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

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2024
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM _ TO _

COMMISSION FILE NUMBER 001-39044

SPRINGWORKS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	83-4066827
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
100 Washington Blvd Stamford, Connecticut	06902
(Address of principal executive offices)	**(Zip Code)**

(203) 883-9490
(Registrant's telephone number, including area code)

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of outstanding shares of the Registrant's Common Stock as of November 5, 2024 was 74,386,403.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, these forward-looking statements can be identified by the use of words such as “may”, “will”, “should”, “expects”, “intends”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential”, “continue” or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our ability to continue commercializing OGSIVEO® (nirogacestat), including our ability to successfully maintain commercial manufacturing and supply chains for OGSIVEO, and our expectations regarding the size and growth potential of the commercial markets for OGSIVEO;
- the timing and outcome of our regulatory submissions and interactions, including the decision on the New Drug Application, or NDA, for mirdametinib for patients with neurofibromatosis type 1-associated plexiform neurofibromas, or NF1-PN, which was accepted by United States Food and Drug Administration, or FDA, in August 2024 and granted priority review with an assigned Prescription Drug User Fee Act, or PDUFA, target action date of February 28, 2025, the decision on the Marketing Authorization Application, or MAA, for mirdametinib for patients with NF1-PN that we received validation for in August 2024 by the European Medicines Agency, or EMA, and the decision on the MAA filing for nirogacestat that we received validation for in February 2024 by the EMA, as well as our interactions with other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies;
- the success, cost and timing of our product development activities and clinical trials, the initiation and completion of any other clinical trials and related preparatory work, the expected timing of the availability of results of our clinical trials, and the registrational nature of the Phase 2b clinical trial of mirdametinib in NF1-PN patients;
- the fact that topline or interim data from our clinical studies may not be predictive of the final or more detailed results of such study or the results of other ongoing or future studies;
- our ability and our partners’ ability to successfully complete clinical trials of our product candidates for additional uses, and in combination with other agents;
- the potential attributes and benefits of our product candidates;
- our plans to commercialize any of our product candidates that achieve approval either alone or in partnership with others;
- the period over which we anticipate our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operating expenses and capital expenditure requirements;
- the potential for our business development efforts to maximize the potential value of our portfolio;
- our ability to identify, in-license or acquire additional product candidates;
- the ability and willingness of our third-party collaborators to continue research and development activities relating to our product candidates, including those that are being developed as combination therapies;
- our ability to obtain and maintain regulatory approval for our product candidates, and any related restrictions, limitations or warnings in the label of an approved product;
- the potential benefit of orphan drug exclusivity, Orphan Drug Designation, Fast Track Designation, Breakthrough Therapy Designation, and Rare Pediatric Disease Designation for nirogacestat, mirdametinib and any other of our product candidates that may receive one or more of these designations;
- our ability to compete with companies currently marketing or engaged in the development of treatments for desmoid tumors, NF1-PN and other oncology and rare disease indications;

- our expectations regarding our ability to obtain and maintain intellectual property protection or market exclusivity for our product candidates and the duration of such protection;
- our ability and the potential to successfully manufacture our product candidates for preclinical studies, clinical trials and, if approved, for commercial use, the capacity of our current contract manufacturing organizations, or CMOs, to support clinical supply and commercial-scale production for product candidates and our potential election to pursue additional CMOs for manufacturing supplies of drug substance and finished drug product in the future;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets, either alone or in partnership with others;
- the rate and degree of market acceptance of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing products that are or may become available;
- risks associated with global economic conditions, including inflation or uncertainty caused by political violence and unrest, including the ongoing global and regional conflicts;
- our ability to attract and retain key scientific, medical, commercial and management personnel;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events and future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part II, Item 1A, Risk Factors and elsewhere in this Quarterly Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information provided. Unless otherwise expressly stated, we obtained this industry information, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in each case, from sources we consider to be reliable, and in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

SPRINGWORKS THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2024
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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

SpringWorks Therapeutics, Inc.
Condensed Consolidated Balance Sheets (Unaudited)

(in thousands, except share and per-share data)	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 84,456	$ 176,053
Marketable securities	292,163	303,149
Accounts receivable, net	32,972	5,930
Inventory	9,826	3,103
Prepaid expenses and other current assets	15,694	12,677
Total current assets	435,111	500,912
Long-term marketable securities	121,504	183,386
Property and equipment, net	19,336	17,943
Operating lease right-of-use assets	6,026	6,144
Equity method investment	5,580	1,955
Restricted cash	621	613
Other assets	20,700	14,835
Total assets	$ 608,878	$ 725,788
Liabilities and Stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,654	$ 7,396
Accrued expenses	59,733	65,569
Operating lease liabilities, current	1,226	1,061
Deferred revenue, current	—	4,144
Total current liabilities	70,613	78,170
Operating lease liabilities, long-term	5,684	5,996
Deferred revenue, long-term	—	15,403
Total liabilities	76,297	99,569
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding at September 30, 2024 and December 31, 2023.	—	—
Common stock, $0.0001 par value, 150,000,000 shares authorized, 74,663,748 and 73,620,361 shares issued and 74,335,279 and 73,486,699 shares outstanding at September 30, 2024 and December 31, 2023, respectively.	7	7
Additional paid-in capital	1,618,891	1,524,196
Accumulated deficit	(1,075,868)	(895,034)
Treasury stock, at cost (194,807 and 133,662 shares of common stock at September 30, 2024 and December 31, 2023, respectively).	(12,056)	(4,141)
Accumulated other comprehensive (loss) income	1,607	1,191
Total stockholders' equity	532,581	626,219
Total liabilities and stockholders' equity	$ 608,878	$ 725,788

See accompanying unaudited notes to condensed consolidated financial statements

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

(in thousands, except share and per-share data)	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Revenue:				
Product revenue, net	$ 49,301	$ —	$ 110,493	$ —
Other revenue	—	—	19,547	—
Total revenue	49,301	—	130,040	—
Operating costs and expenses:				
Cost of product revenue	3,341	—	6,996	—
Selling, general and administrative	61,601	46,546	179,553	137,715
Research and development	42,296	37,453	140,280	106,835
Total operating costs and expenses	107,238	83,999	326,829	244,550
Loss from operations	(57,937)	(83,999)	(196,789)	(244,550)
Interest and other income:				
Interest and other income, net	6,216	5,586	20,565	16,971
Total interest and other income	6,216	5,586	20,565	16,971
Equity method investment loss	(1,809)	(1,024)	(4,610)	(3,203)
Net loss	$ (53,530)	$ (79,437)	$ (180,834)	$ (230,782)
Net loss per share, basic and diluted	$ (0.72)	$ (1.27)	$ (2.44)	$ (3.70)
Weighted average common shares outstanding, basic and diluted	74,264,501	62,521,772	74,052,151	62,386,496

See accompanying unaudited notes to condensed consolidated financial statements

SpringWorks Therapeutics, Inc.
Condensed Consolidated Statements of Comprehensive Loss (Unaudited)

(in thousands)	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Net loss	$ (53,530)	$ (79,437)	$ (180,834)	$ (230,782)
Changes in other comprehensive income:				
Unrealized gain on marketable securities, net	2,127	39	416	454
Total changes in other comprehensive income	$ 2,127	$ 39	$ 416	$ 454
Comprehensive loss	$ (51,403)	$ (79,398)	$ (180,418)	$ (230,328)

See accompanying unaudited notes to condensed consolidated financial statements

SpringWorks Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Common		Treasury					
(in thousands, except share data)	**Shares**	**Amount**	**Shares**	**Amount**	**Additional Paid-In Capital**	**Accumulated Other Comprehensive Income (Loss)**	**Accumulated Deficit**	**Total**
Balance at June 30, 2023	62,679,065	$ 6	114,630	$ (3,624)	$ 1,176,686	$ (352)	$ (721,275)	$ 451,441
Equity-based compensation expense					23,099			23,099
Forfeitures of restricted stock awards	(3,939)	—						—
Restricted stock units vested	17,272	—						—
Exercise of stock options	6,468	—			21			21
Shares of common stock used to satisfy tax withholding obligations			9,170	(264)				(264)
Other comprehensive loss, net of tax						39		39
Net loss							(79,437)	(79,437)
Balance at September 30, 2023	62,698,866	$ 6	123,800	$ (3,888)	$ 1,199,806	$ (313)	$ (800,712)	$ 394,899
Balance at June 30, 2024	74,571,844	$ 7	315,458	$ (11,557)	$ 1,591,138	$ (520)	$ (1,022,338)	$ 556,730
Equity-based compensation expense					25,963			25,963
Forfeitures of restricted stock awards	(1,392)	—						—
Restricted stock units vested	28,815	—						—
Exercise of stock options	64,481	—			1,790			1,790
Shares of common stock used to satisfy tax withholding obligations			13,011	(499)				(499)
Other comprehensive loss, net of tax						2,127		2,127
Net loss							(53,530)	(53,530)
Balance at September 30, 2024	74,663,748	$ 7	328,469	$ (12,056)	$ 1,618,891	$ 1,607	$ (1,075,868)	$ 532,581

	Common		Treasury					
(in thousands, except share data)	**Shares**	**Amount**	**Shares**	**Amount**	**Additional Paid-In Capital**	**Accumulated Other Comprehensive Income (Loss)**	**Accumulated Deficit**	**Total**
Balance at December 31, 2022	62,453,328	$ 6	30,199	$ (1,341)	$ 1,130,224	$ (767)	$ (569,930)	$ 558,192
Equity-based compensation expense					69,467			69,467
Forfeitures of restricted stock awards	(15,485)	—						—
Restricted stock units vested	219,142	—						—
Exercise of stock options	41,881	—			115			115
Shares of common stock used to satisfy tax withholding obligations			93,601	(2,547)				(2,547)
Other comprehensive income, net of tax						454		454
Net loss							(230,782)	(230,782)
Balance at September 30, 2023	62,698,866	$ 6	123,800	$ (3,888)	$ 1,199,806	$ (313)	$ (800,712)	$ 394,899
Balance at December 31, 2023	73,620,361	$ 7	133,662	$ (4,141)	$ 1,524,196	$ 1,191	$ (895,034)	$ 626,219
Equity-based compensation expense					82,670			82,670
Forfeitures of restricted stock awards	(4,815)	—						—
Restricted stock units vested	514,760	—						—
Exercise of stock options	533,442	—			12,025			12,025
Shares of common stock used to satisfy tax withholding obligations			194,807	(7,915)				(7,915)
Other comprehensive loss, net of tax						416		416
Net loss							(180,834)	(180,834)
Balance at September 30, 2024	74,663,748	$ 7	328,469	$ (12,056)	$ 1,618,891	$ 1,607	$ (1,075,868)	$ 532,581

See accompanying unaudited notes to condensed consolidated financial statements

SpringWorks Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**
Operating activities		
Net loss	$ (180,834)	$ (230,782)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	2,451	1,129
Non-cash operating lease expense	1,523	1,176
Equity-based compensation expense	82,670	69,467
Equity method investment loss	4,610	3,203
Changes in operating assets and liabilities		
Accounts receivable, net	(27,042)	—
Inventory	(6,723)	—
Prepaid expenses and other current assets	(3,017)	(2,416)
Other assets	(1,298)	(686)
Accounts payable	1,940	(2,261)
Accrued expenses	720	1,943
Deferred revenue	(19,547)	—
Lease liability	(1,552)	(863)
Net cash used in operating activities	$ (146,099)	$ (160,090)
Investing activities		
Capital expenditures	(3,399)	(9,687)
Payment for intangible asset	(11,250)	—
Equity method investment	(8,235)	(2,800)
Purchases of marketable securities	(204,257)	(309,276)
Proceeds from sale and maturity of marketable securities	277,541	515,722
Net cash provided by investing activities	$ 50,400	$ 193,959
Financing activities		
Treasury stock	(7,915)	(2,547)
Proceeds from stock option exercises	12,025	115
Net cash provided by (used in) financing activities	$ 4,110	$ (2,432)
Net (decrease) increase in cash and cash equivalents	(91,589)	31,437
Cash and cash equivalents including Restricted cash, beginning of period	176,666	68,068
Cash and cash equivalents including Restricted cash, end of period	$ 85,077	$ 99,505
Non-cash investing activities		
Right-of-use assets obtained in exchange for operating lease obligations	$ 877	$ 2,637

See accompanying unaudited notes to condensed consolidated financial statements

SpringWorks Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Nature of Operations

SpringWorks Therapeutics, Inc., together with its wholly-owned subsidiaries, collectively, the Company, is a commercial-stage biopharmaceutical company applying a precision medicine approach to developing and commercializing life-changing medicines for underserved patient populations suffering from devastating rare diseases and cancer. The Company has a differentiated portfolio of small molecule targeted oncology assets, including one approved product, one product candidate under regulatory review for approval, and several clinical candidates, and is advancing programs in both rare tumor types as well as highly prevalent, genetically defined cancers. OGSIVEO® (nirogacestat) is the Company's first commercial product. OGSIVEO was approved by the United States Food and Drug Administration, or FDA, on November 27, 2023 for the treatment of adult patients with progressing desmoid tumors who require systemic treatment.

The Company has incurred losses and negative operating cash flows since inception and had an accumulated deficit of $1.1 billion and $895.0 million, and working capital of $364.5 million and $422.7 million, as of September 30, 2024 and December 31, 2023, respectively. For the three and nine months ended September 30, 2024, the Company recorded net product revenue of $49.3 million and $110.5 million, respectively, from sales of OGSIVEO.

The Company had cash, cash equivalents and marketable securities of $498.1 million and $662.6 million as of September 30, 2024 and December 31, 2023, respectively. Based on the Company's cash, cash equivalents and marketable securities as of September 30, 2024, management estimates that its current liquidity will enable it to meet operating expenses through at least twelve months after the date that these financial statements are issued.

2. Basis of Presentation

The Company's unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP, for interim financial information and Article 10 of Regulation S-X of the Securities and Exchange Commission, or SEC, and should be read in conjunction with the Company's consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 27, 2024. The condensed consolidated financial statements presented in this Quarterly Report on Form 10-Q are unaudited; however, in the opinion of management, such financial statements reflect all adjustments, consisting solely of normal recurring adjustments, necessary for a fair presentation of the results for the interim periods presented.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, research and development expenses, valuation of equity-based compensation awards and variable consideration and other relevant inputs impacting the gross to net revenue recognition adjustments. Management bases its estimates on historical experience, known trends and other market-specific or relevant factors that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions. On an ongoing basis, management evaluates its estimates, and adjusts those estimates and assumptions when facts or circumstances change. Changes in estimates are recorded in the period in which they become known.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 3 to the Company's audited consolidated financial statements included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 27, 2024. There have been no significant changes in the Company's significant accounting policies from those disclosed in its Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 27, 2024.

Recently Adopted Accounting Pronouncements

There were no recently adopted accounting pronouncements that had a material impact on the Company's financial statements.

In November 2023, the FASB issued ASU 2023-07, Improvements to Reportable Segment Disclosures, which requires disclosure of incremental segment information on an annual and interim basis. The effective date for the standard is for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. The Company is currently evaluating the effect of this pronouncement on its disclosures.

3. Marketable Securities

The following table summarizes the Company's available-for-sale marketable securities as of September 30, 2024 and December 31, 2023:

(in thousands)	As of September 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Marketable securities:				
Short-term investments:				
U.S. government securities	$ 191,957	$ 600	$ —	$ 192,557
Corporate debt securities	40,063	193	—	40,256
Commercial paper	59,350	—	—	59,350
Long-term investments:				
U.S. government securities	77,101	292	—	77,393
Corporate debt securities	43,589	522	—	44,111
Total	$ 412,060	$ 1,607	$ —	$ 413,667

(in thousands)	As of December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Marketable securities:				
Short-term investments:				
U.S. government securities	$ 228,579	$ 212	$ —	$ 228,791
Corporate debt securities	9,629	2	—	9,631
Commercial paper	64,724	3	—	64,727
Long-term investments:				
U.S. government securities	141,102	755	—	141,857
Corporate debt securities	41,310	219	—	41,529
Total	$ 485,344	$ 1,191	$ —	$ 486,535

The Company's marketable securities are available-for-sale securities and consist of high-quality, highly liquid debt securities including corporate debt securities, U.S. government securities, non-U.S. government securities, and commercial paper.

The Company's securities classified as short-term marketable securities mature within one year or less of the balance sheet date. Marketable securities that mature greater than one year from the balance sheet date are classified as long-term. As of September 30, 2024, the Company did not hold any investments with maturity dates greater than five years.

As of, and for, the three and nine months ended September 30, 2024, the Company did not have any allowance for credit losses or impairments of its marketable securities.

4. Fair Value Measurements

The fair value of the Company's financial assets measured on a recurring basis are classified based upon a fair value hierarchy consisting of the following three levels:

Level 1 — Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets, or liabilities.

Level 2 — Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the instrument.

Level 3 — Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The fair value hierarchy is based on inputs to valuation techniques used to measure fair value that are either observable or unobservable. Observable inputs reflect assumptions market participants would use in pricing an asset or liability based on market data obtained from independent sources while unobservable inputs reflect a reporting entity's pricing based upon their own market assumptions.

As of September 30, 2024 and December 31, 2023, the Company's financial assets and liabilities measured at fair value on a recurring basis consisted of the following:

	As of September 30, 2024			
		Fair Value Hierarchy		
(in thousands)	**Total**	**Level 1**	**Level 2**	**Level 3**
Financial instruments carried at fair value (asset position):				
Cash equivalents:				
Money market funds	$ 54,605	$ 54,605	$ —	$ —
Short-term investments:				
U.S. government securities	192,557	192,557	—	—
Corporate debt securities	40,256	—	40,256	—
Commercial paper	59,350	—	59,350	—
Long-term investments:				
U.S. government securities	77,393	77,393	—	—
Corporate debt securities	44,111	—	44,111	—
Total	$ 468,272	$ 324,555	$ 143,717	$ —

	As of December 31, 2023			
		Fair Value Hierarchy		
(in thousands)	**Total**	**Level 1**	**Level 2**	**Level 3**
Financial instruments carried at fair value (asset position):				
Cash equivalents:				
Money market funds	$ 14,434	$ 14,434	$ —	$ —
Commercial paper	49,631	—	49,631	—
Short-term investments:				
U.S. government securities	228,791	228,791	—	—
Corporate debt securities	9,631	—	9,631	—
Commercial paper	64,727	—	64,727	—
Long-term investments:				
U.S. government securities	141,857	141,857	—	—
Corporate debt securities	41,529	—	41,529	—
Total	$ 550,600	$ 385,082	$ 165,518	$ —

As of September 30, 2024 and December 31, 2023, the Company’s financial assets measured at fair value on a recurring basis using a market approach included cash equivalents, which consist of money market funds, and marketable securities, which consist of high-quality, highly liquid available-for-sale debt securities including corporate debt securities, U.S. government securities, and commercial paper.

The Company's money market funds are readily convertible into cash and the net asset value of each fund on the last day of the quarter is used to determine fair value. The U.S. government securities are classified as Level 1 and valued utilizing quoted market prices. The Company's corporate debt securities, and commercial paper are classified as Level 2 and valued utilizing various market and industry inputs.

The Company considers all highly liquid instruments that have maturities of three months or less when acquired to be cash equivalents. The carrying amounts for cash equivalents, accounts payable, and accrued expenses approximate fair value due to their short-term maturities.

5. Collaboration, Licensing and Variable Interest Entities

MapKure

In June 2019, the Company announced the formation of MapKure LLC, or MapKure, an entity jointly owned by the Company and BeiGene Ltd., or BeiGene. BeiGene licensed to MapKure exclusive rights to brimarafenib (BGB-3245), an investigational oral, small molecule selective inhibitor of specific BRAF driver mutations and genetic fusions. MapKure is advancing brimarafenib through clinical development for solid tumor patients harboring BRAF driver mutations and genetic fusions that were observed to be sensitive to the compound in preclinical studies. In addition to the Company's equity ownership in MapKure, the Company maintains a member on each of MapKure's joint steering committee and board of directors. The Company also contributes to clinical development and other operational activities for brimarafenib through a service agreement with MapKure.

In June 2019, the Company purchased 3,500,000 Series A preferred units of MapKure for $3.5 million and in June 2020, the Company purchased an additional 3,500,000 Series A preferred units of MapKure for $3.5 million, each pursuant to the terms of the Series A preferred unit purchase agreement. In June 2022, the Company made an additional investment in MapKure and purchased 4,200,000 Series B preferred units of MapKure for $4.2 million and in January 2023, the Company purchased an additional 2,800,000 Series B preferred units of MapKure for $2.8 million, pursuant to the terms of the Series B preferred unit purchase agreement.

In January 2024, the Company made an additional investment in MapKure and purchased 8,235,200 Series C preferred units of MapKure for $8.2 million, pursuant to the terms of a Series C preferred unit purchase agreement. The Company is required to make subsequent purchases at each of the second and third closings established by such agreement, in each case for an additional 6,176,400 Series C preferred units of MapKure for $6.2 million. As of September 30, 2024, the Company's ownership interest in MapKure was 39.7%.

The Company determined that MapKure is a variable interest entity. The Company is not the primary beneficiary, as the Company does not have the power to direct the activities that most significantly impact the economic performance of MapKure. Accordingly, the Company does not consolidate the financial statements of this entity and accounts for this investment using the equity method of accounting based on a one quarter lag.

The Company recognized an equity loss of $1.8 million and $4.6 million for the three and nine months ended September 30, 2024, respectively, and $1.0 million and $3.2 million for the three and nine months ended September 30, 2023, respectively. The Company's ownership interest in MapKure is included in Equity method investments. As of September 30, 2024, the Company's maximum exposure to loss as a result of the Company's involvement with MapKure is $18.0 million, representing the carrying value of the investment of $5.6 million plus the unfunded obligation of $12.4 million.

GSK Expanded Non-exclusive License and Collaboration Agreement

In September 2022, the Company announced an expansion of its non-exclusive clinical collaboration with GSK plc, formerly GlaxoSmithKline plc, which originally commenced in June 2019. The announcement coincided with the entry by the Company and GlaxoSmithKline Intellectual Property Development Ltd, or GSK, into an amended and restated collaboration and license agreement, or the GSK License Agreement, for the potential continued development and commercialization of nirogacestat in combination with either belantamab mafodotin (belamaf), GSK's antibody-drug conjugate, or ADC, targeting B-cell maturation antigen, or BCMA, or any other cytotoxic ADC targeting BCMA derived from belantamab that is controlled by GSK, either alone as a combination therapy, or together with other pharmaceutical agents.

Pursuant to the terms of the GSK License Agreement and concurrent with the execution of such agreement, the Company entered into a Stock Purchase Agreement with an affiliate of GSK, Glaxo Group Limited, or GGL, under which GGL purchased 2,050,819 shares of the Company's Common Stock, par value $0.0001 per share, or Common Stock, in a private placement transaction for an aggregate purchase price of approximately $75.0 million, or $36.57 per share. The shares were sold at a 25% premium to the volume-weighted average share price of the Common Stock for a specified 30-day period prior to entering into the Stock Purchase Agreement. The fair value of the Common Stock based on the closing price of Common Stock on the day prior to the effective date of the Stock Purchase Agreement was $55.5 million and was recorded to equity. The $19.5 million of consideration received in excess of the fair value of the Common Stock represented consideration for the license for the potential continued development and commercialization of nirogacestat in combination with GSK compounds, together with the clinical supply of nirogacestat for future belamaf clinical trials and certain research and development costs associated with nirogacestat. The Company recorded the $19.5 million as deferred revenue in September of 2022, and determined that the Company would recognize revenue as the corresponding performance obligations were satisfied in proportion to expenses incurred, including clinical supply and research and development expenses, associated with the GSK License Agreement.

On June 6, 2024, the Company announced that it received notice of termination of the GSK License Agreement from GSK. The termination becomes effective 180 days after the date of receipt of the notice of termination. Once the termination becomes effective, the non-exclusive licenses granted by the Company to GSK under the GSK License Agreement will terminate. Termination of the GSK License Agreement does not trigger any payment obligations on the part of the Company or any other material costs. As a result of the termination, the Company fully recognized all previously deferred revenue associated with the GSK License Agreement during the quarter ended June 30, 2024. The $19.5 million recognized is classified as "Other Revenue" in the condensed consolidated statement of operations.

6. Accrued Expenses

Accrued expenses consists of the following:

(in thousands)	September 30, 2024	December 31, 2023
Accrued compensation and benefits	$ 20,311	$ 26,047
Accrued research and development	14,223	15,129
Accrued milestone	5,000	11,250
Accrued other	20,199	13,143
Total accrued expenses	$ 59,733	$ 65,569

7. Commitments and Contingencies

The Company enters into contracts in the normal course of business for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore the Company believes that non-cancelable obligations under these agreements are not material.

Additionally, the Company has excluded milestone or royalty payments or other contractual payment obligations as the timing and amounts of such obligations are unknown or uncertain.

Contingencies

From time to time, the Company may be involved in disputes or regulatory inquiries that arise in the ordinary course of business. When the Company determines that a loss is both probable and reasonably estimable, a liability is recorded and disclosed if the amount is material to the financial statements taken as a whole. When a material loss contingency is only reasonably possible, the Company does not record a liability, but instead discloses the nature and the amount of the claim, and an estimate of the loss or range of loss, if such an estimate can reasonably be made.

As of September 30, 2024, there was no litigation or contingency with at least a reasonable possibility of a material loss.

8. Equity-Based Compensation

2019 Equity Incentive Plan

The Company's 2019 Stock Option and Incentive Plan, or 2019 Equity Incentive Plan, provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards and dividend equivalent rights to the Company's officers, employees, directors and other key persons (including consultants). The number of shares available for issuance under the 2019 Equity Incentive Plan is cumulatively increased each January 1, through and including January 1, 2030, by 5% of the number of shares of Common Stock outstanding on the immediately preceding December 31 or such lesser number of shares as determined by the compensation committee of the Company's board of directors.

As of September 30, 2024, there were 3,518,295 shares available for issuance in connection with future awards under the 2019 Equity Incentive Plan.

Equity-Based Awards

During the nine months ended September 30, 2024, the Company granted 2,448,123 stock option awards to its officers, employees and directors under the 2019 Equity Incentive Plan.

During the nine months ended September 30, 2024, the Company awarded 1,284,075 restricted stock units to its officers, employees and directors under the 2019 Equity Incentive Plan.

During the nine months ended September 30, 2024, 80,796 restricted stock awards previously issued to employees of the Company were released, 514,760 restricted stock units vested and 533,442 stock options were exercised. As of September 30, 2024, there were 7,977,198 stock options vested and exercisable.

Performance Stock Units

On January 4, 2024, the Company's Chief Executive Officer, or CEO, was granted 88,000 performance based restricted stock units (the target amount) that are subject to a total shareholder return, or TSR, market condition based on the Company's relative TSR percentile rank compared to companies in the NASDAQ Biotechnology Index during the performance period, and are eligible to be earned and vested from 0% to 150% of the target amount.

Equity-based compensation expense included in the condensed consolidated statements of operations for each of the periods presented is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
Research and development	$ 8,481	$ 8,502	$ 29,690	$ 25,976
Selling, general and administrative	17,482	14,597	52,980	43,491
Total equity-based compensation expense	$ 25,963	$ 23,099	$ 82,670	$ 69,467

As of September 30, 2024, the unrecognized compensation expense related to unvested stock options, restricted stock units, performance stock units and restricted stock awards was $114.3 million, $50.7 million, $6.1 million and $0.2 million, respectively, which is expected to be recognized over a weighted-average remaining period of approximately 2.35 years, 1.83 years, 1.57 years and less than one year, respectively.

As of September 30, 2024, the Company had 12,802,129 stock options outstanding, 2,035,609 unvested restricted stock units, 372,362 unvested performance stock units and 21,223 unvested restricted stock awards.

9. Net Loss per Share

Since the Company had a net loss in each of the periods presented, basic and diluted net loss per share are the same. The table below provides potentially dilutive securities not included in the computation of the diluted net loss per share for the periods ended September 30, 2024 and September 30, 2023 because to do so would be anti-dilutive:

	As of September 30,	
	2024	**2023**
Common stock options issued and outstanding	12,802,129	11,540,679
Restricted stock units subject to future vesting	2,035,609	1,736,109
Performance stock units subject to future vesting	372,362	—
Restricted stock awards subject to future vesting	21,223	125,615
Total potentially dilutive securities	15,231,323	13,402,403

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of the financial condition and results of operations of SpringWorks Therapeutics, Inc. should be read in conjunction with the condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and our consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, or 2023 Form 10-K, filed with the Securities and Exchange Commission, or SEC, on February 27, 2024. Unless the context otherwise requires, all references to "we," "us," "our," "SpringWorks," or the "Company" refer to SpringWorks Therapeutics, Inc., together with its subsidiaries. This discussion and analysis contains forward-looking statements based upon current expectations that involve risks and uncertainties. We caution you that forward-looking statements are not guarantees of future performance, and that our actual results of operations, financial condition and liquidity, and the developments in our business and the industry in which we operate, may differ materially from the results discussed or projected in the forward-looking statements contained in this Quarterly Report. We discuss risks and other factors that we believe could cause or contribute to these potential differences elsewhere in this Quarterly Report, including in Part II, Item 1A. "Risk Factors" and under "Special Note Regarding Forward-Looking Statements." In addition, even if our results of operations, financial condition and liquidity, and the developments in our business and the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods. We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC to publicly update or revise any such statements to reflect any change in our 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.

Overview

We are a commercial-stage biopharmaceutical company applying a precision medicine approach to developing and commercializing life-changing medicines for underserved patient populations suffering from devastating rare diseases and cancer. We have a differentiated portfolio of small molecule targeted oncology assets, including one approved product, one product candidate under regulatory review for approval, and several clinical candidates, and are advancing programs in both rare tumor types as well as highly prevalent, genetically defined cancers. Our strategic approach and operational excellence across research, translational science, and clinical development have enabled us to successfully launch our first product, advance our second lead product candidate to regulatory review for approval, investigate additional product candidates across various clinical trials, and enter into multiple shared-value partnerships with industry leaders to expand our portfolio. From this foundation, we are continuing to build a differentiated, fully-integrated, commercial biopharmaceutical company intensely focused on understanding patients and their diseases in order to develop transformative targeted medicines.

OGSIVEO® (nirogacestat) is our first commercial product. OGSIVEO was approved by the United States Food and Drug Administration, or FDA, on November 27, 2023. OGSIVEO is a novel, oral, selective gamma secretase inhibitor that is the first and only FDA-approved therapy for the treatment of adult patients with progressing desmoid tumors who require systemic treatment.

The FDA approval of OGSIVEO was based on the results from the Phase 3 DeFi trial, which were published in the March 9, 2023 edition of the New England Journal of Medicine. DeFi is a global, randomized (1:1), double-blind, placebo-controlled Phase 3 trial evaluating the efficacy, safety and tolerability of OGSIVEO in adult patients with progressing desmoid tumors. The study randomized 142 patients to receive 150 mg of OGSIVEO or placebo twice daily. OGSIVEO met the primary endpoint of improving progression-free survival, or PFS, demonstrating a statistically significant improvement for OGSIVEO over placebo, with a 71% reduction in the risk of disease progression (hazard ratio (HR) = 0.29 (95% CI: 0.15, 0.55); p< 0.001). Median PFS was not reached in the OGSIVEO arm and was 15.1 months in the placebo arm. Confirmed objective response rate, or ORR, based on RECIST v1.1 was 41% with OGSIVEO versus 8% with placebo (p<0.001); the complete response rate was 7% in the OGSIVEO arm and 0% in the placebo arm. The median time to first response was 5.6 months with OGSIVEO and 11.1 months with placebo. PFS and ORR improvements were in favor of OGSIVEO regardless of baseline characteristics including sex, tumor location, tumor focality, treatment status, previous treatments, mutational status and history of familial adenomatous polyposis. OGSIVEO also demonstrated early and sustained improvements in patient-reported outcomes, including pain, desmoid tumor-specific symptoms, physical/role function and overall health-related quality of life. OGSIVEO exhibited a manageable safety and tolerability profile. The most common adverse events (>15%) reported in patients receiving OGSIVEO were diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, upper respiratory tract infection and dyspnea. Warnings & Precautions include diarrhea, ovarian toxicity, hepatotoxicity, non-melanoma skin cancers, electrolyte abnormalities and embryo-fetal toxicity.

Long-term efficacy and safety data from DeFi will be presented at the Connective Tissue Oncology Society, or CTOS, 2024 Annual Meeting on November 16, 2024. These results, utilizing an August 2024 data cutoff date, showed that longer-term treatment with OGSIVEO was associated with further reductions in tumor size, increase in ORR with additional complete responses, sustained improvement in desmoid tumor symptoms, and no new safety signals relative to the April 2022 primary data cut.

OGSIVEO is the first and only FDA-approved treatment indicated specifically for desmoid tumors. In December 2023, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma V.3.2023 were updated to recommend nirogacestat as an NCCN Category 1, Preferred treatment option for desmoid tumors. In June 2024, the Desmoid Tumor Working Group, or DTWG, published an updated review of the current management of desmoid tumors, which highlighted nirogacestat's role as the first approved drug for the disease and its incorporation into the desmoid tumor treatment algorithm.

We are advancing a targeted launch strategy focused on continuing to establish OGSIVEO as the systemic standard of care for adult desmoid tumor patients. For the three and nine months ended September 30, 2024, we recorded net product revenue of $49.3 million and $110.5 million, respectively, from sales of OGSIVEO in the United States. On April 4, 2024, we received FDA approval of a Supplemental New Drug Application, or sNDA, providing for the addition of two higher dosage strengths of 150 mg and 100 mg OGSIVEO tablets in blister packaging, which were developed to enhance patient convenience with OGSIVEO. The blister packs became commercially available in May 2024.

We are also seeking to expand the reach of OGSIVEO to additional geographies; in February 2024, we received validation for a Marketing Authorization Application, or MAA, from the European Medicines Agency, or EMA. Pre-commercial preparations in Europe are underway ahead of potential approval and first launches in Germany and France in the first half of 2025. Beyond the United States and Europe, we continue to advance our efforts to commercialize OGSIVEO in additional territories, such as Japan.

We are also evaluating nirogacestat for the treatment of ovarian granulosa cell tumors, or GCT, a subtype of ovarian cancer. In May 2023, we announced full enrollment of a Phase 2 trial evaluating nirogacestat as a monotherapy in adult patients with recurrent ovarian GCT. We expect to report initial data from the trial in the first half of 2025.

Our second product candidate is mirdametinib, an investigational oral, small molecule MEK inhibitor, currently in development for the treatment of neurofibromatosis type 1-associated plexiform neurofibromas, or NF1-PN, a rare tumor of the peripheral nerve sheath that causes significant pain and disfigurement. We believe that mirdametinib has the potential to offer a best-in-class profile in order to enable the long-term treatment required for this patient population, as compared to other MEK inhibitors. In November 2023, we announced positive topline results from the ReNeu trial, a registrational Phase 2b clinical trial of mirdametinib for pediatric and adult patients with NF1-PN, and we presented additional data from the ReNeu trial at the American Society of Clinical Oncology, or ASCO, Annual Meeting and the Global NF Conference in June 2024. The results of the ReNeu trial were subsequently published in the Journal of Clinical Oncology. As of the data cutoff date of September 20, 2023, 52% (29/56) of pediatric patients and 41% (24/58) of adult patients had Blinded Independent Central Review, or BICR, confirmed objective responses within the 24-cycle treatment period (cycle length: 28 days). An additional pediatric patient and two additional adult patients achieved confirmed objective responses after Cycle 24 in the long-term follow up phase of the trial, where patients continue to receive mirdametinib treatment. Median (range) best percent change from baseline in target tumor volume was -42% (-91% to 48%) and -41% (-90% to 13%) in the pediatric and adult cohorts, respectively; among study participants with a confirmed objective response on mirdametinib, 52% of children and 62% of adults achieved a >50% reduction in tumor volume. As of the data cutoff, the median duration of treatment was 22 months in both the pediatric and adult cohorts; the median time to onset of response was 7.9 months in pediatric patients and 7.8 months in adult patients. Median duration of response was not reached in either cohort. Pediatric and adult patients in the ReNeu trial also experienced statistically significant improvements from baseline in worst tumor pain severity, pain interference, and health-related quality of life, as assessed across multiple patient-reported outcome, or PRO, tools. Children and adults with NF1-PN in the ReNeu trial reported early, sustained, and clinically meaningful reductions in worst tumor pain severity and pain interference over the course of mirdametinib treatment. Mirdametinib was generally well tolerated in the ReNeu trial, with the majority of adverse events, or AEs, being Grade 1 or Grade 2. Among all study participants, 21% of adults and 9% of children discontinued the study due to treatment-related adverse events, or TRAEs, and dose reductions due to TRAEs were 17% in adults and 12% in children. The most frequently reported TRAEs were dermatitis acneiform, diarrhea, paronychia, nausea, decrease in ejection fraction, and increase in blood creatinine phosphokinase in the pediatric cohort and dermatitis acneiform, diarrhea, nausea, vomiting, and fatigue in the adult cohort. 25% of pediatric patients and 16% of adult patients experienced a Grade 3 or higher TRAE.

The FDA granted mirdametinib both Orphan Drug designation and Fast Track designation for NF1-PN, and the European Commission granted mirdametinib Orphan Drug designation for NF1. The FDA also granted mirdametinib Rare Pediatric Disease designation for the treatment of NF1, and as such, mirdametinib will be eligible to receive a priority review voucher, if approved. In August 2024, the FDA accepted our NDA submission for mirdametinib in pediatric and adult patients with NF1-PN and granted priority review with an assigned Prescription Drug User Fee Act, or PDUFA, target action date of February 28, 2025. Also, in August 2024, the Company received validation for an MAA from the EMA for mirdametinib for the treatment of adult and pediatric patients with NF1-PN.

In hematologic malignancies, we are evaluating novel combination regimens of nirogacestat alongside B-cell maturation antigen, or BCMA, directed therapies for the treatment of multiple myeloma. We have entered into several, non-exclusive clinical collaboration agreements with industry partners to evaluate nirogacestat in combination with multiple different BCMA-directed therapies. Each partner is responsible for the conduct and expenses of a clinical trial to evaluate the combination of nirogacestat with its respective BCMA agent in multiple myeloma. To date, we have generated clinical data across several modalities that support nirogacestat's ability to potentiate BCMA and enhance activity of BCMA targeted therapies at clinically achievable doses. In addition, several Phase 1 studies are currently ongoing through our collaborators.

In genetically defined metastatic solid tumors, our current clinical-stage efforts center on the mitogen activated protein kinase, or MAPK, pathway. We are evaluating mirdametinib for the treatment of solid tumors harboring MAPK aberrations in both monotherapy and combination approaches. In collaboration with BeiGene, Ltd., or BeiGene, we are exploring the combination of mirdametinib with BeiGene's lifirafenib (BGB-283) in NRAS mutant solid tumors. In addition, we are exploring the use of brimarafenib (BGB-3245) in a distinct set of genetically defined BRAF mutated tumors via MapKure, LLC an entity jointly owned by us and BeiGene. In February 2023, we dosed the first patient in a Phase 1/2a open-label, dose escalation and expansion trial evaluating mirdametinib in combination with brimarafenib in patients with advanced solid tumors harboring MAPK-activating mutations. In April 2023, we presented clinical data from the Phase 1a/1b trial evaluating brimarafenib in patients with advanced or refractory solid tumors harboring MAPK pathway aberrations at the American Association for Cancer Research, or AACR, Annual Meeting 2023. We also presented clinical data from the Phase 1b clinical trial evaluating mirdametinib in combination with BeiGene's RAF dimer inhibitor, lifirafenib at the AACR Annual Meeting 2023. These clinical data showed manageable safety profiles and clinical activity in various solid tumors with MAPK pathway aberrations. Dose expansion studies are currently ongoing for each program. In the first quarter of 2024, MapKure initiated a Phase 1b combination trial of brimarafenib with panitumumab, a monoclonal antibody targeting Epidermal Growth Factor Receptor, or EGFR, in colorectal and pancreatic cancer patients with known MAPK pathway mutations; patient dosing is currently underway.

In an academic-sponsored study supported by SpringWorks, mirdametinib is being evaluated for the treatment of low-grade gliomas in children and young adults. Initial data from the Phase 1 portion of the study were presented at the International Symposium on Pediatric Neuro-Oncology in June 2024 and demonstrated encouraging clinical activity in patients with recurrent / progressive pediatric low-grade glioma. The Phase 2 portion of the study is ongoing and recruiting patients.

Furthermore, we intend to continue to build our portfolio with assets that have strong biological rationales and validated mechanisms of action, such as the TEA Domain, or TEAD, inhibitor program that we in-licensed from Katholieke Universiteit Leuven and the Flanders Institute for Biotechnology. In June 2024, we initiated a Phase 1a trial of SW-682, our TEAD inhibitor development candidate, in Hippo mutant solid tumors; patient enrollment and dosing is ongoing. Additionally, we are pursuing several discovery programs that represent potentially first-in-class and best-in-class product candidates designed to address tumors where no or limited treatment options exist.

We continue to invest in our R&D infrastructure in a focused manner in order to support both our drug discovery capabilities and our translational medicine activities for development programs. We also plan to continue exploring shared-value partnerships to maximize the potential of our therapies to transform the lives of oncology patients.

Components of our results of operations

Product revenue, net

In November 2023, the FDA approved OGSIVEO for the treatment of adult patients with progressing desmoid tumors who require systemic treatment. In December 2023, we began to generate revenue from sales of OGSIVEO in the United States. We record product revenue net of estimated discounts, chargebacks, rebates, product returns, and other gross-to-net revenue deductions.

Other Revenue

On June 6, 2024, we received a notice of termination of the GSK License Agreement from GSK, effective 180 days after the date of receipt of the notice of termination. Once the termination becomes effective, the non-exclusive licenses granted by us to GSK under the GSK License Agreement will terminate. Termination of the GSK License Agreement does not trigger any payment obligations on our part or any other material costs. As a result of this termination, we fully recognized all previously deferred revenue associated with the GSK License Agreement during the quarter ended June 30, 2024. The $19.5 million recognized is classified as “Other Revenue”.

Operating costs and expenses

Cost of product revenue

Our cost of product revenue includes the cost of goods sold, amortization expense for commercial milestones and royalty expense. Our cost of goods sold consists of raw materials, third-party manufacturing costs to manufacture the raw materials into finished product, freight and other costs associated with sales of commercial products.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of salaries and related costs, including equity-based compensation, for personnel in executive, finance, corporate, commercial, business development and administrative functions. Selling, general and administrative expenses also include consulting services, legal fees relating to patent and corporate matters; professional fees for accounting, auditing and tax services; insurance costs; administrative travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We anticipate that our selling, general and administrative expenses will increase in the future as we increase our headcount to expand operations to support the organization, including commercialization efforts.

Research and development expenses

Our research and development expenses consist of expenses incurred in connection with the development of our product candidates. These expenses include:

- employee-related expenses, which include salaries, benefits and equity-based compensation for our research and development personnel;
- fees paid to consultants for services directly related to our research and development programs;
- expenses incurred under agreements with third-party contract research organizations, investigative clinical trial sites, academic institutions and consultants that conduct research and development activities on our behalf or in collaboration with us;
- costs associated with discovery biology and medicinal chemistry efforts and with preclinical and clinical trials;
- costs associated with the manufacture of drug substance and finished drug product for preclinical testing and clinical trials;
- costs associated with technology and intellectual property licenses; and
- an allocated portion of facilities and facility-related costs, which include expenses for rent and other facility-related costs and other supplies.

External costs for research and development expenses are tracked on a program-by-program basis. Expenditures for clinical development, including upfront licensing fees and milestone payments associated with our product candidates, are charged to research and development expense as incurred. These expenses consist of expenses incurred in performing development activities, including salaries and benefits, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, depreciation of equipment, contract services and other outside expenses. Costs for certain development activities, such as manufacturing and clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using either time-based measures or data such as information provided to us by our vendors on actual activities completed or costs incurred.

We expect our research and development expenses to increase for the foreseeable future as we continue to invest in activities related to developing our product candidates and our preclinical programs, and as certain product candidates advance into later stages of development, including nirogacestat, which is being studied in ovarian granulosa cell tumors as well as other studies undertaken to fulfill post-approval regulatory commitments, and mirdametinib with the ReNeu trial. The process of conducting the necessary clinical trials to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Interest and other income

Interest and other income consists primarily of interest income. Interest income consists of interest earned on our cash, cash equivalents and available-for-sale marketable securities.

Equity method investment loss

The equity method investment loss represents our share of the losses from the MapKure investment, which is accounted for using the equity method of accounting.

Results of Operations

Comparison of the three months ended September 30, 2024 and September 30, 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and September 30, 2023:

	Three Months Ended September 30,			
(in thousands)	**2024**	**2023**	**$ Change**	**% Change**
Revenue:				
Product revenue, net	$ 49,301	$ —	$ 49,301	— %
Other revenue	—	—	—	— %
Total revenue	49,301	—	49,301	— %
Operating costs and expenses:				
Cost of product revenue	3,341	—	3,341	— %
Selling, general and administrative	61,601	46,546	15,055	32 %
Research and development	42,296	37,453	4,843	13 %
Total operating costs and expenses	107,238	83,999	23,239	28 %
Loss from operations	(57,937)	(83,999)	26,062	(31)%
Interest and other income:				
Interest and other income, net	6,216	5,586	630	11 %
Total interest and other income	6,216	5,586	630	11 %
Equity method investment loss	(1,809)	(1,024)	(785)	77 %
Net loss	$ (53,530)	$ (79,437)	$ 25,907	(33)%

Revenue

In November 2023, the FDA approved OGSIVEO for the treatment of adult patients with progressing desmoid tumors who require systemic treatment. For the three months ended September 30, 2024, we recorded net product revenue of $49.3 million from sales of OGSIVEO in the United States.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $15.1 million to $61.6 million for the three months ended September 30, 2024 from $46.5 million for the three months ended September 30, 2023, an increase of 32%.

The increase in selling, general and administrative expenses included a $9.4 million increase in consulting and professional services and a $5.7 million increase in internal costs. The increase in consulting and professional services was largely attributable to commercial readiness activities to support the U.S. launch of mirdametinib, if approved. The increase in internal costs was attributable to the growth in employee costs associated with increases in the number of personnel, including an increase in equity-based compensation expense, driven by the growth of our commercial organization, which included establishing certain sales support, marketing, and commercialization functions to support the U.S. launch of mirdametinib, if approved.

Research and development expenses

Research and development expenses increased by $4.8 million to $42.3 million for the three months ended September 30, 2024 from $37.5 million for the three months ended September 30, 2023, an increase of 13%.

The increase in research and development expenses was primarily attributable to an increase of $4.2 million in external costs related to drug manufacturing, clinical trials, other research, consulting and professional services.

We track research and development expenses on a program-by-program basis to the extent such spend is attributable to a specific program. Our research and development expenses by program for the periods presented were as follows:

	Three Months Ended September 30, 2024		
(in thousands)	**2024**	**2023**	**$ Change**
Program specific costs:			
Nirogacestat	$ 14,118	$ 8,859	$ 5,259
Mirdametinib	10,730	7,860	2,870
Other	4,516	1,727	2,789
Total program specific costs	29,364	18,446	10,918
Non-program specific costs	12,932	19,007	(6,075)
Total research and development expenses	$ 42,296	$ 37,453	$ 4,843

Interest and other income

The increase in interest and other income was driven by an increase in interest income, net, for the three months ended September 30, 2024 as compared to the three months ended September 30, 2023. This increase was attributable to higher market yield and increased cash from financing activities during the year ended December 31, 2023.

Comparison of the nine months ended September 30, 2024 and September 30, 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and September 30, 2023:

	Nine Months Ended September 30,			
(in thousands)	**2024**	**2023**	**$ Change**	**% Change**
Revenue:				
Product revenue, net	$ 110,493	$ —	$ 110,493	— %
Other revenue	19,547	—	19,547	— %
Total revenue	130,040	—	130,040	— %
Operating costs and expenses:				
Cost of product revenue	6,996	—	6,996	— %
Selling, general and administrative	179,553	137,715	41,838	30 %
Research and development	140,280	106,835	33,445	31 %
Total operating costs and expenses	326,829	244,550	82,279	34 %
Loss from operations	(196,789)	(244,550)	47,761	(20)%
Interest and other income:				
Interest and other income, net	20,565	16,971	3,594	21 %
Total interest and other income	20,565	16,971	3,594	21 %
Equity method investment loss	(4,610)	(3,203)	(1,407)	44 %
Net loss	$ (180,834)	$ (230,782)	$ 49,948	(22)%

Revenue

In November 2023, the FDA approved OGSIVEO for the treatment of adult patients with progressing desmoid tumors who require systemic treatment. For the nine months ended September 30, 2024, we recorded net product revenue of $110.5 million from sales of OGSIVEO in the United States.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $41.8 million to $179.6 million for the nine months ended September 30, 2024 from $137.7 million for the nine months ended September 30, 2023, an increase of 30%.

The increase in selling, general and administrative expenses included a $21.2 million increase in consulting and professional services and a $20.6 million increase in internal costs. The increase in consulting and professional services was largely attributable to commercial readiness activities to support the U.S. launch of mirdametinib, if approved, as well as commercial activities supporting the U.S. launch of OGSIVEO. The increase in internal costs was attributable to the growth in employee costs associated with increases in the number of personnel, including an increase in equity-based compensation expense, driven by the growth of our commercial organization, which included establishing certain sales support, marketing, and commercialization functions to support the U.S. launch of mirdametinib, if approved.

Research and development expenses

Research and development expenses increased by $33.4 million to $140.3 million for the nine months ended September 30, 2024 from $106.8 million for the nine months ended September 30, 2023, an increase of 31%.

The increase in research and development expenses was primarily attributable to an increase of $25.2 million in external costs related to licensing fees, drug manufacturing, clinical trials, other research, consulting and professional services, and an increase of $8.2 million in internal costs driven by the growth in employee costs associated with increases in the number of personnel, including an increase in equity-based compensation expense.

We track research and development expenses on a program-by-program basis to the extent such spend is attributable to a specific program. Our research and development expenses by program for the periods presented were as follows:

	Nine Months Ended September 30, 2024		
(in thousands)	**2024**	**2023**	**$ Change**
Program specific costs:			
Nirogacestat	$ 40,909	$ 24,854	$ 16,055
Mirdametinib	39,055	21,468	17,587
Other	19,979	5,665	14,314
Total program specific costs	99,943	51,987	47,956
Non-program specific costs	40,337	54,848	(14,511)
Total research and development expenses	$ 140,280	$ 106,835	$ 33,445

Interest and other income

The increase in interest and other income was driven by an increase in interest income, net, for the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023. This increase was attributable to higher market yield and increased cash from financing activities during the year ended December 31, 2023.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred operating losses and experienced negative operating cash flows since our inception and anticipate that we will continue to incur losses for at least the foreseeable future. Our net loss was $180.8 million and $230.8 million for the nine months ended September 30, 2024 and September 30, 2023, respectively. We had an accumulated deficit of $1.1 billion and

$895.0 million as of September 30, 2024 and December 31, 2023, respectively. Based on our cash, cash equivalents and marketable securities balances as of September 30, 2024, management estimates that our liquidity position will enable us to meet operating expenses through at least twelve months after the date that this Quarterly Report is filed. Our marketable securities consist of high-quality, highly liquid available-for-sale debt securities including corporate debt securities, U.S. government securities, and commercial paper.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2024 and September 30, 2023:

	Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**
Net cash used in operating activities	$ (146,099)	$ (160,090)
Net cash provided by investing activities	50,400	193,959
Net cash provided by (used in) financing activities	4,110	(2,432)
Net (decrease) increase in cash and cash equivalents	(91,589)	31,437
Cash and cash equivalents including Restricted cash, beginning of period	176,666	68,068
Cash and cash equivalents including Restricted cash, end of period	$ 85,077	$ 99,505

Net Cash Used in Operating Activities

Net cash used in operating activities was $146.1 million for the nine months ended September 30, 2024, which was driven by a net loss of $180.8 million and a net decrease from changes in operating assets and liabilities of $56.5 million, partially offset by equity-based compensation expense of $82.7 million, equity investment loss of $4.6 million, non-cash operating lease and depreciation and amortization expense of $4.0 million. Net cash used in operating activities was $160.1 million for the nine months ended September 30, 2023, which was driven by a net loss of $230.8 million and a net decrease from changes in operating assets and liabilities of $4.3 million, partially offset by stock-based compensation expense of $69.5 million, equity investment loss of $3.2 million, non-cash operating lease and depreciation expense of $2.3 million.

Net Cash Provided by Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2024 was driven by the sale and maturities of available-for-sale debt securities of $277.5 million, partially offset by purchases of available-for-sale debt securities of $204.3 million, the payment of a commercial milestone of $11.3 million, an investment in MapKure of $8.2 million and capital expenditures of $3.4 million. Net cash provided by investing activities for the nine months ended September 30, 2023 was driven by the sale and maturities of available-for-sale debt securities of $515.7 million, partially offset by purchases of available-for-sale debt securities of $309.3 million, capital expenditures of $9.7 million and our investment in MapKure of $2.8 million.

Net Cash Provided by and Used in Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 consisted of proceeds from stock option exercises of $12.0 million, partially offset by stock repurchased to satisfy employee tax withholding obligations upon vesting of restricted stock awards of $7.9 million. Net cash used in financing activities for the nine months ended September 30, 2023 consisted of stock repurchased to satisfy employee tax withholding obligations on restricted stock releases, partially offset by proceeds from stock option exercises.

Funding Requirements

Our primary use of cash is to fund operating expenses, including our research and development programs, as well as our commercialization activities and corporate operations. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Our future funding requirements will depend on many factors, including the following:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the degree of commercial success achieved following the successful completion of development and regulatory approval activities for a product candidate;
- the clinical development plans we establish for our product candidates;
- the number and characteristics of product candidates that we develop;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable foreign regulatory authorities;
- the terms of our existing and any future license or collaboration agreements we may choose to enter into, including the amount of upfront, milestone and royalty obligations;
- the other costs associated with in-licensing new technologies, such as any increased costs of research and development and personnel;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments; and
- the cost and timing of completion of commercial-scale outsourced manufacturing activities.

We may need additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, commercial activities and business development efforts. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

Until such time, if ever, as we can generate sufficient product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, current ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Effects of Inflation

Although our operations are influenced by general economic conditions, we do not believe that inflation has had a material impact on our business, financial condition, or operating results during the periods presented.

Contractual Obligations

During the nine months ended September 30, 2024, there were no other material changes to our contractual obligations and commitments than those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual obligations and other commitments” in Part II Item 7. of our 2023 Form 10-K.

Critical Accounting Policies and Use of Estimates

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts and the related disclosures in the financial statements and accompanying notes. These accounting policies involve critical accounting estimates because they are particularly dependent on estimates and assumptions made by management about matters that are uncertain at the time the accounting estimates are made. We base our estimates on historical experience, known trends and other market-specific or relevant factors that we believe to be reasonable under the circumstances, the results of which form the basis of making judgments; however, because future events and their effects cannot be determined with certainty, actual results may differ from those estimates, judgments or assumptions, and such differences could be material. On an ongoing basis, we evaluate our estimates, judgments and assumptions, and adjust those estimates, judgments and assumptions when facts or circumstances change. Changes in estimates are recorded in the period in which they become known. Although we believe that these estimates are reasonable, actual results could differ.

We describe our significant accounting policies in Note 3, Summary of Significant Accounting Policies, of the notes to the financial statements included in our 2023 Form 10-K. We discuss our critical accounting estimates in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, in our 2023 Form 10-K. There have been no changes in our significant accounting policies or critical accounting estimates during the nine months ended September 30, 2024.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

There were no material changes to our market risks from those described in Part II Item 7A. Quantitative and Qualitative Disclosures About Market Risk in our 2023 Form 10-K.

Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act), as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at a reasonable assurance level in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms; and (ii) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. Other Information

Item 1. Legal Proceedings

As of the date of this Quarterly Report on Form 10-Q, we are not a party to any material legal proceedings. In the future, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. The outcome of litigation cannot be predicted with certainty and some lawsuits, claims or proceedings may be disposed of unfavorably to us, which could materially affect our financial condition or results of operations.

Item 1A. Risk Factors

In addition to the other information contained elsewhere in this report, you should carefully consider the risks and uncertainties described in "Part I, Item 1A—Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2023, or 2023 Form 10-K, filed with the Securities and Exchange Commission on February 27, 2024, which could materially and adversely affect our business, prospects, financial condition and results of operations. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations. The risk factors disclosure in our 2023 Form 10-K is qualified by the information that is described in this Quarterly Report on Form 10-Q. The risks described in our 2023 Form 10-K are not our only risks. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results. There have been no material changes in our risk factors previously disclosed in our 2023 Form 10-K.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

Rule 10b5-1 Trading Plans

During the three months ended September 30, 2024, none of the Company's directors or officers adopted, materially modified, or terminated any contract, instruction, or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any non-Rule 10b5-1 trading arrangement.

Item 6. Exhibits

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EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation, as amended, of the Registrant, as currently in effect. (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 17, 2019).
3.2	Bylaws of the Registrant, as currently in effect. (Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 17, 2019).
3.3	Amendment to Bylaws of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrants' Current Report on Form 8-K filed with the Securities and Exchange Commission on May 27, 2020).
4.1	Specimen Stock Certificate evidencing shares of common stock (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S 1/A (File No. 333 233351) filed with the Securities and Exchange Commission on September 12, 2019).
4.2	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated August 30, 2019 (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-233351) filed with the Securities and Exchange Commission on September 12, 2019).
4.3	Amended Description of the Registrant's Securities (Incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023, filed February 27, 2024).
4.4	Amendment to the Amended and Restated Investors' Rights Agreement, dated as of February 25, 2021 (Incorporated by Reference to Exhibit 4.4 to the Registrant's Annual Report on Form 10-K filed with the Securities and Exchanges Commission on February 25, 2021).
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2†	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

† This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, except to the extent specifically incorporated by reference into such filing.

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 thereunto duly authorized.

SPRINGWORKS THERAPEUTICS, INC.

Date: November 12, 2024	By:	/s/ Saqib Islam
		Saqib Islam
		Chief Executive Officer
Date: November 12, 2024	By:	/s/ Francis I. Perier, Jr.
		Francis I. Perier, Jr.
		Chief Financial Officer

Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATIONS

I, Saqib Islam, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of SpringWorks Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)):

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

By: /s/ Saqib Islam
Saqib Islam
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATIONS

I, Francis I. Perier, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of SpringWorks Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)):

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

By: /s/ Francis I. Perier, Jr.
Francis I. Perier, Jr.
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of SpringWorks Therapeutics, Inc. (the “Company”) for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Saqib Islam, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2024	By:	/s/ Saqib Islam
		Saqib Islam
		Chief Executive Officer
		(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of SpringWorks Therapeutics, Inc. (the “Company”) for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Francis I. Perier, Jr., Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2024	By:	/s/ Francis I. Perier, Jr.
		Francis I. Perier, Jr.
		Chief Financial Officer
		(Principal Financial Officer)