October at the Gastrointestinal Oncology Conference and additional data at the ASCO-Gastrointestinal Cancers Symposium in January 2020.

Before we conclude today's call, I'd like to comment on our cash position. As of March 31st, 2019, we had a cash balance of approximately $11.3 million, which includes the $3.3 million from the exercising of warrants in 2019. This does not include two subsequent investments totaling gross proceeds of $3.0 million by Lincoln Park Capital. In addition, PoC Capital has committed to the funding of our current metastatic colorectal cancer trial. To-date in 2019, we have raised capital and clinical research support commitments totaling approximately $8.0 million. With our current cash balance, and anticipated quarterly burn rate, we believe we have runway to continue advancing our clinical development programs into 2020.

We look forward to sharing regular updates on our progress with you and thank you once again for participating on today's call. This concludes our prepared remarks.

Operator, we are now ready to take questions.

Operator

We will now begin the question-and-answer session. To ask a question you may press * then 1 on your telephone keypad. If you are using a speakerphone, please pick up your handset before pressing the keys. To withdraw your question please press * then 2. At this time, we will pause momentarily to assemble our roster.

Taking First Question:
Thank you. The first question comes from [name] with [Company].

Reprompt for Questions:
Again, if you have a question, please press *then 1.

After the final question:

Tom Adams

I'd like to thank you all again for joining us on today's call. I trust we've laid out our near-term roadmap for advancing the development of onvansertib, and

demonstrated our enthusiasm and commitment to our business model and market opportunities.

We look forward to keeping you abreast of our progress through news releases and periodic update conference calls, such as this one. In the meantime, enjoy the rest of your day.

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