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, 2021

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 5, 2021, there were 79,806,487 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, 2021	December 31, 2020
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 28,185	$ 49,224
Prepaid expenses and other current assets	702	1,019
Total current assets	28,887	50,243
Long-term assets		
Property and equipment, net	26	19
Operating lease right-of-use assets	489	124
Other long-term assets	40	15
Intangible assets, net	13,123	14,581
Total assets	$ 42,565	$ 64,982
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,858	$ 3,489
Accrued compensation	809	1,005
Accrued clinical trial site costs	3,593	3,789
Operating lease liabilities	290	139
Other current liabilities	492	196
Total current liabilities	9,042	8,618
Long-term liabilities		
2018 PIPE Warrant liability	170	539
Contingent liability for Essentialis purchase price	12,876	10,278
Operating lease liabilities, net of current	274	-
Total liabilities	22,362	19,435
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, $0.001 par value, 250,000,000 shares authorized, 79,806,487 and 79,615,692 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively.	80	80
Additional paid-in-capital	230,650	227,912
Accumulated deficit	(210,527)	(182,445)
Total stockholders' equity	20,203	45,547
Total liabilities and stockholders' equity	$ 42,565	$ 64,982

See accompanying notes to condensed consolidated financial statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses				
Research and development	$ 4,968	$ 4,827	$ 17,719	$ 17,625
General and administrative	2,767	2,256	8,210	6,507
Change in fair value of contingent consideration	551	774	2,598	4,200
Total operating expenses	8,286	7,857	28,527	28,332
Operating loss	(8,286)	(7,857)	(28,527)	(28,332)
Other income (expense)				
Change in fair value of warrants liabilities	112	(689)	369	6,532
Interest income	34	1	76	13
Total other income (expense)	146	(688)	445	6,545
Net loss	$ (8,140)	$ (8,545)	$ (28,082)	$ (21,787)
Net loss per common share, basic and diluted	$ (0.10)	$ (0.11)	$ (0.35)	$ (0.38)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	79,791,075	79,583,254	79,744,807	56,916,137

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, 2021 and 2020
(unaudited)
(In thousands except share data)

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balances at January 1, 2021	79,615,692	$ 80	$ 227,912	$ (182,445)	$ 45,547
Stock-based compensation			1,095		1,095
Issuance of common stock under equity incentive plan, net of tax withholdings	167,060	—			—
Tax withholding payments for net share-settled equity awards	(59,072)		(120)		(120)
Net loss				(8,954)	(8,954)
Balances at March 31, 2021	79,723,680	80	228,887	(191,399)	37,568
Stock-based compensation			857		857
Issuance of common stock under equity incentive plan, net of tax withholdings	35,545	—			—
Net loss				(10,988)	(10,988)
Balances at June 30, 2021	79,759,225	80	229,744	(202,387)	27,437
Stock-based compensation			906		906
Issuance of common stock under equity incentive plan, net of tax withholdings	47,262	—			—
Net loss				(8,140)	(8,140)
Balances at September 30, 2021	79,806,487	$ 80	$ 230,650	$ (210,527)	$ 20,203

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balances at January 1, 2020	44,658,054	$ 45	$ 172,708	$ (157,806)	$ 14,947
Stock-based compensation			392		392
Issuance of common stock under equity incentive plan, net of tax withholdings	28,757	—			—
Net loss				(5,858)	(5,858)
Balances at March 31, 2020	44,686,811	45	173,100	(163,664)	9,481
Stock-based compensation			341		341
Issuance of common stock under equity incentive plan, net of tax withholdings	24,979	—	17		17
Sale of common stock in public offering, net of costs of $3,778	34,848,484	35	53,687		53,722
Net loss				(7,384)	(7,384)
Balances at June 30, 2020	79,560,274	80	227,145	(171,048)	56,177
Stock-based compensation			374		374
Issuance of common stock under equity incentive plan, net of tax withholdings	33,347	—			—
Net loss				(8,545)	(8,545)
Balances at September 30, 2020	79,593,621	$ 80	$ 227,519	$ (179,593)	$ 48,006

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,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (28,082)	$ (21,787)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,471	1,466
Non-cash lease expense	220	210
Stock-based compensation expense	2,858	1,107
Change in fair value of stock warrants	(369)	(6,532)
Change in fair value of contingent consideration	2,598	4,200
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	317	122
Other long-term assets	(40)	-
Accounts payable	369	1,215
Accrued compensation	(196)	473
Accrued clinical trial site costs	(196)	1,400
Operating lease liabilities	(156)	(224)
Other liabilities	299	(7)
Net cash used in operating activities	(20,907)	(18,357)
Cash flows from investing activities:		
Purchases of property and equipment	(9)	(3)
Net cash used in investing activities	(9)	(3)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of costs	-	53,760
Tax withholding payments for net share-settled equity awards	(120)	-
Proceeds from stock option exercises	-	17
Principal paid on finance lease liabilities	(3)	(13)
Net cash provided by (used in) financing activities	(123)	53,764
Net increase (decrease) in cash and cash equivalents	(21,039)	35,404
Cash and cash equivalents, beginning of period	49,224	20,733
Cash and cash equivalents, end of period	$ 28,185	$ 56,137
Supplemental disclosure of non-cash activities		
Purchase of property and equipment in accounts payable	$ -	$ 3
Right-of-use assets obtained in exchange for operating lease obligations	$ 581	$ -
Deferred financing costs included in accounts payable	$ -	$ 38

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 $28.1 million during the nine months ended September 30, 2021 and has an accumulated deficit of $210.5 million at September 30, 2021 resulting from having incurred losses since its inception. The Company had $28.2 million of cash and cash equivalents on hand at September 30, 2021 and used $20.9 million of cash in its operating activities during the nine months ended September 30, 2021.

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. For example, in July 2021, the Company entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. (Cantor) pursuant to which the Company may offer and sell, from time to time, shares of its common stock through Cantor up to an aggregate purchase price of $25.0 million (the ATM Offering). 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, the Company 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. Summary of Significant Accounting Policies

There have been no material changes to the significant accounting policies during the nine months ended September 30, 2021 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, 2020. Below are those policies with current period updates.

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, 2021, are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2021. 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, 2020, which are included in the Company's annual report on Form 10-K filed with the SEC on March 3, 2021.

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, value and life of acquired intangibles, and the valuation of contingent liabilities for the purchase price of assets obtained through acquisition. The contingent liability represents the fair value of the contingent consideration arising from the Company's acquisition of Essentialis in 2017. As part of the purchase price, the Company is obligated to make cash earn out payments to Essentialis stockholders up to a maximum of $30 million upon the achievement of certain commercial milestones.

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, 2021, 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, 2021			
	Total	Level 1	Level 2	Level 3
Liabilities				
2018 PIPE warrant liability	$ 170	$ —	$ —	$ 170
Essentialis purchase price contingency liability	12,876	—	—	12,876
Total common stock warrant and contingent consideration liability	$ 13,046	$ —	$ —	$ 13,046

	Fair Value Measurements at December 31, 2020			
	Total	Level 1	Level 2	Level 3
Liabilities				
2018 PIPE warrant liability	$ 539	$ —	$ —	$ 539
Essentialis purchase price contingency liability	10,278	—	—	10,278
Total common stock warrant and contingent consideration liability	$ 10,817	$ —	$ —	$ 10,817

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. The difference in valuation as a result of using the Black-Scholes pricing model compared to the Monte Carlo simulation model is not significant.

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 FDA as well as reaching cumulative sales milestones. The Level 3 estimates are based, in part, on subjective assumptions. During the periods presented, the Company has not changed the manner in which it values its Essentialis purchase price contingent liability.

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, 2021 and 2020 (dollars in thousands).

	2018 PIPE Warrants		Purchase Price Contingent Liability
	Number of Warrants	Liability	
Balance at January 1, 2021	513,617	$ 539	$ 10,278
Change in value of 2018 PIPE Warrants	—	(369)	—
Change in value of contingent liability	—	—	2,598
Balance at September 30, 2021	513,617	$ 170	$ 12,876

	Series C Warrants		2017 PIPE Warrants		2018 PIPE Warrants		Purchase Price Contingent Liability
	Number of Warrants	Liability	Number of Warrants	Liability	Number of Warrants	Liability	
Balance at January 1, 2020	118,083	$ —	6,024,425	$ 10,822	513,617	$ 1,354	$ 5,938
Expiration of Series C Warrants	(118,083)	—	—	—	—	—	—
Change in value of 2017 PIPE Warrants	—	—	—	(6,045)	—	—	—
Change in value of 2018 PIPE Warrants	—	—	—	—	—	(487)	—
Change in value of contingent liability	—	—	—	—	—	—	4,200
Balance at September 30, 2020	—	$ —	6,024,425	$ 4,777	513,617	$ 867	$ 10,138

Note 5. Warrant Liabilities

The Company has issued multiple warrant series, of which the Series C Warrants, the 2017 PIPE Warrants and the 2018 PIPE Warrants (Warrants) were determined to be liabilities pursuant to the guidance established by *ASC 815 Derivatives and Hedging.* Only the 2018 PIPE Warrants remain outstanding at September 30, 2021.

Accounting Treatment

The Company accounts for Warrants in accordance with the guidance in *ASC 815*. As indicated below, the Company may be obligated to settle Warrants in cash. The Company classified 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.

Series C Warrants

The Series C Warrants expired in March 2020. The Company calculated the fair value of the Series C Warrants as of January 1, 2020 using a Black-Scholes pricing model.

Warrants Issued as Part of the Units in the 2017 PIPE Offering

The 2017 PIPE Warrants expired on December 15, 2020. The Company calculated the fair value of the 2017 PIPE Warrants for periods ended prior to December 15, 2020 using a Monte Carlo simulation of a geometric Brownian motion model. The increase in the fair value of the liability for the 2017 PIPE Warrants of $0.5 million during the three months ended September 30, 2020 and the decrease in the fair value of $6.0 million during the nine months ended September 30, 2020 were recorded as other income (expense) in the condensed consolidated statements of operations.

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

The 2018 PIPE Warrants were issued on December 19, 2018 in a private offering of common stock and warrants (2018 PIPE Offering), pursuant to a Warrant Agreement with each of the investors in the 2018 PIPE Offering, and entitle the holders to purchase 513,617 shares of the Company's common stock at an exercise price equal to $2.00 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 $2.00.

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.

As of September 30, 2021, the fair value of the 2018 PIPE Warrants was estimated at $0.2 million. The $0.1 million decrease in the fair value of the liability for the 2018 PIPE Warrants during the three and nine months ended September 30, 2021 was recorded as other income (expense) in the condensed consolidated statements of operations.

The Company has calculated the fair value of the 2018 PIPE Warrants as of September 30, 2021 and December 31, 2020 using a Black-Scholes pricing model which requires the input of highly subjective assumptions including the expected stock price volatility. The following summarizes certain key assumptions used in estimating the fair values.

	September 30, 2021	December 31, 2020
Volatility	98%	88%
Contractual term (years)	2.2	3.0
Expected dividend yield	—%	—%
Risk-free rate	0.34%	0.17%

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 those of expected volatility.

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 was accounted at inception with a right-of-use asset equal to $0.6 million and a liability for $0.5 million. As of September 30, 2021, the short-term liability is equal to $0.3 million and the long-term liability is equal to $0.3 million. The weighted average discount rate was 9% over a remaining term of 20 months. The discount rate was determined based on the estimate of the interest to be paid on a loan collateralized by such contract according to small business bank loans comparable rates. The Company has elected to utilize the available practical expedient to not separate lease and non-lease components for the office lease.

The following table presents a reconciliation of the undiscounted future minimum lease payments remaining under the operating lease reported as operating lease liability on the condensed consolidated balance sheet as of September 30, 2021:

Undiscounted future minimum lease payments:		
2021 (remainder of the year)	$	100,296
2022		334,320
2023		179,100
Total undiscounted future minimum lease payments		613,716
Less: amount representing imputed interest		(49,592)
Total	$	564,124

The components of lease expense during the three and nine months ended September 30, 2021 and 2020 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease cost	$ 81	$ 76	$ 235	$ 229
Finance lease cost:				
Amortization of right-of-use assets	$ —	$ 2	$ 4	$ 7
Interest on lease liabilities	—	—	—	1
Total finance lease cost	$ -	$ 2	$ 4	$ 8

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

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" offering as defined in Rule 415 under the Securities Act of 1933, as amended. During the three months ended September 2021, no shares were sold under the at the market program.

Equity Incentive Plans

2014 Plan

The Company has adopted 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, 2021, a total of 1,255,927 shares are available for future grant under the 2014 Plan.

Inducement Plan

On September 28, 2020, the Company adopted the 2020 Inducement Equity Incentive Plan (the Inducement Plan) and, subject to the adjustment provisions of the Inducement Plan, reserved 1,500,000 shares of the Company's common stock for issuance pursuant to equity awards granted under 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. There have been no awards granted under the Inducement Plan as of September 30, 2021. As of September 30, 2021, a total of 1,500,000 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 statements of operations for stock-based compensation arrangements during any of the periods presented

Stock-based compensation expense was recognized in the condensed consolidated statements of operations as follows (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 222	$ 91	$ 635	$ 252
General and administrative	684	283	2,223	855
Total	$ 906	$ 374	$ 2,858	$ 1,107

Stock Options

The Company granted options to purchase 0 and 47,500 shares of the Company's common stock during the three months ended September 30, 2021 and 2020, respectively, and granted options to purchase 3,387,810 and 500,150 of the Company's common stock during the nine months ended September 30, 2021 and 2020, respectively. Of the total options granted during the nine months ended September 30, 2021, 708,750 were performance-based options. The fair value of each award granted during the three and nine months ended September 30, 2021 and 2020 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,	
	2021	2020	2021	2020
Expected life (years)	—	6.0	5.5-6.0	5.5-6.0
Risk-free interest rate	— %	0.4%	0.6%-1.0%	0.4%-0.5%
Volatility	— %	84%	91%-108%	64%-84%
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 term 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 time to liquidity.
- *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, 2021 as issued under the 2014 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, 2021	2,837,739	$ 4.18	7.62	
Options granted	3,387,810	$ 2.16		
Options exercised	—			
Options canceled/forfeited	(140,626)	$ 1.95		
Balance at September 30, 2021	6,084,923	$ 3.11	8.12	
Options vested at September 30, 2021	2,529,332	$ 4.37	6.76	$ —
Options vested and expected to vest at September 30, 2021	6,084,923	$ 3.11	8.12	$ —

The weighted-average grant date fair value of options granted was $1.73 and $1.89 per share for the nine months ended September 30, 2021 and 2020, respectively. At September 30, 2021 total unrecognized employee stock-based compensation related to stock options that are likely to vest was $5.3 million, which is expected to be recognized over the weighted-average remaining vesting period of 3.7 years.

Restricted Stock Units

There were 52,472 and 23,347 restricted stock units granted by the Company during the three months ended September 30, 2021 and 2020, respectively, and 113,745 and 727,065 restricted stock units granted during the nine months ended September 30, 2021 and 2020, respectively, to employees and directors. The shares granted to directors were 100% vested on the grant date and represent compensation for past Board services. The shares granted to employees typically vest annually over a period of four years. 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, 2021 as issued under the 2014 Plan:

	Number of Restricted Stock Units	Weighted-Average Grant-Date Fair Value per Share
Outstanding at January 1, 2021	581,000	$ 3.85
Restricted stock units granted	113,745	$ 1.22
Restricted stock units vested	(258,995)	$ 2.69
Outstanding at September 30, 2021	435,750	$ 3.85

The weighted-average grant-date fair value of all restricted stock units granted during the nine months ended September 30, 2021 and 2020 was $1.22 and $3.74, respectively. The fair value of all restricted stock units vested during the nine months ended September 30, 2021 and 2020 was $0.8 million and approximately $0.2 million, respectively. At September 30, 2021, total unrecognized employee stock-based compensation related to restricted stock units was $1.3 million, which is expected to be recognized over the weighted-average remaining vesting period of 2.3 years.

2014 Employee Stock Purchase Plan

The Company's Board and stockholders have adopted the 2014 Employee Stock Purchase Plan (ESPP). The ESPP has become effective, and the Board will implement commencement of offers thereunder in its discretion. A total of 27,967 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 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;
- 55,936 shares; or
- such amount as determined by the Board.

As of September 30, 2021, there were no purchases by employees under this plan.

Common Stock Warrants

As of September 30, 2021, the Company had 102,070 common stock warrants outstanding that are related to convertible notes issued in 2010 and 2012, with an exercise price of $24.35 and a term of 10 years expiring in November 2024. The Company also had 16,500 common stock warrants issued to the underwriter in the Company's IPO, with an exercise price of $35.70 and a term of 10 years, expiring in November 2024.

Note 8. Net loss per share

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock actually outstanding during the period. For the three and nine months ended September 30, 2021 and 2020, the effect of issuing potential common stock upon the exercise or vesting of common stock awards and exercise of common stock warrants 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,	
	2021	2020
Warrants issued to 2010/2012 convertible note holders to purchase common stock	102,070	102,070
Options to purchase common stock	6,084,923	2,513,739
Outstanding restricted stock units	435,750	581,000
Warrants issued to underwriter to purchase common stock	16,500	16,500
Series D warrants to purchase common stock	—	540,540
2017 PIPE warrants	—	6,024,425
2018 PIPE warrants	513,617	513,617
Total	7,152,860	10,291,891

Note 9. Subsequent Events

The Company has evaluated its subsequent events from September 30, 2021 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 other than the item noted below.

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, 2020, 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, 2020. 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 are eligible to receive DCCR for up to 36 months 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 March 2021, the FDA informed us that an additional clinical trial would be necessary to support a New Drug Approval submission. In July 2021, we announced that we had received official meeting minutes from a Type B meeting with the FDA on June 11, 2021. Included in the meeting was the "patient voice" represented by the PWS advocacy organizations, as well as the family of a DCCR trial participant. The FDA continued to assert that an additional clinical trial is necessary for the submission of a New Drug Application (NDA). However, the FDA strongly encouraged us to submit the available data and clinical study reports for ours C601 and C602 studies to allow it to assess if these studies may provide adequate evidence of safety and efficacy to support the submission of an NDA. In September 2021, we announced top line 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 have submitted the data and are in communication with the regulatory authorities to determine next steps.

The spread of the COVID-19 virus during 2020 has caused an economic downturn on a global scale, as well as significant volatility in the financial markets. We have not experienced a significant financial impact directly related to the COVID-19 pandemic. In June 2020, subsequent to the announcement of top line results from DESTINY PWS, we completed a public offering of shares of our common stock and raised $53.7 million in net proceeds. As of September 30, 2021, we have cash and cash equivalents of $28.2 million. As of September 30, 2021, we had an accumulated deficit of $210.5 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.

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, 2021 and 2020

	Three Months Ended September 30,		Increase (decrease)	
	2021	2020	Amount	Percentage
	(in thousands)			
Operating expenses				
Research and development	$ 4,968	4,827	$ 141	3%
General and administrative	2,767	2,256	511	23%
Change in fair value of contingent consideration	551	774	(223)	29%
Total operating expenses	8,286	7,857	429	5%
Operating loss	(8,286)	(7,857)	(429)	5%
Other income (expense)				
Change in fair value of warrants liabilities	112	(689)	801	116%
Interest income	34	1	33	3300%
Total other income (expense)	146	(688)	834	121%
Net loss	$ (8,140)	$ (8,545)	$ 405	5%

Revenue

We have yet not commenced commercialization of DCCR, our current sole novel therapeutic product, and accordingly, through September 30, 2021, have generated no revenue from operations.

Research and development expense

Research and development expense of $5.0 million for the three months ended September 30, 2021 increased by $0.1 million over the three months ended September 30, 2020. The cadence of our research and development expenditures will fluctuate depending upon the state of our clinical programs and the timing of CMC projects necessary to support the submission of an NDA.

General and administrative expense

General and administrative expense of $2.8 million for the three months ended September 30, 2021 increased $0.5 million over the three months ended September 30, 2020. The increase was primarily related to increased compensation costs due to headcount growth and increased stock-based compensation expense, partly offset by a decline in the costs for corporate expenses, including consulting, intellectual property and legal costs.

Change in fair value of contingent consideration

We are obligated to make cash payments of up to a maximum of $30 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 $12.9 million as of September 30, 2021, a $0.6 million increase from the estimate as of June 30, 2021. During the three months ended September 30, 2020, the estimate increased $0.8 million from the $9.3 million estimated at June 30, 2020.

Other income (expense)

We had other income of $0.1 million in the three months ended September 30, 2021, compared to other expense of $0.7 million during the three months ended September 30, 2020. The increase of $0.8 million was primarily due to a decrease in the fair value of our outstanding warrants during the three months ended September 30, 2021 compared to the three months ended September 30, 2020.

Results of Operations

Comparison of the nine months ended September 30, 2021 and 2020

	Nine Months Ended September 30,		Increase (decrease)	
	2021	2020	Amount	Percentage
	(in thousands)			
Operating expenses				
Research and development	$ 17,719	$ 17,625	$ 94	1%
General and administrative	8,210	6,507	1,703	26%
Change in fair value of contingent consideration	2,598	4,200	(1,602)	38%
Total operating expenses	28,527	28,332	195	1%
Operating loss	(28,527)	(28,332)	(195)	1%
Other income				
Change in fair value of warrants liabilities	369	6,532	(6,163)	94%
Interest income	76	13	63	485%
Total other income	445	6,545	(6,100)	93%
Net loss	$ (28,082)	$ (21,787)	$ (6,295)	29%

Revenue

We have yet not commenced commercialization of DCCR, our current sole novel therapeutic product, and accordingly, through September 30, 2021, have generated no revenue from operations.

Research and development expense

Research and development expense of $17.8 million for the nine months ended September 30, 2021 remained constant with the nine months ended September 30, 2020. The cadence of our research and development expenditures will fluctuate depending upon the state of our clinical programs and the timing of CMC projects necessary to support the submission of an NDA.

General and administrative expense

General and administrative expense of $8.2 million for the nine months ended September 30, 2021 increased $1.7 million over the nine months ended September 30, 2020. The increase was primarily related to increased compensation costs due to increased headcount and increased stock-based compensation expense.

Change in fair value of contingent consideration

We are obligated to make cash payments of up to a maximum of $30 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 $12.9 million as of September 30, 2021, a $2.6 million increase from the estimate as of December 31, 2020. During the nine months ended September 30, 2020, the estimate increased $4.2 million from the $5.9 million estimated at December 31, 2019.

Other income

We had other income of $0.4 million in the nine months ended September 30, 2021, compared to $6.5 million during the nine months ended September 30, 2020. The decrease of $6.1 million was primarily due to a $6.2 million decrease in the fair value of our

outstanding warrants during the nine months ended September 30, 2021 compared the nine months ended September 30, 2020. An increase in interest income also contributed slightly to the overall decrease in the comparative periods.

Liquidity and Capital Resources

We had a net loss of $28.1 million during the nine months ended September 30, 2021 and an accumulated deficit of $210.5 million at September 30, 2021 as a result of having incurred losses since our inception. We had $28.2 million in cash and cash equivalents and $19.8 million of working capital at September 30, 2021, and used $20.9 million of cash in operating activities during the nine months ended September 30, 2021. We have financed our operations principally through issuances of equity securities. In June 2020, we sold 34,848,484 shares of common stock in an underwritten public offering at a price of $1.65 per share for net proceeds of $53.8 million. In July 2021, we announced an ATM Offering for up to $25.0 million.

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 are 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 this filing.

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,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	$ (20,907)	$ (18,357)
Net cash used in investing activities	(9)	(3)
Net cash provided by (used in) financing activities	(123)	53,764
Net increase (decrease) in cash and cash equivalents	$ (21,039)	$ 35,404

Cash used in operating activities

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 reduced by adding back the non-cash loss of $2.2 million for 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, the usage of cash during the nine months ended September 30, 2021 was decreased by $0.4 million due to changes in operating assets and liabilities.

During the nine months ended September 30, 2020, operating activities used net cash of $18.4 million, which was primarily due to the net loss of $21.8 million increased by adding back the net non-cash income of $2.3 million for the change in the fair value of stock warrants and contingent consideration and reduced by adding back other non-cash expenses of $1.5 million for depreciation and

amortization, $1.1 million for stock-based compensation and $0.2 million for non-cash lease expense. Additionally, the usage of cash during the nine months ended September 30, 2020 was reduced by $3.0 million due to changes in operating assets and liabilities.

Cash provided by (used in) investing activities

Minimal cash was used for investing activities in the nine months ended September 30, 2021 related to the costs of acquiring property and equipment.

Cash used in financing activities

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

In June 2020, we obtained $53.8 million of cash from the sale of shares of our common stock in a public offering, net of underwriting discounts and other offering expenses.

In addition, minimal cash was used during the nine months ended September 30, 2021 and 2020, for payments made on our finance lease.

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, 2021. 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, 2021, 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). Other than as set forth below, there are no material changes from the disclosure provided in the Form 10-K with respect to the Risk Factors.

The regulatory approval process for DCCR is subject to uncertainty based on FDA's recommendation that at least an additional clinical trial may be necessary to support a marketing application for the treatment of PWS.

We have been in discussions with the FDA regarding the clinical data necessary to support the submission of a new drug application (NDA) seeking approval to market DCCR for the treatment of PWS, after our Phase 3 trial, DESTINY PWS (C601) trial failed to demonstrate statistical significance on the primary efficacy endpoints. As we previously disclosed, the FDA has indicated that based on the data the agency has seen to date, at least an additional clinical trial will be necessary to support our planned NDA. As part of the ongoing discussions with the FDA, we have provided the agency with the clinical study report for the DESTINY PWS Phase 3 trial and available data from our long-term, open-label extension study (C602) to allow FDA to further assess if those data may provide adequate evidence of safety and efficacy to permit us to submit a 505(b)(2) NDA for the product candidate. We cannot be certain that the FDA will agree that these additional data, once reviewed by FDA, are sufficient for the agency to determine that we have demonstrated substantial evidence that DCCR is safe and effective for the treatment of PWS.

Complying with any additional requests for information from the FDA, or designing and conducting a new randomized controlled clinical trial if the agency continues to assert that an additional controlled data is necessary, will be time-consuming, expensive, and delay or prevent our ability to continue to study and develop DCCR, or may result in a change in our regulatory strategy such as pursuing a narrower indication of use. If we are unable to adequately address any previous or further recommendations, concerns, requests, or objections in a manner satisfactory to the FDA, as applicable, in a timely manner, or at all, we could be delayed or prevented from seeking approval of DCCR for any intended use. Moreover, there can be no assurance that any future randomized controlled trial will be successfully enrolled or completed.

We will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our product candidates.

We have yet not commenced commercialization of DCCR, our current sole novel therapeutic product, and accordingly, through September 30, 2021, have generated no revenue from operations. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We had a net loss of $28.1 million during the nine months ended September 30, 2021 and an accumulated deficit of $210.5 million at September 30, 2021 as a result of having incurred losses since our inception. We had $28.2 million in cash and cash equivalents and $19.8 million of working capital at September 30, 2021, used $20.9 million of cash in operating activities during the nine months ended September 30, 2021 and expect to continue incurring losses for the foreseeable future. These matters raise substantial doubt about our ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern within 12 months after the date the financial statements are issued.

We intend to raise additional capital, either through debt or equity financings to achieve our business plan objectives, including ongoing expenses related to resources being deployed to manage patients participating in our current ongoing clinical trial of DCCR and other activities necessary to support the submission of an NDA to the FDA. Because of the numerous risks and uncertainties

associated with our product development and planned commercialization efforts, many of which are discussed above and in the risk factors section of our Form 10-K, we are unable to predict the extent of our future losses or when, or if, we will generate meaningful revenue or become profitable, and it is possible we will never achieve these goals. Our ability to obtain additional financing will depend on a number of factors, including, among others, our ability to generate positive data from our clinical studies, our ability to obtain FDA clearance for DCCR, the condition of the capital markets and the other risks described in our risk factors. If any one of these factors is unfavorable, we may not be able to obtain additional funding, in which case, our business could be jeopardized and we may not be able to continue our operations or pursue our strategic plans. If we are forced to scale down, limit or cease operations, our stockholders could lose all of their investment. Even if we are successful at raising capital, there is no assurance that any funds raised will be sufficient to enable us to attain profitable operations or continue as a going concern.

To the extent that we are unsuccessful raising sufficient capital, we may need to curtail or cease our operations and implement a plan to extend payables or reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful. If adequate funds are not available, we may be required to curtail our operations significantly or to obtain funds on unfavorable terms, through dilutive financings or entering into arrangements with collaborative partners or others that may require us to relinquish rights to certain of our product candidates that we would not otherwise relinquish. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders would experience further dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we incur debt, our fixed payment obligations, liabilities and leverage relative to our equity capitalization would increase, which could increase the cost of future capital. Further, the terms of any debt securities we issue or borrowings we incur, if available, could impose significant restrictions on our operations, such as limitations on our ability to incur additional debt or issue additional equity or other operating restrictions that could adversely affect our ability to conduct our business, and any such debt could be secured by any or all of our assets pledged as collateral. Additionally, we may incur substantial costs in pursuing future capital, including investment banking, legal and accounting fees, printing and distribution expenses and other costs.

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			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
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 10, 2021

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 10, 2021

/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 10, 2021

/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, 2021, 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 10, 2021

/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, 2021, 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 10, 2021

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