UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **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: 001-36593

SOLENO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0523891**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

100 Marine Parkway, Suite 400
Redwood City, California
(Address of principal executive offices)

94065
(Zip Code)

(650) 213-8444
(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, $0.001 par value	SLNO	NASDAQ

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, 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 ☒

As of October 31, 2024, there were 43,117,432 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

SOLENO THERAPEUTICS, INC.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

Soleno Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2024	December 31, 2023
Assets	**(unaudited)**	
Current assets		
Cash and cash equivalents	$ 48,413	$ 169,681
Marketable securities	208,363	—
Prepaid expenses and other current assets	1,423	1,677
Total current assets	258,199	171,358
Long-term assets		
Property and equipment, net	196	12
Operating lease right-of-use assets	2,992	407
Intangible assets, net	7,291	8,749
Long-term marketable securities	27,945	-
Other long-term assets	83	165
Total assets	$ 296,706	$ 180,691
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 6,243	$ 3,149
Accrued compensation	3,408	3,135
Accrued clinical trial site costs	1,762	3,393
Operating lease liabilities	448	273
Other current liabilities	3,101	1,555
Total current liabilities	14,962	11,505
Long-term liabilities		
Contingent liability for Essentialis purchase price	14,464	11,549
Long-term lease liabilities	2,581	130
Total liabilities	32,007	23,184
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 41,041,216 and 31,678,159 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	41	32
Additional paid-in-capital	660,041	433,885
Accumulated other comprehensive gain	895	-
Accumulated deficit	(396,278)	(276,410)
Total stockholders' equity	264,699	157,507
Total liabilities and stockholders' equity	$ 296,706	$ 180,691

See accompanying notes to condensed consolidated financial statements

Soleno Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 30,138	$ 6,043	$ 57,082	$ 16,500
General and administrative	49,197	3,318	68,558	9,341
Change in fair value of contingent consideration	877	1,021	2,915	1,633
Total operating expenses	80,212	10,382	128,555	27,474
Operating loss	(80,212)	(10,382)	(128,555)	(27,474)
Other income (expense), net				
Change in fair value of warrants liabilities	—	(653)	—	(652)
Interest income, net	3,596	174	8,687	434
Total other income (expense), net	3,596	(479)	8,687	(218)
Net loss	$ (76,616)	$ (10,861)	$ (119,868)	$ (27,692)
Other comprehensive income (loss)				
Net unrealized gain on marketable securities	1,049	—	898	—
Foreign currency translation adjustment	(1)	(1)	(3)	(1)
Total comprehensive loss	$ (75,568)	$ (10,862)	$ (118,973)	$ (27,693)
Net loss per common share, basic and diluted	$ (1.83)	$ (0.95)	$ (3.08)	$ (2.65)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	41,879,025	11,436,748	38,917,169	10,443,186

See accompanying notes to condensed consolidated financial statements

Soleno Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
For the Three and Nine Months Ended September 30, 2024 and 2023
(unaudited)
(in thousands, except share data)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income	Accumulated	Total Stockholders'
	Shares	Amount	Capital	(Loss)	Deficit	Equity
Balances at January 1, 2024	31,678,159	$ 32	$ 433,885	$ -	$ (276,410)	$ 157,507
Stock-based compensation	-	-	6,445	-	-	6,445
Issuance of restricted stock units under equity incentive plans	11,034	-	-	-	-	-
Exercise of common stock warrants and pre-funded common stock warrants	1,644,886	1	922	-	-	923
Exercise of stock options	3,000	-	15	-	-	15
Unrealized loss on marketable securities	-	-	-	(105)	-	(105)
Foreign currency translation adjustment	-	-	-	(1)	-	(1)
Net loss	-	-	-	-	(21,398)	(21,398)
Balances at March 31, 2024	33,337,079	33	441,267	(106)	(297,808)	143,386
Stock-based compensation	-	-	7,160	-	-	7,160
Issuance of restricted stock units under equity incentive plans	75,750	-	-	-	-	-
Sale of common stock, net of issuance costs of $9,746	3,450,000	4	148,951	-	-	148,955
Exercise of common stock warrants and pre-funded common stock warrants	1,435,319	1	2,619	-	-	2,620
Exercise of stock options	88,631	-	537	-	-	537
Unrealized loss on marketable securities	-	-	-	(46)	-	(46)
Foreign currency translation adjustment	-	-	-	(1)	-	(1)
Net loss	-	-	-	-	(21,854)	(21,854)
Balances at June 30, 2024	38,386,779	38	600,534	(153)	(319,662)	280,757
Stock-based compensation	-	-	56,598	-	-	56,598
Issuance of restricted stock units under equity incentive plans	789,500	1	-	-	-	1
Exercise of common stock warrants and pre-funded common stock warrants	1,782,048	2	2,145	-	-	2,147
Exercise of stock options	82,889	-	764	-	-	764
Unrealized gain on marketable securities	-	-	-	1,049	-	1,049
Foreign currency translation adjustment	-	-	-	(1)	-	(1)
Net loss	-	-	-	-	(76,616)	(76,616)
Balances at September 30, 2024	41,041,216	$ 41	$ 660,041	$ 895	$ (396,278)	$ 264,699

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income (Loss)	Accumulated	Total Stockholders'
	Shares	Amount	Capital		Deficit	Equity
Balances at January 1, 2023	8,159,382	$ 8	$ 247,762	$ -	$ (237,422)	$ 10,348
Stock-based compensation	-	-	495	-	-	495
Issuance of restricted stock units under equity incentive plans	9,534	-	136	-	-	136
Tax withholding payments for net share-settled equity awards	(128)	-	-	-	-	-
Foreign currency translation adjustment	-	-	-	16	-	16
Net loss	-	-	-	-	(8,356)	(8,356)
Balances at March 31, 2023	8,168,788	8	248,393	16	(245,778)	2,639
Stock-based compensation	-	-	1,204	-	-	1,204
Issuance of common stock warrants, net of issuance costs	-	-	9,973	-	-	9,973
Sale of common stock, net of costs	1,772,397	2	7,099	-	-	7,101
Foreign currency translation adjustment	-	-	-	(16)	-	(16)
Net loss	-	-	-	-	(8,475)	(8,475)
Balances at June 30, 2023	9,941,185	10	266,669	-	(254,253)	12,426
Stock-based compensation	-	-	2,201	-	-	2,201
Exercise of common stock warrants, net of issuance costs	5,522,113	5	19,440	-	-	19,445
Exercise of stock options	3,931	-	10	-	-	10
Foreign currency translation adjustment	-	-	-	(1)	-	(1)
Net loss	-	-	-	-	(10,861)	(10,861)
Balances at September 30, 2023	15,467,229	$ 15	$ 288,320	$ (1)	$ (265,114)	$ 23,220

See accompanying notes to condensed consolidated financial statements

Soleno Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (119,868)	$ (27,692)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,484	1,469
Accretion of premium/discount on marketable securities	(3,495)	-
Non-cash lease expense	250	254
Stock-based compensation expense	70,203	4,036
Change in fair value of stock warrants	-	652
Change in fair value of contingent consideration	2,915	1,633
Other non-cash reconciling items	(3)	(1)
Change in operating assets and liabilities:		
Prepaid expenses, other current assets and other assets	279	(177)
Accounts payable	3,094	1,338
Accrued compensation	273	(177)
Accrued clinical trial site costs	(1,631)	15
Operating lease liabilities	(152)	(242)
Other liabilities	1,546	266
Net cash used in operating activities	(45,105)	(18,626)
Cash flows from investing activities		
Purchases of property and equipment	(210)	-
Purchases of marketable securities	(308,915)	-
Maturities of marketable securities	77,000	-
Net cash used in investing activities	(232,125)	-
Cash flows from financing activities:		
Proceeds from the sale of common stock, net of issuance costs	148,955	-
Proceeds from the sale of common stock and common stock warrants, net of costs	-	17,074
Proceeds from exercise of common stock warrants and pre-funded common stock warrants, net of costs	5,690	19,445
Proceeds received prior to and for the issuance of common stock and pre-funded warrants	-	19,932
Proceeds from exercise of stock options	1,317	10
Net cash provided by financing activities	155,962	56,461
Net (decrease) increase in cash and cash equivalents	(121,268)	37,835
Cash and cash equivalents, beginning of period	169,681	14,602
Cash and cash equivalents, end of period	$ 48,413	$ 52,437
Supplemental disclosure of non-cash operating and financing information		
Operating lease right-of-use assets obtained in exchange for operating lease obligations	$ 2,835	$ 597
Unpaid financing costs included in accounts payable and accrued liabilities	$ -	$ 199

See accompanying notes to condensed consolidated financial statements.

Note 1. Overview

Soleno Therapeutics, Inc. (the Company or Soleno) is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Its lead candidate is DCCR (Diazoxide Choline) Extended-Release tablets, a once-daily oral tablet for the treatment of Prader-Willi syndrome (PWS). DCCR has received Fast-Track and Breakthrough Therapy designations for the treatment of PWS in the United States (U.S.) and orphan designation for the treatment of PWS in the U.S. as well as in the European Union (E.U.). On June 28, 2024, the Company submitted a new drug application (NDA) to the FDA for DCCR for the treatment of PWS in individuals four years and older who have hyperphagia and on August 27, 2024 announced that the FDA granted Priority Review for the NDA and assigned a Prescription Drug User Fee Act (PDUFA) target action date of December 27, 2024.

The Company incorporated in the State of Delaware on August 25, 1999, and is located in Redwood City, California. It initially established its operations as Capnia, a diversified healthcare company that developed and commercialized innovative diagnostics, devices and therapeutics addressing unmet medical needs. During 2017, the Company merged with Essentialis, Inc (Essentialis) and subsequently received stockholder approval to amend its Amended and Restated Certificate of Incorporation to change its name from “Capnia, Inc.” to “Soleno Therapeutics, Inc.”. Essentialis was a privately held clinical-stage company focused on the development of breakthrough medicines for the treatment of rare diseases where there is increased mortality and risk of cardiovascular and endocrine complications. After the merger, the Company’s primary focus has been the development and commercialization of novel therapeutics for the treatment of rare diseases and the Company divested all prior business efforts.

Note 2. Liquidity

The Company used $45.1 million of cash in its operating activities and had a net loss of $119.9 million during the nine months ended September 30, 2024 and has an accumulated deficit of $396.3 million at September 30, 2024 resulting from having incurred losses since its inception. The Company had $48.4 million of cash and cash equivalents on hand, $208.4 million of marketable securities and $27.9 million of long-term marketable securities on September 30, 2024.

The Company has financed its operations principally through issuance of equity securities. On May 9, 2024, the Company closed an underwritten public offering of 3,450,000 shares of its common stock at a public offering price of $46.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the public offering were $158.7 million, before deducting the underwriter discount and other offering expenses, totaling approximately $9.7 million. On July 19, 2024, the Company entered into an Open Market Agreement^{SM} (the "Sales Agreement") with Jefferies LLC, as sales agent ("Jefferies"), pursuant to which the Company may offer and sell, from time to time, through Jefferies shares of its common stock having an aggregate offering price of up to $150,000,000.

In December 2022, the Company entered into a Securities Purchase Agreement providing for the sale of up to $60.0 million in warrants (Tranche A and Tranche B) and the common stock issuable upon the exercise thereof. Cumulative to date through September 30, 2024, the Company has received $10.0 million from the sale of these warrants and $37.7 million in proceeds from the exercise of certain of these warrants. Warrants with an aggregate exercise price of $12.3 million are still outstanding.

The Company expects to continue incurring losses for the foreseeable future. However, the Company expects that its current cash, cash equivalents and marketable securities balances will be sufficient to enable the Company to meet its obligations for at least the next twelve months from the date of this filing.

Note 3. Basis of Presentation and Summary of Significant Accounting Policies

Significant Accounting Policies

There have been no material changes to the significant accounting policies during the three and nine months ended September 30, 2024 as compared to the significant accounting policies described in Note 3 of the “Notes to Consolidated Financial Statements” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, except as noted below.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair

presentation of the interim financial information have been included. When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2024. For further information, refer to the financial statements and footnotes included in the Company's annual financial statements for the fiscal year ended December 31, 2023, which are included in the Company's annual report on Form 10-K filed with the SEC on March 7, 2024.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and reported amounts of expenses in the financial statements and accompanying notes. Actual results could differ from those estimates. Key estimates included in the financial statements include the valuation of deferred income tax assets, the valuation of financial instruments, stock-based compensation, accrued costs for services rendered in connection with third-party contractor clinical trial activities, and the valuation of contingent liabilities for the purchase price of assets obtained through acquisition.

Marketable Securities

The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the balance sheets, with unrealized gains and non-credit related losses that are determined to be temporary, if any, reported as a component of other comprehensive income (loss) within the statements of operations and comprehensive loss and as a separate component of stockholders' equity. The Company classifies marketable securities with remaining maturities greater than three months but less than one year as marketable securities, and those with remaining maturities greater than one year are classified as long-term marketable securities. Realized gains and losses are calculated using the specific identification method and recorded as interest income and were immaterial for all periods presented.

Recently Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that are adopted by the Company as of the specified effective date.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting – Improvements to Reportable Segment Disclosures*, which provides updates to qualitative and quantitative reportable segment disclosure requirements, including enhanced disclosures about significant segment expenses and increased interim disclosure requirements, among others. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. Early adoption is permitted, and the amendments should be applied retrospectively. The Company is currently evaluating the disclosure requirements related to the new standard but does not anticipate a material impact on its consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures,* which amends the guidance in *ASC 740, Income Taxes*. This ASU is intended to improve the transparency of income tax disclosures by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. This ASU is effective for fiscal years beginning after December 15, 2024. Adoption is permitted either prospectively or retrospectively, and the Company will adopt this ASU on a prospective basis. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements and disclosures.

Other accounting standards that have been issued or proposed by FASB or other standards-setting bodies that do not require adoption until a future date are not currently expected to have a material impact on the Company's financial statements upon adoption.

Note 4. Fair Value of Financial Instruments

The carrying value of the Company's cash, cash equivalents and accounts payable, approximate fair value due to the short-term nature of these items.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

- Level I — Unadjusted quoted prices in active markets for identical assets or liabilities;

- Level II — Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- Level III — Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The fair value of marketable securities, which are Level 2 financial instruments, is based upon market prices quoted on the last day of the fiscal period or other observable market inputs. The Company obtains pricing information from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, bids and/or offers. Marketable securities, all of which are classified as available-for-sale securities, consisted of the following at September 30, 2024 (in thousands):

	September 30, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ 235,410	$ 903	$ (5)	$ 236,308
Total	$ 235,410	$ 903	$ (5)	$ 236,308

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Fair Value Measurements at September 30, 2024			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents:				
Money market funds	$ 26,400	$ 26,400	$ -	$ -
Total cash equivalents	$ 26,400	$ 26,400	$ —	$ —
Marketable securities:				
U.S. Treasury securities	$ 236,308	$ —	$ 236,308	$ —
Total marketable securities	$ 236,308	$ —	$ 236,308	$ —
Total assets	$ 262,708	$ 26,400	$ 236,308	$ —
Liabilities				
Essentialis purchase price contingency liability	$ 14,464	$ —	$ —	$ 14,464
Total liabilities	$ 14,464	$ —	$ —	$ 14,464

	Fair Value Measurements at December 31, 2023			
	Total	Level 1	Level 2	Level 3
Liabilities				
Essentialis purchase price contingency liability	$ 11,549	$ —	$ —	$ 11,549
Total liabilities	$ 11,549	$ —	$ —	$ 11,549

Based on the terms of the Company's completed merger with Essentialis on March 7, 2017, the Company is obligated to make cash earnout payments of up to a maximum of $21.2 million to the former Essentialis stockholders. The fair value of the Essentialis purchase price contingent liability is estimated using scenario-based methods based upon the Company's analysis of the likelihood of obtaining specified approvals from the U.S. Food and Drug Administration (FDA) as well as achieving two commercial sales milestones of $100 million and $200 million in cumulative revenue. The Level 3 estimates are based, in part, on subjective assumptions. In determining the likelihood of this occurring, the analysis relied on published research relating to clinical development success rates. Based on management's assessment, an 88% probability of achieving all three milestones was determined to be reasonable as of both September 30, 2024 and December 31, 2023. During the periods presented, the Company has not changed the manner in which it values its Essentialis purchase price contingent liability.

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers between levels within the hierarchy during the periods presented.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 liabilities for the nine months ended September 30, 2024 and 2023 (dollars in thousands):

	Purchase Price Contingent Liability
Balance at January 1, 2024	$ 11,549
Change in value of contingent liability	2,915
Balance at September 30, 2024	$ 14,464

	2018 PIPE Warrants		Purchase Price Contingent Liability
	Number of Warrants	Liability	
Balance at January 1, 2023	34,241	$ 1	$ 8,835
Change in value of 2018 PIPE Warrants	—	652	—
Change in value of contingent liability	—	—	1,633
Balance at September 30, 2023	34,241	$ 653	$ 10,468

Note 5. Warrants

The Company has issued multiple warrant series, of which the 2018 PIPE Warrants were determined to be liabilities pursuant to the guidance established by *ASC 815 Derivatives and Hedging.*

Warrants Issued as Part of the Units in the 2018 PIPE Offering

The 2018 PIPE Warrants were issued on December 19, 2018 in the 2018 PIPE Offering, pursuant to a Warrant Agreement with each of the investors in the 2018 PIPE Offering, and prior to their expiration on December 21, 2023, entitled the holders to purchase 34,241 shares of the Company's common stock at an exercise price equal to $30.00 per share, subject to adjustments.

In the event of a change of control of the Company, the holders of unexercised warrants may present their unexercised warrants to the Company, or its successor, to be purchased by the Company, or its successor, in an amount equal to the per share value determined by the Black Scholes methodology.

Since the Company may be obligated to settle the 2018 PIPE Warrants in cash, the Company classified the 2018 PIPE Warrants as long-term liabilities at their fair value and will re-measure the warrants at each balance sheet date until they are exercised or expire. Any change in the fair value is recognized as Other income (expense) in the Company's condensed consolidated statements of operations.

The 2018 PIPE Warrants were either exercised prior to or expired on December 21, 2023.

Note 6. Commitments and Contingencies

Facility Leases

On June 13, 2024, the Company entered into a new office lease in Redwood City, California for office space for its headquarters facility. The lease provides office space of approximately 18,026 square feet and for base monthly rent payments beginning at $57,400 that increase annually by approximately 3.0% over the term of five years from the date of occupancy. In addition to base rent, the Company has agreed to reimburse the landlord for certain operating expenses under the terms of the lease. The lease commencement date was September 1, 2024 when the premises became available for occupancy and the related operating lease ROU assets and liabilities were recorded in the Company's condensed consolidated balance sheet as of September 30, 2024.

The Company's operating lease ROU assets, current operating lease liabilities and long-term operating lease liabilities each appear as a separate line within the Company's condensed consolidated balance sheets. In September 2024, the Company recorded an increase to its right-of-use assets by $2.8 million and an increase to its lease liability of $2.8 million as a result of the June 2024 office lease. As of September 30, 2024 and December 31, 2023, the Company's short-term liabilities were equal to $0.4 million and $0.3 million, respectively, and the long-term operating lease liabilities were equal to $2.6 million and $0.1 million, respectively.

The Company's prior operating lease for its predecessor headquarters facility office space in Redwood City, California began in June 2021 and expired in May 2023. In April 2023, the Company entered into a twenty-four month lease extension commencing on June 1, 2023. The term of the lease extension expires in May 2025. On February 8, 2024, the Company entered into a six-month office license agreement to license 4,141 square feet of additional space adjacent to its existing office where the Company was located and in

July 2024, the Company provided notice of early termination of the license agreement for the additional space effective September 17, 2024. As a result of the lease extension, in 2023, the Company recorded an increase to its right-of-use assets by $0.6 million and an increase to its lease liability by $0.6 million.

The weighted average discount rate related to the Company's lease liabilities as of September 30, 2024 was 8.5% over a remaining term of 5 years. The weighted average discount rate related to the Company's lease liabilities as of December 31, 2023 was 8.25% over a remaining term of 17 months. The discount rate was determined based on estimates of the Company's incremental borrowing rate, as the discount rate implicit in the lease cannot be readily determined. Due to the short-term nature of the February 2024 office license agreement, the license agreement obligations are not included in the Company's right-of-use assets and lease liabilities on the Company's condensed consolidated balance sheets.

The components of lease expense during the three and nine months ended September 30, 2024 and 2023 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating lease cost:				
Operating lease cost	$ 137	$ 76	$ 291	$ 235
Variable lease cost	4	—	12	—
Short-term lease cost	54	12	147	33
Total operating lease cost	$ 195	$ 88	$ 450	$ 268

Supplemental cash flow information related to leases was as follows (in thousands):

Cash paid for amounts included in the measurement of lease liabilities:

	Nine Months Ended September 30,	
	2024	2023
Operating cash flows from operating leases	$ 248	$ 264

The following is a schedule by year of future maturities of the Company's operating lease liabilities as of September 30, 2024 (in thousands):

2024 (remainder of the year)	$ 64
2025	526
2026	751
2027	861
2028	942
Thereafter	665
Total lease payments	3,809
Less interest	(780)
Total	$ 3,029

Other Commitments

The Company enters into agreements in the normal course of business, including with contract research organizations for clinical trials, contract manufacturing organizations for certain manufacturing services, and vendors for preclinical studies as well as other services and products for operating purposes, which are generally cancelable upon written notice. As of September 30, 2024, the Company's non-cancelable other commitments aggregated $2.8 million.

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated.

Note 7. Stockholders' Equity

Convertible Preferred Stock

The Company is authorized to issue 10,000,000 shares of Preferred Stock.

Public Offering of Common Stock

On May 9, 2024, the Company closed an underwritten public offering of 3,450,000 shares of its common stock at a public offering price of $46.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the public offering were $158.7 million, before deducting the underwriter discount and other offering expenses, totaling approximately $9.7 million.

Public Offering of Common Stock and Concurrent Private Placement of Common Stock and Pre-Funded Warrants

On October 2, 2023, the Company closed an underwritten public offering of 3,450,000 shares of its common stock at a public offering of $20.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the public offering were $69.0 million, before deducting the underwriting discount and other offering expenses. Concurrently, the Company also completed the closing of 1,825,000 shares of its common stock and 1,175,000 pre-funded warrants in a private offering pursuant to a securities purchase agreement with certain investors, including entities affiliated with existing stockholders, at a price per share of common stock equal to the public offering price of $20.00 and a price per pre-funded warrant of $19.99, for total gross proceeds of approximately $60.0 million. In aggregate, the Company received $129.0 million of gross proceeds less offering costs of $8.2 million. The Company is not required under any circumstance to settle any of the pre-funded warrants for cash, and therefore classified the pre-funded warrants as permanent equity.

Securities Purchase Agreement

On December 16, 2022, the Company entered into a Securities Purchase Agreement for a private placement (Private Placement) with certain entities and members of management (collectively, Purchasers). Pursuant to the Securities Purchase Agreement, the Company agreed to sell to the Purchasers warrants to purchase up to an aggregate of 22,598,870 shares of the Company's common stock, at a purchase price of $0.4425 per warrant. The closing of the Private Placement occurred on May 8, 2023 (the Issue Date), following the satisfaction of certain closing conditions, including the completion of enrollment in the randomized withdrawal period of Study C602. The Company received gross proceeds of $10.0 million for the sale and issuance of warrants to purchase common stock.

The warrants were separated into two tranches with 8,598,870 Tranche A Warrants with an exercise price of $1.75 per share and aggregate proceeds of up to approximately $15.0 million, and 14,000,000 Tranche B Warrants with an exercise price of $2.50 per share and aggregate proceeds of up to $35.0 million. The Tranche A warrants were immediately exercisable and were required to be exercised within 30 days of announcement of positive top-line data from the randomized withdrawal period of Study C602. On September 26, 2023, the Company announced positive top-line data and subsequently received $15.0 million from the exercise of the Tranche A warrants. The Tranche B warrants are also immediately exercisable and expire upon the earlier of 3.5 years from the date of issuance or 30 days following receipt of FDA approval of DCCR for the treatment of PWS. Through September 30, 2024, certain investors had exercised their Tranche B warrants and the Company has received $22.7 million. The receipt of the aggregate exercise price of up to $12.3 million for the remaining Tranche B warrants is contingent upon the exercise of such warrants.

Underwritten Public Offering

On March 31, 2022, the Company sold 2,666,667 shares of its common stock at a public offering price of $3.75 per share, and for certain investors, in lieu of common stock, pre-funded warrants (the 2022 pre-funded warrants) to purchase 1,333,333 shares of its common stock at a public offering price $3.60 per pre-funded warrant, which represents the per share public offering price for the common stock less the $0.15 per share exercise price for each 2022 pre-funded warrant. The March 2022 pre-funded warrants are immediately exercisable and may be exercised at any time until all of the March 2022 pre-funded warrants are exercised in full. Each share of common stock or March 2022 pre-funded warrant was sold together with one, immediately exercisable, common warrant (the 2022 common warrants) with a five-year term to purchase one share of common stock at an exercise price of $4.50 per share. The net proceeds of the offering were $13.8 million, after deducting the underwriting discount and other offering expenses. The Company is not required under any circumstance to settle any of the 2022 pre-funded warrants or the 2022 common warrants for cash, and therefore classified both types of warrants as permanent equity.

Through September 30, 2024, 2,145,073 of the March 2022 common warrants had been exercised for gross proceeds of $9.7 million and 581,850 warrants were exercised using the cashless exercise option with no proceeds to the Company. As of September

30, 2024, 1,273,077 of the March 2022 common warrants remain outstanding. All 1,333,333 of the March 2022 pre-funded warrants were exercised in 2023 using the cashless exercise option with no additional proceeds received by the Company.

At the Market Offering

In July 2021, the Company entered into a Controlled Equity Offering Sales Agreement under which the Company was able to sell shares of its common stock having an aggregate offering price of up to $25.0 million from time to time in any method permitted by law deemed to be an "at-the-market" Rule 415 under the Securities Act of 1933, as amended. The Controlled Equity Offering Sales Agreement was terminated in connection with the October 2, 2023 financing. While active, the Company sold 1,877,170 shares of common stock through the at the market program, totaling $7.4 million in net proceeds.

On July 19, 2024, the Company entered into the Sales Agreement with Jefferies, pursuant to which the Company may offer and sell up to $150.0 million of shares of its common stock, from time to time, through Jefferies.

The Company will pay Jefferies a commission of 3.0% of the aggregate gross proceeds from the sale of shares and has agreed to provide Jefferies with customary indemnification and contribution rights. The Company has also agreed to reimburse Jefferies for certain specified expenses. The Company is not obligated to sell any shares under the Sales Agreement. The offering of the shares pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement by Jefferies or the Company, as permitted therein.

Common Stock Warrants

As of September 30, 2024 and December 31, 2023, the following table summarizes the Company's outstanding common stock warrants:

	As of September 30, 2024		As of December 31, 2023		
	Number of Common Warrant Shares	Weighted Average Exercise Price per Share	Number of Common Warrant Shares	Weighted Average Exercise Price per Share	Expiration Date
Common stock warrants	7,904	$ 388.94	7,904	$ 388.94	November 2024
March 2022 Common warrants	1,273,077	$ 4.50	1,929,066	$ 4.50	March 2027
May 2023 Tranche A pre-funded warrants	1,250,647	$ 0.01	2,758,281	$ 0.01	November 2026
May 2023 Tranche B warrants	4,935,305	$ 2.50	6,750,000	$ 2.50	November 2026 [1]
May 2023 Tranche B pre-funded warrants	451,632	$ 0.01	451,632	$ 0.01	November 2026
October 2023 pre-funded warrants	250,000	$ 0.01	1,175,000	$ 0.01	N/A
Total	8,168,565		13,071,883		

[1] Subject to earlier expiration as described above.

Equity Incentive Plans

2014 Plan

The Company maintains the 2014 Equity Incentive Plan (the 2014 Plan). Under the 2014 Plan the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance units or performance shares to employees, directors, advisors, and consultants. Options granted under the 2014 Plan may be incentive stock options (ISOs) or nonqualified stock options (NSOs). ISOs may be granted only to Company employees, including officers and directors.

The Board has the authority to determine to whom stock options will be granted, the number of options, the term, and the exercise price. Options are to be granted at an exercise price not less than fair value. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price of an option will not be less than 110% of fair value. Performance-based grants have vesting contingent upon the achievement of certain performance criteria related to the Company’s commercialization of its therapeutics. The contractual term of an option is no longer than five years for ISOs for which the grantee owns greater than 10% of the voting power of all classes of stock and no longer than ten years for all other options. The terms and conditions governing restricted stock units is at the sole discretion of the Board.

On January 17, 2024, the Company filed a Registration Statement on Form S-8 which registered an additional 1,000,000 shares automatically available for issuance under the 2014 Plan as of December 31, 2023. On June 6, 2024, the stockholders approved the Amended and Restated 2014 Plan which included an increase of 2,000,000 shares, which became immediately available for grant and issuance. As of September 30, 2024, a total of 609,179 shares are available for future grant under the 2014 Plan.

Inducement Plan

The Company maintains the 2020 Inducement Equity Incentive Plan (the Inducement Plan). The Inducement Plan provides for the grant of equity-based awards, including non-statutory stock options, restricted stock units, restricted stock, stock appreciation rights, performance shares and performance units, and its terms are substantially similar to the 2014 Plan.

In accordance with Rule 5635(c)(4) and Rule 5635(c)(3) of the Nasdaq Listing Rules, awards under the Inducement Plan may only be made to individuals not previously employees or non-employee directors of the Company (or following such individuals' bona fide period of non-employment with the Company), as an inducement material to the individuals' entry into employment with the Company, or, to the extent permitted by Rule 5635(c)(3) of the Nasdaq Listing Rules, in connection with a merger or acquisition. On January 31, 2024, the Company filed a Registration Statement on Form S-8 which registered 500,000 shares available for issuance under the Inducement Plan, which became available for issuance following approval of the Board of Directors on January 24, 2024.

As of September 30, 2024, a total of 5,318 shares are available for future grant under the Inducement Plan.

Stock-based compensation expense

The Company recognizes stock-based compensation expense related to options and restricted stock units granted to employees, directors and consultants. The compensation expense is allocated on a departmental basis, based on the classification of the award holder. No income tax benefits have been recognized in the condensed consolidated statements of operations and comprehensive loss for stock-based compensation arrangements during any of the periods presented.

Stock-based compensation expense was recognized in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 18,516	$ 935	$ 23,682	$ 1,587
General and administrative	38,082	1,266	46,521	2,449
Total	$ 56,598	$ 2,201	$ 70,203	$ 4,036

Stock Options

The Company granted options to purchase 288,850 and 77,000 shares of the Company's common stock to employees during the three months ended September 30, 2024 and 2023, respectively. During the nine months ended September 30, 2024, the Company granted options to purchase 1,369,230 of the Company's common stock to employees and a consultant, and during the nine months ended September 30, 2023, the Company granted 1,663,454 of the Company's common stock to employees. There were no performance-based options granted during the three and nine months ended September 30, 2024 and 2023, respectively. The fair value of each award granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Expected life (years)	6.1	5.3-6.0	5.8-6.1	5.3-6.0
Risk-free interest rate	3.7%-3.8%	4.0%-4.4%	3.7%-4.6%	3.5%-4.4%
Volatility	121%	98%-100%	121%-124%	98%-100%
Dividend rate	— %	— %	— %	— %

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. These assumptions include the following estimates:

- *Expected life:* The expected life of stock options represents the period of time that the options are expected to be outstanding. Due to the lack of historical exercise history, the expected life of the Company's service-based stock options has been determined utilizing the "simplified method", based on the average of the contractual term of the options and the weighted-average vesting period. The expected life for the performance-based options was determined based on consideration of the contractual term of the stock options, an estimate of the date the performance criteria would be met and expectations of employee behavior.
- *Risk-free interest rate:* The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected life of the stock options.

- *Volatility:* The estimated volatility rate is based on the volatilities of the Company's common stock for a historical period equal to the expected life of the stock options.
- *Dividend rate:* The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.

The following table summarizes stock option transactions for the nine months ended September 30, 2024 which were for awards issued under the 2014 Plan and the Inducement Plan:

	Number of Options Outstanding	Weighted-Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at January 1, 2024	2,369,665	$ 11.56	8.72	$ 70,834
Options granted	1,369,230	42.91		
Options exercised	(171,520)	7.59		
Options canceled/forfeited	(44,124)	42.30		
Balance at September 30, 2024	3,523,251	$ 23.55	8.55	$ 97,143
Options exercisable at September 30, 2024	1,116,184	$ 15.67	7.40	$ 41,095
Options vested and expected to vest at September 30, 2024	3,523,251	$ 23.55	8.55	$ 97,143

The weighted-average grant date fair value of options granted was $37.84 and $3.80 per share for the nine months ended September 30, 2024 and 2023, respectively. At September 30, 2024, total unrecognized employee stock-based compensation related to stock options that are likely to vest was $50.1 million, which is expected to be recognized over the weighted-average remaining vesting period of 2.7 years.

Restricted Stock Units

There were 1,239,375 performance-based restricted stock units and 366,625 restricted stock units granted to employees and a director during the three months ended September 30, 2024 and zero granted during the three months ended September 30, 2023. During the nine months ended September 30, 2024, there were 1,249,375 performance-based restricted stock units and 758,155 restricted stock units granted to employees and directors. During the nine months ended September 30, 2023, 414,710 restricted stock units were granted to employees. The shares were valued based on the Company's common stock price on the grant date.

The following table summarizes restricted stock unit transactions for the nine months ended September 30, 2024 as issued under the 2014 Plan:

	Number of Restricted Stock Units	Weighted-Average Grant-Date Fair Value per Share
Outstanding at January 1, 2024	15,534	$ 43.92
Restricted stock units granted	2,007,530	$ 46.47
Restricted stock units vested	(950,534)	$ 45.81
Restricted stock units canceled/forfeited	-	$ 0.00
Outstanding at September 30, 2024	1,072,530	$ 47.02

The weighted-average grant-date fair value of all restricted stock units granted during the nine months ended September 30, 2024 and 2023 was $46.47 and $5.25, respectively. The fair value of all restricted stock units vested during the nine months ended September 30, 2024 and 2023 was $44.67 million and $23,000, respectively. At September 30, 2024, total unrecognized employee stock-based compensation related to restricted stock units was $34.5 million, which is expected to be recognized over the weighted-average remaining vesting period of 0.4 years. 74,250 restricted stock units vested on September 30, 2024 and are included in the Restricted stock units vested line item above. The shares of common stock were subsequently issued after September 30, 2024 and therefore are not included in the outstanding common stock as of September 30, 2024.

2014 Employee Stock Purchase Plan

The Company's board of directors and stockholders have adopted the 2014 Employee Stock Purchase Plan (ESPP). The ESPP has become effective, and the board of directors will implement commencement of offers thereunder in its discretion. A total of 1,864 shares of the Company's common stock has been made available for sale under the ESPP. In addition, the ESPP provides for annual

increases in the number of shares available for issuance under the plan on the first day of each year beginning in the year following the initial date that the board of directors authorizes commencement, equal to the least of:

- 1.0% of the outstanding shares of the Company's common stock on the first day of such year;
- 3,729 shares; or
- such amount as determined by the board of directors.

As of September 30, 2024, there were no purchases by employees under this plan.

Note 8. Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common stock outstanding during the period. Shares of common stock that are potentially issuable for little or no cash consideration at issuance, such as the Company's pre-funded warrants issued in March 2022 and October 2023 and in connection with the exercise of certain May 2023 Tranche A and Tranche B warrants, are considered outstanding common stock and are included in the calculation of basic and diluted net loss per share in connection with *ASC 260 Earnings Per Shares*. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock outstanding and dilutive potential common stock that would be issued upon the exercise or vesting of common stock awards and exercise of common stock warrants that are not pre-funded. The Company applies the two-class method to calculate basic and diluted earnings per share as its warrants issued in March 2022, May 2023 and October 2023 are participating securities. However, the two-class method does not impact the net loss per share of common stock as the March 2022, May 2023 and October 2023 common warrants issued do not participate in losses. For the three and nine months ended September 30, 2024 and 2023, the effect of issuing potential common stock is anti-dilutive due to the net losses in those periods and therefore the number of shares used to compute basic and diluted net loss per share are the same in each of those periods.

The following securities are the weighted-average common shares outstanding used to calculate basic and diluted net loss per common share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Common stock	39,360,966	10,287,620	35,824,742	9,206,650
March 2022 pre-funded warrants	-	1,122,819	-	1,227,670
May 2023 Tranche A pre-funded warrants	1,816,427	26,309	2,154,299	8,866
May 2023 Tranche B pre-funded warrants	451,632	-	451,632	-
October 2023 pre-funded warrants	250,000	-	486,496	-
Total	41,879,025	11,436,748	38,917,169	10,443,186

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted-average shares outstanding for the periods presented because such securities have an antidilutive impact due to losses reported (in common stock equivalent shares):

	As of September 30,	
	2024	2023
Warrants issued to 2010/2012 convertible note holders to purchase common stock	6,804	6,804
Warrants issued to underwriter to purchase common stock	1,100	1,100
2018 PIPE warrants	-	34,241
March 2022 common warrants	1,273,077	2,130,656
May 2023 Tranche A warrants	-	2,867,908
May 2023 Tranche B warrants	4,935,305	14,000,000
Options to purchase common stock	3,523,251	2,300,412
Outstanding restricted stock units	1,072,530	424,244
Total	10,812,067	21,765,365

Note 9. Subsequent Events

The Company has evaluated its subsequent events from September 30, 2024 through the date these condensed consolidated financial statements were issued and has determined that there are no subsequent events disclosure required.

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

The interim consolidated financial statements included in this Quarterly Report on Form 10-Q and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2023, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in our Form 10-K for the year ended December 31, 2023. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These forward-looking statements are subject to risks and uncertainties, including those set forth in Part II – Other Information, Item 1A. Risk Factors below and elsewhere in this report that could cause actual results to differ materially from historical results or anticipated results.

Business Overview

We are focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Our lead candidate is DCCR (Diazoxide Choline) Extended-Release tablets, a once-daily oral tablet for the treatment of Prader-Willi syndrome (PWS). We have Fast-Track and Breakthrough Therapy designations for DCCR for the treatment of PWS in the United States (U.S.) and orphan designation for the treatment of PWS in the U.S. as well as in the European Union (E.U.).

DCCR has been evaluated in a Phase 3 study (C601 or DESTINY PWS), a 3-month randomized, double-blind placebo-controlled study, which completed enrollment in January 2020, with 127 patients at 29 sites in the U.S. and U.K. Participants who completed treatment in DESTINY PWS were eligible to receive DCCR in a long-term open-label extension period (C602). Top line results from DESTINY PWS were announced in June 2020. Although the trial did not meet its primary endpoint of change from baseline in hyperphagia, significant improvements were observed in two of three key secondary endpoints.

In January 2022, the FDA recommended that additional controlled data be included in a New Drug Approval (NDA) submission and in October 2022, we initiated the RW period of Study C602. This was a multi-center, randomized, double-blind, placebo-controlled study of DCCR in 77 patients with PWS at 17 sites in the U.S. and 5 sites in the U.K. This RW period consisted only of patients enrolled in Study C602 and did not enroll any new patients. In September 2023, we announced positive statistically significant top-line results from the RW period of Study C602.

In April 2024, the FDA granted Breakthrough Therapy Designation for DCCR, the first ever breakthrough designation for a drug being developed for PWS, in June 2024 we submitted an NDA for DCCR to the FDA, and on August 27, 2024, we announced the FDA granted Priority Review for the NDA and assigned a Prescription Drug User Fee Act (PDUFA) target action date of December 27, 2024.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our critical accounting estimates and significant accounting policies are more fully described in Note 3 of our most recent Form 10-K and including the policy below.

Marketable Securities

The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the balance sheets, with unrealized gains and non-credit related losses that are determined to be temporary, if any, reported as a component of other comprehensive income (loss) within the statements of operations and comprehensive loss and as a separate component of stockholders' equity. The Company classifies marketable securities with remaining maturities greater than three months but less than one year as marketable securities, and those with remaining maturities greater than one year are classified as long-term marketable securities. Realized gains and losses are calculated using the specific identification method and recorded as interest income and were immaterial for all periods presented.

Results of Operations

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

	Three Months Ended September 30,		Increase (decrease)	
	2024	2023	Amount	Percentage
	(in thousands)			
Operating expenses				
Research and development	$ 30,138	$ 6,043	$ 24,095	399 %
General and administrative	49,197	3,318	45,879	1383 %
Change in fair value of contingent consideration	877	1,021	(144)	14 %
Total operating expenses	80,212	10,382	69,830	673 %
Operating loss	(80,212)	(10,382)	(69,830)	673 %
Other income (expense), net				
Change in fair value of warrants liabilities	-	(653)	653	100 %
Interest income, net	3,596	174	3,422	1967 %
Total other income (expense), net	3,596	(479)	4,075	851 %
Net loss	$ (76,616)	$ (10,861)	$ (65,755)	605 %

Revenue

To date, we have earned no revenue from the commercial development and sale of novel therapeutic products.

Research and development expense

Research and development expense was $30.1 million, which includes $18.5 million of non-cash stock-based compensation, for the three months ended September 30, 2024, compared to $6.0 million, which includes $0.9 million of non-cash stock-based compensation, in the same period of 2023. Personnel and other associated costs increased $2.4 million as we hired additional employees in support of our research and development activities. Costs in support of our NDA submission increased $2.7 million and we invested $1.3 million in supply chain activities in preparation for commercial launch. The cadence of our research and development expenditures will fluctuate depending upon the state of our clinical programs, the timing of manufacturing and other projects necessary to support the submission of an NDA and prepare for commercial launch. The $17.6 million of additional non-cash stock-based compensation being recognized in the period is predominantly due to performance-based RSU grants which partially vested upon the acceptance by the FDA of the NDA submission and fully vest upon the approval by the FDA.

General and administrative expense

General and administrative expense was $49.2 million, which includes $38.1 million of non-cash stock-based compensation, for the three months ended September 30, 2024, compared to $3.3 million, which includes $1.3 million of non-cash stock-based compensation, in the same period of 2023. Personnel and associated costs increased $3.0 million as we have hired additional employees in preparation for commercial launch and in support of our increased business activities. Professional services expenses and other program costs associated with preparation for commercial launch, including medical affairs activities, increased by $5.9 million. The $36.8 million of additional non-cash stock-based compensation being recognized in the period is predominantly due to performance-based RSU grants which partially vested upon acceptance by the FDA of the NDA submission and fully vest upon approval by the FDA.

Change in fair value of contingent consideration

We are obligated to make cash payments up to a maximum of $21.2 million to the former Essentialis stockholders upon the achievement of certain future commercial milestones associated with the sales of DCCR in accordance with the terms of our merger agreement with Essentialis. The fair value of the liability for the contingent consideration payable by us achieving two commercial sales milestones of $100 million and $200 million in cumulative revenue in future years was estimated to be $14.5 million as of September 30, 2024, a $0.9 million increase from the estimate as of June 30, 2024. During the three months ended September 30, 2023, the estimate increased by $1.1 million from the $9.4 million estimate as of June 30, 2023.

Other income, net

We had other income, net of approximately $3.6 million in the three months ended September 30, 2024, compared to other expense, net of approximately $479,000 during the three months ended September 30, 2023. The increase was primarily due to an

increase in interest income driven by higher cash and cash equivalents, marketable securities and long-term marketable securities during the three months ended September 30, 2024, compared to the three months ended September 30, 2023.

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

	Nine months ended September 30,		Increase (decrease)	
	2024	2023	Amount	Percentage
	(in thousands)			
Operating expenses				
Research and development	$ 57,082	16,500	$ 40,582	246 %
General and administrative	68,558	9,341	59,217	634 %
Change in fair value of contingent consideration	2,915	1,633	1,282	79 %
Total operating expenses	128,555	27,474	101,081	368 %
Operating loss	(128,555)	(27,474)	(101,081)	368 %
Other income (expense), net				
Change in fair value of warrants liabilities	-	(652)	652	100 %
Interest income, net	8,687	434	8,253	1902 %
Total other income (expense), net	8,687	(218)	8,905	4085 %
Net loss	$ (119,868)	$ (27,692)	$ (92,176)	333 %

Revenue

To date, we have earned no revenue from the commercial development and sale of novel therapeutic products.

Research and development expense

Research and development expense was $57.1 million, which includes $23.7 million of non-cash stock-based compensation, for the nine months ended September 30, 2024, compared to $16.5 million, which includes $1.6 million of non-cash stock-based compensation, in the same period of 2023. Personnel and associated costs increased $4.9 million as we hired additional employees in support of our research and development activities. Costs in support of our NDA submission increased $9.9 million and we invested $3.7 million in supply chain activities in preparation for commercial launch. The cadence of our research and development expenditures will fluctuate depending upon the state of our clinical programs, the timing of manufacturing and other projects necessary to support the submission of an NDA and prepare for commercial launch. The $22.1 million of additional non-cash stock-based compensation being recognized in the period is predominantly due to performance-based RSU grants which partially vested upon the acceptance by the FDA of the NDA submission and fully vest upon the approval by the FDA.

General and administrative expense

General and administrative expense was $68.6 million, which includes $46.5 million of non-cash stock-based compensation, for the nine months ended September 30, 2024, compared to $9.3 million, which includes $2.4 million of non-cash stock-based compensation, in the same period of 2023. Personnel and associated costs increased $5.5 as we have hired additional employees in preparation for commercial launch and in support of our increased business activities. Professional services expenses and other program costs associated with preparation for commercial launch, including medical affairs activities, increased by $9.4 million. The $44.1 million of additional non-cash stock-based compensation being recognized in the period is predominantly due to performance-based RSU grants which partially vested upon the acceptance by the FDA of the NDA submission and fully vest upon the approval by the FDA.

Change in fair value of contingent consideration

We are obligated to make cash payments up to a maximum of $21.2 million to the former Essentialis stockholders upon the achievement of certain future commercial milestones associated with the sales of DCCR in accordance with the terms of our merger agreement with Essentialis. The fair value of the liability for the contingent consideration payable by us achieving two commercial sales milestones of $100 million and $200 million in cumulative revenue in future years was estimated to be $14.5 million as of September 30, 2024, a $2.9 million increase from the estimate as of December 31, 2023. During the nine months ended September 30, 2023, the estimate increased by $1.6 million from the $8.9 million estimate as of December 31, 2022.

Other income, net

We had other income, net of approximately $8.7 million in the nine months ended September 30, 2024, compared to other expense, net of approximately $0.2 million during the nine months ended September 30, 2023. The increase was primarily due to an increase in interest income driven by higher cash and cash equivalents, marketable securities and long-term marketable securities during the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023.

Liquidity and Capital Resources

We used $45.1 million of cash in operating activities and had a net loss of $119.9 million during the nine months ended September 30, 2024. We had an accumulated deficit of $396.3 million at September 30, 2024 as a result of having incurred losses since our inception. We had $48.4 million in cash and cash equivalents, $208.4 million of marketable securities, $27.9 million of long-term marketable securities and $243.2 million of working capital on September 30, 2024. As of September 30, 2024, we had lease obligations totaling $3.0 million to be paid through August 2029, consisting of two operating leases for office space in Redwood City, California.

We have financed our operations principally through issuances of equity securities. In May 2024, we closed an underwritten public offering of 3,450,000 shares of our common stock at a public offering price of $46.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the public offering were $158.7 million, before deducting the underwriter discount and other offering expenses of $9.7 million. In July 2024, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, as sales agent ("Jefferies"), pursuant to which we may offer and sell, from time to time, through Jefferies, shares of our common stock having an aggregate offering price of up to $150,000,000.

Previously in October 2023, we announced the closing of the underwritten public offering of 3,450,000 shares of our common stock at a public offering of $20.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the public offering were $69.0 million, before deducting the underwriting discount and other estimated offering expenses. We also announced the closing shares of our common stock and pre-funded warrants in a concurrent private offering pursuant to the securities purchase agreement with certain investors, including entities affiliated with existing stockholders, at a price per share of common stock equal to the public offering price of $20.00 and a price per pre-funded warrant of $19.99, for gross proceeds of approximately $60.0 million. In aggregate, we received $129.0 million of gross proceeds from this financing.

In December 2022, we entered into a securities purchase agreement providing for the sale of up to $60.0 million in warrants and the common stock issuable upon the exercise thereof. Through September 30, 2024, we have received $10.0 million from the sale of these warrants and $37.7 million in proceeds from the exercise of certain of these warrants. Warrants with an aggregate exercise price of $12.3 million are still outstanding.

We expect to continue incurring losses for the foreseeable future and may require additional capital to complete our clinical trials, pursue product development initiatives and penetrate markets for the sale of our products. We believe that we will continue to have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means, but the access to such capital resources is uncertain and is not assured. In the future, if we are unable to secure additional capital, we may be required to curtail our clinical trials and development of new products and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our efforts to complete clinical trials and commercialize our products, which is critical to the realization of our business plan and our future operations.

Cash flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (45,105)	$ (18,626)
Net cash used in investing activities	(232,125)	—
Net cash provided by financing activities	155,962	56,461
Net (decrease) increase in cash and cash equivalents	$ (121,268)	$ 37,835

Net cash used in operating activities

During the nine months ended September 30, 2024, operating activities used net cash of $45.1 million, which was primarily due to the net loss of $119.9 million, less non-cash expense of $70.2 million for stock-based compensation, $1.5 million for depreciation and amortization, $0.3 million for non-cash lease expense, $2.9 million related to the change in fair value of contingent consideration, and $3.5 million added back for accretion of premium/discount on marketable securities. Additionally, usage of cash during the nine months ended September 30, 2024 increased by $3.4 million due to changes in operating assets and liabilities.

During the nine months ended September 30, 2023, operating activities used net cash of $18.6 million, which was primarily due to the net loss of $27.7 million less non-cash expense of $4.0 million for stock-based compensation, $1.5 million for depreciation and amortization, $0.3 million for non-cash lease expense, and $2.3 million related to the change in fair value of common stock warrants and contingent consideration. Additionally, usage of cash during the nine months ended September 30, 2023 decreased by $1.0 million due to changes in operating assets and liabilities.

Net cash used in investing activities

During the nine months ended September 30, 2024, we used $308.9 million for purchases of marketable securities and $0.2 million for purchases of property and equipment. We received proceeds of $77.0 million from maturities of marketable securities.

During the nine months ended September 30, 2023, there were no investing activities.

Net cash provided by financing activities

During the nine months ended September 30, 2024, we received $149.0 million from the sale of common stock, net of issuance costs and $5.7 million from the exercise of common stock and pre-funded stock warrants. We also received $1.3 million from the exercise of stock options.

During the nine months ended September 30, 2023, we received $33.4 million from the sale and issuance of warrants pursuant to the Securities Purchase Agreement and $16.0 million prior to and for the issuance of common stock in conjunction with our October 2, 2023 financing. We also received net proceeds of $7.1 million from the sale of common stock through the at the market program.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have not been any material changes to our exposure to market risk during the nine months ended September 30, 2024. For additional information regarding market risk, refer to the *Qualitative and Quantitative Disclosures About Market Risk* section of the Form 10-K.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended (Exchange Act), is recorded, processed, summarized and reported within the time periods specified in U.S. Securities and Exchange Commission, or SEC, rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective.

(b) Changes in Internal Control over Financial Reporting

There have been no changes to our internal control over financial reporting that occurred during the three months ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, even if determined effective and no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives to prevent or detect misstatements. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We may, from time to time, be party to litigation and subject to claims that arise in the ordinary course of business. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications. We currently believe that these ordinary course matters will not have a material adverse effect on our business; however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties. 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 conditions and/or operating results. If any of these risks actually occur, our business, operating results and financial condition could be harmed, and the value of our stock could go down. This means you could lose all or a part of your investment. We have included in Part I, Item 1A of our Form 10-K, a description of certain risks and uncertainties that could affect our business, future performance or financial condition (the Risk Factors). There have been no material changes from the disclosure provided in the Form 10-K with respect to the Risk Factors.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

We have social media posts at Twitter (X) - @SolenoTX and LinkedIn - Soleno Therapeutics, Inc. It is possible that information we post on social media channels could be deemed to be material information. The information on, or that may be accessed through, our website and social media channels is not incorporated by reference into this Quarterly Report on Form 10-Q and should not be considered a part of this Quarterly Report on Form 10-Q.

(c) Insider Adoption or Termination of Trading Arrangements

The following provides information regarding Rule 10b5-1 trading arrangements (as defined in Item 408 of Regulation S-K under the Securities Exchange Act of 1934, each a "10b5-1 Plan") adopted in the third quarter of 2024 by any director or officer who is subject to the filing requirements of Section 16 of the Securities Exchange Act of 1934 ("Section 16 Director or Officer"):

Anish Bhatnagar, our Chief Executive Officer, President and Chief Operating Officer, and a member of our board of directors adopted a 10b5-1 Plan on September 6, 2024. Mr. Bhatnagar's 10b5-1 Plan provides for the potential sale of up to 300,000 shares of

our common stock, and expires on September 6, 2025, or upon the earlier completion of all authorized transactions thereunder. The first trade will not occur until January 15, 2025, at the earliest.

Jim Mackaness, our Chief Financial Officer, adopted a 10b5-1 Plan on September 6, 2024. Mr. Mackaness' 10b5-1 Plan provides for the potential sale of up to 60,000 shares of our common stock, and expires on September 6, 2025, or upon the earlier completion of all authorized transactions thereunder. The first trade will not occur until January 15, 2025, at the earliest.

Patricia C. Hirano, our Senior Vice President, Regulatory Affairs, adopted a 10b5-1 Plan on September 13, 2024. Ms. Hirano's 10b5-1 Plan provides for the potential sale of up to 124,026 shares of our common stock, and expires on September 13, 2025, or upon the earlier completion of all authorized transactions thereunder. The first trade will not occur until January 2, 2025, at the earliest.

Kristen Yen, our Senior Vice President, Clinical Operations, adopted a 10b5-1 Plan on September 13, 2024. Ms. Yen's 10b5-1 Plan provides for the potential sale of up to 95,089 shares of our common stock, and expires on September 30, 2025, or upon the earlier completion of all authorized transactions thereunder. The first trade will not occur until January 2, 2025, at the earliest.

These trading arrangements are intended to satisfy the affirmative defense of Rule 10b5-1(c). Certain of our Section 16 Directors or Officers may participate in employee stock purchase plans, 401(k) plans or dividend investment plans of us that have been designed to comply with Rule 10b5-1(c). No non-Rule 10b5-1 trading arrangements (as defined in Item 408 of Regulation S-K under the Securities Exchange Act of 1934) were adopted by any Section 16 Director or Officer during the third quarter of 2024. Additionally, no Rule 10b5-1 or non-Rule 10b5-1 trading arrangements were terminated by any Section 16 Director or Officer in the third quarter of 2024.

Item 6. Exhibits

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Quarterly Report on Form 10-Q, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
10.1	Open Market Sale Agreement℠, dated July 19, 2024, by and between Soleno Therapeutics, Inc. and Jefferies LLC	8-K	July 19, 2024	10.1	
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934, as amended				X
31.2	Certification of Principal Financial and Accounting Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934, as amended				X
32.1†	Certification of Principal Executive Officer Required Under Rule 13a-14(b) of the Securities and Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
32.2†	Certification of Principal Financial and Accounting Officer Required Under Rule 13a-14(b) of the Securities and Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.				X
104	Cover Page formatted as Inline XBRL and contained in Exhibit 101.				X

† The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in 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.

Date: November 6, 2024

SOLENO THERAPEUTICS, INC.

By: /s/ James Mackaness

James Mackaness
Chief Financial Officer
(authorized officer and principal financial and accounting officer)

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, Anish Bhatnagar, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Soleno 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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(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(s) 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 6, 2024

/s/ Anish Bhatnagar
Anish Bhatnagar
President, Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, James Mackaness, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Soleno 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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(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(s) 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 6, 2024

/s/ James Mackaness
James Mackaness
Chief Financial Officer
(principal financial and accounting 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 of Soleno Therapeutics, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2024, as filed with the Securities and Exchange Commission (the "Report"), Anish Bhatnagar, President, Chief Executive Officer of the Company does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 6, 2024

/s/ Anish Bhatnagar
Anish Bhatnagar
President, 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 of Soleno Therapeutics, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2024, as filed with the Securities and Exchange Commission (the "Report"), James Mackaness, Chief Financial Officer of the Company does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 6, 2024

/s/ James Mackaness
James Mackaness
Chief Financial Officer
(principal financial and accounting officer)