REFINITIV

DELTA REPORT

10-Q

COYA - COYA THERAPEUTICS, INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	664
CHANGES	117
DELETIONS	279
ADDITIONS	268

REFINITIV

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, March 31, 2023 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-41583

Coya Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**85-4017781**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5850 San Felipe St., Suite 500 Houston, TX	**77057**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (800) 587-8170

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	COYA	The Nasdaq Stock Market LLC

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 ☒

The number of shares of Registrant’s common stock outstanding as of November 2, 2023 May 7, 2024 was 10,030,436 14,618,172.

Table of Contents

Part I – Financial Information

Item 1. Financial Statements.

COYA THERAPEUTICS, INC.

CONDENSED BALANCE SHEETS

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
	(unaudited)		(unaudited)	
Assets				
Current assets:				
Cash and cash equivalents	$ 10,886,282	$ 5,933,703	$ 35,989,406	$ 32,626,768
Collaboration receivable			-	7,500,000
Prepaids and other current assets	936,354	1,261,264	1,344,955	1,069,557
Total current assets	11,822,636	7,194,967	37,334,361	41,196,325
Fixed assets, net	72,790	93,310	59,109	65,949
Deferred financing costs	-	1,117,290		
Total assets	$ 11,895,426	$ 8,395,566	$ 37,393,470	$ 41,262,274

Liabilities and Stockholders' Equity (Deficit)				
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	633,951	1,815,270	$ 1,587,943	$ 1,155,656
Accrued expenses	1,172,674	2,008,361	2,041,530	2,973,215
Deferred collaboration revenue			689,669	923,109
Total current liabilities	1,806,625	3,823,631	4,319,142	5,051,980
Convertible promissory notes	-	12,965,480		
Deferred collaboration revenue			681,287	574,685
Total liabilities	1,806,625	16,789,111	5,000,429	5,626,665
Commitments and contingencies (Note 5)				
Commitments and contingencies (Note 6)				
Stockholders' equity (deficit):				
Series A convertible preferred stock, $0.0001 par value: 10,000,000 shares authorized, none and 7,500,713 issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	-	8,793,637		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 9,947,915 and 2,590,197 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	996	259		
Stockholders' equity:				
Series A convertible preferred stock, $0.0001 par value: 10,000,000 shares authorized, none issued or outstanding as of March 31, 2024 or December 31, 2023			-	-

Common stock, $0.0001 par value; 200,000,000 shares authorized; 14,613,172 and 14,405,325 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively			1,462	1,441
Additional paid-in capital	37,210,163	681,106	63,449,125	61,501,801
Subscription receivable			(149,250)	(11,250)
Accumulated deficit	(27,122,358)	(17,868,547)	(30,908,296)	(25,856,383)
Total stockholders' equity (deficit)	10,088,801	(8,393,445)		
Total liabilities and stockholders' equity (deficit)	11,895,401	8,395,561		
	$ 26	$ 6		
Total stockholders' equity			32,393,041	35,635,609
Total liabilities and stockholders' equity			$ 37,393,470	$ 41,262,274

The accompanying notes are an integral part of these condensed unaudited interim financial statements.

COYA THERAPEUTICS, INC.

CONDENSED UNAUDITED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2023	2022	2024	2023
Collaboration revenue					$ 126,838	$ -
Operating expenses:						

Research and development	$ 1,592,232	$ 1,278,289	$ 3,891,896	$ 3,704,466	3,138,159	1,231,712
In-process research and development	—	135,000	350,000	135,000	25,000	-
General and administrative	1,964,990	1,236,127	5,456,087	3,948,434	2,439,841	1,661,544
Depreciation	6,841	12,455	20,521	20,521	6,840	6,840
Total operating expenses	3,564,063	2,661,871	9,718,504	7,808,421	5,609,840	2,900,096
Loss from operations	(3,564,063)	(2,661,871)	(9,718,504)	(7,808,421)	(5,483,002)	(2,900,096)
Other income:						
Change in fair value of convertible promissory notes	—	(1,398,375)	—	(1,376,030)		
Other income, net	142,089	39,420	464,693	47,343	431,089	163,634
Net loss	$ (3,421,974)	$ (4,020,826)	$ (9,253,811)	$ (9,137,108)	$ (5,051,913)	$ (2,736,462)
Per share information:						
Net loss per share of common stock, basic and diluted	$ (0.34)	$ (1.55)	$ (0.94)	$ (3.53)	$ (0.35)	$ (0.28)
Weighted-average shares of common stock outstanding, basic and diluted	9,947,915	2,590,197	9,873,388	2,590,148	14,457,839	9,721,847

The accompanying notes are an integral part of these condensed unaudited interim financial statements.

COYA THERAPEUTICS, INC.

CONDENSED UNAUDITED INTERIM STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Convertible Preferred Stock				Additional		Total
	Series A		Common Stock		Paid-In	Accumulated	Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2022	7,500,713	$ 8,793,637	2,590,197	$ 259	$ 681,106	$ (17,868,547)	$ (8,393,545)
Conversion of convertible preferred stock upon initial public offering	(7,500,713)	(8,793,637)	1,316,926	132	8,793,505	-	-
Conversion of convertible promissory notes upon initial public offering	-	-	2,736,488	274	12,965,206	-	12,965,480
Sale of common stock in initial public offering and over-allotment option, net of issuance costs of $2.3 million	-	-	3,287,804	329	14,136,099	-	14,136,428
Stock-based compensation expense and vesting of restricted stock units	-	-	16,500	2	180,385	-	180,387
Net loss	-	-	-	-	-	(2,736,462)	(2,736,462)
Balance, March 31, 2023	-	-	9,947,915	996	36,756,301	(20,605,009)	16,152,288
Stock-based compensation expense	-	-	-	-	191,110	-	191,110
Net loss	-	-	-	-	-	(3,095,375)	(3,095,375)

Balance as of June 30, 2023	-	-	9,947,915	996	36,947,411	(23,700,384)	13,248,023
Stock-based compensation expense	-	-	-	-	262,752	-	262,752
Net loss	-	-	-	-	-	(3,421,974)	(3,421,974)
Balance as of September 30, 2023	-	$ -	9,947,915	$ 996	$ 37,210,163	$ (27,122,358)	$ 10,088,801

	Convertible Preferred Stock				Additional			Total
	Series A		Common Stock		Paid-In	Subscription	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Capital	Receivable	Deficit	Equity
Balance, December 31, 2023	-	$ -	14,405,325	$ 1,441	$ 61,501,801	$ (11,250)	$ (25,856,383)	$ 35,635,609
Stock-based compensation expense	-	-	-	-	435,663	-	-	435,663
Exercise of stock options	-	-	1,829	-	1,975	-	-	1,975
Proceeds from subscription receivable	-	-	-	-	-	11,250	-	11,250
Exercise of warrants	-	-	206,018	21	1,509,686	(149,250)	-	1,360,457
Net loss	-	-	-	-	-	-	(5,051,913)	(5,051,913)
Balance, March 31, 2024	-	$ -	14,613,172	$ 1,462	$ 63,449,125	$ (149,250)	$ (30,908,296)	$ 32,393,041

	Convertible Preferred Stock				Additional		Total
	Series A		Common Stock		Paid-In	Accumulated	Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)

Balance, December 31, 2021	7,500,713	$ 8,793,637	2,590,051	$ 259	$ 473,602	$ (5,623,771)	$ 3,643,727
Exercise of stock options	-	-	146	-	158	-	158
Stock-based compensation expense	-	-	-	-	21,425	-	21,425
Net loss	-	-	-	-	-	(1,703,378)	(1,703,378)
Balance as of March 31, 2022	7,500,713	8,793,637	2,590,197	259	495,185	(7,327,149)	1,961,932
Stock-based compensation expense	-	-	-	-	44,658	-	44,658
Net loss	-	-	-	-	-	(3,412,904)	(3,412,904)
Balance as of June 30, 2022	7,500,713	8,793,637	2,590,197	259	539,843	(10,740,053)	(1,406,314)
Stock-based compensation expense	-	-	-	-	69,834	-	69,834
Net loss	-	-	-	-	-	(4,020,826)	(4,020,826)
Balance as of September 30, 2022	7,500,713	8,793,637	2,590,197	$ 259	$ 609,677	$ (14,760,879)	$ (5,357,306)

	Convertible Preferred Stock				Additional		Total
	Series A		Common Stock		Paid-In	Accumulated	Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2022	7,500,713	8,793,637	2,590,197	$ 259	$ 681,106	$ (17,868,547)	$ (8,393,545)
Conversion of convertible preferred stock upon initial public offering	(7,500,713)	(8,793,637)	1,316,926	132	8,793,505	-	-
Conversion of convertible promissory notes upon initial public offering	-	-	2,736,488	274	12,965,206	-	12,965,480

Sale of common stock in initial public offering and over-allotment option, net of issuance costs of $2.3 million	-	-	3,287,804	329	14,136,099	-	14,136,428
Stock-based compensation expense and vesting of restricted stock units	-	-	16,500	2	180,385	-	180,387
Net loss	-	-	-	-	-	(2,736,462)	(2,736,462)
Balance, March 31, 2023	-	$ -	9,947,915	$ 996	$ 36,756,301	$ (20,605,009)	$ 16,152,288

The accompanying notes are an integral part of these condensed unaudited interim financial statements.

COYA THERAPEUTICS, INC.

CONDENSED UNAUDITED INTERIM STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	**2022**	**2024**	**2023**
Cash flows from operating activities:				
Net loss	$ (9,253,811)	$ (9,137,108)	$ (5,051,913)	$ (2,736,462)
Adjustment to reconcile net loss to net cash used in operating activities:				
Depreciation	20,521	20,521	6,840	6,840
Change in fair value of convertible promissory notes	-	1,376,030		
Stock-based compensation, including the issuance of restricted stock	634,249	135,917	435,663	180,387

Debt issuance costs	-	997,367		
Acquired in-process research and development assets	350,000	135,000	25,000	-
Changes in operating assets and liabilities:				
Collaboration receivable			7,500,000	-
Prepaids and other current assets	314,910	276,011	(275,398)	239,295
Accounts payable	(177,911)	456,178	477,265	(270,111)
Accrued expenses	(835,689)	723,805	(844,745)	(1,283,674)
Net cash used in operating activities	(8,947,731)	(5,016,279)		
Deferred collaboration revenue			(126,838)	-
Net cash provided by (used in) operating activities			2,145,874	(3,863,725)
Cash flows from investing activities:				
Purchase of in-process research and development assets	(350,000)	(135,000)	(25,000)	-
Net cash used in investing activities	(350,000)	(135,000)	(25,000)	-
Cash flows from financing activities:				
Proceeds from issuance of common stock upon initial public offering, net of offering costs	14,250,311	-	-	14,250,311
Proceeds from issuance of convertible promissory notes	-	10,468,970		
Payment of deferred financing costs related to the IPO	-	(9,812)		
Payment of debt issuance costs	-	(997,367)		
Proceeds from subscription receivable			11,250	-
Payment of financing costs related to the 2023 Private Placement			(131,918)	-
Proceeds from the exercise of stock options	-	158	1,975	-
Proceeds from the exercise of warrants			1,360,457	-
Net cash provided by financing activities	14,250,311	9,461,949	1,241,764	14,250,311
Net increase in cash and cash equivalents	4,952,580	4,310,670	3,362,638	10,386,586
Cash and cash equivalents as of beginning of the period	5,933,702	4,340,178	32,626,768	5,933,702

Cash and cash equivalents as of end of the period	10,886,2	8,650,84		
	$ 82	$ 8	$ 35,989,406	$ 16,320,288
Supplemental disclosures of non-cash financing and investing activities:				
Conversion of convertible preferred stock upon initial public offering	8,793,63			
	$ 7	$ -	$ -	$ 8,793,637
Conversion of convertible promissory notes upon initial public offering	12,965,4			
	$ 80	$ -	$ -	$ 12,965,480
Deferred financing costs in accrued expenses	$ -	$ 248,436		
Subscription receivable related to warrant exercise			$ 149,250	$ -

The accompanying notes are an integral part of these condensed unaudited interim financial statements.

COYA THERAPEUTICS, INC.

NOTES TO CONDENSED UNAUDITED INTERIM FINANCIAL STATEMENTS

1. Organization and description of business

Coya Therapeutics, Inc. (“Coya”, or the “Company”) is a clinical-stage biotechnology company focused on developing proprietary new therapies to enhance the function of Regulatory T cells (“Tregs”). Coya’s initial developmental programs are focused on neurodegenerative, chronic inflammatory, autoimmune, and metabolic diseases of high unmet medical need.

Going Concern concern and Liquidity liquidity

The Company has incurred losses and since inception, negative cash flows from operations since inception through 2023 and has an accumulated deficit of $27,122,358 30.9 million as of September 30, 2023 March 31, 2024. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. No assurance can be given that any such financing will be available when needed or that the Company’s research and development efforts will be successful.

The Company follows the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements—Going Concern*, which requires management to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for one year after the date that the financial statements are issued (or when applicable, one year after the date that the financial statements are available to be issued). As of September 30, 2023 March 31, 2024, the Company had cash and cash equivalents of $10,886,282 36.0, million, which is expected to enable the Company to fund its operating expenses and capital expenditure requirements into the second quarter of 2024, 2026, at which time the Company will need to secure additional funding. If the Company is unable to obtain additional financing, the lack of liquidity could have a material adverse effect on the Company's future prospects. As a result of these factors, there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that these financial statements are issued.

The accompanying condensed unaudited interim financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Management is currently evaluating different strategies to obtain the required funding of future operations. These strategies may include, but are not limited to, additional funding from current investors, funding from new investors including strategic corporate investors, and additional registrations of the Company's common stock. There can be no assurance these future funding efforts will be successful.

On January 3, 2023, the Company completed its initial public offering ("IPO") in which the Company sold 3,050,000 shares of its common stock and accompanying warrants to purchase 1,525,000 shares of common stock. The warrants were sold at the rate of one warrant for every two shares of common stock purchased in the IPO, with each full warrant having an exercise price of $7.50 per share. Each share of common stock and accompanying warrant was sold at a combined offering price of $5.00 for net gross proceeds of approximately $13,432,500 15.3 after million, before deducting underwriting discounts, commissions, and other offering expenses paid by the Company. On January 25, 2023, the underwriters exercised their over-allotment option in part and thereby purchased an additional 237,804 shares of common stock and 145,000 warrants to purchase common stock at a combined offering price of $5.00 per share. The warrants have an exercise price of $7.50 per share. In total the Company raised $16,439,020 16.4 million in gross proceeds and $14,136,428 14.1 million in net proceeds in its IPO (as discussed in detail in Note 6).

IPO.

Risks and uncertainties

The Company is subject to a number of risks associated with companies at a similar stage, including dependence on key individuals, competition from similar products and larger companies, volatility of the industry, ability to obtain adequate financing to support growth, the ability to attract and retain additional qualified personnel to manage the anticipated growth of the Company, and general economic conditions.

2. Basis of presentation and significant accounting policies

Basis of presentation

The accompanying condensed unaudited condensed financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the ASC and Accounting Standards Updates ("ASU") of the FASB.

In the opinion of management, the accompanying unaudited interim financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's balance sheet as of September 30, 2023 March 31, 2024, and its statements of operations, and stockholders' equity (deficit) for the three and nine months ended September 30, 2023 and 2022, , and its cash flows for the nine three months ended September 30, 2023 March 31, 2024 and 2022. 2023. Operating results for the three and nine months ended September 30, 2023 March 31, 2024 and 2022, 2023, are not necessarily indicative of the results that may be expected for the year ending December 31, 2023 December 31, 2024. The condensed unaudited interim financial statements, presented herein do not contain all of the required disclosures under GAAP for annual financial statements. The accompanying condensed unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2022 December 31, 2023 found in the Annual Report on Form 10-K.

Use of estimates

The preparation of the 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 at the date of the financial statements and reported amounts of expenses during the reporting period. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed, and the effects of revisions are reflected in the financial statements in the period they are determined to be necessary.

Significant areas that require management's estimates include fair value of the Company's convertible promissory notes, the fair value of the Company's equity, prior to being publicly traded, and related inputs, including discount for lack of marketability and volatility, the grant date fair value of stock options (Note 7) 8), the allocation of transaction price as it relates to the Company's DRL Development Agreement, and accrued research and development expenses.

Fair value of financial instruments

Management believes that the carrying amounts of the Company's cash equivalents, accounts payable, and accrued expenses approximate fair value due to the short-term nature of those instruments.

Collaboration revenues

The Company's revenues have been solely generated through the DRL Development Agreement (Note 9), which falls under the scope of ASC Topic 808, Collaborative Arrangements ("ASC 808") as both parties are active participants in the arrangement that are exposed to significant risks and rewards. While this arrangement is within the scope of ASC 808, the Company analogizes to ASC 606 for some aspects of this arrangement, including delivery of a good or service (i.e. unit of account). Revenue recognized by analogizing to ASC 606 is recorded as collaboration revenue on the statements of operations. The terms of the arrangement includes payments to the Company of the following: nonrefundable, up-front license fees; regulatory and commercial milestone payments and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company's revenue arrangements may include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes regulatory or commercial milestone payments, the Company evaluates whether each milestone is considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At each reporting period, the Company assesses the probability of achievement of each milestone under its current agreements.

Royalties: If the Company is entitled to receive sales-based royalties from its collaborator, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, provided the reported sales are reliably measurable, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Amounts due to the Company for satisfying the revenue recognition criteria or that are contractually due based upon the terms of the collaboration agreements are recorded as collaboration receivable in the Company's balance sheet. Contract liabilities consist of amounts received prior to satisfying the revenue recognition criteria, which are recorded as deferred collaboration revenue in the Company's balance sheet. See Note 9 for a full discussion of the Company's collaboration arrangement.

Concentration of credit risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company deposits its cash with reputable financial institutions that are insured by the Federal Deposit Insurance Corporation ("FDIC"). At times, the Company's cash balances may exceed the current insured amounts provided by the FDIC. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash and cash equivalents.

Research and development costs

Research and development costs are expensed as incurred and consist primarily of funds paid to third parties for the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, regulatory compliance costs, and personnel and stock-based compensation expenses. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record a net prepaid or accrued expense relating to these costs.

Upfront milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Costs incurred in obtaining technology licenses are charged to research and development expense as acquired in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use.

In-Process Research In-process research and Development

development

Research and development costs incurred in obtaining technology licenses are charged to in-process research and development expense if the technology licensed has not reached technological feasibility which includes manufacturing, clinical, intellectual property and/or regulatory success which has no alternative future use. The licenses purchased by the Company, which are further described in Note 5, 6, require substantial completion of research and development and regulatory and marketing approval efforts in order to reach technological feasibility. As such, since inception, the purchase price of licenses acquired is classified as acquired in-process research and development expenses in the statements of operations.

Stock-based compensation

The Company measures share-based employee and nonemployee awards at their grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the awards. The Company accounts for forfeitures in the period in which they occur.

Estimating the fair value of share-based awards requires the input of subjective assumptions, including the estimated fair value of the Company's common stock, prior to being a publicly-traded company, and, for stock options, the expected life of the options and stock price volatility. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in estimating the fair value of share-based awards represent management's estimates and involve inherent uncertainties and the application of management's judgments. As a result, if factors change and management uses different assumptions, share-based compensation expense could be materially different for future awards.

The expected term of the stock options is estimated using the "simplified method" as the Company has no does not have sufficient historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting period and the contractual term of the option. For stock price volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of option grants. The risk-free rate is based on the U.S. Treasury yield curve commensurate with the expected

---

term of the option. The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay a dividend on its common stock.

Income taxes

Income taxes are accounted for under the asset and liability method. The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities, and the expected benefits of net operating loss and income tax credit carryforwards. The impact of changes in tax rates and laws on deferred taxes, if any, applied during the period in which temporary differences are expected to be settled, is reflected in the Company's financial statements in the period of enactment. The measurement of deferred tax assets is reduced, if necessary, if, based on weight of the evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. As of September 30, 2023 March 31, 2024, the Company has concluded that a full valuation allowance is necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest, or penalties in the accompanying financial statements. Although there are no unrecognized income tax benefits, when applicable, the Company's policy is to report interest and penalties related to unrecognized income tax benefits as a component of income tax expense.

Net loss per share

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period. Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock, common stock warrants and stock options, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, potentially dilutive securities are not included in the calculation when the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive (unaudited):

	As of September 30,		As of March 31,	
	2023	2022	2024	2023
Series A Convertible Preferred Stock	-	1,316,926		
Convertible promissory notes (as converted)	-	1,044,498		
Common stock warrants	2,174,737	92,184	2,286,223	2,174,737
Stock options	1,238,612	478,570	1,698,730	1,014,543
	3,413,349	2,932,178	3,984,953	3,189,280

Amounts in the above table reflect the common stock equivalents.

Recently issued but not yet adopted accounting pronouncements

In June 2016, November 2023, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses 2023-07, Segment Reporting (Topic 326) 280): Improvements to Reportable Segment Disclosures (ASU 2023-07), *Measurement which requires disclosure of Credit Losses incremental segment information on Financial Instruments.* an

annual and interim basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. The standard amends Company is currently evaluating the impairment model by requiring entities effect of this pronouncement on its disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to use a forward-looking approach based on expected losses to estimate credit losses Income Tax Disclosures (ASU 2023-09), which expands the disclosure required for most financial assets and certain other instruments that aren't measured at fair value through net income. For available-for-sale debt securities, entities will be required to recognize an allowance income taxes. This ASU is effective for credit losses rather than a reduction in carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses fiscal years beginning after December 16, 2024, with early adoption permitted. The amendment should be recognized. applied on a prospective basis while retrospective application is permitted. The Company adopted company is currently evaluating the guidance using a modified retrospective approach as effect of January 1, 2023 which resulted in no cumulative-effect adjustment to retained earnings. this pronouncements on its disclosures.

3. Fair value measurements

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

- Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to t reporting entity at the measurement date.

- Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liabil either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.

In accordance with the fair value hierarchy described above, the following table sets forth the Company's assets and liabilities measured at fair value on a recurring basis:

September 30, 2023
(unaudited)

March 31, 2024 (unaudited)

	Note Reference	Input Level	Fair Value	Carrying Value	Note Reference	Input Level	Fair Value	Carrying Value
Assets:								
Cash and cash equivalents (money market funds)		Level 1	10,88 $ 6,282	10,88 $ 6,282		Level 1	$ 35,989,406	$ 35,989,406

December 31, 2022

	Note Reference	Input Level	Fair Value	Carrying Value
Assets:				
Cash and cash equivalents (money market funds)		Level 1	$ 5,933,702	$ 5,933,702
Liabilities:				
Convertible promissory notes			12,965,48	12,965,48
	Note 6	Level 3	$ 0	$ 0

December 31, 2023

	Note Reference	Input Level	Fair Value	Carrying Value
Assets:				
Cash and cash equivalents (money market funds)			32,626,76	32,626,76
		Level 1	$ 8	$ 8

10 4. Prepaids and other current assets

Prepaids and other current assets consist of:

In connection with the IPO, the Company's convertible promissory notes converted into an aggregate of 2,736,488 shares of common stock. As a result, the remaining convertible promissory note balance, including accrued interest, was eliminated, increasing additional paid-in capital.

Balance at December 31, 2022	$ 12,965,480
Conversion of convertible promissory notes upon IPO	(12,965,480)
Balance at September 30, 2023	$ —

(unaudited)

	March 31, 2024	December 31, 2023
Prepaid research and development	$ 553,724	$ 125,000
Prepaid insurance	642,443	858,541
Prepaid other	148,788	86,016
	$ 1,344,955	$ 1,069,557

4. 5. Accrued expenses

Accrued expenses consist of:

	(unaudited) September 30, 2023	December 31, 2022	(unaudited) March 31, 2024	December 31, 2023
Accrued research and development	$ 497,563	$ 135,864	$ 842,480	$ 686,883
Accrued payroll	546,396	927,006	235,400	1,081,262
Accrued professional fees	128,715	945,491	239,798	481,218
Accrued income tax			723,852	723,852
	$ 1,172,674	$ 2,008,361	$ 2,041,530	$ 2,973,215

5. 6. Commitments and Contingencies contingencies, including license and sponsored research agreements

License Agreements agreements

Dr. Reddy's License and Supply Agreement

In March 2023, the Company entered into an exclusive License and Supply Agreement (the "DRL Agreement") with Dr. Reddy's Laboratories ("DRL"). DRL. The DRL Agreement became effective on April 1, 2023. Pursuant to the terms of the DRL Agreement, the Company will in-license DRL's proposed abatacept biosimilar for use in the development of Coya's combination product for neurodegenerative diseases ("COYA 302"). COYA 302 is a dual biologic intended to suppress neuroinflammation via multiple immunomodulatory pathways, for

the treatment of neurodegenerative conditions. The DRL Agreement also provides for the license of the Company's low dose IL-2 ("COYA 301") to DRL to permit the commercialization by DRL of COYA 302 in territories not otherwise granted to Coya. In consideration for the license the Company has paid a non-refundable upfront fee of $350,000 0.4. million. The Company will pay to DRL up to an aggregate of approximately $2,900,000 2.9 million of pre-approval regulatory milestone payments for the first indication in the Field (as defined in the DRL Agreement), of which the Company has paid an aggregate of $0.2 million to date, and an additional approximately $20,000,000 20.0 million if all other development, regulatory approval and sales milestones are incurred under the DRL Agreement. The Company will also pay to DRL a low-six figure milestone payment per additional indication. Further, pursuant to the DRL Agreement, the Company will pay to DRL single-digit royalties on Net Sales (as defined in the DRL Agreement). In December 2023, the Company granted DRL an exclusive, royalty-bearing right and license to commercialize COYA 302 (Note 9).

ARScience ARS License Agreement

In August 2022, the Company entered into a License Agreement (the “ARS License Agreement”) with ARScience Biotherapeutics, Inc. (“ARS”) pursuant to which ARS granted the Company an option, which was exercised in December 2022, to acquire an exclusive, royalty-bearing license for two patents, regarding certain formulations of IL-2, with the right to grant sublicenses through multiple tiers under these patents (the “ARS Option”).

The Company may owe tiered payments to ARS based on its achievement of certain developmental milestones. Under the ARS License Agreement, the Company will pay an aggregate of $13,250,000 13.3 million in developmental milestone payments for the first Combination Product (as defined in the ARS License Agreement) in a new indication. The Company will then pay an aggregate of $11,600,000 11.6 million in developmental milestone payments for each Combination Product in each subsequent new indication. Further, for the first Mono Product (as defined In the ARS License Agreement) the Company will pay an aggregate of $11,750,000 11.8 million in developmental milestone payments. The Company will then pay an aggregate of $5,850,000 5.9 million in developmental milestone payments for each Mono Product in each subsequent new indication, and an aggregate of $5,850,000 5.9 million if all developmental milestones are achieved for each new indication. The Company will also owe royalties on net sales of licensed products ranging from low to mid-single digit percentages. In the event the Company sublicenses its rights under the ARS License Agreement, the Company will owe royalties on sublicense income within the range of 10% to 20%.

Houston Methodist Agreements

In September 2022, the Company entered into an Amended and Restated Patent Know How and License Agreement, effective as of October 2020 (the “Methodist License Agreement”), with The Methodist Hospital (“Methodist”) to make, sell and sublicense products and services using the intellectual property and know-how of Methodist. As part of the Methodist License Agreement, the Company will pay Methodist a four-figure license maintenance fee annually until the first sale of licensed product occurs. The term of the Methodist License Agreement is effective until no intellectual property

patent rights remain, unless terminated sooner by (1) bankruptcy or insolvency, (2) the failure by the Company to monetize the intellectual property within five years of the date of the agreement (further discussed below), (3) due to breach of contract, or (4) at our election for any or no reason.

Patent reimbursements paid by the Company to Methodist and its attorneys are included in general and administrative expenses in the accompanying statements of operations. Such costs were immaterial for the three months ended March 31, 2024 and 2023. In addition to the equity issuance issued to Methodist in 2020 and reimbursement of patent related expenses, the Methodist License requires the Company to make payments of up to $425,000 0.4 million per product candidate in aggregate upon the achievement of specific development and regulatory milestone events by such licensed product. The Company is also required to pay Methodist, on a licensed product-by-licensed product and country-by-country basis, tiered royalties (subject to customary reductions) equal to high-single digit to low-double digit percentages of annual worldwide net sales of such licensed product during a defined royalty term. The Company is also required to pay a low single digit percentage for certain licensed services. Commencing on January 1, 2025, the minimum amount which will be owed by the Company once commercialization occurs is $50,000 0.1 million annually.

The Methodist License Agreement provides that in the event the Company sublicense products and services covered by the Methodist License Agreement, then royalties owed to Houston Methodist would be computed as a percentage of payments received by the Company from the sublicensee. In addition, the termination provisions provide that Houston Methodist may only terminate the Methodist License Agreement, among other things, in the event that after five years the Company is not “Actively Attempting to Develop or Commercialize,” as such term is defined in the Methodist License Agreement.

Sponsored Research Agreement

In February 2021, the Company entered into a one-year Sponsored Research Agreement (“SRA”) with Houston Methodist Research Institute (“HMRI”), a Texas nonprofit corporation and an affiliate of Methodist, which can be extended or renewed by mutual agreement. Under the SRA, the Company agreed to fund up to $1,547,094 1.5 million in research in the area of neurodegenerative diseases performed by HRMI. HMRI. In return, the Company will gain expanded access to data methods and know-how per the SRA, and, if the research

---

produces intellectual property, the Company will have all first rights to the intellectual property. As of September 15, 2022, the Company provided notice to HMRI regarding termination of the SRA in expectation that a reduced yearly budget be negotiated post termination. On May 4, 2023, the Company executed the a new SRA with HMRI, in which the Company agreed to fund approximately $0.5 million through May 2024. The Company incurred $108,634 0.1 and $254,802 million in research and development expenses under the SRA during each of the three months ended September 30, 2023 March

31, 2024 and 2022, respectively. The Company incurred $211,038 and $1,242,083 in research and development expenses under the SRA during the nine months ended September 30, 2023 and 2022, respectively. 2023.

Employment contracts

The Company has entered into employment contracts with its officers and certain employees that provide for severance and continuation of benefits in the event of termination of employment either by the Company without cause or by the employee for good reason, both as defined in the agreements. In addition, in the event of termination of employment following a change in control, as defined in each agreement, either by the Company without cause or by the employee for good reason, any unvested portion of the employee's initial stock option grant becomes immediately vested.

Litigation

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. There are no matters currently outstanding.

6. Convertible promissory notes, convertible preferred stock and stockholders' 7. Stockholders' equity (deficit)

Initial Public Offering

On January 3, 2023, the Company completed its IPO in which the Company sold 3,050,000 shares of its common Common stock and accompanying warrants to purchase 1,525,000 shares of common stock. The warrants were sold at the rate of one warrant for every two shares of common stock purchased in the IPO, with each full warrant having an exercise price of $7.50 per share. Each share of common stock and accompanying warrant was sold at a combined offering price of $5.00. The Company received net proceeds of $13,030,639 after deducting underwriting discounts, commissions, and other offering expenses paid by the Company, including additional costs incurred during the three months ended March 31, 2023. The Company issued its underwriters 213,500 warrants with an exercise price of $6.25 per warrant and a contractual life of four years as additional consideration. In connection with the closing of the IPO, (i) all of the Company's outstanding shares of Series A converted into an aggregate of 1,316,926 shares of common stock, (ii) the Company's Notes converted into an aggregate of 2,736,488 shares of common stock, and (iii) the Company filed an amended and restated certificate

of incorporation to, among other things, increase the number of authorized shares of common stock to 200,000,000 and increase the number of authorized shares of preferred stock to 10,000,000.

In connection with the IPO, the Company granted its underwriters a 30-day over-allotment option ("Over-Allotment") to purchase up to an additional 290,000 shares of common stock and warrants to purchase 145,000 shares of common stock to cover over-allotments at a combined offering price of $5.00, less underwriting discount. The warrants have an exercise price of $7.50 per share. On January 25, 2023, the underwriters purchased 237,804 shares of common stock and 145,000 warrants to purchase common stock at a combined offering price of $5.00 per share in connection with

Over-Allotment. Upon the sale of the Over-Allotment, the Company issued its underwriters an additional 16,646 warrants with an exercise price of $6.25 per warrant and a contractual life of four years. The Company received net proceeds of $1,105,789 after deducting underwriting discounts for the common stock and warrants issued in connection with the Over-Allotment.

Common Stock Warrants

During its evaluation of equity classification for the Company's common stock warrants, the Company considered the conditions as prescribed within ASC 815-40, Derivatives and Hedging, Contracts in an Entity's own Equity. The conditions within ASC 815-40 are not subject to a probability assessment. The warrants do not fall under the liability criteria within ASC 480 Distinguishing Liabilities from Equity as they are not puttable and do not represent an instrument that has a redeemable underlying security. The warrants do meet the definition of a derivative instrument under ASC 815, but are eligible for the scope exception as they are indexed to the Company's own stock and would be classified in permanent equity if freestanding.

As of September 30, 2023 March 31, 2024, the Company had the following warrants outstanding to acquire shares of its common stock (unaudited):

Warrant Type	Outstanding	Exercise price per share	Expiration date	Outstanding	Exercise price per share	Expiration date
Common stock warrants issued related to the IPO	1,525,000	$ 7.50	December 2024	1,345,825	$ 7.50	December 2024
Common stock warrants issued related to the Over-Allotment option	145,000	$ 7.50	December 2024	145,000	$ 7.50	December 2024
Common stock warrants issued to underwriters as compensation for IPO	230,146	$ 6.25	December 2026	201,803	$ 6.25	December 2026
Common stock warrants issued to placement agent as part of the convertible promissory notes conversion	182,407	$ 6.00	January 2028	182,407	$ 6.00	January 2028
Common stock warrants issued in connection with the Series A convertible preferred stock issued in 2020	92,184	$ 9.15	December 2025	92,184	$ 9.15	December 2025

Common stock warrants issued as compensation for the 2023 Private Placement	319,004	$ 7.58	December 2027
	2,174,737		
	2,286,223		

7. 8. Stock-based compensation

In January 2021, the Company adopted the 2021 Equity Incentive Plan (“2021 Plan”). The 2021 Plan provides for the granting of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, equity appreciation rights, performance awards, and other equity-based awards. The Company's employees, officers, independent directors, and other persons are eligible to receive awards under the 2021 Plan. The 2021 Plan provides for increases to the number of shares reserved for issuance thereunder each January 1 equal to 4% of the total shares of the Company's common stock outstanding as of immediately preceding December 31, unless a lesser amount is stipulated by the Company's board of directors. Accordingly, 576,213 shares were added to the reserve as of January 1, 2024. As of September 30, 2023 March 31, 2024, 1,244,857 1,821,070 shares of the Company’s common stock were authorized to be issued, of which 5,807 34,545 shares were available for future issuance.

The amount, terms of grants, and exercisability provisions are determined and set by the Company's Board of Directors or compensation committee. The Company measures employee stock-based awards at grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the award. The Company has recorded stock-based compensation related to its options and RSU's in the accompanying statements of operations as follows (unaudited):

	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2023	2022	2024	2023
General and administrative	$ 145,394	$ 21,883	$ 389,899	$ 57,520	$ 267,438	$ 132,214

Research and development	117,358	47,951	244,350	78,397	168,225	48,173
	262,752	69,834	634,249	135,917		
	$ 2	$ 4	$ 49	$ 17	$ 435,663	$ 180,387

Stock options

The Company has issued service-based stock options that generally have a contractual life of up to 10years and may be exercisable in cash or as otherwise determined by the Board of Directors. Vesting generally occurs over a period of not greater than four years.

The following table summarizes the activity for the periods indicated (unaudited):

	Options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value
Outstanding at January 1, 2023	478,570	$ 1.85	8.7	
Granted	760,042	$ 3.90		
Outstanding at September 30, 2023	1,238,612	$ 3.11	8.9	$ 966,515
Exercisable at September 30, 2023	465,954	$ 2.19	8.2	$ 774,038
Vested and expected to vest at September 30, 2023	1,238,612	$ 3.11	8.9	$ 966,515

	Options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value
Outstanding at January 1, 2024	1,134,145	$ 3.24	8.7	
Granted	566,414	$ 6.04		
Exercised	(1,829)	$ 1.08		$ 8,249
Outstanding at March 31, 2024	1,698,730	$ 4.18	8.9	$ 9,752,881

Exercisable at March 31, 2024	543,396	$ 2.76	8.1	$ 3,889,268
Vested and expected to vest at March 31, 2024	1,698,730	$ 4.18	8.9	$ 9,752,881

As of September 30, 2023 March 31, 2024, the unrecognized compensation cost was $2.1 4.1 million, and will be recognized over an estimated weighted-average amortization period of 2.3 years.

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the estimated fair value of the underlying common stock at the grant date, expected term, estimated stock price volatility, risk-free interest rate, and dividend yield. The fair value of stock options granted during the period ended September 30, 2023 March 31, 2024 was determined using the methods and assumptions discussed below.

- The expected term of employee stock options with service-based vesting is determined using the “simplifie method, as prescribed in SEC’s Staff Accounting Bulletin (“SAB”) No. 107, whereby the expected life equals t arithmetic average of the vesting term and the original contractual term of the option due to the Company’s lack sufficient historical data.
- The expected stock price volatility is based on historical volatility of comparable public entities within t Company’s industry, which were commensurate with the expected term assumption as described in SAB No. 107
- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time grant for a period that is commensurate with the expected term.
- The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay a dividend on its common stock.
- The Company's common stock became publicly traded on December 29, 2022. However, prior to the Company's common stock being publicly traded, its Board of Directors periodically estimated the fair value of the Company’s common stock considering, among other things, contemporaneous valuations of its common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation.*

The grant date fair value of each option grant for the period three months ended September 30, 2023 March 31, 2024 and 2023 was estimated using the Black-Scholes option-pricing model using the following weighted-average assumptions (unaudited):

Nine Months Ended September 30,		Three Months Ended March 31,	
2023	2022	2024	2023

Risk-free interest rate	4.1%	3.3%	4.0%	4.1%
Expected term (years)	5.8	5.6	5.7	5.8
Expected volatility	92.30%	83.48%	103.37%	89.71%
Expected dividend yield	-	-	-	-

Restricted Stock Unit Awards stock unit awards

During the nine three months ended September 30, 2023 March 31, 2023, the Company issued 16,500 restricted stock units ("RSU") to external consultants which immediately vested upon grant. The fair value of an RSU is equal to the fair market value price of the Company's common stock on the date of grant. The Company recorded stock-based compensation expense of $76,080 for the nine three months ended September 30, 2023.

The following table summarizes activity March 31, 2023 related to RSU stock-based payment awards (unaudited): these RSUs.

	Number of Shares	Weighted average grant date fair value
Outstanding at January 1, 2023	-	$ -
Granted and Vested	16,500	4.61
Outstanding at September 30, 2023	16,500	$ 4.61

8. 9. DRL Development Agreement

In December 2023, the Company entered into a Development and License Agreement (the “DRL Development Agreement”) with DR. Reddy's, pursuant to which, among other things, the Company granted to DR. Reddy's an exclusive, royalty-bearing right and license (the "License") to commercialize COYA 302, a proprietary co-pack kit containing low dose IL-2 and CTLA4-Ig, (“COYA 302” or the “Product”) solely for use in patients with amyotrophic lateral sclerosis (“ALS" or the “Field”) in the United States, Canada, the European Union and the United Kingdom (collectively, the “New Territories”). The Company previously granted DRL an exclusive license to obtain regulatory approval and commercialize the Product for ALS and certain other indications in all other countries (other than the New Territories, Japan, Mexico, and in each country in South America), pursuant to the DRL Agreement entered between the Company and DRL, effective as of April 1, 2023 (Note 6). As part of the DRL Development Agreement, the Company is responsible for certain development activities to advance the Product through clinical development ("R&D Services").

The collaboration is managed by a joint steering committee (“JSC”) which is comprised of representatives from both parties. Decisions of the JSC are made by consensus. If the JSC is unable to reach a consensus, and the parties’

executives are not able to resolve the dispute, then Dr. Reddy's has final decision-making authority, subject to specified limitations (as set forth in the DRL Development Agreement).

Pursuant to the DRL Development Agreement, the Company received an up-front, nonrefundable payment of $7.5 million in January 2024. Additionally, the Company is entitled to receive (i) an additional $4.2 million upon FDA acceptance of an Investigational New Drug ("IND"), application for COYA 302 for the treatment of ALS and (ii) an additional $4.2 million payment upon the dosing of the first patient in the first phase 2 clinical trial for COYA 302 for the treatment of ALS in the United States. The DRL Development Agreement also calls for up to an aggregate of approximately $40.0 million in development milestones and up to an aggregate of approximately $677.3 million in sales milestones, related to the New Territories, should all such development and sales milestones be achieved. The Company will also be owed royalties by Dr. Reddy's on Net Sales (as defined in the DRL Development Agreement) of the Product in the low to mid-teens.

Both parties shall discuss in good faith and agree in writing on the terms of a commercial supply agreement for the purpose of supply of COYA 302 to Dr. Reddy's. No such agreement has been entered into at the time of the filing of this Quarterly Report on Form 10-Q.

The DRL Development Agreement expires on a country-by-country basis upon expiration of Dr. Reddy's obligation to make royalty payments for Product in each territory. Dr. Reddy's has the right to terminate the agreement upon specified prior written notice to the Company. Additionally, either party may terminate the agreement in the event of an uncured material breach of the agreement by, or insolvency of, the other party. Either party may terminate the agreement in the event that the other party commences a legal action challenging the validity, enforceability or scope of any licensed patent rights.

In accordance with the guidance, the Company identified the following commitments under the arrangement: 1) the License and 2) the R&D Services. The Company determined that these two commitments represent distinct performance obligations for purposes of recognizing revenue as the Company fulfills these performance obligations. The Company included the $7.5 million upfront payment in the transaction price as of the outset of the arrangement and allocated that transaction price to the two performance obligations based on the estimated stand-alone selling prices at contract inception. The stand-alone selling price of the License was based on a discounted

---

cash flow approach and considered several factors including, but not limited to, discount rate, development timeline, regulatory risks, estimated market demand and future revenue potential using an adjusted market approach. The stand-alone selling price of the R&D Services was estimated using the expected cost-plus margin approach. The Company has recognized the License portion of the transaction price of $6.0 million in prior periods upon delivery of the License. The Company will recognize the remaining transaction price of $1.5 million allocated to the R&D Services over the period of performance, using an inputs approach. During the three months ended March 31, 2024, the Company recognized $0.1

million of collaboration revenue, which was included in deferred revenue as of December 31, 2023, associated with the performance of R&D Services. Any portion of a change in transaction price that is allocated to a satisfied or partially satisfied performance obligation will be recognized as revenue (or as a reduction in revenue) in the period of the transaction price change on a cumulative catch-up basis. The commercial milestones and sales-based royalties will be recognized when earned (i.e., the later of when the subsequent sales occur or the performance obligation has been satisfied). As of March 31, 2024, $1.4 million of the upfront payment was recorded in deferred revenue in the accompanying balance sheets, of which $0.7 million is estimated to be recognized within one year.

10. Subsequent events

The Company has evaluated subsequent events through November 8, 2023 May 9, 2024, the date at which the condensed unaudited interim financial statements were available to be issued and has determined that there are no such events to report.

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

You should read the following discussion and analysis of our financial condition and operating results together with our unaudited interim consolidated financial statements and the notes appearing elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the section of this Quarterly Report on Form 10-Q captioned "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions, and future performance, and involve known and unknown risks, uncertainties, and other factors, which may be

beyond our control, and which may cause our actual results, performance, or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as “may,” “can,” “anticipate,” “assume,” “should,” “indicate,” “would,” “believe,” “contemplate,” “expect,” “seek,” “estimate,” “continue,” “plan,” “point to,” “project,” “predict,” “could,” “intend,” “target,” “potential” and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our ability to develop, obtain regulatory approval for and commercialize our product candidates;
- the timing of future investigational new drug, or IND, submissions, initiation of preclinical studies and clinical trials, timing of expected clinical results for our product candidates;
- our success in early preclinical studies, which may not be indicative of results obtained in later studies or clinical tr
- the impact of COVID-19 and resulting pandemic on our preclinical studies and any future clinical trials;
- the potential benefits of our product candidates;
- our ability to identify patients with the diseases treated by our product candidates, and to enroll patients in clir trials;
- the success of our efforts to expand our pipeline of product candidates and develop marketable products through use of our therapeutic modalities;
- our expectations regarding collaborations and other agreements with third parties and their potential benefits;
- our ability to obtain, maintain and protect our intellectual property;
- our reliance upon intellectual property licensed from third parties;
- our ability to identify, recruit and retain key personnel;
- our current and future capital requirements to support our development and commercialization efforts for our pro candidates and our ability to satisfy our capital needs;
- our ability to raise additional capital, which may be adversely impacted by potential worsening of global econc conditions, potential future global pandemics or health crises, and the recent disruptions to, and volatility in, the cı and financial markets in the United States;
- our financial performance;
- developments or projections relating to our competitors or our industry;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act; an
- other factors and assumptions described in this Quarterly Report on Form 10-Q under “Risk Factors,” “Manageme Discussion and Analysis of Financial Condition and Results of Operations,” and “Overview”, and elsewhere in Quarterly Report on Form 10-Q.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipate in our forward-looking statements.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs, or projections will result or be achieved or accomplished.

Overview

We are a clinical-stage biotechnology company focused on developing proprietary new therapies to enhance the function of Tregs. regulatory T cells ("Tregs"). Tregs are a subpopulation of T-lymphocytes consisting of CD4+CD25high hFOXP3+ cells that suppress inflammatory responses. Tregs were first discovered in 1995 by Dr. Shimon Sakaguchi and since their discovery, multiple lines of research have contributed to elucidate Treg biology and its role in health and disease. Tregs and their transcription factors have been shown to be essential to maintaining cellular homeostasis by regulating autoimmune and inflammatory responses and maintaining self-tolerance in mammals. Dysfunctional Tregs underlie numerous disease states, and this cellular dysfunction is driven by the chronic inflammatory environment and high levels of oxidative stress commonly observed in certain diseases. Further, the degree of Treg dysfunction is correlated with the severity and progression of serious and life-threatening conditions. These and other recent advances in the understanding of Treg biology, have made this subset of T lymphocytes T-lymphocytes an important potential therapeutic target, which we believe may provide new treatments for serious diseases.

We have built a diversified product candidate pipeline that includes both *ex vivo*and *in vivo* approaches intended to restore the suppressive and immunomodulatory functions of Tregs. Our product candidate pipeline is based on our three distinct potential therapeutic modalities: Treg-enhancing biologics, Treg-derived exosomes, and autologous Treg cell therapy, allogeneic Treg-derived exosomes and Treg-enhancing biologics. therapy. “Autologous” means the treatment of a patient with human cells derived from the patient itself, whereas “Allogeneic” means the treatment of a patient with human cells derived from a donor other than the patient, where such donor is genetically non-identical. We are initially focused on developing our Treg-based Our core focus is to develop these therapies for neurodegenerative, autoimmune and metabolic diseases where to target Treg dysfunction, which has been identified to be an important pathophysiological component of the disease neurodegenerative, autoimmune, and metabolic diseases, where new and effective therapies are urgently needed.

Since Our lead asset, COYA 302, is a Treg-enhancing biologic, which has been developed from key learnings established in our inception in 2020, we have generated preclinical early work and clinical data in multiple models and diseases. discoveries of our autologous Treg cell therapy asset. Our autologous Treg cell therapy program has completed a Phase 1 and Phase 2a studies in amyotrophic lateral sclerosis, or ALS. The We believe the clinical data from these initial studies has served as an important confirmation of the underlying immunomodulatory properties of Tregs and their potential therapeutic benefits. These studies have also significantly expanded our own foundational knowledge of the biological activity of Tregs and key biomarkers of disease progression and drug effect, which we believe will be critical for the design of our future clinical and preclinical studies, the selection of future targeted diseases and the overall advancement of our development pipeline. We believe our findings have also established mechanistic benefits of combination biologics to address Treg dysfunction as well as highlighted important advantages of scalability and cost.

COYA 302 is the combination of our proprietary low dose interleukin-2 (COYA 301, or LD IL-2) and the immunomodulatory drug CTLA4-Ig, and we believe this combination has the potential to provide a sustained and durable effect on our first series of indications (neurodegenerative disorders) through targeting of multiple pathways. Our research and clinical efforts have led us to believe that combination biologics using our LD IL-2 as a backbone modality could be the best way to treat neurodegenerative conditions that are inherently driven by a complexity of pathways. We believe COYA 302 represents the most clinically advanced of what we hope will be a family of combination therapies that all feature our LD IL-2. Moreover, given its growing list of indications, we can now refer to COYA 302 as a “Pipeline in a Product.”

Our operations have consisted of developing our clinical and preclinical product candidates and we have devoted substantially all of our resources to developing product and technology rights, conducting research and development, organizing and staffing our company, business planning and raising capital. We have funded our operations primarily through private convertible preferred stock offerings, a convertible debt financing, and the public offering of our securities that closed in January 2023. 2023 and private securities offerings. Our net losses were $3.4 million $5.1 million and $4.0 million $2.7 million for the three months ended September 30, 2023 March 31, 2024 and 2022, respectively. Our net losses were $9.3 million and $9.1 million for the nine months ended September 30, 2023 and 2022, 2023, respectively. As of September 30, 2023 March 31, 2024, we had an accumulated deficit of $27.1 million $30.9 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. In addition, if we obtain

marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities as we:

- continue our ongoing and planned research and development of our product candidates;
- initiate nonclinical studies and clinical trials for any additional product candidates that we may pursue;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capa requirements for clinical trials and potential commercialization;

- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets know-how;
- acquire or in-license other product candidates and technologies;
- add clinical, operational, financial and management information systems and personnel, including personne support our product development and planned future commercialization efforts; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a pu company.

Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We will need to raise substantial additional capital to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we plan to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing as and when needed to finance our operations on terms acceptable to us or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to secure adequate additional funding, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more product candidates or delay our pursuit of potential in-licenses or acquisitions. The financial statements included elsewhere in this Quarterly Report on Form 10-Q have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business and do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Recent Product Developments

During the first half of 2023, our combination product for neurodegenerative diseases, or COYA 302, and our low dose IL-2, or COYA 301, showed positive results in a proof of concept, or POC, open label study in amyotrophic lateral sclerosis, or ALS, patients and in Alzheimer's Disease, or AD, patients, respectively. Both POC studies were conducted with commercially available products as investigator-initiated trials.

The POC study in support of COYA 302, an open label study conducted in 4 ALS patients, evaluated the safety and tolerability, function of regulatory T-cells, biomarkers, and preliminary efficacy (as measured by the ALSFRS-R scale) utilizing commercially available IL-2 and abatacept. Study data showed no decline or minimal decline at 24 and 48 weeks respectively after initiation of treatment and appeared to be well tolerated in all study patients as no serious adverse events were reported. Twenty-four weeks is an important timepoint as this is the period that ALS studies are usually benchmarked to measure differences in the ALSFRS-R scale for a treatment versus placebo. Based on this POC data, we intend to design a well-powered and well-controlled study to demonstrate the safety and efficacy of COYA 302 (COYA 301 or low dose IL-2, plus an abatacept proposed biosimilar, or DRL_AB, licensed from Dr. Reddy's Laboratories Ltd., or DRL_AB) DRL) in patients with ALS. We are now preparing for an IND filing with the FDA in the first half second quarter of 2024. We intend to initiate a Phase 2 trial after the acceptance of our IND application by the FDA.

The POC study in support of COYA 301, an open label study conducted in 8 patients with AD, evaluated the safety and tolerability, biological activity, blood biomarkers, and preliminary efficacy of commercially available IL-2. Study data found that (i) cognitive function, as measured by 3 validated tools, either improved or did not decline, (ii) Treg function was significantly enhanced, (iii) pro-inflammatory blood cytokines and chemokines were significantly reduced with evidence of reduced neuroinflammation in the brain and (iv) COYA 301 the study treatment appeared to be well tolerated as no serious adverse events were reported. Currently, an ongoing academic Phase 2 double blind, placebo controlled, double-blind, placebo-controlled, randomized trial for use of low dose IL-2 in mild to moderate AD patients is underway at Houston Methodist and we anticipate reporting top line data in the summer of 2024. On October 9, 2023, we announced that this study was fully enrolled with 38 patients. The study will evaluate the safety and tolerability, biological activity, blood and

---

cerebrospinal fluid biomarkers, neuroimaging, and changes in cognitive function of LD IL-2 compared to placebo at pre-specified timepoints over the course of the 21-week treatment period and at 9 weeks after the last dose of study treatment.

During Pipeline Expansion

In January of 2024, we announced that we are expanding our pipeline in neurodegenerative conditions for COYA 302 beyond ALS to include FTD and PD. Our updated pipeline can be viewed below. More recently, in February of 2024, we announced our expansion of COYA 302 to AD. This expansion advances our approach of combination biologics with low dose IL-2 as a backbone which we believe may represent a new approach to target complex immune pathways in neurodegenerative diseases.

FTD, AD and PD share a similar disease pathogenesis to ALS that is associated with a heightened proinflammatory cascade involving dysfunctional Tregs and proinflammatory microglia and macrophages. We believe the third quarter biological redundancies in molecular immune pathways in these complex diseases limit the efficacy of 2023, many single drug therapies, requiring the development of novel therapeutics that can address this pathophysiologic complexity.

We intend to file an IND for COYA 302 for the treatment of FTD before the end of 2024. In addition, studies in animal models of PD are planned in 2024, and based on those studies, a subsequent IND filing is anticipated for the treatment of PD. We will await the results of the ongoing double-blind placebo-controlled trial being conducted by Dr. Appel of low dose IL-2, one of the key components of COYA 302, prior to determining our development plan for COYA 302 in AD patients.

Financings

On December 5, 2023, we increased entered into a Securities Purchase Agreement with certain accredited investors for the size issuance and sale in a private placement of 4,370,382 shares of our Board common stock, or the 2023 Private Placement, at a price of Directors from five to six, with the appointment $6.06 per share which resulted in net proceeds of Dieter Weinand. approximately $24.0 million. In connection with the appointment 2023 Private Placement, we issued to the placement agents and our financial advisor warrants to purchase up to an aggregate of Mr. Weinand to our Board 319,004 shares of Directors, common stock with an exercise price of $7.58 per share. These warrants have a term of four years from issuance, and will be exercisable beginning six months from the Board of Directors increased the size closing of the Audit Committee and Nominating and Governance Committee from three to four directors, with Mr. Weinand being appointed to fill each of the newly created vacancies. 2023 Private Placement.

On January 3, 2023, we closed our initial public offering, or IPO, of 3,050,000 shares of our common stock and accompanying warrants to purchase up to 1,525,000 shares of common stock. The warrants were offered and sold at the rate of one warrant for every two shares of common stock purchased in the offering, with each full warrant having an exercise price of $7.50 per share. Each share of common stock and accompanying warrant were sold at a combined offering price of $5.00, for gross proceeds of approximately $15.25 million $15.3 million, before deducting underwriting discounts and offering expenses. We issued the underwriters an additional 213,500 warrants with an exercise price of $6.25 per warrant as additional consideration. We granted the underwriters a 30-day over-allotment option to purchase up to an additional 290,000 shares of common stock and/or and warrants to purchase 145,000 shares of common stock at the IPO price, less the underwriting discount. On January 25, 2023, we sold an additional 237,804 shares of common stock and accompanying warrants to purchase up to 145,000 shares of common stock upon the underwriters' underwriters' exercise in part of their over-allotment option for additional gross proceeds of approximately $1.1 million, before deducting underwriting discounts and offering expenses. Upon the sale of the over-allotment option, we issued the underwriters an additional 16,646 warrants with an exercise price of $6.25 per warrant. Our shares of common stock began trading on the Nasdaq Capital Market under the ticker symbol “COYA” on December 29, 2022.

Components of Results of Operations

Collaboration Revenue

To date, we have not recognized any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all. Collaboration revenue represents revenue from the Development and License Agreement, or DRL Development Agreement, pursuant to which we granted DRL, and its affiliate, Dr. Reddy's Laboratories SA, or collectively, Dr. Reddy's, an exclusive, royalty-bearing right and license to commercialize COYA 302, solely for use in patients with ALS in the United States, Canada, the European Union and the United Kingdom, or collectively, the New Territories.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our potential therapeutic candidates. We expense research and development costs as incurred, including:

- Expenses incurred to conduct discovery-stage laboratory work and preclinical studies including supplies, reagen chemicals as well as external costs of funding research performed by third parties including consultants, acaden and other institutions and clinical research organizations, or CROs that conduct our preclinical and nonclini studies;
- activities being performed under our sponsored research arrangement with Houston Methodist;
- personnel expenses, including salaries, benefits and stock-based compensation expense for our employe engaged in research and development functions;
- clinical trial expenses and related clinical expenses to obtain regulatory approval of our therapeutic candidat including costs of research performed by third parties, costs associated with CRO's that conduct our clinical tria costs to operate, manage, and monitor investigative sites and clinical, regulatory, manufacturing and oth professional services;
- clinical expenses incurred under agreements with contract manufacturing organizations, or CMOs, or incurr directly by us for manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical stu and clinical trial materials;
- fees paid to consultants who assist with research and development activities;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

We classify and evaluate our research and development expenses in two dimensions: clinical and preclinical, and external and internal. We do not further classify or evaluate our internal research and development expenses by product candidate or by Series as these expenses primarily relate to compensation, materials and supplies, and other costs which

are deployed across multiple potential therapeutic modalities, multiple product candidates, and multiple potential therapeutic areas under development.

Once a product candidate has received approval from the FDA of its IND application, we consider it a clinical product candidate. For each of our clinical product candidates, we report or will report external development costs and other external research and development costs attributable to such clinical product candidates. These external development costs include: fees paid to CROs, CMOs and research laboratories, process development, manufacturing and clinical development activities. Any internal research and development expenses associated with clinical product candidates are captioned as internal research and development costs as described in the paragraph above.

Until such time as a product candidate has received approval of its IND application, we consider it a preclinical product candidate. Each of our preclinical product candidates is being developed on one of our three potential therapeutic modalities: (1) Treg-enhancing biologics; (2) Treg-derived exosomes; and (3) autologous Treg cell therapy. The product candidates utilizing our Treg-enhancing biologics are collectively referred to as the “300 Series.” The product candidates utilizing our Treg-derived exosomes are collectively

referred to as the “200 Series.” The product candidates utilizing our autologous Treg cell therapy are collectively referred to as the “100 Series.” Currently, our 300 Series product candidates include COYA 301 and COYA 302, our 200 Series product candidates include COYA 201 and COYA 206, and our 100 Series product candidate is COYA 101. For our preclinical candidates we report external development costs and other external research and development costs collectively by Series. These external development costs include: fees paid to CROs, CMOs and research laboratories, process development, manufacturing and clinical development activities. Preclinical research and development activities often benefit more than one preclinical product candidate within a given Series and so disaggregating the data would neither be practicable or meaningful.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct our clinical trials, including later-stage clinical trials, for current and future product candidates and prepare regulatory filings for our product candidates. In addition, we expect spending in 2023 2024 to increase over 2022 2023 spending levels and will be focused primarily on advancing COYA 301 and COYA 302. As described in the notes to financial statements contained elsewhere in this Quarterly Report on Form 10-Q, under the terms of our license we may be required to make payments to Methodist if certain milestones are achieved. This could result in significant charges to research and development in the period such milestones become probable of being achieved.

In-Process Research and Development

Research and development costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility which includes manufacturing, clinical, intellectual property and/or

regulatory success which has no alternative future use. The licenses purchased by us require substantial completion of research and development and regulatory and marketing approval efforts in order to reach technological feasibility. As such, and since our inception, the purchase price of licenses acquired is classified as acquired in-process research and development expenses in the statements of operations.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for employees and consultants in executive, finance and accounting, legal, operations support, information technology and human resource functions. General and administrative expense also includes corporate facility costs not otherwise included in research and development expense, including rent, utilities, depreciation and maintenance, as well as legal fees related to intellectual property and corporate matters and fees for accounting and consulting services.

We expect that our general and administrative expense will increase in the future to support our continued research and development activities, potential commercialization efforts and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, legal support and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of the Nasdaq Capital Market and the Securities and Exchange Commission, or SEC, director and officer insurance, investor and public relations costs. If any of our current or future product candidates obtains U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

Depreciation

Depreciation expense relates to the fixed assets which consist mainly of lab equipment. The lab equipment is depreciated over its estimated useful life of five years.

Change in Fair Value of Convertible Promissory Notes

Under the fair value election as prescribed by ASC 815, we recognize the qualifying change in fair value of our convertible promissory notes each reporting period until the notes are settled. Changes in fair value attributable to changes

in instruments specific credit risk are recorded in other comprehensive income to the extent they are material.

Other Income, Net

Other income, net consists primarily of interest earned on our excess cash and federal tax credits. cash.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net operating losses, or NOLs, we have incurred or for our research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our NOLs and tax credits will not be realized. As such, we have a full valuation allowance against all NOLs and tax credits for all periods presented.

Results of Operations

Comparison of the three months ended September 30, 2023 March 31, 2024 and 2022 2023

	Three Months Ended September 30,			Three Months Ended March 31,		
	2023	2022	Change	2024	2023	Change
Collaboration revenue				$ 126,838	$ -	$ 126,838
Operating expenses:						
Research and development	$ 1,592,232	$ 1,278,289	$ 313,943	3,138,159	1,231,712	1,906,447
In-process research and development	-	135,000	(135,000)	25,000	-	25,000
General and administrative	1,964,990	1,236,127	728,863	2,439,841	1,661,544	778,297
Depreciation	6,841	12,455	(5,614)	6,840	6,840	-
Total operating expenses	3,564,063	2,661,871	902,192	5,609,840	2,900,096	2,709,744
Loss from operations	(3,564,063)	(2,661,871)	(902,192)	(5,483,002)	(2,900,096)	(2,582,906)
Other income:						

Change in fair value of convertible promissory notes	-	(1,398,375)	1,398,375			
Other income, net	142,089	39,420	102,669	431,089	163,634	267,455
Net loss	$ (3,421,974)	$ (4,020,826)	$ 598,852	$ (5,051,913)	$ (2,736,462)	$ (2,315,451)

Research and Development Expenses

Research and development expenses increased by $0.3 million $1.9 million from $1.3 million $1.2 million for the three months ended September 30, 2022 March 31, 2023 to $1.6 million $3.1 million for the three months ended September 30, 2023 March 31, 2024. The increase was mainly due to a $0.3 million $1.7 million increase in our preclinical expenses

---

and a $0.1 million $0.2 million increase in internal research and development expenses, partially offset by a decrease of $0.1 decrease attributable to our sponsored research agreement with Houston Methodist Hospital. For our product candidates (COYA 101), we track our external research and development expenses on a candidate-by-candidate basis. For our preclinical product candidates, we track our external research and development expenses in aggregate by Series. expenses. External research and development expenses include fees paid to CROs and CMOs and research laboratories fees paid to regulatory, clinical trial and manufacturing professional service firms largely in connection with our preclinical development, process development, manufacturing activities necessary to prepare COYA 302 for its initial IND filing and launch of a Phase 2 clinical development activities. trial. We expect these expenses to continue to grow in the second quarter of 2024. Once the IND for COYA 302 has been approved, we intend to separately classify the expenses for COYA 302 in the table below under “Clinical Product Candidates.”

We do not further classify or evaluate our internal research and development expenses by product candidate or by Series as these expenses primarily relate to compensation, materials and supplies, and other costs which are deployed across multiple therapeutic modalities, multiple product candidates, and multiple therapeutic areas under development.

Research and development expenses disaggregated and classified by clinical and preclinical, and external and internal expenses are summarized in the table below:

	Three Months Ended September 30,	
	2023	**2022**

External costs:		
Clinical product candidates:		
COYA 101	$ -	$ 14,477
Preclinical product candidates:		
COYA 200 Series	18,186	404,926
COYA 300 Series	894,971	180,665
Sponsored research	108,634	254,802
Internal costs:		
Internal research and development expenses, including stock-based compensation	570,441	423,419
Total	$ 1,592,232	$ 1,278,289

In-Process Research and Development

Under the terms of our License Agreement, or ARS License Agreement, with ARScience Biotherapeutics, Inc., or ARS, we paid an option fee of $0.1 million, which was expensed as in-process research and development expense during the three months ended September 30, 2022. We had no such in-process research and development option fees during the three months ended September 30, 2023.

	For the Three Months Ended March 31,	
	2024	**2023**
Preclinical product candidates:		
COYA 200 Series	$ -	$ 7,684
COYA 300 Series	2,495,289	746,961
Sponsored research	101,986	130,000
Internal costs:		
Internal research and development expenses, including stock-based compensation	540,884	347,067
Total	$ 3,138,159	$ 1,231,712

General and Administrative Expenses

General and administrative expenses increased by $0.7 million from $1.2 million $1.7 million for the three months ended September 30, 2022 March 31, 2023 compared to $2.0 million $2.4 million for the three months ended September 30, 2023 March 31, 2024. The increase was primarily due to a $0.7 million an increase due in personnel related expenses and consulting fees as we continue to additional costs associated with being a public company including investor expand

our operations to support our research and public relations, director and officer insurance, financial advisory and compliance, as well as an increased headcount. development efforts.

Other income, net Income, Net

Other income, net increased by $0.1 million $0.3 million from the three months ended September 30, 2022 March 31, 2023 compared to the three months ended September 30, 2023 March 31, 2024. The increase is primarily due to interest and dividend income earned on cash balances received from our IPO.

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

	Nine Months Ended September 30,		
	2023	**2022**	**Change**
Operating expenses:			
Research and development	$ 3,891,896	$ 3,704,466	$ 187,430
In-process research and development	350,000	135,000	215,000
General and administrative	5,456,087	3,948,434	1,507,653
Depreciation	20,521	20,521	-
Total operating expenses	9,718,504	7,808,421	1,910,083
Loss from operations	(9,718,504)	(7,808,421)	(1,910,083)
Other income:			
Change in fair value of convertible promissory notes	-	(1,376,030)	1,376,030
Other income, net	464,693	47,343	417,350
Net loss	$ (9,253,811)	$ (9,137,108)	$ (116,703)

Research and Development Expenses

Research and development expenses increased by $0.2 million from $3.7 million for the nine months ended September 30, 2022 to $3.9 million for the nine months ended September 30, 2023. The increase was due to a $1.3 million increase in our preclinical expenses, and a $0.2 million increase in internal research and development expenses, partially offset by a $1.0 million decrease in costs attributable to our sponsored research agreement with Houston Methodist Hospital, and a $0.3 million decrease in costs for our clinical product candidate.

Research and development expenses disaggregated and classified by clinical and preclinical, and external and internal expenses are summarized in the table below:

	For the Nine Months Ended September 30,	
	2023	**2022**

External costs:		
Clinical product candidates:		
COYA 101	$ -	$ 291,838
Preclinical product candidates:		
COYA 200 Series	25,870	808,969
COYA 300 Series	2,373,664	298,010
Sponsored research	211,038	1,242,083
Internal costs:		
Internal research and development expenses, including stock-based compensation	1,281,324	1,063,566
Total	$ 3,891,896	$ 3,704,466

In-Process Research and Development

Under the terms of our exclusive License and Supply Agreement, or DRL Agreement, with Dr. Reddy's Laboratories, or DRL, we paid a license fee of $0.4 million, which was expensed as in-process research and development expense during the nine months ended September 30, 2023. For the nine months ended September 30, 2022, we incurred 0.1 million of in-process research and development license fees.

General and Administrative Expenses

General and administrative expenses increased by $1.5 million from $3.9 million for the nine months ended September 30, 2022 compared to $5.5 million for the nine months ended September 30, 2023. The increase was primarily due to $2.4 million in additional costs associated with being a public entity such as increased investor and public relations, director and office insurance, financial advisory and compliance, as well as increased employee headcount, partially offset by $1.0 million of reduced costs attributable to the convertible note financing completed in the second quarter of 2022.

Other income, net

Other income, net increased by $0.4 million from the nine months ended September 30, 2022 compared to the nine months ended September 30, 2023. The increase is primarily due to interest and dividend income earned on cash balances received from our IPO. balances.

Liquidity and Capital Resources

Overview

Since our inception, we have not recognized any revenue and have incurred operating losses and incurred negative cash flows from our operations. operations through 2023. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. Since our inception through September 30, 2023 March 31, 2024 we have funded our operations through the sale of convertible promissory notes and

convertible preferred stock, our initial public offering, IPO, the 2023 Private Placement, and the exercise DRL upfront payment. As of the underwriter's over-allotment option. We incurred a net loss of $3.4 million March 31, 2024 we had $36.0 million in cash and $4.0 million for the three months ended September 30, 2023 and 2022 and $9.3 million and $9.1 million for the nine months ended September 30, 2023 and 2022, respectively, cash equivalents and had an accumulated deficit of $27.1 million as of September 30, 2023 $30.9 million. As of September 30, 2023 we had $10.9 million in cash and cash equivalents. We expect our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2024. 2026. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical tri for our product candidates;
- the costs of manufacturing our product candidates for clinical trials and in preparation for marketing approval a commercialization;

- the extent to which we enter into collaborations or other arrangements with additional third parties in order further develop our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual prope rights and defending intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates technologies;
- expenses needed to attract and retain skilled personnel;
- costs associated with being a public company;
- the costs required to scale up our clinical, regulatory and manufacturing capabilities;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing a distribution capabilities, for any of our product candidates for which we receive marketing approval; and

---

- revenue, if any, received from commercial sales of our product candidates, should any of our product candidat

receive marketing approval.

We will need significant additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. Our ability to raise additional capital may be adversely impacted by potential worsening of global economic conditions, potential future global pandemics or health crises, and the recent disruptions to, and volatility in, the credit, banking and financial markets in the United States. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	**2022**	**2024**	**2023**
Cash used in operating activities	$ (8,947,731)	$ (5,016,279)		
Cash provided by (used in) operating activities			$ 2,145,874	$ (3,863,725)
Cash used in investing activities	(350,000)	(135,000)	(25,000)	-
Cash provided by financing activities	14,250,311	9,461,949	1,241,764	14,250,311
Net increase in cash and cash equivalents	$ 4,952,580	$ 4,310,670	$ 3,362,638	$ 10,386,586

Operating Activities

During the nine three months ended September 30, 2023 March 31, 2024, cash provided by operating activities was $2.1 million. Cash provided by operating activities reflected our net loss of $5.1 million, offset by a $6.7 million net increase in our operating assets and liabilities and noncash charges of $0.4 million related to stock-based compensation. The net increase in our operating assets was mainly related to the receipt of a $7.5 million payment from DRL pursuant to the DRL Development Agreement during the three months ended March 31, 2024.

During the three months ended March 31, 2023, we used $8.9 million $3.9 million of cash in operating activities. Cash used in operating activities reflected our net loss of $9.3 million $2.7 million and a $0.7 million $1.3 million net decrease in our operating assets and liabilities, partially offset by noncash charges of $0.7 million $0.2 million related to stock-based compensation and depreciation, and other charges of $0.4 million related to acquired in-process research and development. The primary use of cash was to fund our operations related to the development of our product candidates.

During the nine months ended September 30, 2022, we used $5.0 million of cash in operating activities. Cash used in operating activities reflected our net loss of $9.1 million, offset by a $1.5 million net increase in our operating assets and liabilities and noncash charges of $1.5 million, which consisted of depreciation, change in fair value of convertible debt, and stock-based compensation, and other charges of $1.1 million related to debt issuance costs and acquired in-process research and development. compensation. The primary use of cash was to fund our operations related to the development of our product candidates.

Investing Activities

During the nine three months ended September 30, 2023 March 31, 2024, investing activities used $0.4 million of cash for the purchase we purchased $25,000 of in-process research and development relating to assets. There were no such activities during the DRL Agreement.

During the nine three months ended September 30, 2022, investing activities used $0.1 million of cash for the purchase of in-process research and development. March 31, 2023.

Financing Activities

During the nine three months ended September 30, 2023 March 31, 2024, financing activities provided $1.2 million of cash from the proceeds received from the exercise of warrants of $1.3 million, partially offset by $0.1 million in payments of offering costs related to the 2023 Private Placement.

During the three months ended March 31, 2023, financing activities provided $14.3 million of cash resulting from the issuance of common stock upon our initial public offering, net of deferred financing costs.

During

DRL Development Agreement

In December 2023, we entered into the nine months ended September 30, 2022 DRL Development Agreement with Dr. Reddy's, pursuant to which, among other things, we granted to Dr. Reddy's an exclusive, royalty-bearing right and license to commercialize COYA 302 solely for use in patients with ALS in the United States, Canada, the European Union and the United Kingdom, or collectively, the New Territories. We previously granted DRL an exclusive license to obtain regulatory approval and commercialize COYA 302 for ALS and certain other indications in all other countries (other than the New Territories, Japan, Mexico, and in each country in South America), financing activities provided $9.5 million pursuant to the License and Supply Agreement entered between with DRL, or the DRL Agreement, effective as of cash primarily resulting from the issuance April 1, 2023. COYA 302 is comprised of convertible promissory notes, net of issuance costs. The convertible promissory notes automatically converted into shares of common stock in connection two components, COYA 301 and DRL_AB. In accordance with the closing DRL Agreement, we in-licensed DRL_AB for the development and commercialization of our IPO. COYA 302. Further, under the DRL Development Agreement, Dr. Reddy's is responsible for the development of DRL_AB. We will have the responsibility for the clinical development of COYA 302 and for seeking regulatory approval in the United States for COYA 302 in ALS.

The collaboration is managed by a joint steering committee, or JSC, which is comprised of representatives from both parties. Decisions of the JSC are made by consensus. If the JSC is unable to reach a consensus, and the parties' executives are not able to resolve the dispute, then Dr. Reddy's has final decision-making authority, subject to specified limitations (as set forth in the DRL Development Agreement).

Pursuant to the DRL Development Agreement, we received an up-front, nonrefundable payment of $7.5 million in January 2024. Additionally, we are entitled to receive (i) an additional $4.2 million upon FDA acceptance of an Investigational New Drug, or IND, application for COYA 302 for the treatment of ALS and (ii) an additional $4.2 million payment upon the dosing of the first patient in the first phase 2 clinical trial for COYA 302 for the treatment of ALS in the United States. We anticipate an IND filing will be made in the second quarter of 2024. The DRL Development Agreement also calls for up to an aggregate of $40.0 million in development milestones and up to an aggregate of $677.3 million in sales milestones, related to the New Territories, should all such development and sales milestones be achieved. We will also be owed royalties by Dr. Reddy's on Net Sales (as defined in the DRL Development Agreement) of COYA 302 in the low to mid-teens (prior to paying royalties due pursuant to previously disclosed license agreements related to COYA 302).

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. We therefore believe that we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Critical Accounting Policies

During the nine three months ended September 30, 2023 March 31, 2024, there were no material changes to our critical accounting policies and estimates from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2022 2023 Annual Report filed on Form 10-K.

Commitments and contingencies, Contingencies, including license License and sponsored research agreements Sponsored Research Agreements

25

Patent Know How and License Agreement with The Methodist Hospital

In September 2022, we entered into the Methodist License Agreement with Methodist to make, sell and sublicense products and services using the intellectual property and know-how of Methodist. As part of the Methodist License Agreement, we will pay Methodist a four-figure license maintenance fee annually until the first sale of licensed product occurs. The term of the Methodist License Agreement is effective until no intellectual property patent rights remain, unless terminated sooner by (1) bankruptcy or insolvency, (2) the failure by us to monetize the intellectual property within five years of the date of the agreement (further discussed below), (3) due to breach of contract, or (4) at our election for any or no reason.

In addition to the equity issuance and reimbursement of patent related expenses, we agreed to make contingent milestone payments to Methodist on a Licensed Product-by-Licensed Product or Licensed Service-by-Licensed Service basis upon the achievement of certain development, approval and sales milestones (i) related to the treatment of ALS totaling up to $325,000 $0.3 million in the aggregate, and (ii) related to the treatment of each other indication (that is not ALS) totaling between $212,500 $0.2 million and up to $425,000 $0.4 million in the aggregate per indication. We are also required to pay Methodist, on a licensed product-by-licensed product and country-by-country basis, royalties (subject to customary reductions) equal to 1% to 10% of annual worldwide net sales of such licensed product during a defined royalty term. The applicable royalty percentage increases as Licensed Products are used to treat from one to more than three indications and if a given Licensed Product utilizes only T-reg cell therapy or is a combination of both T-reg cell therapy and exosomes. Therefore, the lowest tier is paid when there is only a single indication being addressed with a single product. The highest tier is paid only on combination products where there are three or more indications being served. We are also required to pay a low single digit percentage for certain licensed services. We are required to pay royalties at between 10%-20% of sublicense revenue. Commencing on January 1, 2025, the minimum amount which will be owed by us once commercialization occurs is $50,000 $0.1 million annually.

The Methodist License Agreement provides that in the event we sublicense products and services covered by the Methodist License Agreement, then royalties owed to Houston Methodist would be computed as a percentage of payments

received by us from the sublicensee. In addition, the termination provisions provide that Houston Methodist may only terminate the Methodist License

Agreement, among other things, in the event that after five years we are not "Actively Attempting to Develop or Commercialize," as such term is defined in the Methodist License Agreement.

Sponsored Research Agreement with Houston Methodist Research Institute

In February 2021, we executed the SRA with HMRI. Pursuant to the SRA, we agreed to fund $1.5 million in research in the area of neurodegenerative diseases through February 2022. We subsequently amended the executed a new SRA to extend the term through February 2025, which includes an annual funding commitment of $1.5 million per year. As of September 15, 2022, we have provided notice to HMRI regarding termination of the SRA in expectation that a reduced yearly budget be negotiated post termination. On on May 4, 2023, we executed the SRA with HMRI, in which we agreed to fund $0.5 million through May 2024.

ARScience License Agreement

In August 2022, we entered into the ARS License Agreement with ARS pursuant to which ARS granted us an option to, if we choose to exercise such option, to acquire an exclusive, royalty-bearing license for two patents regarding certain formulations of IL-2 (the product that serves as the basis for COYA 301), with the right to grant sublicenses through multiple tiers under these patents. In consideration for the ARS Option, we paid ARS a one-time, non-refundable, non-creditable option fee of $100,000. $0.1 million.

On December 1, 2022, we exercised the ARS Option by written notice to ARS, or the Option Exercise Notice. Upon the delivery of the Option Exercise Notice (such date of delivery, the "Effective Date"), ARS automatically was deemed to have granted to us the licenses and all provisions of the ARS License Agreement and the ARS License Agreement became effective as of the Effective Date. Pursuant to the terms of the ARS License Agreement, we paid to ARS a mid-six-figure up-front fee.

In addition, we may also owe tiered payments to ARS based on our achievement of certain developmental milestones. Under the ARS License Agreement, we will pay an aggregate of $13.25 million $13.3 million in developmental milestone payments for the first Combination Product (as defined in the ARS License Agreement) in a new indication. We will then pay an aggregate of $11.6 million in developmental milestone payments for each Combination Product in each subsequent new indication. Further, for the first Mono Product (as defined in the ARS License Agreement), we will pay an aggregate of $11.75 million $11.8 million in developmental milestone payments. We will then pay an aggregate of $5.85 million $5.9 million in developmental milestone payments for each Mono Product in each subsequent new indication, and we will owe an aggregate of $5.85 million $5.9 million if all developmental milestones are achieved for each new indication. We will also owe royalties on net sales of licensed products ranging from low to mid-single digit percentages. In the event we sublicense our rights under the ARS License Agreement, we will owe royalties on sublicense income within the range of 10% to 20%. To date, the $100,000 $0.1 million option fee and the mid-six-figure up-front fee (upon exercise of the ARS Option) are the only payments made to ARS under ARS License Agreement.

Dr. Reddy's License and Supply Agreement

In March 2023, we entered into the DRL Agreement with DRL. The DRL Agreement became effective on April 1, 2023. Pursuant to the terms of the DRL Agreement, we will in-license DRL_AB to be used in the development and commercialization of COYA 302 in the U.S., Canada, Mexico, South America, the European Union, the United Kingdom, and Japan. In consideration for the license, we paid a one-time, non-refundable upfront fee of $350,000. $0.4 million. We will pay to DRL up to an aggregate of approximately $2.9 million of pre-approval regulatory milestone payments for the first indication in the Field (as defined in the DRL Agreement) and an additional approximately $20.0 million if all other development, regulatory approval and sales milestones are incurred under the DRL Agreement. We will also pay to DRL a low-six figure milestone payment per additional indication. Further, pursuant to the DRL Agreement, we will pay to DRL single-digit royalties on Net Sales (as defined in the DRL Agreement).

Recent Accounting Pronouncements

See Note 2 in our condensed unaudited interim financial statements found elsewhere in this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023 March 31, 2024. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and

procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2023 March 31, 2024, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Evaluation of Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. From time to time, we make changes to our internal control over financial reporting that are intended to enhance its effectiveness and which do not have a material effect on our overall internal control over financial reporting.

PART II – Other Information

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

As of the date of this Quarterly Report on Form 10-Q, there have been no material changes from the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023 filed with the Securities and Exchange Commission, or SEC, on March 29, 2023, as amended on May 1, 2023 March 19, 2024. Any of these factors could result in a significant or material adverse effect on our result of operations or financial conditions. Additional risk factors not presently known to us may also impair our business or results of operations. We may disclose changes to such factors or disclose additional factors from time to time in our future filings with the SEC.

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

Initial Public Offering

On December 28, 2022, our registration statement on Form S-1 (Registration No. 333-268482) was declared effective by the SEC for our initial public offering pursuant to which we sold an aggregate of 3,050,000 shares of our common stock and accompanying warrants to purchase up to 1,525,000 shares of our common stock. Each share of common stock was sold together with one warrant to purchase one share of our common stock with an exercise price of $7.50 per share at a combined offering price of $5.00, for gross proceeds of approximately $15.3 million, before deducting expenses. Chardan Capital Markets, LLC acted as the representative of the several underwriters for the offering. We issued our underwriters 213,500 warrants with an exercise price of $6.25 per warrant and a contractual life of four years as additional consideration.On January 3, 2023, we closed the sale of the shares of our common stock and accompanying warrants to purchase shares of our common stock, resulting in net proceeds to us of approximately $13.4 million, after deducting underwriting discounts and commissions and other offering expenses. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates.

In connection with our initial public offering, we granted the underwriters a 30-day over-allotment option to purchase up to an additional 290,000 shares of our common stock and accompanying warrants to purchase 145,000 shares of our common stock to cover over-allotments at $5.00 per share and accompanying warrant, less underwriting discounts. On January 25, 2023, the underwriters purchased 237,804 shares of common stock and 145,000 warrants to purchase our common stock at $5.00 per share and accompanying warrant in connection with the over-allotment. Upon the sale of the over-allotment, we issued our underwriters an additional 16,646

---

warrants with an exercise price of $6.25 per warrant and a contractual life of five years. We received net proceeds of approximately $1.1 million, after deducting underwriting discounts for the common stock and warrants issued in connection with the over-allotment.

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on December 30, 2022 pursuant to Rule 424(b). None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Insider Trading Arrangements and Policies

During the quarter ended March 31, 2024, none of the Company's directors or officers adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408, that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c).

Item 6. Exhibits.

Exhibit Number	Description
10.1	Amended and Restated Employment Agreement, dated July 11, 2023, between the Company and Dr. Fred Grossman (incorporated by reference to exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on July 14, 2023).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS* 101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because as its XBRL tags are embedded within the Inline XBRL document.
101.SCH* 101.SCH	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104* 104	Cover Page Interactive Data File (embedded within the page formatted as Inline XBRL document) and contained in Exhibit 101

* Filed herewith.

** Furnished, not filed.

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**.**

Coya Therapeutics, Inc.

Date: November 8, 2023 May 9, 2024

By: /s/ Howard Berman

Howard Berman
Chief Executive Officer
(Principal Executive Officer)

Date: November 8, 2023 May 9, 2024

By: /s/ David Snyder

David Snyder
Chief Financial Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Howard Berman, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2023 March 31, 2024 of Coya Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: November 8, 2023 May 9, 2024

/s/ Howard Berman

Howard Berman

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Snyder, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2023 March 31, 2024 of Coya Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2023 May 9, 2024

/s/ David Snyder

David Snyder

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Coya Therapeutics, Inc. (the "Company") for the period ended September 30, 2023 March 31, 2024 (the "Quarterly Report"), each of Howard Berman, as Chief Executive Officer, and David Snyder, as Chief Financial Officer, certifies in his capacity as such officer of the Company, that to such officer's knowledge:

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

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

Dated: November 8, 2023 May 9, 2024

By: /s/ Howard Berman

Howard Berman

Chief Executive Officer

(Principal Executive Officer)

Dated: November 8, 2023 May 9, 2024

By: /s/ David Snyder

David Snyder

Chief Financial Officer

(Principal Financial and Accounting Officer)

This certification shall not be deemed “filed” for any purpose, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act.

DISCLAIMER

THE INFORMATION CONTAINED IN THE REFINITIV CORPORATE DISCLOSURES DELTA REPORT™ IS A COMPARISON OF TWO FINANCIALS PERIODIC REPORTS. THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORT INCLUDING THE TEXT AND THE COMPARISON DATA AND TABLES. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S ACTUAL SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

REFINITIV