

**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, 2023

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
(State or other jurisdiction of
incorporation or organization)

77-0523891
(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 3, 2023, there were 30,499,352 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, 2023	December 31, 2022
Assets	(Unaudited)	
Current assets		
Cash and cash equivalents	\$ 52,437	\$ 14,602
Prepaid expenses and other current assets	1,222	1,045
Total current assets	53,659	15,647
Long-term assets		
Property and equipment, net	15	26
Operating lease right-of-use assets	474	131
Intangible assets, net	9,235	10,693
Other long-term assets	165	-
Total assets	\$ 63,548	\$ 26,497
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 3,216	\$ 1,777
Accrued compensation	1,498	1,675
Accrued clinical trial site costs	3,237	3,222
Common stock purchase liability	19,938	-
Operating lease liabilities - current	256	155
Other current liabilities	848	484
Total current liabilities	28,993	7,313
Long-term liabilities		
2018 PIPE Warrant liability	653	1
Operating lease liabilities - noncurrent	214	-
Contingent liability for Essentialis purchase price	10,468	8,835
Total liabilities	40,328	16,149
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock, \$0.001 par value, 100,000,000 shares authorized, 15,467,229 and 8,159,382 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	15	8
Additional paid-in-capital	288,320	247,762
Accumulated deficit	(265,114)	(237,422)
Accumulated other comprehensive loss	(1)	-
Total stockholders' equity	23,220	10,348
Total liabilities and stockholders' equity	\$ 63,548	\$ 26,497

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,	
	2023	2022	2023	2022
Operating expenses				
Research and development	\$ 6,043	\$ 3,771	\$ 16,500	\$ 11,455
General and administrative	3,318	2,332	9,341	7,442
Change in fair value of contingent consideration	1,021	132	1,633	(110)
Total operating expenses	<u>10,382</u>	<u>6,235</u>	<u>27,474</u>	<u>18,787</u>
Operating loss	<u>(10,382)</u>	<u>(6,235)</u>	<u>(27,474)</u>	<u>(18,787)</u>
Other income (expense), net				
Change in fair value of warrants liabilities	(653)	2	(652)	31
Interest income	174	101	434	175
Total other income (expense), net	<u>(479)</u>	<u>103</u>	<u>(218)</u>	<u>206</u>
Net loss	<u>\$ (10,861)</u>	<u>\$ (6,132)</u>	<u>\$ (27,692)</u>	<u>\$ (18,581)</u>
Other comprehensive loss				
Foreign currency translation adjustment	(1)	(1)	(1)	(2)
Total comprehensive loss	<u>\$ (10,862)</u>	<u>\$ (6,133)</u>	<u>\$ (27,693)</u>	<u>\$ (18,583)</u>
Net loss per common share, basic and diluted	<u>\$ (0.95)</u>	<u>\$ (0.65)</u>	<u>\$ (2.65)</u>	<u>\$ (2.31)</u>
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	<u>11,436,748</u>	<u>9,417,705</u>	<u>10,443,186</u>	<u>8,045,513</u>

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, 2023 and 2022
(unaudited)
(in thousands, except share data)

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

	Common Stock		Additional Paid-In Capital	Accumulate d Deficit	Accumulate d Other Comprehen sive Loss	Total Stockholder s' 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
Foreign currency translation adjustment	-	-	-	-	(2)	(2)
Net loss	-	-	-	(5,724)	-	(5,724)
Balances at March 31, 2022	8,005,921	8	245,534	(219,079)	(2)	26,461
Stock-based compensation	-	-	571	-	-	571
Foreign currency translation adjustment	-	-	-	-	1	1
Net loss	-	-	-	(6,725)	-	(6,725)
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

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,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (27,692)	\$ (18,581)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,469	1,476
Non-cash lease expense	254	215
Stock-based compensation expense	4,036	1,898
Change in fair value of stock warrants	652	(31)
Change in fair value of contingent consideration	1,633	(110)
Other non-cash reconciling items	(1)	(2)
Change in operating assets and liabilities:		
Prepaid expenses, other current assets and other assets	(177)	337
Accounts payable	1,338	(930)
Accrued compensation	(177)	554
Accrued clinical trial site costs	15	(594)
Operating lease liabilities	(242)	(218)
Other liabilities	266	348
Net cash used in operating activities	(18,626)	(15,638)
Cash flows from investing activities		
Purchases of property and equipment	-	(7)
Net cash used in investing activities	-	(7)
Cash flows from financing activities:		
Proceeds from sale of common stock and common stock warrants, net of issuance costs	17,074	-
Proceeds from sale of common stock and pre-funded warrants, net of costs	-	14,108
Proceeds from exercise of common stock warrants, net of costs	19,445	-
Proceeds received prior to and for the issuance of common stock and pre-funded warrants	19,932	-
Proceeds from stock option exercises	10	-
Tax withholding payments for net share-settled equity awards	-	(16)
Net cash provided by financing activities	56,461	14,092
Net increase (decrease) in cash and cash equivalents	37,835	(1,553)
Cash and cash equivalents, beginning of period	14,602	21,304
Cash and cash equivalents, end of period	\$ 52,437	\$ 19,751
Supplemental disclosure of non-cash financing information		
Operating lease right-of-use assets obtained in exchange for operating lease obligations	\$ 597	\$ -
Unpaid financing costs included in accounts payable and accrued liabilities	\$ 199	\$ -

See accompanying notes to condensed consolidated financial statements.

Soleno Therapeutics, Inc.
September 30, 2023
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 1. Overview

Soleno Therapeutics, Inc. (the Company or Soleno) is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Its lead candidate is DCCR (Diazoxide Choline) Extended-Release tablets, a once-daily oral tablet for the treatment of Prader-Willi syndrome (PWS). DCCR has received 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. Liquidity

The Company had a net loss of \$27.7 million during the nine months ended September 30, 2023 and has an accumulated deficit of \$265.1 million at September 30, 2023 resulting from having incurred losses since its inception. The Company had \$52.4 million of cash and cash equivalents on hand at September 30, 2023 and used \$18.6 million of cash in its operating activities during the nine months ended September 30, 2023.

The Company has financed its operations principally through issuance of equity securities. On October 2, 2023, the Company closed a public and concurrent private financing with gross proceeds of \$129.0 million. \$16.0 million was received prior to September 30, 2023, and was included in cash and cash equivalents and current liabilities as of the quarter end. The remaining gross proceeds of \$113.0 million were received in October 2023.

In December 2022, the Company entered into a Securities Purchase Agreement providing for the sale of up to \$60.0 million in warrants (Tranche A and Tranche B) and the common stock issuable upon the exercise thereof. The Company completed the closing of the sale and issued both tranches of warrants for \$10.0 million in May 2023. The announcement of positive top-line data from the randomized withdrawal period of Study C602 triggered the mandatory exercise of the Tranche A warrants, and as of September 30, 2023, the Company had received \$15.0 million. In October 2023, certain investors exercised their Tranche B warrants and the Company received \$17.5 million. The exercise of the remaining Tranche B warrants for up to \$17.5 million is contingent upon the future performance of the Company. The Company also received \$8.4 million in gross proceeds from the exercise of certain March 2022 warrants during the three months ended September 30, 2023.

The Company expects to continue incurring losses for the foreseeable future. However, the Company expects that its current cash and cash equivalents balances together with the cash received in October 2023 will be sufficient to enable the Company to meet its obligations for at least the next twelve months from the date of this filing.

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

Significant Accounting Policies

There have been no material changes to the significant accounting policies during the three and nine months ended September 30, 2023 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, 2022.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared on a going concern basis in accordance with 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, 2023, are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2023. 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, 2022, which are included in the Company's annual report on Form 10-K filed with the SEC on March 22, 2023.

Reverse Stock Split

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.

Recently Adopted Accounting Pronouncements

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

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments*, which, together with subsequent amendments, amends the requirement on the measurement and recognition of expected credit losses for financial assets held. ASU 2016-13 is effective for the Company for the annual periods beginning after December 15, 2022, including interim periods within those fiscal years, with early adoption permitted. The Company adopted this ASU effective January 1, 2023. There was no impact on the Company's financial statements upon the adoption of this ASU.

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

Note 4. Fair Value of Financial Instruments

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

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

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

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

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

The 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, 2023			
	Total	Level 1	Level 2	Level 3
Liabilities				
2018 PIPE warrant liability	\$ 653	\$ —	\$ —	\$ 653
Essentialis purchase price contingency liability	10,468	—	—	10,468
Total common stock warrant and contingent consideration liability	<u>\$ 11,121</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 11,121</u>
	Fair Value Measurements at December 31, 2022			
	Total	Level 1	Level 2	Level 3
Liabilities				
2018 PIPE warrant liability	\$ 1	\$ —	\$ —	\$ 1
Essentialis purchase price contingency liability	8,835	—	—	8,835
Total common stock warrant and contingent consideration liability	<u>\$ 8,836</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 8,836</u>

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 is obligated to make cash earnout payments of up to a maximum of \$21.2 million to the former Essentialis stockholders. The fair value of the Essentialis purchase price contingent liability is estimated using scenario-based methods based upon the Company's analysis of the likelihood of obtaining specified approvals from the U.S. Food and Drug Administration (FDA) as well as achieving two commercial sales milestones of \$100 million and \$200 million in cumulative revenue. The Level 3 estimates are based, in part, on subjective assumptions. In determining the likelihood of this occurring, the analysis relied on published research relating to clinical development success rates. Based on management's assessment, an 88% and a 72% probability of achieving all three milestones was determined to be reasonable as of September 30, 2023 and December 31, 2022, respectively. 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, 2023 and 2022 (dollars in thousands):

	2018 PIPE Warrants		Purchase Price Contingent Liability
	Number of Warrants	Liability	
Balance at January 1, 2023	34,241	\$ 1	\$ 8,835
Change in value of 2018 PIPE Warrants	—	652	—
Change in value of contingent liability	—	—	1,633
Balance at September 30, 2023	<u>34,241</u>	<u>\$ 653</u>	<u>\$ 10,468</u>
	2018 PIPE Warrants		Purchase Price Contingent Liability
	Number of Warrants	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	<u>34,241</u>	<u>\$ —</u>	<u>\$ 9,437</u>

Note 5. Warrants

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

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

The 2018 PIPE Warrants were issued on December 19, 2018 in the 2018 PIPE Offering, pursuant to a Warrant Agreement with each of the investors in the 2018 PIPE Offering, and 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, 2023 and December 31, 2022, the fair value of the 2018 PIPE Warrants was estimated at approximately \$653,000 and \$1,000, respectively.

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, 2023	December 31, 2022
Volatility	392 %	117 %
Contractual term (years)	0.2	1.0
Expected dividend yield	— %	— %
Risk-free rate	5.58 %	4.74 %

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 calculated the estimated volatility rate based on 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 began in June 2021 and expired in May 2023. In April 2023, the Company entered into a twenty-four month lease extension commencing on June 1, 2023. The term of the lease extension expires in May 2025.

The Company recorded an increase to its right-of-use asset by \$0.6 million and an increase to its lease liability by \$0.6 million as a result of the lease extension. The weighted average discount rate related to the Company's lease liabilities as of September 30, 2023 was 8.25% over a remaining term of 20 months. The weighted average discount rate related to the Company's lease liabilities as of December 31, 2022 was 9% over a remaining term of 5 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, 2023 (in thousands):

2023 (remainder of the year)	\$	76
2024		287
2025		143
Total lease payments		506
Less interest		(36)
Total	\$	470

The components of lease expense during the three and nine months ended September 30, 2023 and 2022 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease cost:				
Operating lease cost	\$ 76	\$ 81	\$ 235	\$ 242
Short-term lease cost	12	9	33	22
Total operating lease cost	\$ 88	\$ 90	\$ 268	\$ 264

Contingencies

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

Note 7. Stockholders' Equity

Convertible Preferred Stock

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

Securities Purchase Agreement

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

The warrants are separated into two tranches with 8,598,870 Tranche A Warrants and 14,000,000 Tranche B Warrants. The Tranche A warrants are exercisable for \$1.75 per share, with an aggregate exercise price of up to approximately \$15.0 million, and the Tranche B warrants are exercisable for \$2.50 per share, with an aggregate exercise price of up to \$35.0 million. The Tranche A warrants were immediately exercisable and were required to be exercised within 30 days of announcement of positive top-line data from the randomized withdrawal period of Study C602. The Tranche B warrants are also immediately exercisable and expire upon the earlier of 3.5 years from the date of issuance or 30 days following receipt of the U.S. Food and Drug Administration approval of DCCR for the treatment of PWS. On September 26, 2023, the Company announced positive top-line data and the Tranche A warrants were exercised for gross proceeds of \$15.0 million with 3,310,568 shares and 2,420,394 pre-funded exchange warrants being issued prior to the quarter end, and 526,741 shares and 2,341,167 pre-funded exchange warrants being issued after the quarter end.

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 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.

During the three months ended September 30, 2023, 1,869,327 warrants were exercised for gross proceeds of \$8.4 million and 353,155 pre-funded warrants were exercised using the cashless exercise option with no additional proceeds received by the Company.

At the Market Offering

In July 2021, the Company entered into a Controlled Equity Offering Sales Agreement under which the Company 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, 2023, the Company has sold an aggregate of 1,877,170 shares of common stock through the at the market program, totaling \$7.4 million in net proceeds. The Controlled Equity Offering Sales Agreement was terminated in connection with the October 2, 2023 financing.

Other Common Stock Warrants

As of September 30, 2023, the Company had 6,804 common stock warrants outstanding from the 2010/2012 convertible notes, with an exercise price of \$365.25 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 \$535.50 and a term of 10 years, expiring in November 2024.

As of September 30, 2023 and December 31, 2022, the following table summarizes the Company's outstanding common stock warrants:

	As of September 30, 2023		As of December 31, 2022		Expiration Date
	Number of Common Warrant Shares	Weighted Average Exercise Price per Share	Number of Common Warrant Shares	Weighted Average Exercise Price per Share	
Common stock warrants	7,904	\$ 388.94	7,904	\$ 388.94	November 2024
2018 PIPE warrants	34,241	\$ 30.00	34,241	\$ 30.00	December 2023
March 2022 Common warrants	2,130,656	\$ 4.50	4,000,000	\$ 4.50	March 2027
March 2022 Pre-funded warrants	927,806	\$ 0.15	1,280,965	\$ 0.15	March 2027
May 2023 Tranche A warrants	2,867,908	\$ 1.75	—	\$ —	November 2026 ⁽¹⁾
May 2023 Tranche A Pre-funded warrants	2,420,394	\$ 0.01	—	\$ —	November 2026 ⁽¹⁾
May 2023 Tranche B warrants	14,000,000	\$ 2.50	—	\$ —	November 2026 ⁽¹⁾
Total	22,388,909		5,323,110		

⁽¹⁾ Subject to earlier expiration as described above.

Equity Incentive Plans

2014 Plan

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

The Board has the authority to determine to whom stock options will be granted, the number of options, the term, and the exercise price. Options are to be granted at an exercise price not less than fair value. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price of an option will not be less than 110% of fair value. 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.

On March 23, 2023, the Company filed a Registration Statement on Form S-8 which registered 238,329 shares available for grant and issuance under the 2014 Plan, all of which became available for grant and issuance under the 2014 Plan on January 1, 2023. On May 25, 2023, the stockholders approved the Amended and Restated 2014 Plan which included an increase of 1.8 million shares available for grant and issuance. As of September 30, 2023, a total of 17,780 shares are available for future grant under the 2014 Plan.

Inducement Plan

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

In accordance with Rule 5635(c)(4) and Rule 5635(c)(3) of the Nasdaq Listing Rules, awards under the Inducement Plan may only be made to individuals not previously employees or non-employee directors of the Company (or following such individuals' bona fide period of non-employment with the Company), as an inducement material to the individuals' entry into employment with the Company, or, to the extent permitted by Rule 5635(c)(3) of the Nasdaq Listing Rules, in connection with a merger or acquisition. On March 23, 2023, the Company filed a Registration Statement on Form S-8 which registered 500,000 shares available for issuance under the Inducement Plan, all of which became available for grant and issuance under the Inducement Plan on February 17, 2023.

As of September 30, 2023, a total of 590,668 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,	
	2023	2022	2023	2022
Research and development	\$ 935	\$ 200	\$ 1,587	\$ 511
General and administrative	1,266	483	2,449	1,387
Total	\$ 2,201	\$ 683	\$ 4,036	\$ 1,898

Stock Options

The Company granted options to purchase 77,000 and 157,673 shares of the Company's common stock during the three months ended September 30, 2023 and 2022, respectively, and granted options to purchase 1,663,454 and 283,919 of the Company's common stock during the nine months ended September 30, 2023 and 2022, respectively. There were no performance-based options granted during the three and nine months ended September 30, 2023 and 2022, respectively. The fair value of each award granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Expected life (years)	5.3-6.0	5.2-5.7	5.3-6.0	5.2-6.0
Risk-free interest rate	4.0%-4.4%	2.8%-3.1%	3.5%-4.4%	1.7%-3.0%
Volatility	98%-100%	92%-95%	98%-100%	88%-93%
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, 2023 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, 2023	686,574	\$ 28.83	7.93	
Options granted	1,663,454	4.81		
Options exercised	(3,931)	3		
Options canceled/forfeited	(45,685)	71.99		
Balance at September 30, 2023	<u>2,300,412</u>	<u>\$ 10.65</u>	<u>8.92</u>	<u>\$ 47,959</u>
Options exercisable at September 30, 2023	<u>684,187</u>	<u>\$ 19.86</u>	<u>7.75</u>	<u>\$ 10,695</u>
Options vested and expected to vest at September 30, 2023	<u>2,277,454</u>	<u>\$ 10.39</u>	<u>9.17</u>	<u>\$ 47,959</u>

The weighted-average grant date fair value of options granted was \$3.80 and \$2.62 per share for the nine months ended September 30, 2023 and 2022, respectively. At September 30, 2023 total unrecognized employee stock-based compensation related to stock options that are likely to vest was \$7.4 million, which is expected to be recognized over the weighted-average remaining vesting period of 2.6 years.

Restricted Stock Units

There were no restricted stock units granted by the Company during the three months ended September 30, 2023 and 2022, respectively, and 414,710 and 8,967 restricted stock units granted during the nine months ended September 30, 2023 and 2022, respectively, to employees and directors. The restricted stock units granted to directors in 2023 were 100% vested on the grant date and represent compensation for past board services. Restricted stock units granted during 2023 vest 100% nine months from date of grant. 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, 2023 as issued under the 2014 Plan:

	Number of Restricted Stock Units	Weighted- Average Grant-Date Fair Value per Share
Outstanding at January 1, 2023	19,068	\$ 57.75
Restricted stock units granted	414,710	\$ 5.25
Restricted stock units vested	(9,534)	\$ 57.75
Restricted stock units canceled/forfeited	-	\$ 0.00
Outstanding at September 30, 2023	<u>424,244</u>	<u>\$ 6.43</u>

The weighted-average grant-date fair value of all restricted stock units granted during the nine months ended September 30, 2023 and 2022 was \$5.25 and \$5.33, respectively. The fair value of all restricted stock units vested during the nine months ended September 30, 2023 and 2022 was \$23,000 and \$0.6 million, respectively. At September 30, 2023, total unrecognized employee stock-based compensation related to restricted stock units was \$0.8 million, which is expected to be recognized over the weighted-average remaining vesting period of 0.2 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, 2023, there were no purchases by employees under this plan.

Note 8. Net loss per share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022 ⁽¹⁾	2023	2022 ⁽¹⁾
Common stock	10,287,620	8,136,740	9,206,650	7,156,344
March 2022 pre-funded warrants	1,122,819	1,280,965	1,227,670	889,169
May 2023 Tranche A pre-funded exchange warrants	26,309	-	8,866	-
Total	11,436,748	9,417,705	10,443,186	8,045,513

⁽¹⁾ The Company revised the 2022 weighted-average common shares outstanding calculation to include the March 2022 pre-funded warrants. Management believes this version results in a more appropriate treatment of the pre-funded warrants in calculating the net loss per share.

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,	
	2023	2022
Warrants issued to 2010/2012 convertible note holders to purchase common stock	6,804	6,804
Warrants issued to underwriter to purchase common stock	1,100	1,100
2018 PIPE warrants	34,241	34,241
March 2022 common warrants	2,130,656	4,000,000
May 2023 Tranche A warrants	2,867,908	—
May 2023 Tranche B warrants	14,000,000	—
Options to purchase common stock	2,300,412	686,816
Outstanding restricted stock units	424,244	19,068
Total	21,765,365	4,042,145

Note 9. Subsequent Events

On September 26, 2023, the Company announced positive top-line data from the randomized withdrawal period of Study C602 which triggered the mandatory exercise of the May 2023 Tranche A warrants. As of September 30, 2023, the Company had received \$15.0 million. In addition, certain investors exercised their December 2022 Tranche B warrants, and the Company received \$17.5 million in October 2023.

On October 2, 2023, the Company announced the closing of the underwritten public offering of 3,450,000 shares of its common stock at a public offering price of \$20.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the public offering were \$69.0 million, before deducting the underwriting discount and other estimated offering expenses. The Company also announced the closing of approximately \$60.0 million of shares of its common stock and pre-funded warrants in a concurrent private offering pursuant to the securities purchase agreement with certain investors, including entities affiliated with existing stockholders, at a price per share of common stock equal to the public offering price of \$20.00 and a price per pre-funded warrant of \$19.99. Of these proceeds, the Company had received \$16.0 million prior to the end of the quarter and included these amounts in cash and cash equivalents and current liabilities as of September 30, 2023. The remaining gross proceeds of \$113.0 million were received in October 2023.

The following table summarizes the Company's outstanding common stock and common stock warrants as of October 31, 2023:

	As of October 31, 2023	
	Number of Common Shares	Weighted Average Exercise Price per Shares
Common stock outstanding	30,499,352	\$ -
Common stock warrants	7,904	\$ 388.94
2018 PIPE warrants	34,241	\$ 30.00
March 2022 common warrants	2,122,924	\$ 4.50
March 2022 Pre-funded warrants	—	\$ 0.15
May 2023 Tranche A warrants	—	\$ 1.75
May 2023 Tranche A Pre-funded exchange warrants	3,058,837	\$ 0.01
May 2023 Tranche B warrants	7,000,000	\$ 2.50
May 2023 Tranche B Pre-funded exchange warrants	451,632	\$ 0.01
October 2023 Pre-funded warrants	1,125,019	\$ 0.01
Total	44,299,909	

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, 2022, 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, 2022. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These forward-looking statements are subject to risks and uncertainties, including those set forth in Part II – Other Information, Item 1A. Risk Factors below and elsewhere in this report that could cause actual results to differ materially from historical results or anticipated results.

Business Overview

We are focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Our lead candidate is DCCR (Diazoxide Choline) Extended-Release tablets, a once-daily oral tablet for the treatment of Prader-Willi syndrome (PWS). 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 completed 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 May 2023, we announced the completion of enrollment in the randomized withdrawal (RW) period of Study C602, 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 consisted only of patients previously enrolled in Study C602 and did not enroll any new patients. The FDA has acknowledged that data from the study has the potential to support an NDA submission for DCCR. On September 26, 2023, we announced positive statistically significant top-line results from the RW period of Study C602.

On October 2, 2023, we closed a public and concurrent private financing with gross proceeds of \$129.0 million. \$16.0 million was received prior to September 30, 2023, and was included in cash and cash equivalents and current liabilities as of the quarter end. The remaining gross proceeds of \$113.0 million were received in October 2023. Previously, in December 2022, we entered into a Securities Purchase Agreement providing for the sale of up to \$60.0 million in warrants (Tranche A and Tranche B) and the common stock issuable upon the exercise thereof. We completed the closing of the sale and issued both tranches of warrants for \$10.0 million in May 2023. The announcement of positive top-line data from the randomized withdrawal period of Study C602 triggered the mandatory exercise of the Tranche A warrants and as of September 30, 2023 we had received \$15.0 million. In October 2023, certain investors exercised their Tranche B warrants and we received \$17.5 million. The exercise of remaining Tranche B warrants for up to \$17.5 million is contingent upon our future performance. We also received \$8.4 million in gross proceeds from the exercise of certain March 2022 warrants during the three months ended September 30, 2023.

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, 2023 and 2022

	Three Months Ended September 30,		Increase (decrease)	
	2023	2022	Amount	Percentage
	(in thousands)			
Operating expenses				
Research and development	\$ 6,043	\$ 3,771	\$ 2,272	60 %
General and administrative	3,318	2,332	986	42 %
Change in fair value of contingent consideration	1,021	132	889	673 %
Total operating expenses	10,382	6,235	4,147	67 %
Operating loss	(10,382)	(6,235)	(4,147)	67 %
Other income (expense), net				
Change in fair value of warrants liabilities	(653)	2	(655)	32750 %
Interest income	174	101	73	72 %
Total other income (expense), net	(479)	103	(582)	565 %
Net loss	\$ (10,861)	\$ (6,132)	\$ (4,729)	77 %

Revenue

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

Research and development expense

Research and development expense was \$6.0 million for the three months ended September 30, 2023, an increase of \$2.3 million from the three months ended September 30, 2022. 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. Clinical trial costs increased \$1.2 million with all patients enrolled into the RW period for Study C602, and as patients complete the RW period, increased costs supporting them in an open label extension, Study C614. CMC costs increased \$0.6 million as certain manufacturer processes were initiated, and headcount costs increased as we hired additional employees in support of our research and development activities going forward.

General and administrative expense

General and administrative expense was \$3.3 million for the three months ended September 30, 2023, an increase of \$1.0 million from the three months ended September 30, 2022. The increase was mainly attributable to an increase in stock-based compensation and professional services expenses.

Change in fair value of contingent consideration

We are obligated to make cash payments up to a maximum of \$21.2 million to the former Essentialis stockholders upon the achievement of certain future commercial milestones associated with the sales of DCCR in accordance with the terms of our merger agreement with Essentialis. The fair value of the liability for the contingent consideration payable by us achieving two commercial sales milestones of \$100 million and \$200 million in cumulative revenue in future years was estimated to be \$10.5 million as of September 30, 2023, a \$1.1 million increase from the estimate as of June 30, 2023. During the three months ended September 30, 2022, the estimate increased by \$0.1 million from the \$9.3 million estimate as of June 30, 2022.

Other income (expense), net

We had other expense, net of approximately \$479,000 in the three months ended September 30, 2023, compared to other income of \$103,000 during the three months ended September 30, 2022. The decrease was primarily due to the change in fair value of

warrants liabilities, partially offset by an increase in interest income during the three months ended September 30, 2023 compared to the three months ended September 30, 2022.

Comparison of the nine months ended September 30, 2023 and 2022

	Nine months ended September 30,		Increase (decrease)	
	2023	2022	Amount	Percentage
	(in thousands)			
Operating expenses				
Research and development	\$ 16,500	11,455	\$ 5,045	44 %
General and administrative	9,341	7,442	1,899	26 %
Change in fair value of contingent consideration	1,633	(110)	1,743	1585 %
Total operating expenses	27,474	18,787	8,687	46 %
Operating loss	(27,474)	(18,787)	(8,687)	46 %
Other income (expense), net				
Change in fair value of warrants liabilities	(652)	31	(683)	2203 %
Interest income	434	175	259	148 %
Total other income (expense), net	(218)	206	(424)	206 %
Net loss	\$ (27,692)	\$ (18,581)	\$ (9,111)	49 %

Revenue

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

Research and development expense

Research and development expense was \$16.5 million for the nine months ended September 30, 2023, an increase of \$5.0 million from the nine months ended September 30, 2022. 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. Clinical trial costs increased \$5.0 million as we completed enrolling patients into the RW period for Study C602, and as patients complete the RW period, we are incurring costs supporting them in an open label extension, Study C614. CMC costs decreased \$0.6 million due to the cessation and commencement of various manufacturing processes, and headcount costs increased as we hired additional employees in support of our research and development activities going forward.

General and administrative expense

General and administrative expense was \$9.3 million for the nine months ended September 30, 2023, an increase of \$1.9 million from the nine months ended September 30, 2022. The increase was mainly attributable to an increase in stock-based compensation and professional services expenses.

Change in fair value of contingent consideration

We are obligated to make cash payments up to a maximum of \$21.2 million to the former Essentialis stockholders upon the achievement of certain future commercial milestones associated with the sales of DCCR in accordance with the terms of our merger agreement with Essentialis. The fair value of the liability for the contingent consideration payable by us achieving two commercial sales milestones of \$100 million and \$200 million in cumulative revenue in future years was estimated to be \$10.5 million as of September 30, 2023, a \$1.6 million increase from the estimate as of December 31, 2022. During the nine months ended September 30, 2022, the estimate decreased by \$0.1 million from the \$9.5 million estimate as of December 31, 2021.

Other income (expense), net

We had other expense, net of approximately \$218,000 in the nine months ended September 30, 2023, compared to other income of \$206,000 during the nine months ended September 30, 2022. The decrease was primarily due to the change in fair value of warrants

liabilities, partially offset by an increase in interest income during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022.

Liquidity and Capital Resources

We had a net loss of \$27.7 million during the nine months ended September 30, 2023 and an accumulated deficit of \$265.1 million at September 30, 2023 as a result of having incurred losses since our inception. We had \$52.4 million in cash and cash equivalents and \$24.7 million of working capital at September 30, 2023, and used \$18.6 million of cash in operating activities during the nine months ended September 30, 2023. As of September 30, 2023, we had lease obligations totaling \$470,000 to be paid through 2025, consisting of an operating lease for office space in Redwood City, California.

We have financed our operations principally through issuances of equity securities. On October 2, 2023, we closed a public and concurrent private financing with gross proceeds of \$129.0 million. \$16.0 million was received prior to September 30, 2023, and was included in cash and cash equivalents and current liabilities as of the quarter end. The remaining gross proceeds of \$113.0 million were received in October 2023. Previously, in December 2022, we entered into a Securities Purchase Agreement providing for the sale of up to \$60.0 million in warrants (Tranche A and Tranche B) and the common stock issuable upon the exercise thereof. We completed the closing of the sale and issued both tranches of warrants for \$10.0 million in May 2023. The announcement of positive top-line data from the randomized withdrawal period of Study C602 triggered the mandatory exercise of the Tranche A warrants, and as of September 30, 2023, we had received \$15.0 million. In October 2023, certain investors exercised their Tranche B warrants and we received \$17.5 million. The exercise of remaining Tranche B warrants for up to \$17.5 million is contingent upon our future performance. We also received \$8.4 million in gross proceeds from the exercise of certain March 2022 warrants during the three months ended September 30, 2023. In May 2023, we received net proceeds of \$7.1 million from the sale of common stock through the ATM program which was subsequently terminated in connection with the October 2, 2023 financing.

We expect to continue incurring losses for the foreseeable future. However, we expect that our current cash and cash equivalents balance together with the cash received in October 2023, will be sufficient to enable us to meet our obligations for at least the next twelve months from the date of this filing.

Cash flows

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

	<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>
	(in thousands)	
Net cash used in operating activities	\$ (18,626)	\$ (15,638)
Net cash used in investing activities	—	(7)
Net cash provided by financing activities	56,461	14,092
Net increase (decrease) in cash and cash equivalents	<u>\$ 37,835</u>	<u>\$ (1,553)</u>

Net cash used in operating activities

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

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.

Net cash used in investing activities

During the nine months ended September 30, 2023, there were no purchases of property and equipment. During the nine months ended September 30, 2022, there was minimal cash used in purchasing property and equipment.

Net cash provided by financing activities

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

During the nine months ended September 30, 2022, we received \$14.1 million of net cash proceeds from the sale of 2,666,666 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. The net proceeds amount was slightly offset by payments 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, 2023. For additional information regarding market risk, refer to the *Qualitative and Quantitative Disclosures About Market Risk* section of the Form 10-K.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

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

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

(b) Changes in Internal Control over Financial Reporting

There have been no changes to our internal control over financial reporting that occurred during the three months ended September 30, 2023, 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 modified by our previous Quarterly Reports on Form 10-Q, there have been no material changes from the disclosure provided in the Form 10-K with respect to the Risk Factors.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

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

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	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 7, 2023

SOLENO THERAPEUTICS, INC.

By: /s/ James Mackaness

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

**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 7, 2023

/s/ Anish Bhatnagar

Anish Bhatnagar

President, Chief Executive Officer

(principal executive officer)

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

I, James Mackaness, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Soleno Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2023

/s/ James Mackaness

James Mackaness

Chief Financial Officer

(principal financial and accounting officer)

**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, 2023, 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 7, 2023

/s/ Anish Bhatnagar

Anish Bhatnagar

President, Chief Executive Officer

(principal executive officer)

**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, 2023, 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 7, 2023

/s/ James Mackaness

James Mackaness

Chief Financial Officer

(principal financial and accounting officer)
