
**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): January 10, 2020

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 Stock Market LLC

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 January 10, 2020, Forty Seven, Inc. issued a press release titled “Forty Seven Announces 2020 Strategic Priorities and Expected Milestones” a copy of which is attached as Exhibit 99.1 and is incorporated herein by reference. In the press release, we announced that based upon preliminary estimates, our cash, cash equivalents and short-term investments totaled \$329.1 million at December 31, 2019.

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 Registrant, 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 January 10, 2020, titled “Forty Seven Announces 2020 Strategic Priorities and Expected Milestones”.

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.

Dated: January 10, 2020

Forty Seven, Inc.

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

Forty Seven Announces 2020 Strategic Priorities and Expected Milestones

- *Registration-Enabling Programs in MDS and DLBCL On-Track; Initiation of Phase 3 ENHANCE Trial in MDS and Phase 3 Trial in DLBCL Expected in 1Q and 2Q 2020* —
- *Updated Data from Ongoing Phase 1b Trial in Higher-Risk MDS and AML Expected Mid-Year 2020* —
 - *Initial Data from Phase 3 Trial in DLBCL Expected in 4Q 2020* —
- *FSI-174 and FSI-189 Expected to Enter Phase 1 in 1Q and 2Q 2020, Respectively* —
- *FDA Granted Orphan Drug Designation for Magrolimab in MDS* —

MENLO PARK, Calif., January 10, 2020 - Forty Seven, Inc. (Nasdaq:FTSV), a clinical-stage, immuno-oncology company focused on developing therapies to activate macrophages in the fight against cancer, today outlined its strategic plan and expected milestones for 2020.

“Our vision is to deliver groundbreaking therapies to patients by harnessing the potential of the innate immune system in the fight against disease,” said Mark McCamish, M.D., Ph.D., President and Chief Executive Officer of Forty Seven. “As we enter the new year, we are executing against this strategy with full force. Our potential-registration enabling programs for magrolimab in MDS and DLBCL are underway, and we are pleased to have recently received FDA Orphan Drug designation for magrolimab in MDS. In parallel, we are preparing to advance FSI-174 and FSI-189 into the clinic, where we believe we can leverage our deep understanding of the CD47/SIRP α pathway to engage previously unexploited phagocytic pathways.”

Dr. McCamish continued, “Following our successful follow-on offering in December 2019, we are well financed, with sufficient resources to advance our pipeline through key milestones, including the potential submission of our first biologics license application for magrolimab, while scaling our CMC activities to support future product launches. We expect 2020 to be a year of notable progress across our portfolio, as we read out data for each of our magrolimab programs and accelerate ongoing efforts to offer magrolimab to genomically-defined patient populations, like TP53-mutant AML, where we believe our approach can offer targeted benefit. We will simultaneously progress our earlier-stage assets, FSI-174 and FSI-189, in hopes of delivering on the full potential of macrophage biology for people living with cancer and other serious diseases.”

Magrolimab – Registration-Enabling Programs

Forty Seven is focused on advancing magrolimab in registration-enabling programs for the treatment of patients with untreated, higher-risk myelodysplastic syndrome (MDS) and heavily-pretreated, relapsed or refractory diffuse large B-cell lymphoma (DLBCL). Magrolimab has previously been granted Fast Track designation by the FDA for the treatment of MDS and acute myeloid leukemia (AML), and for the treatment of relapsed or refractory DLBCL and follicular lymphoma, as well as Orphan Drug designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency for the treatment of AML. In December 2019, the FDA granted Orphan Drug designation to magrolimab for the treatment of MDS.

The company expects to achieve the following milestones in 2020:

Myelodysplastic Syndrome:

- Initiate Phase 3 ENHANCE trial evaluating the combination of magrolimab and azacitidine compared to azacitidine alone in patients with untreated, higher risk-MDS in the second quarter;
- Present updated data from the ongoing Phase 1b clinical trial evaluating the combination of magrolimab and azacitidine in untreated patients with higher risk MDS mid-year;
- Complete enrollment in the ongoing Phase 1b clinical trial in the third quarter.

Diffuse Large B-Cell Lymphoma:

- Initiate single-arm, registration-enabling trial evaluating the combination of magrolimab and rituximab in heavily pre-treated relapsed or refractory DLBCL patients who have failed at least two prior lines of therapy in the first quarter;
- Present initial data from the registration-enabling trial in the fourth quarter.

Magrolimab – Other Programs

Forty Seven will expand enrollment in its ongoing Phase 1b clinical trial evaluating the combination of magrolimab and azacitidine to include additional untreated TP53 mutant AML patients who are ineligible for induction chemotherapy to inform a potential registrational path. Updated data from this trial will be presented mid-year.

Additionally, Forty Seven is evaluating magrolimab for the treatment of colorectal (CRC) and ovarian cancer. Clinical data in patients with CRC and ovarian cancer will be presented at the ASCO Gastrointestinal Cancers Symposium (ASCO-GI), held January 23-25, 2020 in San Francisco, and the ASCO-SITC Clinical Immuno-Oncology Symposium, held February 6-8, 2020 in Orlando, respectively. While data from these studies do not support a path to registration, Forty Seven intends to use these results and learnings to identify its next steps in solid tumors.

Additional Pipeline Programs

Forty Seven is developing a broad pipeline of additional programs, which take advantage of the CD47/SIRP α pathway as a rich target for engaging macrophages. FSI-174, an anti-cKIT antibody, is being developed in combination with magrolimab as a novel, all-antibody conditioning regimen to address the limitations of current stem cell transplantation conditioning regimens. FSI-189, an anti-SIRP α antibody, is being developed for the treatment of cancer, as well as certain non-oncology conditions including transplantation conditioning.

The company expects to achieve the following milestones in 2020:

- Initiate a Phase 1 clinical trial evaluating the safety and tolerability of FSI-174 in healthy volunteers in the first quarter;
- File an investigational new drug application with the FDA for FSI-189 in the first quarter; and
- Initiate a Phase 1 clinical trial evaluating the safety and tolerability of FSI-189 for the treatment of cancer in the second quarter.

Cash Position and Financial Guidance:

Based on preliminary estimates, Forty Seven had cash, cash equivalents and short-term investments of \$329.1 million at December 31, 2019. Based on its current operating plans, Forty Seven expects that its cash, cash equivalents and short-term investments will fund operating expenses and capital expenditure requirements into the first quarter of 2022.

About Forty Seven, Inc.

Forty Seven, Inc. is a clinical-stage immuno-oncology company that is developing therapies targeting cancer immune evasion pathways and specific cell targeting approaches 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 "potential," "believe," "expect," "will," "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 potential of the innate immune system in the fight against disease, Forty Seven's potential-registration enabling programs for magrolimab in MDS and DLBCL, Forty Seven's success in advancing and

progressing FSI-174 and FSI-189 into the clinic, Forty Seven's potential to leverage the CD47/SIRP α pathway to engage previously unexploited phagocytic pathways, Forty Seven's progress across its portfolio, Forty Seven's achievement of milestones this year, initiation of and results from the Phase 3 ENHANCE trial evaluating the combination of magrolimab and azacitidine in patients with untreated, higher risk-MDS, the success of the ongoing Phase 1b clinical trial evaluating the combination of magrolimab and azacitidine in untreated patients with higher risk MDS, the initiation of a single-arm, registration-enabling trial evaluating the combination of magrolimab and rituximab in heavily pre-treated relapsed or refractory DLBCL patients, the expansion of enrollment in the ongoing Phase 1b clinical trial evaluating the combination of magrolimab and azacitidine to include additional untreated TP53 mutant AML patients, the outcome of the evaluation of magrolimab for the treatment of colorectal (CRC) and ovarian cancer, the development of FSI-174 in combination with magrolimab as a novel, all-antibody conditioning regimen to address the limitations of current stem cell transplantation conditioning regimens, the development of FSI-189 for the treatment of cancer, as well as certain non-oncology conditions including transplantation conditioning, the timing of reports of data from ongoing clinical trials and preclinical studies, the clinical potential of Forty Seven's product candidates, the expected 2020 milestones for Forty Seven's research programs generally, and Forty Seven's expected cash, cash equivalents and short-term investments as of December 31, 2019 and expected utilization of cash and investments into the first quarter of 2022.

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 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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