

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 13, 2019

FORTY SEVEN, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38554
(Commission File Number)

47-4065674
(IRS Employer
Identification No.)

1490 O'Brien Drive, Suite A
Menlo Park, California
(Address of Principal Executive Offices)

94025
(Zip Code)

(650) 352-4150
(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 filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.0001 par value	FTSV	The Nasdaq Global Select Market

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 August 13, 2019, Forty Seven, Inc., or the Company, issued a press release announcing its financial results for the quarter ended June 30, 2019. The press release is attached as Exhibit 99.1 and is incorporated herein by reference.

The press release is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information in this Current Report shall not be incorporated by reference in any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

<u>Exhibit</u>	<u>Description</u>
99.1	Press release, dated August 13, 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.

Dated: August 13, 2019

By: /s/Mark A. McCamish
Mark A. McCamish, M.D.
President and Chief Executive Officer

Forty Seven Inc. Reports Second Quarter 2019 Financial Results and Recent Business Highlights

- Presented Updated Data for 5F9 in Four Patient Populations at ASCO and EHA Meetings --
- Received FDA Feedback Suggesting Single-Arm Pivotal Trials May Support Registration in MDS and DLBCL --
- Entered Exclusive Licensing Agreement with Ono Pharmaceutical to Develop and Commercialize 5F9 in Japan, South Korea, Taiwan and the ASEAN Countries --
- Raised \$86.3 Million in Follow-On Offering, Extending Cash Runway Through First Quarter of 2021 --
- Management to Host Conference Call at 4:30 p.m. ET Today --

MENLO PARK, Calif., August 13, 2019 – Forty Seven Inc. (NASDAQ:FTSV), a clinical-stage, immuno-oncology company focused on developing therapies to activate macrophages in the fight against cancer, today reported financial results for the second quarter ended June 30, 2019 and provided a business update.

“In recent months, we continued to make significant progress toward our commitment to maximizing the potential of 5F9 as a novel, first-in-class therapeutic for the treatment of cancer,” said Mark McCamish, M.D., Ph.D., President and Chief Executive Officer of Forty Seven, Inc. “In particular, we were excited to present updated data for 5F9 in four patient populations, which showed consistent clinical activity across a range of tumor types, and enabled us to define potential accelerated pathways to approval in both MDS and DLBCL. In addition, we entered into a collaboration with Ono Pharmaceutical, allowing us to extend our reach into Japan and other South and East Asian countries and accelerate 5F9’s development, while still focusing our internal resources on executing against our path to U.S. registration.”

Dr. McCamish continued, “We enter the second half of 2019 in a strong corporate position, buoyed by our recent follow-on offering, and with clear priorities for the year ahead. We look forward to initiating our first registration-enabling studies in early 2020, while continuing to advance our broader development program for 5F9 toward additional data readouts later this year and preparing FSI-174 and FSI-189 for investigational new drug application filings.”

Second Quarter and Recent Business Highlights:

5F9 Clinical Programs:

Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML)

- In June 2019, Forty Seven presented updated initial data from its Phase 1b clinical trial evaluating 5F9 as a monotherapy and in combination with azacitidine for the treatment of MDS and AML at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois and at the 24th Congress of the European Hematology Association in Amsterdam, Netherlands. Among patients treated with the combination regimen, the ORR was 100% in higher-risk MDS and 64% in untreated AML. 5F9 was well-tolerated in combination with azacitidine and AEs were consistent with prior clinical experience. Read the full data [here](#).
- Also in June 2019, Forty Seven received feedback from the FDA and believes that a single-arm trial evaluating durability, complete responses and partial responses may be sufficient to support the registration of 5F9 in combination with azacitidine in patients with untreated, intermediate to very high-

risk MDS. The Company anticipates needing a sample size of approximately 91 patients, with six-month efficacy and 12-month safety follow-up data. Based on this feedback, Forty Seven is expanding its ongoing Phase 1b clinical trial to 91 patients, treated with weekly dosing, to accelerate the acquisition of 12-month safety data. In parallel, the Company will work with the FDA under a Special Protocol Assessment to finalize key parameters of a second trial of 91 patients, treated with bi-weekly dosing. The Company expects to complete enrollment in its ongoing trial in the third quarter of 2020, to initiate the second clinical trial in the first quarter of 2020 and complete enrollment in the first quarter of 2021, and, if successful, to file a biologics license application (BLA) using combined efficacy and safety data in the fourth quarter of 2021.

Non-Hodgkin Lymphoma (NHL)

- In June 2019, Forty Seven presented updated clinical data from its ongoing Phase 1b/2 clinical trial of 5F9 in combination with rituximab for patients with relapsed/refractory (r/r NHL), including diffuse large B-cell lymphoma (DLBCL) and indolent lymphoma at the 24th Congress of the European Hematology Association (EHA) in Amsterdam, Netherlands and at the 15th International Conference of Malignant Lymphoma (ICML) in Lugano, Switzerland. The overall response rate (ORR) for patients treated in the Phase 1b/2 trial was 45% per Lugano criteria (36% in DLBCL and 61% in indolent lymphoma). Among DLBCL patients treated in the Phase 2 portion of the study, all of whom had either primary refractory disease or were relapsed/refractory to ≥ 2 prior lines of therapy and ineligible for CAR-T therapy, the ORR was 29%. 5F9 was well-tolerated in combination with rituximab and adverse events (AEs) were consistent with prior clinical experience. Read the full data [here](#).
- Also in June 2019, Forty Seven received feedback from the U.S. Food and Drug Administration (FDA) and believes that a single-arm pivotal study evaluating ORR and durability may be sufficient to support the registration of 5F9 in combination with rituximab in patients with r/r DLBCL who have failed at least two prior lines of therapy, including those who have been deemed CAR-T ineligible. Based on this feedback, Forty Seven plans to initiate a registration-enabling trial evaluating the combination, dosed bi-weekly, in approximately 100 patients. The Company is refining patient eligibility criteria based on clinical and translational data from its Phase 1b/2 trial, and expects to initiate the study in the first quarter of 2020, with interim efficacy data available by the fourth quarter of 2020.

Corporate:

- In July 2019, Forty Seven entered into an amendment of its agreement with The Leukemia & Lymphoma Society (LLS) to accelerate the development of 5F9 in MDS. Under the collaboration, funded through LLS's Therapy Acceleration Program® (TAP), Forty Seven is eligible for up to \$3.0 million in milestone payments from LLS upon the achievement of certain clinical or regulatory milestones. This is on top of the prior LLS TAP funding commitment of \$4.2 million to progress 5F9 through clinical development. LLS also recently purchased \$3.0 million of common stock in Forty Seven's July 2019 public offering.
- In July 2019, Forty Seven announced the closing of an underwritten public offering of 10,781,250 shares of its common stock, including the exercise in full by the underwriters of their option to purchase additional shares of stock. Forty Seven received gross proceeds from the offering of approximately \$86.3 million, before deducting underwriting discounts and commissions and estimated offering expenses.
- In July 2019, Forty Seven entered into an exclusive licensing agreement with Ono Pharmaceutical Co., Ltd. for the development, manufacture and commercialization of 5F9 as a monotherapy or combination agent in Japan, South Korea, Taiwan and the ASEAN countries. Under the terms of the agreement, Forty Seven

will receive a one-time upfront payment of approximately \$15.7 million from Ono, and is eligible to receive up to an additional approximately \$103.3 million at current exchange rates if specified future development and commercial milestones are achieved by Ono, in addition to tiered percentage royalties, spanning from the mid-teens to the low-twenties, on future net sales of 5F9 in the territory.

Key Milestones:

The company expects to achieve the following milestones by the end of 2019:

- Report expanded efficacy and durability data from the Phase 1b trial of 5F9 in combination with azacitidine in patients with MDS and AML in the fourth quarter.
- Report data from the Phase 1b trial of 5F9 in combination with avelumab in patients with ovarian cancer in the fourth quarter.
- Report data from the Phase 1b trial of 5F9 in combination with cetuximab in patients with colorectal cancer in the fourth quarter.
- Report preclinical data and complete investigational new drug (IND)-enabling studies for FSI-174, an anti-cKIT antibody with potential use as a novel conditioning regimen for bone marrow transplantation, in the second half.
- Complete IND-enabling studies for FSI-189, an anti-SIRP α antibody with therapeutic potential for cancer and other indications, in the second half.

Second Quarter 2019 Financial Results:

- **Cash Position:** As of June 30, 2019, cash, cash equivalents and short-term investments were \$99.0 million, as compared to \$139.0 million as of December 31, 2018. Cash and cash equivalents as of June 30, 2019 do not include aggregate gross proceeds of approximately \$86.3 million from the Company's July 2019 public offering, or the approximate \$15.7 million upfront payment received in connection with Forty Seven's entering into the collaboration with Ono Pharmaceutical. The company expects that its cash, cash equivalents and short-term investments will fund operating expenses and capital expenditure requirements through the first quarter of 2021.
- **R&D Expenses:** R&D expenses were \$18.8 million for the second quarter of 2019, as compared to \$13.6 million for the second quarter of 2018. The increase was primarily due to a \$3.2 million increase in third-party costs related to advancing Forty Seven's current clinical programs focused on lead product candidate, 5F9, and associated contract manufacturing costs, a \$1.1 million increase in preclinical and discovery program costs, and a \$0.9 million increase in personnel-related costs.
- **G&A Expenses:** G&A expenses were \$5.1 million for the second quarter of 2019, as compared to \$3.4 million for the second quarter of 2018. The increase was primarily due to a \$0.8 million increase in personnel-related costs driven by an increase in headcount, a \$0.6 million increase in accounting and consulting expenses incurred in connection with operating as a public company and business expansion, and a \$0.2 million increase in directors and officer's insurance expense.
- **Net Loss:** Net loss was \$23.2 million for the second quarter of 2019, or a net loss per share of \$0.74, as compared to \$16.7 million for the second quarter of 2018, or a net loss per share of \$2.52.

Conference Call Information:

Forty Seven will host a live conference call and webcast at 4:30 p.m. ET today to discuss second quarter 2019 financial results and recent business activities. The conference call may be accessed by (866) 953-0780 (domestic) or (630) 652-5854 (international), and by referring to conference ID 3387853. A webcast of the conference call will be available in the Investors section of the Forty Seven website at <https://ir.fortyseveninc.com>. The archived webcast will be available on Forty Seven's website approximately two hours after the conference call and will be available for 30 days following the call.

About Forty Seven Inc.

Forty Seven, Inc. is a clinical-stage immuno-oncology company that is developing therapies targeting cancer immune evasion pathways based on technology licensed from Stanford University. Forty Seven's lead program, 5F9, is a monoclonal antibody against the CD47 receptor, a "don't eat me" signal that cancer cells commandeer to avoid being ingested by macrophages. This antibody is currently being evaluated in multiple clinical studies in patients with solid tumors, myelodysplastic syndrome, acute myeloid leukemia, non-Hodgkin's lymphoma, ovarian cancer and colorectal carcinoma.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those related to the presentation of, timing of and outcome of results from the Phase 1b clinical trial evaluating 5F9 as a monotherapy and in combination with azacitidine for the treatment of MDS and AML, the Phase 1b/2 clinical trial of 5F9 in combination with rituximab for patients with relapsed/refractory (r/r NHL), including diffuse large B-cell lymphoma (DLBCL), the Phase 1b trial of 5F9 in combination with avelumab in patients with ovarian cancer, the Phase 1b trial of 5F9 in combination with cetuximab in patients with colorectal cancer, and other ongoing trials of 5F9 for the treatment of solid tumors and colorectal cancer; the timing of and quality of results from investigational new drug-application enabling studies for FSI-189 and FSI-174 and their respective potential for approval by the FDA; the sufficiency of a single-arm trial evaluating durability, complete responses and partial responses to support the registration of 5F9 in combination with azacitidine in patients with untreated, higher-risk MDS; the sufficiency of a single-arm pivotal study evaluating ORR and durability to support the registration of 5F9 in combination with rituximab in patients with r/r DLBCL; the potential of macrophage activation for the treatment of cancer; the potential of FSI-174 as a potential conditioning regimen for bone marrow transplantation; the safety, tolerability and efficacy of 5F9, FSI-189 and FDI-174; the success of Forty Seven's collaboration and licensing agreement with Ono Pharmaceutical; Forty Seven's ability to fund its clinical programs and the sufficiency of its cash and short-term investments; and Forty Seven's financial outlook.

Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward looking statements. The potential product candidates that Forty Seven develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all. In addition, clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release. Such product candidates may not be beneficial to patients or successfully commercialized. The failure to meet expectations with respect to any of the foregoing matters may have a negative effect on Forty Seven's stock price. Additional information concerning these and other risk factors affecting Forty Seven's business can be found in Forty Seven's periodic filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof, and, except as required by law, Forty Seven disclaims any obligation to update these forward-looking statements to reflect future events or circumstances.

For more information please visit www.fortyseveninc.com or contact info@fortyseveninc.com.

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Forty Seven Inc.
Condensed Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 18,829	\$ 13,596	\$ 37,955	\$ 24,749
General and administrative	5,057	3,362	9,641	7,205
Total operating expenses	<u>23,886</u>	<u>16,958</u>	<u>47,596</u>	<u>31,954</u>
Loss from operations	(23,886)	(16,958)	(47,596)	(31,954)
Interest and other income, net	680	236	1374	1374
Net loss	(23,206)	(16,722)	(46,222)	(30,580)
Unrealized gains on available-for-sale securities	41	43	141	16
Net loss per share, basic and diluted	<u>\$ (0.74)</u>	<u>\$ (2.52)</u>	<u>\$ (1.48)</u>	<u>\$ (4.76)</u>
Shares used in computing net loss per share, basic and diluted	<u>31,355,135</u>	<u>6,636,862</u>	<u>31,261,182</u>	<u>6,618,736</u>

Forty Seven Inc.
Condensed Balance Sheets
(in thousands)

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
	(Unaudited)	(Audited)
Cash, cash equivalents and short-term investments	\$ 99,007	\$ 139,023
Working capital	88,511	130,449
Total assets	115,802	149,437
Total liabilities	24,318	16,216
Total stockholders' equity	91,484	133,221