# 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, 2020

# SPRINGWORKS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-39044 (Commission File Number) 83-4066827 (I.R.S. Employer Identification No.)

100 Washington Blvd Stamford, CT 06902 (Address of principal executive offices, including zip code)

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(203) 883-9490

(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:

□ 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, par value \$0.0001 per share | SWTX              | 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 imes

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, 2020 SpringWorks Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2020. A copy of the press release issued in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended or the Exchange Act, except as expressly set forth by specific reference in such filing.

#### Item 9.01. Financial Statements and Exhibits.

#### (d) Exhibits.

| Exhibit |  |
|---------|--|
| No.     | Description  |
| 99.1    | Press Release issued by SpringWorks Therapeutics, Inc. on November 12, 2020, furnished herewith. |

#### 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.

SpringWorks Therapeutics, Inc.

By: <u>/s/ Francis I. Perier, Jr.</u>

Francis I. Perier, Jr. Chief Financial Officer

Date: November 12, 2020



## SpringWorks Therapeutics Reports Third Quarter 2020 Financial Results and Recent Business Highlights

- Enrollment Complete in the Phase 3 DeFi Trial of Nirogacestat in Adult Patients with Desmoid Tumors -

- Clinical Collaborations Signed with Janssen, Pfizer and Precision Biosciences to Evaluate Nirogacestat in Combination with BCMA-Directed Therapies Across Modalities for the Treatment of Patients with Relapsed or Refractory Multiple Myeloma -

- Entered into Sponsored Research Agreement with Fred Hutchinson Cancer Research Center to Further Evaluate Nirogacestat as a BCMA Potentiator in Multiple Myeloma -

- Completed an Asset Purchase and Exclusive License Agreement of Global Rights to FAAH Inhibitor PF-04457845 to Jazz Pharmaceuticals, Receiving \$35 Million Upfront Payment and Potential Future Milestone Payments of Up to \$375 Million -

- Raised \$269.5 Million in Net Proceeds Through Follow-On Public Offering -

**STAMFORD, Conn. – November 12, 2020** – SpringWorks Therapeutics, Inc. (Nasdaq: SWTX), a clinical-stage biopharmaceutical company focused on developing life-changing medicines for patients with severe rare diseases and cancer, today reported third quarter financial results for the period ended September 30, 2020 and provided an update on recent company developments.

"We are very pleased with our achievements in the third quarter of 2020 across our clinical development, business development and corporate initiatives. We completed enrollment in the Phase 3 DeFi trial, advanced our strategy to develop nirogacestat as a cornerstone of BCMA combination therapy for patients with multiple myeloma by signing additional collaborations with industry and academic leaders, and continued to progress our trials in biomarker defined metastatic solid tumors," said Saqib Islam, Chief Executive Officer of SpringWorks. "Our ten clinical development programs are progressing as planned and we look forward to providing further updates as we advance our pipeline and continue to execute on our strategy to build a leading targeted oncology company."

#### **Recent Business Highlights and Upcoming Milestones**

#### Late-Stage Rare Oncology

 Completed enrollment in the Phase 3 DeFi trial evaluating nirogacestat in adult patients with progressing desmoid tumors. SpringWorks expects to report topline data from the DeFi study in the second or third quarter of 2021.

- Recruiting patients in a Phase 2 study sponsored by the Children's Oncology Group evaluating nirogacestat in pediatric patients with desmoid tumors.
- Highlighted a publication by investigators at the University of Minnesota and the Dana-Farber Cancer Institute in the *Pediatric Cancer & Blood* journal reporting data from four pediatric and young adult desmoid tumor patients who received nirogacestat under the SpringWorks Expanded Access Program. In these four patients, the investigators reported one complete response, two partial responses, and one stable disease, with no grade 3 or 4 adverse events.
- Enrollment is ongoing in the Phase 2b ReNeu trial evaluating mirdametinib in pediatric and adult patients with NF1-associated plexiform neurofibromas. SpringWorks expects to provide an update on the ReNeu trial in the fourth quarter of 2020 or first quarter of 2021.

# B-cell Maturation Antigen (BCMA) Combinations in Multiple Myeloma

- Enrollment is ongoing in a Phase 1b trial evaluating nirogacestat in combination with BLENREP (belantamab mafodotin-blmf), GSK's anti-B-cell maturation antigen (BCMA) antibody-drug conjugate, in patients with relapsed or refractory multiple myeloma.
- Entered into a clinical collaboration with Janssen Biotech, Inc. (Janssen) to evaluate nirogacestat in combination with Janssen's BCMA CD3 bispecific antibody, teclistamab, in patients with relapsed or refractory multiple myeloma. A Phase 1 study is expected to commence by early 2021, pending discussions with regulators.
- Entered into a clinical collaboration with Pfizer Inc. (Pfizer) to evaluate nirogacestat in combination with Pfizer's BCMA CD3 bispecific antibody, PF-06863135, in patients with relapsed or refractory multiple myeloma. A Phase 1b/2 study is expected to commence in the first half of 2021.
- An IND application is expected to be filed by the end of 2020 to evaluate nirogacestat in combination with Allogene's BCMA AlloCAR T therapy, ALLO-715, in patients with relapsed or refractory multiple myeloma.
- Entered into a clinical collaboration with Precision BioSciences, Inc. (Precision) to evaluate nirogacestat in combination with Precision's allogeneic CAR T candidate targeting BCMA, PBCAR269A, in patients with relapsed or refractory multiple myeloma. A Phase 1/2a clinical study is expected to commence in the first half of 2021, pending discussions with regulators.
- Entered into a sponsored research agreement with Fred Hutchinson Cancer Research Center (Fred Hutch) to further explore the ability of nirogacestat to modulate BCMA and potentiate BCMA-targeting therapies in a variety of preclinical and patient-derived multiple myeloma models developed by researchers at Fred Hutch.

## **Biomarker-Defined Metastatic Solid Tumors**

- Enrollment is ongoing in a Phase 1b/2 trial evaluating mirdametinib with BeiGene's RAF dimer inhibitor, lifirafenib, in patients with *RAS/RAF* mutant and other MAPK pathway aberrant solid tumors. SpringWorks and BeiGene expect to report initial clinical data in 2021.
- Enrollment is ongoing in a Phase 1 trial of BGB-3245 in patients with RAF mutant solid tumors. BGB-3245 is a selective RAF dimer inhibitor being developed by MapKure, LLC, an entity that is jointly owned by SpringWorks and BeiGene, Ltd. Initial clinical data from the Phase 1 study are expected in 2021.

## **General Corporate**

- In October 2020, SpringWorks completed a follow-on public offering that raised \$269.5 million in net proceeds, which included the underwriters' full exercise of their option to purchase additional shares of common stock.
- SpringWorks and Jazz Pharmaceuticals entered into an asset purchase and exclusive license agreement under which Jazz acquired SpringWorks' fatty acid amide hydrolase (FAAH) inhibitor program, PF-04457845. Under the terms of the agreement, Jazz assumed all milestone and royalty obligations owned by SpringWorks to Pfizer under the 2017 license agreement pursuant to which SpringWorks obtained rights to this asset. In addition, Jazz made an upfront payment of \$35 million to SpringWorks, with potential future milestone payments of up to \$375 million payable to SpringWorks based upon the achievement of certain clinical development, regulatory and commercial milestones. SpringWorks is also entitled to receive tiered royalties on future net sales of PF-04457845.

#### Third Quarter and Year to Date 2020 Financial Results

- Research and Development (R&D) Expenses: R&D expenses were \$13.9 million and \$36.6 million for the third quarter and year-to-date periods, respectively, compared to \$10.7 million and \$30.4 million for the comparable periods of 2019, respectively. The increases in R&D expenses in 2020 were primarily attributable to growth in employee costs associated with increases in the number of R&D personnel, an increase in non-cash share-based compensation expense and increases in external costs related to drug manufacturing and clinical trial costs.
- General and Administrative (G&A) Expenses: G&A expenses were \$7.7 million and \$20.9 million for the third quarter and year-to-date periods, respectively, compared to \$4.6 million and \$11.5 million for the comparable periods of 2019, respectively. The increases in G&A expenses in 2020 were primarily attributable to growth in employee costs associated with increases in the number of G&A personnel supporting the growth of the organization, and an increase in non-cash share-based compensation expenses, as well as increases in expenses related to the expansion of business activities.
- Net Loss Attributable to Common Stockholders: SpringWorks reported net losses of \$21.7 million, or \$0.51 loss per share, and \$56.8 million, or \$1.35 loss per share, for the third quarter and year-to-date periods ended September 30, 2020, respectively. This compares to net losses of \$16.8 million, or \$1.77 loss per share, and \$34.4 million, or \$9.24 loss per share, for the comparable periods of 2019, respectively.
- Cash Position: Cash, cash equivalents and marketable securities were \$276.8 million as of September 30, 2020. This does not include the net proceeds of \$269.5 million from the Company's follow-on public offering completed in October 2020 or the \$35 million upfront payment Jazz Pharmaceuticals made to SpringWorks in October 2020.

#### COVID-19 Update

To date, the COVID-19 pandemic has had a relatively modest impact on SpringWorks' business operations, in particular on SpringWorks' clinical trial programs, and SpringWorks is undertaking considerable efforts to mitigate the various challenges presented by this crisis. For further details and descriptions of the risks associated with the COVID-19 pandemic, please see the Risk Factors in SpringWorks' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2020 and refer to the Forward-Looking Statements section in this press release.

# About SpringWorks Therapeutics

SpringWorks is a clinical-stage biopharmaceutical company applying a precision medicine approach to acquiring, developing and commercializing life-changing medicines for underserved patient populations suffering from devastating rare diseases and cancer. SpringWorks has a differentiated portfolio of small molecule targeted oncology product candidates and is advancing two potentially registrational clinical trials in rare tumor types, as well as several other programs addressing highly prevalent, genetically defined cancers. SpringWorks' strategic approach and operational excellence in clinical development have enabled it to rapidly advance its two lead product candidates into late-stage clinical trials while simultaneously entering into multiple shared-value partnerships with industry leaders to expand its portfolio. For more information, visit www.springworkstx.com and follow @SpringWorksTx on Twitter and LinkedIn.

SpringWorks uses its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. Such disclosures will be included on the Company's website in the 'Investors & Media' section. Accordingly, investors should monitor such portions of the SpringWorks website, in addition to following press releases, SEC filings and public conference calls and webcasts.

#### **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding SpringWorks' clinical trials and its strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those related to SpringWorks' financial results, the timing for completion of SpringWorks' clinical trials of its product candidates, whether and when, if at all, SpringWorks' product candidates will receive approval from the U.S. Food and Drug Administration, or FDA, or other foreign regulatory authorities, uncertainties and assumptions regarding the impact of the COVID-19 pandemic on SpringWorks' business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, and other risks identified in SpringWorks' SEC filings. SpringWorks cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. SpringWorks disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent SpringWorks' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

# SpringWorks Therapeutics, Inc. Condensed Consolidated Statements of Operations (Unaudited)

|  | Three Months Ended September 30, |                  |      | Nine Months End |      | ed September 30, |      |           |
|--|----------------------------------|------------------|------|-----------------|------|------------------|------|-----------|
| (in thousands, except share and per-share data)        | 2020                             |                  | 2019 |                 | 2020 |                  | 2019 |           |
| Operating expenses:                                    |                                  |                  |      |                 |      |                  |      |           |
| Research and development                               | \$                               | 13,923           | \$   | 10,745          | \$   | 36,597           | \$   | 30,373    |
| General and administrative                             |                                  | 7,669            |      | 4,584           |      | 20,946           |      | 11,495    |
| Total operating expenses                               |                                  | 21,592           |      | 15,329          |      | 57,543           |      | 41,868    |
|  |                                  |                  |      |                 |      |                  |      |           |
| Loss from operations                                   |                                  | (21,592)         |      | (15,329)        |      | (57,543)         |      | (41,868)  |
| Other income:  |                                  |                  |      |                 |      |                  |      |           |
| Interest income, net                                   |                                  | 63               |      | 997             |      | 1,156            |      | 2,280     |
| Total other income                                     |                                  | 63               |      | 997             |      | 1,156            |      | 2,280     |
| Equity investment loss                                 |                                  | (130)            | _    | (2,501)         |      | (459)            |      | (2,501)   |
| Net loss   | \$                               | (21,659)         | \$   | (16,833)        | \$   | (56,846)         | \$   | (42,089)  |
|  |                                  |                  |      |                 |      |                  |      |           |
| Reconciliation of net loss to net loss attributable to |                                  |                  |      |                 |      |                  |      |           |
| common stockholders:                                   |                                  |                  |      |                 |      |                  |      |           |
| Net loss   | \$                               | (21,659)         | \$   | (16,833)        | \$   | (56,846 <u>)</u> | \$   | (42,089)  |
| Net gain attributable to extinguishment of Series A    |                                  |                  |      |                 |      |                  |      |           |
| convertible preferred and Junior Series A convertible  |                                  |                  |      |                 |      |                  |      |           |
| preferred units  |                                  |                  |      |                 |      |                  |      | 7,729     |
| Net loss attributable to common stockholders           | \$                               | (21,659 <u>)</u> | \$   | (16,833)        | \$   | (56,846 <u>)</u> | \$   | (34,360)  |
|  |                                  |                  |      |                 |      |                  |      |           |
|  |                                  |                  | •    |                 | •    | (1.05)           |      |           |
| Net loss per share, basic and diluted                  | \$                               | (0.51)           | \$   | (1.77)          | \$   | (1.35)           | \$   | (9.24)    |
| Weighted average common shares outstanding, basic      |                                  | 40 1 40 007      |      | 0 407 000       |      | 41 001 001       |      | 0 710 077 |
| and diluted  |                                  | 42,148,837       |      | 9,487,329       |      | 41,961,691       |      | 3,716,877 |

# SpringWorks Therapeutics, Inc. Selected Balance Sheet Data (Unaudited)

| (In thousands)                                   | Se | September 30, 2020 |    | December 31, 2019 |  |  |
|--|----|--------------------|----|-------------------|--|--|
| Cash, cash equivalents and marketable securities | \$ | 276,819            | \$ | 327,652           |  |  |
| Working Capital <sup>(1)</sup>                   |    | 266,150            |    | 319,391           |  |  |
| Total Assets                                     |    | 286,100            |    | 334,831           |  |  |
| Total liabilities                                |    | 13,345             |    | 12,759            |  |  |
| Accumulated deficit                              |    | (129,875)          |    | (73,029)          |  |  |
| Total stockholders' (deficit) equity             |    | 272,755            |    | 322,072           |  |  |

(1) We define working capital as current assets less current liabilities.

# Contact:

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