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, 2022

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.)**

203 Redwood Shores Parkway, Suite 500
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 November 4, 2022, there were 8,159,382 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, 2022	December 31, 2021
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 19,751	$ 21,304
Prepaid expenses and other current assets	821	1,118
Total current assets	20,572	22,422
Long-term assets		
Property and equipment, net	23	33
Operating lease right-of-use assets	206	421
Intangible assets, net	11,178	12,637
Other long-term assets	-	40
Total assets	$ 31,979	$ 35,553
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,324	$ 3,254
Accrued compensation	1,282	728
Accrued clinical trial site costs	2,826	3,420
Operating lease liabilities	239	282
Other current liabilities	671	323
Total current liabilities	7,342	8,007
Long-term liabilities		
2018 PIPE Warrant liability	-	31
Contingent liability for Essentialis purchase price	9,437	9,547
Long-term lease liabilities	-	175
Total liabilities	16,779	17,760
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, $0.001 par value, 100,000,000 shares authorized, 8,159,382 and 5,324,287 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively.	8	80
Additional paid-in-capital	247,130	231,068
Accumulated deficit	(231,936)	(213,355)
Accumulated other comprehensive loss	(2)	-
Total stockholders' equity	15,200	17,793
Total liabilities and stockholders' equity	$ 31,979	$ 35,553

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,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 3,771	$ 4,968	$ 11,455	$ 17,719
General and administrative	2,332	2,767	7,442	8,210
Change in fair value of contingent consideration	132	551	(110)	2,598
Total operating expenses	6,235	8,286	18,787	28,527
Operating loss	(6,235)	(8,286)	(18,787)	(28,527)
Other income				
Change in fair value of warrants liabilities	2	112	31	369
Interest income	101	34	175	76
Total other income	103	146	206	445
Net loss	$ (6,132)	$ (8,140)	$ (18,581)	$ (28,082)
Other comprehensive loss				
Foreign currency translation adjustment	(1)	—	(2)	—
Total comprehensive loss	$ (6,133)	$ (8,140)	$ (18,583)	$ (28,082)
Net loss per common share, basic and diluted	$ (0.76)	$ (1.53)	$ (2.60)	$ (5.28)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	8,093,033	5,319,405	7,156,344	5,316,320

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, 2022 and 2021
(unaudited)
(In thousands except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balances at January 1, 2022	5,324,287	$ 5	$ 231,143	$ (213,355)	$ -	$ 17,793
Stock-based compensation	-	-	464	-	-	464
Issuance of restricted stock units under equity incentive plan	18,650	-	180	-	-	180
Tax withholding payments for net share-settled equity awards	(3,683)	-	(16)	-	-	(16)
Sale of common stock and pre-funded warrants in public offering, net of costs of $1,034	2,666,667	3	13,763	-	-	13,766
Net loss	-	-	-	(5,724)	-	(5,724)
Foreign currency translation adjustment	-	-	-	-	(2)	(2)
Balances at March 31, 2022	8,005,921	8	245,534	(219,079)	(2)	26,461
Stock-based compensation	-	-	571	-	-	571
Net loss	-	-	-	(6,725)	-	(6,725)
Foreign currency translation adjustment	-	-	-	-	1	1
Balances at June 30, 2022	8,005,921	8	246,105	(225,804)	(1)	20,308
Stock-based compensation	-	-	683	-	-	683
Sale of common stock, net of costs	104,773	-	342	-	-	342
Exercise of common stock warrants	48,688	-	-	-	-	-
Foreign currency translation adjustment		-		-	(1)	(1)
Net loss	-	-	-	(6,132)	-	(6,132)
Balances at September 30, 2022	8,159,382	$ 8	$ 247,130	$ (231,936)	$ (2)	$ 15,200

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balances at January 1, 2021	5,307,713	$ 5	$ 227,987	$ (182,445)	$ -	$ 45,547
Stock-based compensation	-	-	1,095	-	-	1,095
Issuance of restricted stock units under equity incentive plan	11,137	-	-	-	-	—
Tax withholding payments for net share-settled equity awards	(3,938)	-	(120)	-	-	(120)
Net loss	-	-	-	(8,954)	-	(8,954)
Balances at March 31, 2021	5,314,912	5	228,962	(191,399)	-	37,568
Stock-based compensation	-	-	857	-	-	857
Issuance of restricted stock units under equity incentive plan	2,370	-	-	-	-	-
Net loss	-	-	-	(10,988)	-	(10,988)
Balances at June 30, 2021	5,317,282	5	229,819	(202,387)	-	27,437
Stock-based compensation	-	-	906	-	-	906
Issuance of restricted stock units under equity incentive plan	3,150	-	-	-	-	—
Net loss	-	-	-	(8,140)	-	(8,140)
Balances at September 30, 2021	5,320,432	$ 5	$ 230,725	$ (210,527)	$ -	$ 20,203

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, 2022	Nine Months Ended September 30, 2021
Cash flows from operating activities:		
Net loss	$ (18,581)	$ (28,082)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,476	1,471
Non-cash lease expense	215	220
Stock-based compensation expense	1,898	2,858
Change in fair value of stock warrants	(31)	(369)
Change in fair value of contingent consideration	(110)	2,598
Other non-cash reconciling items	(2)	—
Change in operating assets and liabilities:		
Prepaid expenses, other current assets and other assets	337	317
Other assets	-	(40)
Accounts payable	(930)	369
Accrued compensation	554	(196)
Accrued clinical trial site costs	(594)	(196)
Operating lease liabilities	(218)	(156)
Other liabilities	348	299
Net cash used in operating activities	(15,638)	(20,907)
Cash flows from investing activities:		
Purchases of property and equipment	(7)	(9)
Net cash used in investing activities	(7)	(9)
Cash flows from financing activities:		
Proceeds from sale of common stock and pre-funded warrants, net of costs	14,108	—
Tax withholding payments for net share-settled equity awards	(16)	(120)
Principal paid on finance lease liabilities	—	(3)
Net cash provided by (used in) financing activities	14,092	(123)
Net decrease in cash and cash equivalents	(1,553)	(21,039)
Cash and cash equivalents, beginning of period	21,304	49,224
Cash and cash equivalents, end of period	$ 19,751	$ 28,185
Supplemental disclosure of non-cash activities		
Right-of-use assets obtained in exchange for operating lease obligations	$ -	$ 581
Deferred financing costs included in accounts payable	$ -	$ -

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 Diazoxide Choline Extended Release tablets (DCCR), a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS). DCCR has received orphan designation for the treatment of PWS in the United States (U.S.) as well as in the European Union (E.U.).

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. Going Concern and Management’s Plans

The Company had a net loss of $18.6 million during the nine months ended September 30, 2022 and has an accumulated deficit of $231.9 million at September 30, 2022 resulting from having incurred losses since its inception. The Company had $19.8 million of cash and cash equivalents on hand at September 30, 2022 and used $15.6 million of cash in its operating activities during the nine months ended September 30, 2022. The Company has financed its operations principally through issuances of equity securities. In March 2022, the Company completed a public offering of 2,666,667 shares of its common stock and, for certain investors, in lieu of common stock, pre-funded warrants to purchase 1,333,333 shares of common stock at an exercise price of $0.15 per share, and raised $13.8 million in net proceeds after deducting the underwriting discount and other offering costs. Each share of common stock or pre-funded warrant was sold together with one immediately exercisable common warrant to purchase one share of common stock. In addition, as of September 30, 2022, we raised $0.3 million from an at the market offering program (Note 7).

The accompanying condensed consolidated financial statements have been prepared under the assumption the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to the Company’s ability to continue as a going concern.

The Company expects to continue incurring losses for the foreseeable future and will be required to raise additional capital to complete its clinical trials, pursue product development initiatives, obtain regulatory approval and penetrate markets for the sale of its products. Management believes that the Company will continue to have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means, but the Company’s access to such capital resources is uncertain and is not assured. If the Company is unable to secure additional capital, it may be required to curtail its clinical trials and development of new products and take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. These measures could cause significant delays in the Company’s efforts to complete its clinical trials and commercialize its products, which are critical to the realization of its business plan and the future operations of the Company.

Management believes that the Company does not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. Additionally, in view of the Company’s expectation to incur significant losses for the foreseeable future it will be required to raise additional capital resources in order to fund its operations, although the availability of, and the Company’s access to such resources is not assured. Accordingly, management believes that there is substantial doubt regarding the Company’s ability to continue operating as a going concern through 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 nine months ended September 30, 2022 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, 2021.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared on a going concern basis in accordance with accounting principles generally accepted in the United States of America (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, 2022, are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2022. 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, 2021, which are included in the Company's annual report on Form 10-K filed with the SEC on March 31, 2022.

Reverse Stock Split

On June 1, 2022, the stockholders of the Company approved a reverse stock split of its common stock at a ratio of one-for-fifteen, to be effected at the sole discretion of the Company's Board of Directors as described in the proxy statement filed with the SEC on April 21, 2022. The implementation of the reverse stock split was approved by the Company's Board of Directors on August 16, 2022.

On August 26, 2022, the Company filed a certificate of amendment to its amended and restated certificate of incorporation in order to effectuate a reverse stock split of the Company's issued and outstanding common stock on a one-for-fifteen basis. All common share and per share data are retrospectively restated to give effect of the split for all periods presented herein. After giving effect to the reverse stock split, the total number of shares of all classes of capital stock that the Corporation is authorized to issue is 110,000,000 shares, consisting of 100,000,000 shares of Common Stock, having a par value of $0.001 and 10,000,000 shares of Preferred Stock, having a par value of $0.001.

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.

Recent Accounting Standards

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.

During the three and nine months ended September 30, 2022, there have been no recently adopted accounting standards and no new, or existing recently issued, accounting pronouncements that are of significance, or potential significance, that impact the Company's condensed consolidated interim financial statements.

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 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, 2022			
	Total	Level 1	Level 2	Level 3
Liabilities				
2018 PIPE warrant liability	$ —	$ —	$ —	$ —
Essentialis purchase price contingency liability	9,437	—	—	9,437
Total common stock warrant and contingent consideration liability	$ 9,437	$ —	$ —	$ 9,437

	Fair Value Measurements at December 31, 2021			
	Total	Level 1	Level 2	Level 3
Liabilities				
2018 PIPE warrant liability	$ 31	$ —	$ —	$ 31
Essentialis purchase price contingency liability	9,547	—	—	9,547
Total common stock warrant and contingent consideration liability	$ 9,578	$ —	$ —	$ 9,578

The Company's estimated fair value of the 2018 PIPE Warrants was calculated using a Black-Scholes pricing model. The Black-Scholes pricing model requires the input of highly subjective assumptions including the expected stock price volatility, the expected term, the expected dividend yield and the risk-free interest rate.

Based on the terms of the Company's completed merger with Essentialis on March 7, 2017, the Company was obligated to make cash earnout payments of up to a maximum of $30.0 million to the former Essentialis stockholders. On December 28, 2021, in connection with the dissolution of two of the former Essentialis stockholders, the two former stockholders entered into an agreement with the Company which assigned the right, title and interest to all their future earnout payments to the Company. As a result of the assignment, as of December 31, 2021, and going forward, the maximum cash earnout payments are $21.2 million. 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 the likelihood and anticipated timing of reaching cumulative revenue milestones. The Level 3 estimates are based, in part, on subjective assumptions. In determining the likelihood of obtaining FDA approval, the analysis relied on published research relating to clinical development success rates. Based on management's assessment, a 72% probability of achieving each milestone was determined to be reasonable as of each of September 30, 2022 and December 31, 2021. 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, 2022 and 2021 (dollars in thousands).

	2018 PIPE Warrants		Purchase Price
	Number of Warrants	Liability	Contingent Liability
Balance at January 1, 2022	34,241	$ 31	$ 9,547
Change in value of 2018 PIPE Warrants	—	(31)	—
Change in value of contingent liability	—	—	(110)
Balance at September 30, 2022	34,241	$ -	$ 9,437

	2018 PIPE Warrants		Purchase Price
	Number of Warrants	Liability	Contingent Liability
Balance at January 1, 2021	34,241	$ 539	$ 10,278
Change in value of 2018 PIPE Warrants	—	(369)	—
Change in value of contingent liability	—	—	2,598
Balance at September 30, 2021	34,241	$ 170	$ 12,876

Note 5. Warrant Liabilities

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 entitle 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 adjustment as discussed below, at any time commencing upon issuance of the 2018 PIPE Warrants and terminating on December 21, 2023.

The exercise price and number of shares of common stock issuable upon exercise of the 2018 PIPE Warrants may be adjusted in certain circumstances, including the event of a stock split, stock dividend, extraordinary dividend, or recapitalization, reorganization, merger or consolidation. However, the exercise price of the 2018 PIPE Warrants will not be reduced below $30.00.

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 and comprehensive loss.

As of September 30, 2022, the fair value of the 2018 PIPE Warrants was estimated at approximately $0. The approximate $2 thousand and $0.1 million decrease in the fair value of the liability for the 2018 PIPE Warrants during the three months ended September 30, 2022 and 2021, respectively, was recorded as other income in the condensed consolidated statements of operations and comprehensive loss.

The Company has calculated the fair value of the 2018 PIPE Warrants using a Black-Scholes pricing model. The following summarizes certain key assumptions used in estimating the fair value.

	September 30, 2022	December 31, 2021
Volatility	77%	95%
Contractual term (years)	1.2	2.0
Expected dividend yield	—%	—%
Risk-free rate	4.09%	0.72%

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

- *Volatility:* The Company calculates the estimated volatility rate based its historical volatility over the expected life of the warrants.
- *Contractual term:* The expected life of the warrants, which is based on the contractual term of the warrants.
- *Expected dividend yield:* The Company has never declared or paid any cash dividends and does not currently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.
- *Risk-free rate:* The risk-free interest rate is based on the U.S. Treasury rate for similar periods as the expected life of the warrants.

Note 6. Commitments and Contingencies

Facility Leases

The Company's operating lease for its headquarters facility office space in Redwood City, California, terminated in May 2021. In April 2021, the Company executed a non-cancellable operating lease agreement for the same 6,368 square feet of space, which began in June 2021 and expires in May 2023. The lease that expired in May 2021 also provided the Company with the right to use office furniture in the space and allowed the purchase of this furniture at the end of the lease term for $1, which it did. The Company has accounted for both leases of office space as operating leases. The office furniture included in the lease that expired in May 2021 was accounted for as a finance lease based on its relative standalone price as compared to the office space.

The current lease was recognized at inception with a right-of-use asset equal to $0.6 million and a liability for $0.5 million. The short-term liability was equal to $0.2 million and $0.3 million as of September 30, 2022 and December 31, 2021, respectively, and the long-term liability was equal to $0 and $0.2 million, as of September 30, 2022 and December 31, 2021, respectively. The weighted average discount rate was 9% over a remaining term of 8 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.

The following is a schedule by year of future maturities of the Company's operating lease liabilities as of September 30, 2022 (in thousands):

2022 (remainder of the year)	$	70
2023		179
Total lease payments		249
Less interest		(10)
Total	$	239

The components of lease expense during the three and six months ended September 30, 2022 and 2021 were as follows (in thousands):

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Operating lease cost:				
Operating lease cost	$ 81	$ 81	$ 242	$ 235
Variable lease cost	—	—	—	6
Short-term lease cost	9	—	22	17
Total operating lease cost	$ 90	$ 81	$ 264	$ 258
Finance lease cost:				
Amortization of right-of-use assets	$ —	$ —	$ —	$ 4
Total finance lease cost	$ —	$ —	$ —	$ 4

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

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, 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 2022 pre-funded warrants are immediately exercisable and may be exercised at any time until all of the 2022 pre-funded warrants are exercised in full. Each share of common stock or 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.

At the Market Offering

In July 2021, the Company entered into a Controlled Equity Offering Sales Agreement under which the Company may 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. As of September 30, 2022, we have sold 104,773 shares of common stock through the at the market program, totaling $0.3 million in net proceeds.

Other Common Stock Warrants

As of September 30, 2022, the Company had 6,804 common stock warrants outstanding from the 2010/2012 convertible notes, with an exercise price of $24.35 and a term of 10 years expiring in November 2024. The Company also had 1,100 common stock warrants issued to the underwriter in the Company's IPO, with an exercise price of $365.25 and a term of 10 years, expiring in November 2024.

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. The vesting period for service-based stock options is normally monthly over a period of 4 years from the vesting date. 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. As of September 30, 2022, a total of 16,688 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. As of September 30, 2022, a total of 85,668 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,	
	2022	2021	2022	2021
Research and development	$ 200	$ 222	$ 511	$ 635
General and administrative	483	684	1,387	2,223
Total	$ 683	$ 906	$ 1,898	$ 2,858

Stock Options

The Company granted options to purchase 157,673 and 0 shares of the Company's common stock during the three months ended September 30, 2022 and 2021, respectively, and granted options to purchase 283,919 and 225,854 of the Company's common stock during the nine months ended September 30, 2022 and 2021, respectively. Of the total options granted during the three and nine months ended September 30, 2021, 47,250 were performance-based options. 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,	
	2022	2021	2022	2021
Expected life (years)	5.2-5.7	— %	5.2-6.0	5.5-6.0
Risk-free interest rate	2.8%-3.1%	— %	1.7%-3.0%	0.6%-1.0%
Volatility	92%-95%	— %	88%-93%	91%-108%
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, 2022 as 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, 2022	408,329	$ 46.28	7.94	
Options granted	283,919	$ 3.56		
Options exercised	—			
Options canceled/forfeited	(5,432)	$ 19.96		
Balance at September 30, 2022	686,816	$ 28.83	8.19	$ —
Options vested at September 30, 2022	297,926	$ 45.37	7.09	$ —
Options vested and expected to vest at September 30, 2022	663,858	$ 28.66	8.19	$ —

The weighted-average grant date fair value of options granted was $2.62 and $1.73 per share for the nine months ended September 30, 2022 and 2021, respectively. At September 30, 2022 total unrecognized employee stock-based compensation related to stock options that are likely to vest was $3.8 million, which is expected to be recognized over the weighted-average remaining vesting period of 1.9 years.

Restricted Stock Units

There were zero and 3,498 restricted stock units granted by the Company during the three months ended September 30, 2022 and 2021, respectively, and 8,965 and 7,583 restricted stock units granted during the nine months ended September 30, 2022 and 2021, respectively, to employees and directors. The restricted stock units granted to directors were 100% vested on the grant date and represent compensation for past board services. The restricted stock units granted to employees typically vest annually over a period of four years. The restricted stock units 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, 2022 as issued under the 2014 Plan:

	Number of Restricted Stock Units	Weighted-Average Grant-Date Fair Value per Share
Outstanding at January 1, 2022	29,050	$ 57.75
Restricted stock units granted	8,965	$ 5.33
Restricted stock units vested	(18,646)	$ 32.55
Restricted stock units canceled/forfeited	(301)	$ 57.85
Outstanding at September 30, 2022	19,068	$ 57.75

The weighted-average grant-date fair value of all restricted stock units granted during the nine months ended September 30, 2022 and 2021 was $5.33 and $18.30, respectively. The fair value of all restricted stock units vested during the nine months ended September 30, 2022 and 2021 was $0.6 million and approximately $0.8 million, respectively. At September 30, 2022, total unrecognized employee stock-based compensation related to restricted stock units was $0.7 million, which is expected to be recognized over the weighted-average remaining vesting period of 1.3 years.

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, 2022, 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 actually outstanding during the period. 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. The Company applies the two-class method to calculate basic and diluted earnings per share as its warrants issued in March 2022 are participating securities. However, the two-class method does not impact the net loss per share of common stock as the warrants issued in March 2022 do not participate in losses. For the three and nine months ended September 30, 2022 and 2021, 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 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,	
	2022	2021
Warrants issued to 2010/2012 convertible note holders to purchase common stock	6,804	6,804
Options to purchase common stock	686,816	405,662
Outstanding restricted stock units	19,068	29,050
Warrants issued to underwriter to purchase common stock	1,100	1,100
2018 PIPE warrants	34,241	34,241
2022 common warrants	4,000,000	—
2022 pre-funded warrants	1,280,965	—
Total	6,028,994	476,857

Note 9. Subsequent Events

The Company has evaluated its subsequent events from September 30, 2022 through the date these condensed consolidated financial statements were issued and has determined that there are no subsequent events requiring disclosure in these condensed consolidated financial statements.

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

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, 2021, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Company's Form 10-K for the year ended December 31, 2021. 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.

Overview

We are focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Our lead candidate is Diazoxide Choline Extended Release tablets (DCCR), a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS). DCCR has orphan designation for the treatment of PWS in the United States (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. Patients who complete treatment in DESTINY PWS were eligible to receive DCCR in C602, an open-label extension study. 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 February 2021, we announced analysis limited to data collected before the onset of the COVID-19 pandemic. The analysis of the data through March 1, 2020 showed statistical significance in the primary, all key secondary and several other efficacy endpoints. In September 2021, we announced interim results from C602 showing statistically significant reduction in hyperphagia and all other PWS behavioral parameters and statistically significant improvements compared to natural history of PWS from the PATH for PWS Study (PfPWS) over a one year treatment period. The PfPWS study is an ongoing study sponsored by the Foundation for Prader-Willi Research (FPWR) to advance the understanding of the natural history in individuals with PWS. We submitted the data in the fourth quarter 2021,

Earlier this year, we submitted a proposal to add a randomized withdrawal period to Study C602 in order to obtain additional controlled data requested by the FDA to support a New Drug Application (NDA) submission for DCCR. The randomized withdrawal (RW) period of Study C602 is a multi-center, randomized, double-blind, placebo-controlled study of DCCR in approximately 80 patients with PWS at 17 sites in the U.S. and 5 sites in the U.K. This RW period consists only of patients currently enrolled in Study C602 and will not enroll any new patients. In October 2022, we announced the initiation of the RW period for Study C602. The FDA has acknowledged that data from the study has the potential to support an NDA submission for DCCR.

The spread of the COVID-19 virus and the outbreak of war between Russia and Ukraine have caused supply chain issues, inflationary pressures and significant volatility in the financial markets. However, we have not experienced a significant financial impact directly related to the COVID-19 pandemic or Russia's invasion of Ukraine.

As of September 30, 2022, we had an accumulated deficit of $231.9 million, primarily as a result of research and development and general and administrative expenses. We may never be successful in commercializing our novel therapeutic-lead candidate DCCR. Accordingly, we expect to incur significant losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits. As of September 30, 2022, we had cash and cash equivalents of $19.7 million.

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 significant accounting policies are more fully described in Note 3 of our most recent Form 10-K.

Results of Operations

Comparison of the three months ended September 30, 2022 and 2021

	Three Months Ended September 30,		Increase (decrease)	
	2022	2021	Amount	Percentage
	(in thousands)			
Operating expenses				
Research and development	$ 3,771	$ 4,968	$ (1,197)	24%
General and administrative	2,332	2,767	(435)	16%
Change in fair value of contingent consideration	132	551	(419)	76%
Total operating expenses	6,235	8,286	(2,051)	25%
Operating loss	(6,235)	(8,286)	2,051	25%
Other income				
Change in fair value of warrants liabilities	2	112	(110)	98%
Interest income	101	34	67	197%
Total other income	103	146	(43)	29%
Net loss	$ (6,132)	$ (8,140)	$ 2,008	25%

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 of $3.8 million for the three months ended September 30, 2022 decreased by $1.2 million from the three months ended September 30, 2021. The cadence of our research and development expenditures will fluctuate depending upon the state of our clinical programs and the timing of CMC and other projects necessary to support the submission of an NDA.

General and administrative expense

General and administrative expense of $2.3 million for the three months ended September 30, 2022 decreased by $0.4 million from the three months ended September 30, 2021. The decrease was mainly attributable to reduction in professional services expense.

Change in fair value of contingent consideration

We are obligated to make cash payments of 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 revenue, respectively, in future years was estimated to be $9.4 million as of September 30,2022, a $0.1 million increase from the estimate as of June 30,2022. During the three months ended September 30, 2021, the estimate increased $0.5 million from the $12.3 million estimated at June 30,2021.

Other income

We had other income of approximately $103,000 in the three months ended September 30,2022, compared to $146,000 during the three months ended September 30,2021. The decrease was primarily due to a higher decrease in the fair value of our outstanding warrants partially offset by an increase in interest income during the three months ended September 30, 2022 compared to the three months ended September 30, 2021.

Results of Operations

Comparison of the nine months ended September 30, 2022 and 2021

	Nine Months Ended September 30,		Increase (decrease)	
	2022	2021	Amount	Percentage
	(in thousands)			
Operating expenses				
Research and development	$ 11,455	17,719	$ (6,264)	35%
General and administrative	7,442	8,210	(768)	9%
Change in fair value of contingent consideration	(110)	2,598	(2,708)	104%
Total operating expenses	18,787	28,527	(9,740)	34%
Operating loss	(18,787)	(28,527)	9,740	34%
Other income				
Change in fair value of warrants liabilities	31	369	(338)	92%
Interest income	175	76	99	130%
Total other income	206	445	(239)	54%
Net loss	$ (18,581)	$ (28,082)	$ 9,501	34%

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 of $11.5 million for the nine months ended September 30, 2022 decreased by $6.2 million from the nine months ended September 30, 2021. The cadence of our research and development expenditures will fluctuate depending upon the state of our clinical programs and the timing of CMC and other projects necessary to support the submission of an NDA.

General and administrative expense

General and administrative expense of $7.4 million for the nine months ended September 30, 2022 decreased $0.8 million from the nine months ended September 30, 2021, primarily due to a decrease in stock-based compensation expense.

Change in fair value of contingent consideration

We were obligated to make cash payments of 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 revenue, respectively, in future years was estimated to be $9.3 million as of September 30, 2022, a $0.2 million decrease from the estimate as of December 31, 2021. During the nine months ended September 30, 2021, the estimate decreased $1.0 million from the $10.3 million estimated at December 31, 2020.

Other income

We had other income of approximately $0.2 million in the nine months ended September 30, 2022, compared to $0.4 million during the nine months ended September 30, 2021. The decrease of $0.2 million was primarily due to a smaller decrease in the fair value of our outstanding warrants during the nine months ended September 30, 2022 compared to the nine months ended September 30, 2022. This decrease was slightly offset by an increase in interest income during the nine months ended September 30, 2022 as compared to the same period of the previous year as a result of cash and cash equivalents earning higher interest rates.

Liquidity and Capital Resources

We had a net loss of $18.6 million during the nine months ended September 30, 2022 and an accumulated deficit of $231.9 million at September 30, 2022 as a result of having incurred losses since our inception. We had $19.7 million in cash and cash equivalents and $13.2 million of working capital at September 30, 2022, and used $15.6 million of cash in operating activities during the nine months ended September 30, 2022. As of September 30, 2022, we had lease obligations totaling $0.2 million to be paid through 2023, consisting of an operating lease for office space in Redwood City, California.

We have financed our operations principally through issuances of equity securities. In March 2022, we completed a public offering of shares of our common stock and pre-funded warrants and raised $13.8 million in net proceeds after deducting the underwriting discount and other offering expenses. Each share of common stock or pre-funded warrant was sold together with one immediately exercisable common warrant to purchase one share of common stock. In addition, we have an "at-the-market" (ATM) offering for up to $25.0 million. As of September 30, 2022, we have sold 104,793 shares of common stock through the ATM, totaling $0.3 million in net proceeds.

We expect to continue incurring losses for the foreseeable future and will be required to raise 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. 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. These matters raise substantial doubt about our ability to continue as a going concern within one year from the date of filing this quarterly report.

The accompanying condensed consolidated financial statements have been prepared under the assumption we will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to our ability to continue as a going concern.

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, 2022	Nine Months Ended September 30, 2021
	(in thousands)	
Net cash used in operating activities	$ (15,638)	$ (20,907)
Net cash used in investing activities	(7)	(9)
Net cash provided by (used in) financing activities	14,092	(123)
Net decrease in cash and cash equivalents	$ (1,553)	$ (21,039)

Cash used in operating activities

During the nine months ended September 30, 2022, operating activities used net cash of $15.6 million, which was primarily due to the net loss of $18.6 million adjusted for non-cash income of $0.1 million related to the change in fair value of common stock warrants and contingent consideration, non-cash expense of $1.5 million for depreciation and amortization, $1.9 million for stock-based compensation, and approximately $0.2 million for non-cash lease expense. Additionally, cash used during the nine months ended September 30, 2022 increased by $0.5 million due to changes in operating assets and liabilities.

During the nine months ended September 30, 2021, operating activities used net cash of $20.9 million, which was primarily due to the net loss of $28.1 million adjusted for non-cash loss of $2.2 million related to the change in fair value of common stock warrants and contingent consideration, non-cash expense of $1.5 million for depreciation and amortization, and $2.9 million for stock-based compensation. Additionally, cash used during the nine months ended September 30, 2021 decreased by $0.4 million due to changes in operating assets and liabilities.

Cash used in investing activities

During the nine months ended September 30, 2022 and 2021, there was minimal cash used in purchasing property and equipment.

Cash provided by (used in) financing activities

During the nine months ended September 30, 2022, we received $13.8 million of net cash proceeds from the sale of 2,666,667 shares of our common stock, and for certain investors, in lieu of common stock, pre-funded warrants to purchase 1,333,333 shares of common stock. Each share of common stock or pre-funded warrant was sold together with one, immediately exercisable common warrant with an exercise price of $4.50 per share. As of September 30, 2022, all offering costs have been paid. The net proceeds amount was slightly offset by payments for the taxes from net share-settled vesting of restricted stock.

During the nine months ended September 30, 2021, we used cash of $0.1 million to pay for the taxes from net share-settled vesting of restricted stock.

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, 2022. 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 third fiscal quarter ended September 30, 2022, 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 are 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

None.

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 Registrant's Form	Incorporated by Reference from Date Filed with the SEC	Incorporated by Reference from Exhibit Number	Filed Herewith
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 Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).				X

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 9, 2022

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 9, 2022

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

Exhibit 31.2

CERTIFICATION OF THE CHIEF EXECUTIVE 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 9, 2022

/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, 2022, 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 9, 2022

/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, 2022, 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 9, 2022

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