

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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): November 12, 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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 November 12, 2019, Forty Seven, Inc., or the Company, issued a press release announcing its financial results for the quarter ended September 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 November 12, 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: November 12, 2019

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



Helping Patients Defeat Their Cancer

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

- On-Track to Initiate Potential Registration-Enabling Trials in MDS and DLBCL in 1Q 2020 –
- Entered into Collaboration with bluebird bio to Evaluate Antibody-Based Conditioning Regimen in Combination with LentiGlobin –
- Management to Host Conference Call at 8:00 a.m. ET Today --

MENLO PARK, Calif. November 12, 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 third quarter ended September 30, 2019 and provided a business update.

“In the third quarter, we continued to enroll patients in our Phase 1b clinical trial of magrolimab in myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML), while preparing to initiate potential registration-enabling trials in MDS and diffuse large B cell lymphoma (DLBCL) in the first quarter of 2020,” said Mark McCamish, M.D., Ph.D., President and Chief Executive Officer of Forty Seven. “We have plans in place for both programs that we believe could enable us to pursue accelerated paths to approval and to address the unmet needs of substantial patient populations in need of safe, well-tolerated and effective new options.”

Dr. McCamish continued, “We also made important progress with our preclinical candidates, FSI-174 and FSI-189, and remain on track to advance both into clinical testing next year. This morning, we announced a new collaboration with bluebird bio to evaluate our antibody-based conditioning regimen, comprised of magrolimab and FSI-174, in combination with LentiGlobin. We believe this partnership will allow us to accelerate and expand our efforts to provide an alternative, antibody-only conditioning regimen that avoids chemotherapy/radiation exposure for patients undergoing hematopoietic stem cell (HSC) transplantation. We are excited to work with the bluebird team as we continue our efforts to fully exploit the CD47 pathway as a novel therapeutic target.”

Third Quarter and Recent Business Highlights:

Magrolimab Clinical Programs:

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

- Forty Seven continues to enroll patients in its ongoing, single-arm trial evaluating magrolimab in combination with azacitidine in approximately 90 patients with untreated, intermediate to very high risk MDS, treated with weekly dosing. The primary endpoint of the trial is overall response rate (ORR) with durability of response. The company expects to complete enrollment in the third quarter of 2020. In parallel, Forty Seven continues to engage with the U.S. Food and Drug Administration (FDA) under its Special Protocol Assessment (SPA) to finalize key parameters of a second clinical trial, evaluating every two week dosing, which may support a potential accelerated approval. The company is moving forward in parallel with chemistry, manufacturing and controls (CMC) activities to support an expected filing of a biologics license application (BLA) in the fourth quarter of 2021, consistent with prior guidance.
- In September 2019, Forty Seven announced that the FDA granted Fast Track designation to magrolimab for the treatment of MDS and AML.

Non-Hodgkin Lymphoma (NHL)

- Forty Seven has finalized the patient eligibility criteria for its planned registration-enabling trial evaluating magrolimab in combination with rituximab in approximately 100 patients with diffuse large B-cell lymphoma (DLBCL). The company plans to enroll patients who have failed at least two prior lines of therapy. The primary endpoint of the trial will evaluate ORR and durability of response. Forty Seven expects to initiate the study in the first quarter of 2020, and to report interim efficacy data by the fourth quarter of 2020. In parallel, the company continues to evaluate biomarkers for potential predictive value, which could enable advancement into earlier lines of treatment.

Solid Tumors

- Forty Seven recently submitted abstracts including data from its ongoing Phase 1b trial of magrolimab in combination with avelumab in patients with ovarian cancer, and its Phase 1b trial of magrolimab in combination with cetuximab in patients with colorectal cancer, to major medical meetings which will occur in the first quarter of 2020. The company plans to announce initial data from both studies at the time of those presentations.

FSI-174:

- In November 2019, Forty Seven entered into a collaboration with bluebird bio to evaluate Forty Seven's antibody-based conditioning regimen, which is comprised of FSI-174 and magrolimab, with bluebird's LentiGlobin gene therapy platform for the treatment of beta thalassemia and sickle cell disease. The companies expect to initiate a Phase 1b trial in 2020.

Key Upcoming Milestones:

Forty Seven will present expanded efficacy and durability data from the Phase 1b trial of magrolimab in combination with azacitidine in patients with MDS and AML in an oral presentation at the 61st American Society of Hematology (ASH) Annual Meeting, which will be held December 7-10, 2019 in Orlando, Florida. Also at ASH, Forty Seven will present a poster detailing preclinical data for FSI-174.

Additionally, the company expects to complete investigational new drug (IND)-enabling studies for both FSI-174 and FSI-189 before year-end.

Third Quarter 2019 Financial Results:

- Cash Position:** As of September 30, 2019, cash, cash equivalents and short-term investments were \$166.7 million, as compared to \$139.0 million as of December 31, 2018. This increase reflects aggregate gross proceeds of approximately \$86.3 million from Forty Seven's underwritten public offering of common stock that closed in July 2019, as well as an approximately \$15.7 million upfront license payment from Forty Seven's entry into its 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.
- Revenue:** Revenues were \$15.7 million for the third quarter of 2019, due to the license granted under the Ono agreement. Forty Seven did not record revenues in the third quarter of 2018.
- R&D Expenses:** R&D expenses were \$27.1 million for the third quarter of 2019, as compared to \$18.0 million for the third quarter of 2018. The increase was primarily due to a \$9.2 million increase in advancing Forty Seven's current clinical programs focused on lead product candidate, magrolimab, and associated contract manufacturing costs for BLA enabling studies, a \$3.2 million increase in preclinical program costs, a \$1.5 million decrease in funding recognition under the California Institute for Regenerative Medicine (CIRM) and Leukemia and Lymphoma Society (LLS) grants, and a \$1.1 million increase in personnel-related costs, partially offset by a \$5.9 million decrease in license fees, primarily due to the non-recurring license fees paid under the BliNK asset purchase and the Synthon license agreements in 2018.
- G&A Expenses:** G&A expenses were \$5.0 million for the third quarter of 2019, as compared to \$4.4 million for the third quarter of 2018. The increase was primarily due to a \$0.4 million increase in personnel and corporate related costs driven by an increase in headcount.
- Net Loss:** Net loss was \$15.1 million for the third quarter of 2019, or a net loss per share of \$0.38, as compared to \$21.7 million for the third quarter of 2018, or a net loss per share of \$0.71.

Conference Call Information:

Forty Seven will host a live conference call and webcast at 8:00 a.m. ET today to discuss third 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 7667736. 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, magrolimab, 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 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 "believe," "continue," "could," "expect," "may," "plan," "potential," "predict," "will," 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 timing of potential registration-enabling trials in MDS and DLBCL; the potential to pursue accelerated paths to approval of Forty Seven's clinical programs; the potential for Forty Seven's clinical programs to address unmet needs of patient populations; the timing of potential clinical trials in FSI-174 and FSI-189; the timing, acceleration and outcome of Forty Seven's collaboration with bluebird bio to provide an alternative, antibody-only condition regimen; the presentation of, timing of and outcome of results from the Phase 1b clinical trial evaluating magrolimab as a monotherapy and in combination with azacitidine for the treatment of MDS and AML; the timing of complete enrollment and acceleration in the Phase 1b clinical trial evaluating magrolimab as a monotherapy and in combination with azacitidine for the treatment of MDS and AML; the timing and outcome of a BLA filing; the Phase 1b/2 clinical trial of magrolimab in combination with rituximab for patients with relapsed/refractory NHL, including DLBCL; the timing of, enrollment in and outcome of the Phase 1b/2 clinical trial of magrolimab in combination with rituximab for patients with r/r NHL, DLBCL; the outcome of the evaluation of biomarkers for potential predictive value and the advancement into earlier lines of treatment; the timing of initial results from the Phase 1b trial of magrolimab in combination with avelumab in patients with ovarian cancer; the timing of initial results from the Phase 1b trial of magrolimab in combination with cetuximab in patients with colorectal cancer; the timing of a clinical trial to evaluate Forty Seven's antibody-based conditioning regimen, comprised of FSI-174 and magrolimab, with bluebird's LentiGlobin gene therapy platform for the treatment of beta thalassemia and sickle cell disease; the sufficiency of a single-arm trial evaluating efficacy and durability to support the registration of magrolimab in combination with azacitidine in patients with MDS and AML; the timing of and quality of results from investigational new drug-application enabling studies for FSI-174 and FSI-189 and their respective potential for approval by the FDA; the sufficiency of a single-arm pivotal study evaluating ORR and durability to support the registration of magrolimab in combination with rituximab in patients with r/r DLBCL; 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.

For journalist enquiries please contact Sarah Plumridge at fortyseven@hdmz.com or phone (312) 506-5218.

For investor enquiries please contact Hannah Deresiewicz at Stern Investor Relations Inc. at hannah.deresiewicz@sternir.com or phone (212) 362-1200.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
License revenue	\$ 15,678	\$ -	\$ 15,678	\$ -
Operating expenses:				
Research and development	27,074	17,984	65,029	42,733
General and administrative	4,977	4,383	14,618	11,588
Total operating expenses	<u>32,051</u>	<u>22,367</u>	<u>79,647</u>	<u>54,321</u>
Loss from operations	(16,373)	(22,367)	(63,969)	(54,321)
Interest and other income, net	1,210	708	2,584	1,165
Net loss	(15,163)	(21,659)	(61,385)	(53,156)
Unrealized gains on available-for-sale securities	31	(4)	172	12
Comprehensive loss	<u>(15,132)</u>	<u>(21,663)</u>	<u>(61,213)</u>	<u>(53,144)</u>
Net loss per share, basic and diluted	<u>\$ (0.38)</u>	<u>\$ (0.71)</u>	<u>\$ (1.80)</u>	<u>\$ (3.63)</u>
Shares used in computing net loss per share, basic and diluted	39,772,452	30,430,898	34,129,449	14,643,348

Forty Seven Inc.
Condensed Balance Sheets
(in thousands)

	September 30, 2019	December 31, 2018
	(Unaudited)	(Audited)
Cash, cash equivalents and short-term investments	\$ 166,742	\$ 139,023
Working capital	153,623	130,449
Total assets	183,583	149,437
Total liabilities	25,253	16,216
Total stockholders' equity	158,330	133,221