UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2023
OR
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission File Number: 001-36361

Aravive, Inc.
(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**26-4106690** **(I.R.S. Employer Identification No.)**

River Oaks Tower
3730 Kirby Drive, Suite 1200
Houston, Texas 77098
(Address of principal executive offices) (Zip Code)
(936) 355-1910
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	ARAV	Nasdaq Global Select Market

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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 3, 2023, there were 73,562,648 outstanding shares of common stock, par value $0.0001 per share, of Aravive, Inc.

ARAVIVE, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2023

PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ARAVIVE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current Assets		
Cash and cash equivalents	$ 8,535	$ 53,689
Prepaid expenses and other current assets	1,027	4,281
Total current assets	9,562	57,970
Restricted cash	2,408	2,445
Property and equipment, net	167	270
Operating lease right-of-use assets	907	1,462
Other assets	5	6
Total assets	$ 13,049	$ 62,153
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 5,423	$ 8,765
Accrued liabilities	2,233	6,738
Operating lease obligation, current portion	2,121	2,195
Current portion of deferred revenue	-	4,414
Total current liabilities	9,777	22,112
Deferred revenue, net of current portion	-	621
Operating lease obligation, net of current portion	306	1,882
Warrant liability	1,265	26,881
Total liabilities	11,348	51,496
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, $0.0001 par value, 250,000,000 shares authorized at September 30, 2023 and 100,000,000 shares authorized at December 31, 2022; 73,562,648 shares issued and outstanding at September 30, 2023 and 59,844,850 shares issued and outstanding at December 31, 2022	7	6
Additional paid-in capital	628,543	626,778
Accumulated deficit	(626,849)	(616,127)
Total stockholders' equity	1,701	10,657
Total liabilities and stockholders' equity	$ 13,049	$ 62,153

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

ARAVIVE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue				
Collaboration revenue	$ 2,756	$ 4,956	$ 5,520	$ 7,663
Total revenue	2,756	4,956	5,520	7,663
Operating expenses				
Research and development	8,730	18,668	35,435	48,985
General and administrative	2,940	2,836	9,499	9,651
Total operating expenses	11,670	21,504	44,934	58,636
Loss from operations	(8,914)	(16,548)	(39,414)	(50,973)
Other income (expense), net:				
Interest income	209	147	1,028	220
Change in fair value of warrant liability	29,231	—	25,616	1,410
Other income, net	700	738	2,048	2,146
Total other income (expense), net	30,140	885	28,692	3,776
Net income (loss)	$ 21,226	$ (15,663)	$ (10,722)	$ (47,197)
Net income (loss) per share				
Basic	$ 0.28	$ (0.51)	$ (0.14)	$ (1.72)
Diluted	$ 0.28	$ (0.51)	$ (0.38)	$ (1.72)
Weighted-average shares used to compute net income (loss) per share				
Basic	75,739	30,518	75,727	27,419
Diluted	76,093	30,518	95,441	27,419

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

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ARAVIVE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY
(unaudited)
(in thousands, except share data)

	Three and Nine Months Ended September 30, 2023				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Capital	Deficit	Equity
Balances at January 1, 2023	59,844,850	$ 6	$ 626,778	$ (616,127)	$ 10,657
Stock-based compensation	—	—	688	—	688
Net loss	—	—	—	(49,956)	(49,956)
Balances at March 31, 2023	59,844,850	$ 6	$ 627,466	$ (666,083)	$ (38,611)
Issuance of common stock under employee benefit plans	23,703	—	25	—	25
Stock-based compensation	—	—	761	—	761
Net income	—	—	—	18,008	18,008
Balances at June 30, 2023	59,868,553	$ 6	$ 628,252	$ (648,075)	$ (19,817)
Issuance of common stock upon exercise of pre-funded warrants	13,694,095	1	(1)	—	—
Stock-based compensation	—	—	292	—	292
Net income	—	—	—	21,226	21,226
Balances at September 30, 2023	73,562,648	$ 7	$ 628,543	$ (626,849)	$ 1,701

	Three and Nine Months Ended September 30, 2022				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balances at January 1, 2022	21,039,594	$ 2	$ 582,025	$ (539,805)	$ 42,222
Issuance of common stock and common stock warrants in registered direct offering, net of issuance costs of $706	3,185,216	—	9,291	—	9,291
Issuance of common stock in at the market offering, net of issuance costs of $3	54,763	—	123	—	123
Stock-based compensation	—	—	620	—	620
Net loss	—	—	—	(13,057)	(13,057)
Balances at March 31, 2022	24,279,573	$ 2	$ 592,059	$ (552,862)	$ 39,199
Issuance of common stock upon exercise of pre-funded warrants	6,210,480	1	8,592	—	8,593
Issuance of common stock under employee benefit plans	28,216	—	26	—	26
Stock-based compensation	—	—	725	—	725
Net loss	—	—	—	(18,477)	(18,477)
Balances at June 30, 2022	30,518,269	$ 3	$ 601,402	$ (571,339)	$ 30,066
Stock-based compensation	—	—	639	—	639
Net loss	—	—	—	(15,663)	(15,663)
Balances at September 30, 2022	30,518,269	$ 3	$ 602,041	$ (587,002)	$ 15,042

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

ARAVIVE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities		
Net loss	$ (10,722)	$ (47,197)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	658	664
Stock-based compensation expense	1,741	1,984
Warrant issuance costs	—	123
Warrant liability fair value adjustment	(25,616)	(1,410)
Changes in assets and liabilities		
Accounts receivable	—	(6,000)
Prepaid expenses and other assets	3,255	(622)
Accounts payable	(3,342)	6,164
Deferred revenue	(5,035)	(1,663)
Accrued and other liabilities	(6,155)	(2,886)
Net cash used in operating activities	(45,216)	(50,843)
Cash flows from financing activities		
Proceeds from issuance of common stock in connection with employee benefit plans	25	26
Proceeds from issuance of common stock and common stock warrants in direct offering, net of issuance costs	—	19,171
Proceeds from issuance of common stock in at the market offering	—	123
Net cash provided by financing activities	25	19,320
Net change in cash, cash equivalents, and restricted cash	(45,191)	(31,523)
Cash, cash equivalents, and restricted cash at beginning of period	56,134	61,855
Cash, cash equivalents, and restricted cash at end of period	$ 10,943	$ 30,332
Supplemental disclosure of noncash items		
Warrant liability reclass to additional-paid-in-capital upon warrant exercise	—	8,590

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

ARAVIVE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS *(unaudited)*

1. Formation and Business of the Company

Aravive, Inc. (“Aravive” or the “Company”) was incorporated on December 10, 2008 in the State of Delaware. Aravive Biologics, Inc. (“Aravive Biologics”), the Company's wholly owned subsidiary, was incorporated in 2007. Aravive has historically been a clinical-stage oncology company developing transformative treatments designed to halt the progression of life-threatening diseases, including cancer and fibrosis. The Company historically had one product candidate, batiraxcept, in clinical development. In August 2023, the Company announced the Phase 3 AXLerate-OC (“AXLerate”) trial evaluating the safety and efficacy of batiraxcept in platinum-resistant ovarian cancer (“PROC”) did not meet its primary endpoint and announced a significant reduction in force. The Company is currently exploring various strategic alternatives, including strategic partnerships and financing opportunities. If the Company does not raise capital or successfully engage a strategic partner, it will be forced to cease operations, liquidate assets through an assignment for the benefit of creditors and possibly seek bankruptcy protection or engage in a similar process.

Unaudited Interim Financial Information

In the opinion of the Company’s management, the accompanying unaudited condensed consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of its financial position as of September 30, 2023 and, its results of operations for the three and nine months ended September 30, 2023 and 2022, the condensed consolidated statement of stockholders' (deficit) equity for the three and nine months ended September 30, 2023 and 2022, and cash flows for the nine months ended September 30, 2023 and 2022. The December 31, 2022 consolidated balance sheet was derived from audited financial statements but does not include all disclosures required by generally accepted accounting principles in the United States of America (“GAAP”). The results for interim periods are not necessarily indicative of the results for the entire year or any other interim period. The accompanying consolidated financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2022 included in the Company’s Annual Report on Form 10-K filed by the Company on March 15, 2023, with the U.S. Securities and Exchange Commission (the “SEC”).

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying consolidated financial statements have been prepared in accordance with GAAP. The preparation of the accompanying consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The accompanying unaudited condensed consolidated statement of financial position as of September 30, 2023, the results of operations for the three and nine months ended September 30, 2023 and 2022, the condensed consolidated statement of stockholders' (deficit) equity for the three and nine months ended September 30, 2023 and 2022, and the consolidated statement cash flows for the nine months ended September 30, 2023 and 2022 include the accounts of Aravive, Inc. and its wholly-owned subsidiary Aravive Biologics. All intercompany accounts and transactions have been eliminated. The U.S. dollar is the functional currency for the Company's subsidiary and consolidated operations.

Going Concern Uncertainty

Since inception, the Company has incurred net losses from operations and negative cash flows from operations. At September 30, 2023, the Company had an accumulated deficit of $626.8 million and a working capital deficit of $0.2 million. The Company expects to continue to incur losses from costs related to the expenses incurred in connection with the previously conducted clinical trials of batiraxcept, wind down costs of trials and related administrative activities for the foreseeable future. The Company does not generate any revenue from operations. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should the Company be unable to continue as a going concern. As of October 31, 2023, the Company had a cash and cash equivalents balance of $5.1 million consisting of cash and investments in highly liquid U.S. money market funds. In August 2023, the Company announced the Phase 3 AXLerate-OC trial evaluating the safety and efficacy of batiraxcept in PROC did not meet its primary endpoint. As a result, the Company has terminated the Phase 3 PROC trial and the PROC program. The Company’s existing cash and cash equivalents were not sufficient to complete the clinical development and commercialization of batiraxcept for clear cell renal cell carcinoma (ccRCC) or pancreatic cancer. In order to preserve cash, the Company discontinued the P1b/P2 trials in ccRCC and pancreatic ductal adenocarcinoma and will not continue either the renal or pancreatic programs unless the Company raises additional capital. The Company is currently exploring various strategic alternatives, including strategic partnerships and financing opportunities. If the Company does not raise capital or successfully engage a strategic partner, it will be forced to cease operations, liquidate its assets through an assignment for the benefit of creditors and possibly seek bankruptcy protection or engage in a similar process.

ARAVIVE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) *(unaudited)*

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. All long-lived assets are maintained in the United States of America.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. All of the Company's cash and cash equivalents are held at several financial institutions that management believes are of high credit quality. Such deposits may exceed federally insured limits.

Risk and Uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of exploring various strategic alternatives, including strategic partners and financing opportunities.

In August 2023, the Company announced that its Phase 3 AXLerate-OC trial evaluating the safety and efficacy of batiraxcept in platinum-resistant ovarian cancer did not meet its primary endpoint of progression-free survival (PFS) in the pre-specified subset of patients naïve to prior bevacizumab treatment. The trial also did not show any difference between the two arms in the overall population (which included patients previously treated with bevacizumab). No new safety signals were identified. Based on the efficacy results, the Company has terminated the PROC trial and program. In order to preserve cash, the Company has also terminated the P1b/P2 studies in clear cell renal cell cancer and pancreatic adenocarcinoma and will not continue either the renal or pancreatic programs unless the Company raises additional capital. The Company is currently exploring various strategic alternatives, including strategic partnerships and financing opportunities. If the Company does not raise capital or successfully engage a strategic partner, it will be forced to cease operations, liquidate assets and possibly seek bankruptcy protection or engage in a similar process.

Cash and Cash Equivalents, Restricted Cash

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. At September 30, 2023 and December 31, 2022, the Company's cash and cash equivalents were held in multiple institutions within the United States and included deposits in money market funds which were unrestricted as to withdrawal or use. Restricted cash consists of a letter of credit to secure the Company's obligations under the right-of-use lease.

Property and Equipment, Net

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheets and any resulting gain or loss is reflected in operations in the period realized.

Leases

The Company leases all of its office space in conducting its business. At inception, the Company determines whether an agreement represents a lease and at commencement the Company evaluates each lease agreement to determine whether the lease is an operating or financing lease.

The Company records an operating lease right-of-use (“ROU”) asset and an operating lease obligation on the consolidated balance sheet when entering into a lease. ROU assets represent the Company’s ROU of the underlying asset for the lease term and the lease obligation represents the Company’s commitment to make the lease payments arising from the lease. Lease obligations are recognized at the commencement date based on the present value of remaining lease payments over the lease term and ROU assets are calculated as the lease liability, adjusted by unamortized initial direct costs, unamortized lease incentives received, cumulative deferred or prepaid lease payments, and accumulated impairment losses. As the Company’s leases do not provide an implicit rate, the Company has used an estimated incremental borrowing rate based on the information available at the lease inception date in determining the present value of lease payments. The lease term may include options to extend or terminate the lease and the Company includes renewal options in its calculation of the estimated lease term when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. Variable lease costs such as common area costs and property taxes are expensed as incurred. Variable lease costs and short-term lease payments not included in the lease liability are classified within operating activities in the consolidated statements of cash flows. For all lease agreements, the Company has combined lease and non-lease components. Leases with an initial term of 12 months or less are not recorded on the consolidated balance sheet. These expenses are recognized within operating expenses in the consolidated statements of operations.

Warrant Liability

Warrants for the purchase of shares of common stock issued in connection with the October 2022 financing (the “October 2022 Warrants”) were classified as liabilities on the consolidated balance sheets as of December 31, 2022 because the Company did not have enough authorized shares to cover the outstanding warrants, if exercised. In January 2023, the Company amended its Certificate of Incorporation to increase the number of its authorized shares of common stock from 100 million to 250 million. However, the October 2022 Warrants provide the holder the option to require the Company to purchase the warrants for cash at the Black Scholes Value upon occurrence of certain fundamental transactions. The Company has determined that such fundamental transactions are not within the Company’s control because certain holders of the warrants hold the majority seats in the Company’s board of directors. Consequently, because the Company does not control the events that may lead to the cash redemption of the warrants, the October 2022 Warrants remain classified as liabilities as of September 30, 2023. The change in estimated fair value during the period was recognized as a component of other income (expense), net in the Company's statement of operations for the three and nine months ended September 30, 2023 and reflected accordingly in the reconciliation of net loss to net cash used in operating activities.

The Company estimated the fair value of these liabilities using assumptions that are based on the individual characteristics of the warrants on the valuation date. The Company used the Black-Scholes option-pricing model and the fair value of the underlying stock to determine the fair value of these liabilities. The valuation model is based on inputs as of the valuation dates, including the estimated volatility of the Company's stock, the remaining contractual term of the warrants and the risk-free interest rates. Refer to Note 3.

Impairment of Long-Lived Assets

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by the comparison of the carrying amount to the future net cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value (i.e., determined through estimating projected discounted future net cash flows or other acceptable methods of determining fair value) arising from the asset. There were no such impairments of long-lived assets as of September 30, 2023.

Fair Value of Financial Instruments

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

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

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

Level 1 - Unadjusted quoted prices in active markets for identical assets or liabilities;

Level 2 - Inputs other than quoted prices included within Level 1 that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3 - Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

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

The Company's financial instruments consist of Level 1 assets and Level 3 liabilities as of September 30, 2023 and December 31, 2022. Level 1 securities are comprised of highly liquid money market funds. Level 3 liabilities are comprised of warrant liabilities.

Clinical Trial Accruals

The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and Clinical Research Organizations ("CROs") that conduct and manage clinical trials on the Company's behalf.

The Company estimates preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and CROs that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs include, but are not limited to, payroll and personnel expenses, laboratory supplies, consulting costs, external research and development expenses and allocated overhead, including rent, equipment depreciation, and utilities. Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are expensed to research and development costs when incurred.

ARAVIVE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) *(unaudited)*

Income Taxes

The Company accounts for income taxes under the asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is more than likely to be realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Stock-Based Compensation

For stock options granted to employees, the Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. The determination of fair value for stock-based awards on the date of grant using an option pricing model requires management to make certain assumptions regarding a number of complex and subjective variables.

Stock-based compensation expense related to stock options granted to nonemployees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as they are earned. The awards generally vest over the time period the Company expects to receive services from the nonemployee.

Stock-based compensation expense, net of estimated forfeitures, is reflected in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating Expenses				
Research and development	$ (121)	$ 256	$ 480	$ 676
General and administrative	413	383	1,261	1,308
Total	$ 292	$ 639	$ 1,741	$ 1,984

Net Income (Loss) per Share of Common Stock

Basic net income (loss) per common share is calculated by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net income (loss) per share calculation, warrants and stock options are considered to be potentially dilutive securities.

Collaborative Arrangements

The Company records the elements of its collaboration agreements that represent joint operating activities in accordance with ASC Topic 808, *Collaborative Arrangements* (ASC 808). Accordingly, the elements of the collaboration agreements that represent activities in which both parties are active participants and to which both parties are exposed to the significant risks and rewards that are dependent on the commercial success of the activities are recorded as collaborative arrangements. The Company considers the guidance in ASC 606-10-15, *Revenue from Contracts with Customers – Scope and Scope Exceptions*, in determining the appropriate treatment for the transactions between the Company and its collaborative partner and the transactions between the Company and third parties. Generally, the classification of transactions under the collaborative arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. Currently, the Company has one collaboration agreement with 3D Medicines, see Note 4 for further discussion.

Revenue Recognition

The Company’s sole source of revenue for 2023 and 2022 has been generated through its collaboration and license agreement. The Company’s collaboration and license agreements frequently contain multiple elements including (i) intellectual property licenses, and (ii) research and development services. Consideration received under these arrangements may include upfront payments, research and development funding, cost reimbursements, milestone payments, payments for product sales and royalty payments.

The Company follows ASC 606, *Revenue from Contracts with Customers* (ASC 606) for recognition of its collaboration and license agreements. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that the Company expects to be entitled to receive in exchange for goods or services and excludes sales incentives and amounts collected on behalf of third parties. The Company analyzes the nature of these performance obligations in the context of individual agreements in order to assess the distinct performance obligations.

The Company applies the following five-step model to recognize revenue: (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.

i) Identify the contract with a customer. The Company considers the terms and conditions of its agreements to identify contracts within the scope of ASC 606. The Company concludes it has a contract with a customer when the contract is approved, each party's rights regarding the goods and services to be transferred can be identified, the payment terms for the goods and services can be identified, it has been determined that the customer has the ability and intent to pay and the contract has commercial substance. The Company uses judgment in determining the customer's ability and intent to pay, which is based upon factors including the customer's historical payment experience or, for new customers, credit and financial information pertaining to the customers.

ii) Identify the performance obligations in the contract. Performance obligations in the agreements are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct, whereby the customer can benefit from the service either on its own or together with other resources that are readily available from third parties or from the Company, and are distinct in the context of the contract, whereby the transfer of the services is separately identifiable from other promises in the contract. The Company’s performance obligations generally consist of intellectual property licenses and research and development services with respect to license and service agreements, and the manufacture and supply of product for product sales agreements.

iii) Determine the transaction price. The Company determines the transaction price based on the consideration to which the Company expects to be entitled in exchange for transferring goods and services to the customer. In determining the transaction price, any variable consideration would be considered, to the extent applicable, if, in the Company’s judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. In accordance with the royalty exception under ASC 606 for licenses of intellectual property, the transaction price excludes future royalty payments to be received from the Company’s customers. None of the Company’s revenue generating contracts contain consideration payable to its customer or a significant financing component.

iv) Allocate the transaction price to performance obligations in the contract. If the contract contains a single performance obligation, the entire transaction price is allocated to that performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price.

v) Recognize revenue when, or as the Company satisfies a performance obligation. Revenue is recognized at the time the related performance obligation is satisfied by transferring the promised goods or services to a customer. The Company recognizes revenue when control of the goods or services is transferred to the customers for an amount that reflects the consideration that the Company expect to receive in exchange for those goods or services.

Performance Obligations

The following is a general description of principal goods and services from which the Company generates revenue.

License to Intellectual Property

The Company generates revenue from licensing its intellectual property ("IP") including know-how and development and commercialization rights. The license provides a customer with the right to further research, develop and commercialize internally-discovered or collaborated drug candidates, or the right to use batiraxcept to further research, develop and commercialize customer drug candidates. The consideration the Company receives is in the form of nonrefundable upfront consideration related to the functional intellectual property licenses and is recognized when the Company transfers such license to the customer unless the license is combined with other goods or services into one performance obligation, in which case the revenue is recognized over a period of time based on the estimated pattern in which the Company satisfies the combined performance obligation. The Company's licensing agreements are generally cancelable.

Research and Development Services

The Company generates revenue from research and development services it provides to its customers and primarily includes clinical trials, and assistance during regulatory approval application process. Revenue associated with these services is recognized based on the Company's estimate of total consideration to be received for such services and the pattern in which the Company performs the services. The pattern of performance is generally determined to be the amount of incurred costs related to the service portion of the contract with the customer as a percentage of total expected costs associated with the service portion of the contract.

Contracts with Multiple Performance Obligations

Most of the Company's collaboration and license agreements with customers contain multiple promised goods or services. Based on the characteristics of the promised goods and services the Company analyzes whether they are separate or combined performance obligations. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. The estimated standalone selling price is based on the adjusted market assessment approach including estimated present value of future cash flows and cost-plus margin approach, taking into consideration the type of services, estimates of hourly market rates, and stage of the development.

Variable Consideration

The Company's contracts with customers primarily include two types of variable consideration: (i) development and regulatory milestone payments, which are due to the Company upon achievement of specific development and regulatory milestones and (ii) one-time sales-based payments and sales-based royalties associated with licensed intellectual property.

Due to uncertainty associated with achievement of the development and regulatory milestones, the related milestone payments are excluded from the contract consideration and the corresponding revenue is not recognized until the Company concludes it is probable that reversal of such milestone revenue will not occur. As part of the Company's evaluation of the constraint, the Company considers numerous factors, including whether the achievement of the milestone is outside of the Company's control, contingent upon regulatory approval or dependent on licensee efforts.

Product sales-based royalties under licensed intellectual property and one-time payments are accounted for under the royalty exception. The Company recognizes revenue for sales-based royalties under licensed intellectual property and one-time payments at the later of when the sales occur or the performance obligation is satisfied or partially satisfied.

The transaction price is reevaluated each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective is not expected to have a material impact on the Company's financial position or results of operations upon adoption.

3. Fair Value Measurements

The Company’s financial instruments consist principally of cash and cash equivalents, prepaid expenses, accounts payable, accrued liabilities, and a warrant liability. These financial instruments are reported on the Company’s consolidated balance sheets at amounts that approximate current fair value. The following table sets forth the Company’s financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Fair Value Measurements at September 30, 2023 (unaudited)			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets				
Money market funds	$ 7,889	$ 7,889	$ —	$ —
Liabilities				
Warrant liability	$ 1,265	$ —	$ —	$ 1,265

	Fair Value Measurements at December 31, 2022			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets				
Money market funds	$ 52,905	$ 52,905	$ —	$ —
Liabilities				
Warrant liability	$ 26,881	$ —	$ —	$ 26,881

Warrant Liability

The Company’s warrant liability for the October 2022 warrants which was classified as a derivative liability on the consolidated balance sheet as of September 30, 2023 and December 31, 2022 contained unobservable inputs that reflected the Company’s own assumptions in which there was little, if any, market activity at the measurement date and was classified as a Level 3 input. Refer to Note 2.

The fair value of the warrants was estimated using the Black-Scholes option-pricing model. As of December 31, 2022, the fair value of the common share has been adjusted for a discount for lack of marketability due to the uncertainty and timing of obtaining shareholder approval to increase the Company's authorized number of common shares. For warrants that do not have a fixed termination date, the expected terms represent the periods that the warrants are expected to be outstanding based upon managements' estimate. The risk-free interest rates are based on the U.S. Constant Maturity treasury curve commensurate with the time outstanding. The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its common stock in the foreseeable future. The expected volatilities are estimated by the Company's historical volatility over a similar time period.

The assumptions used in calculating the estimated fair value at the end of the reporting period represent the Company’s best estimate. However, inherent uncertainties are involved. If factors or assumptions change, the estimated fair value could be materially different.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) *(unaudited)*

At September 30, 2023 and December 31, 2022, the Company estimated the fair values of the financial liability arising from the October 2022 Warrants using the following weighted average assumptions:

	October 2022 Warrants	
	September 30, 2023	December 31, 2022
Expected term (in years)	1.2	1.9
Expected volatility	147.4%	49.9%
Risk-free interest rate	5.28%	4.48%
Expected dividend yield	0.00%	0.00%
Fair value of common share	$ 0.13	$ 1.25
Exercise price	$ 0.7949	$ 0.7949

The following table provides a summary of changes in the estimated fair value of the Company's warrant liability (in thousands):

	October 2022 Warrants
Balance at December 31, 2022	$ 26,881
Change in fair value	33,207
Balance at March 31, 2023	60,088
Change in fair value	(29,592)
Balance at June 30, 2023	$ 30,496
Change in fair value	(29,231)
Balance at September 30, 2023	$ 1,265

Fair Value Hierarchy Transfers

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the periods ended September 30, 2023 or December 31, 2022.

4. Collaboration and License Agreement

On November 6, 2020, the Company entered into the 3D Medicines Agreement, whereby the Company granted 3D Medicines an exclusive license to develop and commercialize products that contain batiraxcept as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in China, Taiwan, Hong Kong and Macau (the "Territory").

Under the terms of the Agreement, the Company was paid $27 million (inclusive of $15 million in milestone payments) and is eligible to receive from 3D Medicines cash payments of up to an aggregate of $207 million (inclusive of the $27 million received) in clinical development, regulatory and commercial milestone payments. There can be no guarantee that any additional milestones will in fact be met. The Company is obligated to make certain payments to The Board of Trustees of Stanford University based on certain amounts received from 3D Medicines under the Agreement pursuant to the existing license agreement by and between the Company and Stanford, dated January 25, 2012, and as amended to date.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) *(unaudited)*

The Company will also be entitled to receive tiered royalties ranging from low double digits to mid-teens on sales in the Territory, if any, of products containing batiraxcept. Royalties are payable with respect to each jurisdiction in the Territory until the latest to occur of: (i) the last-to-expire of specified patent rights in such jurisdiction in the Territory; or (ii) ten (10) years after the first commercial sale of a product in such jurisdiction in the Territory. In addition, royalties payable under the Agreement will be subject to reduction on account of generic competition under certain specified conditions, with any such reductions capped at certain percentages of the amounts otherwise payable during the applicable royalty payment period.

Under the terms and conditions of the Agreement, 3D Medicines will be solely responsible for the development and commercialization of licensed products in the Territory.

If either the Company or 3D Medicines materially breaches the Agreement and does not cure such breach, the non-breaching party may terminate the Agreement in its entirety. Either party may also terminate the Agreement, upon written notice, if the other party files for bankruptcy, is dissolved or has a receiver appointed for substantially all of its property. The Company may terminate the Agreement if 3D Medicines, its affiliates or its sublicensees challenges the validity or enforceability of any of the Company’s patents covering any of the licensed compounds or products or ceases substantially all development and commercialization of licensed products in the Territory for a specified period, subject to certain exceptions. 3D Medicines may also terminate the Agreement for convenience provided certain notice is provided to the Company.

The Company assessed this arrangement in accordance with ASC 606 and identified the following performance obligations: 1) license to intellectual property, batiraxcept, and 2) research and development services, including conducting clinical trials. The Company concluded that each of these performance obligations were distinct because 3D Medicines can benefit from the good or service either on its own or together with other resources that are readily available, and each performance obligation is separately identifiable from other promises within the contract. Specifically, the batiraxcept drug was in a Phase 3 clinical trial at the time that 3D Medicines acquired the license and the Company concluded that: (i) the R&D services for such later-stage, Phase 3 IP, primarily involved validating the drug’s efficacy, and (ii) the ongoing R&D services do not significantly modify or customize the drug compound such that the IP is not significantly different at the end of the arrangement as a result of those services.

The estimated total transaction price was allocated between performance obligations based on their relative standalone selling prices. The Company uses a discounted cash flow approach and an expected cost plus a margin approach to estimate the standalone selling price for the performance obligations. The Company allocated the $27.0 million transaction price as such: $14.5 million to the research and development services performance obligation and $12.5 million to the license to intellectual property. Accordingly, the Company will recognize revenue related to the allocable research and development services obligation on a proportional performance basis as the underlying services are performed pursuant to the current development plan which is commensurate with the period and consistent with the pattern over which the Company’s research and development services obligation is satisfied. The Company will recognize the revenue related to the license to intellectual property at a point in time. This is due to the fact the license was determined to be a functional license due to current stage in development of batiraxcept. Batiraxcept has been developed, dosing levels have already been determined and the drug is currently in a Phase III clinical trial related to its PROC study.

As of September 30, 2023, no clinical or regulatory milestones have been assessed as probable of being reached and thus have been fully constrained. The Company continues to re-assess the probability of achievement of future milestones at the end of each reporting period.

The Company recognized in revenue $5.4 and $4.9 million related to the research and development services and the clinical supply agreement with 3D medicines for the nine months ended September 30, 2023 and 2022, respectively. The Company recognized no revenue related to the intellectual property for the nine months ended September 30, 2023 and $2.8 million for the nine months ended September 30, 2022. The Company recognized revenue of $5.0 million for the nine months ended September 30, 2023, related to the contract liability balance of $5.0 million as of December 31, 2022. In August 2023, due to the announcement of the Company's Phase 3 PROC trial the Company has terminated all activity related to that trial and therefore all deferred revenue associated with the 3D medicines agreement has been recognized during the three months ended September 30, 2023.

5. Leases

In March 2017, the Company entered into an operating facility lease agreement for approximately 34,500 rentable square feet located at the 1020 Marsh Facility. The lease commenced in August 2017 for a period of 87 months with one renewal option for a five-year term. The Company did not include the renewal option period as the Company determined it was not reasonably certain the lease would be renewed as of the modification date.

In August 2020, the Company entered into a lease agreement in North Carolina for approximately 4,128 square feet for office space. The monthly lease payments will be approximately $9 thousand per month for a period of 63 months with a three-month rent abatement period. The lease commenced in the fourth quarter of 2020.

The Company's operating lease cost including both short-term and variable lease components of $0.3 million associated with the facility leases was $1.5 million and $1.4 million for the nine months ended September 30, 2023 and 2022, respectively. Cash paid for amounts included in the measurement of lease obligations for operating cash flows from operating leases was $2.3 million and $2.2 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, the Company's operating leases had a weighted average remaining lease term of 1.2 years and a weighted average discount rate of 7.59%, which approximates the Company's incremental borrowing rate.

As of September 30, 2023, minimum lease payments under non-cancelable operating leases by period were expected to be as follows (in thousands):

Year Ending December 31,		
2023 (3 months remaining)	$	775
2024		2,619
2025		116
2026		30
Total future minimum lease payments		3,540
Less: discount	$	(1,113)
Total lease liabilities	$	2,427

1020 Marsh Facility Sublease

On June 8, 2021, the Company entered into an operating sublease with a subtenant (the "Subtenant") for the 1020 Marsh Facility. The final agreement and consent received from the landlord was obtained on July 13, 2021. The term of the sublease commenced on August 1, 2021 and continues through October 31, 2024, unless the master lease is terminated earlier due to a breach by Subtenant. Subtenant will also pay to the Company, as additional rent, an amount equal to the Company's share of operating expenses attributable to the subleased premises due under the master lease. The terms entered into for this sublease agreement did not result in an impairment of the Company's long-lived assets for the nine months ended September 30, 2023 and 2022. Lease income associated with this sublease is recorded in other income in the accompanying consolidated statements of operations. The Company has recorded lease income associated with this sublease of approximately $0.7 million for the three months ended September 30, 2023 and 2022, and approximately $2.1 million for the nine months ended September 30, 2023 and 2022. During the nine months ended September 30, 2023 and 2022, cash received from the Subtenant was $2.1 million which was included in operating cash flows.

Future base rent the Subtenant shall pay to the Company over the sublease term as of September 30, 2023, are as follows (in thousands):

Year Ending December 31,		
2023 (3 months remaining)	$	603
2024		2,029
Total	$	2,632

6. Commitments and Contingencies

Purchase Commitments

The Company has conducted research and development programs through a combination of internal and collaborative programs that include, among others, arrangements with contract manufacturing organizations and contract research organizations. The Company had contractual arrangements with these organizations including license agreements with milestone obligations and service agreements with obligations largely based on services performed.

In the normal course of business, the Company enters into various firm purchase commitments related to certain preclinical and clinical studies.

Contingencies

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

On August 18, 2023, the Company's Board of Directors approved a workforce reduction of approximately 70% of its current employee base. The decision was based on the Company's cash position and decision to terminate all clinical trials and conserve cash following its announcement that the Phase 3 clinical trial of batiraxcept for the treatment of PROC failed to meet its primary endpoint.

As a result of the expense reduction, the Company estimated that it will incur approximately $900,000 in costs resulting from severance payments and an additional $300,000 for previously accrued paid time off. The Company made cash payments of approximately $1.2 million for the employee reduction, during the three months ended September 30, 2023.

Indemnification

In accordance with the Company's amended and restated Certificate of Incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date and the Company has a director and officer insurance policy that may enable it to recover a portion of any amounts paid for future claims.

Litigation

The Company may from time to time be involved in legal proceedings arising from the normal course of business. There are no pending or threatened legal proceedings as of September 30, 2023.

7. Common Stock and Common Stock Warrants

The Amended and Restated Certificate of Incorporation authorizes the Company to issue 250,000,000 shares of common stock. The Certificate of Incorporation was amended on January 17, 2023 to increase the number of shares of common stock that the Company may issue from 100,000,000 to 250,000,000. Common stockholders are entitled to dividends as and when declared by the Company's Board of Directors (the "Board"), subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. The holder of each share of common stock is entitled to one vote.

At the Market Offering Program

In September 2020, the Company filed a shelf registration statement on Form S-3 with the SEC which was declared effective by the SEC on November 20, 2020 (the "Form S-3"). On September 4, 2020, the Company entered into an Equity Distribution Agreement with Piper Sandler & Co. and Cantor Fitzgerald to sell shares of the Company's common stock, par value $0.0001 per common share, from time to time, through an "at the market offering" program having an aggregate offering price of up to $60,000,000 through which Piper Sandler and Cantor Fitzgerald will act as sales agents. The Company did not sell any common stock nor receive any proceeds under the Equity Distribution Agreement during the three months ended September 30, 2023 and 2022.

Registered Direct Offerings

Related Party Transaction

On March 31, 2022, the Company closed a registered direct offering of the Company's common stock with a single healthcare-focused institutional investor and Eshelman Ventures, LLC a related party, pursuant to which the Company issued 3,185,216 shares of common stock (consisting of 2,325,000 shares for the investor and 860,216 shares for Eshelman Ventures), 1,665,025 pre-funded warrants issued to the investor and common stock warrants to purchase up to 4,850,241 shares of common stock (consisting of 3,990,025 common stock warrants for the investor and 860,216 common stock warrants for Eshelman Ventures) in a registered direct offering priced at-the-market under Nasdaq Stock Market LLC ("Nasdaq") rules. The combined purchase price of each share of common stock and accompanying common stock warrant was $2.005 for the institutional investor and $2.325 for Eshelman Ventures, LLC. The purchase price per pre-funded warrant and accompanying common stock warrant was $2.004 for the institutional investor. The net proceeds from the offering was $9.3 million, after deducting underwriting discounts, commission and offering expenses. The 3,990,025 common stock warrants issued to the institutional investor are exercisable immediately, will expire five years from the exercisable date and have an exercise price of $1.88 per share. The 860,216 common stock warrants issued to Eshelman Ventures, LLC are exercisable upon the approval by the Company's stockholders of the exercise of previously issued securities, the January 2022 Warrants, will expire five years following the exercise date and have an exercise price of $2.20 per share. The 1,665,025 pre-funded warrants are exercisable at any time until all of the pre-funded warrants are exercised in full and have an exercise price of $0.001. The Company evaluated the pre-funded warrants and the common stock warrants under ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*, and determined the warrants meet the requirements to be classified in permanent equity.

The 1,665,025 pre-funded warrants issued to the institutional investor were exercised on June 6, 2022.

As of September 30, 2023, the Company has outstanding common stock warrants related to the registered direct offering as set forth below:

Number of Shares	Exercise Price	Expiration Date
3,990,025	$ 1.88	March 30, 2027
860,216	$ 2.20	March 30, 2027

Private placement equity financing

On October 27, 2022, the Company closed on definitive agreements with new biotechnology investors, existing investors, Company management and certain Company directors for the issuance and sale of an aggregate of 45,178,811 shares of its common stock (or pre-funded warrants in lieu thereof) and warrants to purchase up to an aggregate of 45,178,811 shares of common stock and/or pre-funded warrants in a private placement offering priced at-the-market under Nasdaq rules. The purchase price per share and accompanying warrant was $0.9199 for all who participated in the deal (or $0.9198 per pre-funded warrant and accompanying warrant). Fifty percent of the warrants have an exercise price of $0.7949 per share and will expire on the date that is the later of: (i) 15 months from the date an increase in the number of authorized shares of common stock is effected, or (ii) one month after the public announcement of the topline Phase 3 PROC data. The remaining 50% of the warrants will have an exercise price of $0.7949 per share and will expire 30 months from the date an increase in the number of authorized shares of common stock is effected. All of the warrants other than the pre-funded warrants are exercisable for cash only. The net proceeds from the private placement equity financing were approximately $40 million and will be used to fund the Company's clinical development programs.

As of September 30, 2023, the Company has outstanding common stock warrants related to the private placement as set forth below:

Security	Number of Shares		Exercise Price	Expiration Date
Pre-Funded	2,174,149	$	0.0001	No expiration
Series A	22,589,410	$	0.7949	April 16, 2024 (1)
Series B	22,589,401	$	0.7949	July 16, 2025

(1) These warrants expire on the date that is the later of: (i) 15 months from the date an increase in the number of authorized shares of common stock is effected (which occurred on January 17, 2023), or (ii) one month after the public announcement of the topline Phase 3 platinum-resistant ovarian cancer PROC data.

8. Stock Based Awards

Equity Incentive Plans

The Company’s Board and stockholders approved the 2019 Equity Incentive Plan (the "2019 Plan") which became effective on September 12, 2019. The 2019 Plan is a successor to and continuation of all prior plans including the Company’s 2014 Equity Incentive Plan and Aravive Biologics 2017 Equity Incentive Plan and the 2010 Equity Incentive Plan, as amended (the “Prior Plans”). As of September 30, 2023, the total number of shares of common stock available for issuance under the 2019 Plan was 2,587,941. In addition, if the shares subject to outstanding stock options or other awards under the Prior Plans: (I) terminate or expire prior to exercise or settlement; (II) are not issued because the award is settled in cash; (III) are forfeited because of failure to vest; (IV) or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, such shares will become available for issuance under the 2019 Plan. Unless the Board provides otherwise, beginning January 1, 2020 with expiration of January 1, 2029, the total number of shares of common stock available for issuance will automatically increase annually on January 1 of each calendar year by 4.5% of the total number of issued and outstanding shares of common stock as of December 31 of the immediately preceding year. The 2019 Plan provides for granting of equity awards to employees, directors and consultants, including incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance awards.

Inducement Stock Options

The Company granted employment inducement stock option awards, for 440,000 shares of common stock during the three months ended June 30, 2023. The employment inducement stock options were awarded in accordance with the employment inducement award exemption provided by Nasdaq listing rule 5635(c)(4) and was therefore not awarded under the Company’s stockholder approved equity plan. The option awards will vest under the Company's standard vesting terms for new employees as follows: 25% of the shares underlying the stock option award vesting on the first anniversary of the date of hire and the remaining 75% of the shares subject to the Option will vest in equal monthly installments over the next 36 months of continuous service. As discussed in Note 6, the Company approved a workforce reduction, as a result all of these inducement stock option awards were cancelled during the three months ended September 30, 2023.

Activity under the Company's stock option plan and inducement stock options is set forth below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Balances, January 1, 2023	4,570,432	$ 2.50		
Options granted	3,207,654	1.69		
Options expired	(43,838)	6.18		
Options forfeited	(2,385,156)	1.83		
Balances, September 30, 2023	5,349,092	$ 2.29	6.6	$ -
Outstanding and expected to vest as of September 30, 2023	5,028,804	$ 2.32	6.4	$ -
Exercisable as of September 30, 2023	3,300,921	$ 2.54	5.0	$ -

The intrinsic values of outstanding, expected-to-vest and exercisable options were determined by multiplying the number of shares by the difference in exercise price of the options and the fair value of the common stock. There were no stock options exercised during the nine months ended September 30, 2022 or 2023, respectively.

Stock Options Granted to Employees

During each of the nine months ended September 30, 2023 and 2022, the Company granted stock options to officers, directors and employees to purchase shares of common stock with a weighted-average grant date fair value of $1.45 and $1.54 per share, respectively. The fair value is being expensed over the vesting period of the options, which is usually 4 years on a straight-line basis as the services are being provided. No tax benefits were realized from options and other share-based payment arrangements during the periods.

As of September 30, 2023, total unrecognized employee stock-based compensation related to stock options granted was $2.3 million, which is expected to be recognized over the weighted-average remaining vesting period of 2.2 years.

The fair value of employee stock options was estimated using the Black-Scholes model with the following weighted-average assumptions:

	September 30, 2023	September 30, 2022
Expected volatility	115.9%	113.0%
Risk-free interest rate	3.5%	2.1%
Dividend yield	0.0%	0.0%
Expected life (in years)	6.0	6.0

Determining Fair Value of Stock Options – The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Expected Volatility – The expected volatility is based on the historical volatility of the Company's common stock over the most recent period commensurate with the estimated expected term of its stock options.

Risk-Free Interest Rate – The risk-free rate assumption was based on the U.S. Treasury instruments with terms that were consistent with the expected term of the Company's stock options.

Expected Dividend – The expected dividend assumption was based on the Company's history and expectation of dividend payouts.

Expected Term – The expected term of stock options represents the weighted average period the stock options are expected to be outstanding. For option grants that are considered to be "plain vanilla", the Company has opted to use the simplified method for estimating the expected term as provided by the SEC. The simplified method calculates the expected term as the average time-to-vesting and the contractual life of the options.

Forfeiture Rate – Forfeitures were estimated based on historical experience.

Fair Value of Common Stock – The fair value of the underlying common stock is based upon quoted prices on Nasdaq.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) *(unaudited)*

9. Net Income (Loss) Per Share of Common Stock

The following table summarizes the computation of basic and diluted net income (loss) per share of the Company (in thousands, except per share data):

	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Numerator:				
Net income (loss) attributable to common stockholders - basic	$ 21,226	$ (15,663)	$ (10,722)	$ (47,197)
Subtract: fair value adjustment of warrant liability (1)	-	—	25,616	—
Net income (loss) attributable to common stockholders - diluted	$ 21,226	$ (15,663)	$ (36,338)	$ (47,197)
Denominator:				
Weighted-average shares outstanding - basic	75,739	30,518	75,727	27,419
Dilutive effect of common stock warrants		—	19,003	—
Dilutive effect of options outstanding	354	—	711	—
Weighted-average shares outstanding - diluted	76,093	30,518	95,441	27,419
Net income (loss) per share:				
Basic	$ 0.28	$ (0.51)	$ (0.14)	$ (1.72)
Diluted	$ 0.28	$ (0.51)	$ (0.38)	$ (1.72)

(1) The Company assumes that the warrants will be share settled as they are considered dilutive and therefore the fair value adjustment is removed from the numerator in the diluted earnings per share calculation.

Basic net income (loss) attributable to common stockholders per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the period. For the calculation of basic net income (loss) per share, the weighted-average number of common shares outstanding for the period includes the weighted average effect of the Company’s 2,174,149 pre-funded warrants for the three months ended September 30, 2023, the exercise of which is not subject to contingencies and requires little or no consideration. Diluted net income (loss) attributable to common stockholders per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period, determined using the treasury-stock method and the as-if converted method, for convertible securities, if inclusion of these is dilutive. Because the Company has reported a net loss for the three months ended September 30, 2022 and for the nine months ended September 30, 2022, and the effect of the Company's common stock equivalents is anti-dilutive, diluted net loss per common share is the same as basic net loss per common share for those periods. For the three months ended September 30, 2023 the Company reported net income, however the effect of the Company’s common stock equivalents is anti-dilutive, diluted net loss per common share is the same as basic net income per common share for that period.

However, for the nine months ended September 30, 2023, and as a result of certain warrants and stock options having a dilutive effect, net income (loss) per share is calculated separately on a basic and diluted basis for that period.

The following potentially dilutive securities outstanding have been excluded from the computation of diluted shares outstanding for the three months ended September 30, 2023 and the nine months ended September 30, 2023:

	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Options to purchase common stock	4,995,483	4,638,530
Common stock warrants	50,029,052	31,025,632

ARAVIVE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) *(unaudited)*

10. Balance Sheet Components

Accrued Liabilities (in thousands)

	September 30,	
	2023	2022
Payroll and related	$ 274	$ 1,699
Clinical	1,680	4,943
Sublease prepayment	239	233
Professional services	40	116
Other	—	266
Total	$ 2,233	$ 7,257

11. Subsequent Events

On October 2, 2023, the Company's stockholders approved a proposal to transfer of all or substantially all of the Company assets through an assignment for the benefit of creditors if the Company's Board of Directors deems such transfer to be in the best interests of the Company's stockholders and a proposal to effect the voluntary dissolution and liquidation of the Company pursuant to a plan of dissolution if the Company's Board of Directors deems such action to be in the best interests of the Company's stockholders.

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

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our unaudited consolidated financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto for the year ended December 31, 2022, included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed on March 15, 2023 (the "Annual Report") with the U.S. Securities and Exchange Commission (the "SEC"). This discussion, particularly information with respect to our future results of operations or financial condition, business strategy, plans and objectives for future operations, includes forward-looking statements that involve risks and uncertainties as described under the heading "Special note regarding forward-looking statements" in this Quarterly Report on Form 10-Q. You should review the disclosure under the heading "Risk Factors" in this Quarterly Report on Form 10-Q and under Part 1, Item 1A of the Annual Report for a discussion of important factors that could cause our actual results to differ materially from those anticipated in these forward-looking statements. References in this Quarterly Report on Form 10-Q to "we," "us," "our" and similar first-person expressions refer to Aravive, Inc. and its subsidiary, Aravive Biologics, Inc. ("Aravive Biologics").

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. The statements contained in this report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "seek," "should," "strategy," "target," "will," "would" and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" included under Part II, Item 1A below and those identified under Part 1, Item 1A of the Annual Report. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Recent Clinical Developments

Topline Results for Global Phase 3 PROC Trial

In August 2023, we announced that our Phase 3 AXLerate-OC ("AXLerate") trial evaluating the safety and efficacy of batiraxcept in platinum-resistant ovarian cancer ("PROC") did not meet its primary endpoint of progression-free survival ("PFS") in the pre-specified subset of patients naïve to prior bevacizumab treatment. The trial also did not show any difference between the two arms in the overall population (which included patients previously treated with bevacizumab).

AXLerate enrolled 366 patients, and randomization was stratified for prior bevacizumab treatment; 50% of patients received bevacizumab prior to study entry. The statistical analysis plan called for a hierarchical approach for the assessment of PFS first in the bevacizumab-naïve population and then in the overall cohort of patients. In the bevacizumab-naïve population (n=179), the median PFS in the batiraxcept plus paclitaxel arm was 5.4 months, compared to 5.4 months in the paclitaxel arm. In the overall population, the median PFS in the batiraxcept plus paclitaxel arm was 5.1 months, compared to 5.5 months in the paclitaxel arm. None of these differences were statistically different. No new safety signals were identified.

Based on these data, we have terminated our P3 PROC trial and the PROC program.

Phase 2 Clear Cell Renal Cell Carcinoma (ccRCC) And Phase 1b Pancreatic Adenocarcinoma Trial

In order to preserve cash, we have terminated our P1b/P2 trials of batiraxcept in ccRCC and pancreatic adenocarcinoma and will not continue either the ccRCC or the pancreatic adenocarcinoma programs unless we raise additional capital.

Advancing either our ccRCC or pancreatic cancer program, would require us to raise significant additional capital or engage a strategic partner, which we believe would be very difficult in light of our recent PROC trial results and market conditions. In fact, we estimated that a Phase 2 clinical trial of batiraxcept in renal cancer patients will require funding of between $30 and $50 million and that a Phase 3 clinical trial of batiraxcept in ccRCC patients will require funding of between $80 and $100 million. We are currently exploring various strategic alternatives, including strategic partnerships, reverse merger candidates and financing opportunities related and unrelated to our historical operations. If we do not raise capital or successfully engage a strategic partner, we will be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection or engage in a similar process. On October 2, 2023, our stockholders approved the transfer of all or substantially all of our assets through an assignment for the benefit of creditors if our Board of Directors deems such transfer to be in the best interests of our stockholders and the voluntary dissolution and liquidation of the Company pursuant to a plan of dissolution that was attached to our proxy statement.

Other Cost Savings Measures

On August 18, 2023, our Board of Directors approved a workforce reduction of approximately 70% of our current employee base. The decision was based on our cash position and decision to terminate all clinical trials and conserve cash following our announcement that the Phase 3 clinical trial of batiraxcept for the treatment of PROC failed to meet its primary endpoint.

Overview

Historically, we have been a clinical-stage oncology company developing transformative treatments designed to halt the progression of life-threatening diseases, including cancer and fibrosis. We historically had one product candidate, batiraxcept, in clinical development. In August 2023, we announced a significant reduction in force, termination of all clinical activities, and that we were exploring strategic alternatives to maximize stockholder value. We are currently exploring various strategic alternatives, including strategic partnerships and financing opportunities related and unrelated to our historical operations. If we do not raise capital or successfully engage a strategic partner, we will be forced to cease operations, liquidate assets and possibly seek bankruptcy protection or engage in a similar process.

Important Note

This Management's Discussion and Analysis of Financial Condition and Results of Operations includes a discussion of our operations for the three and nine months ended September 30, 2023 and 2022.

References in this report to "we," "us," "our" and similar first-person expressions refer to Aravive, Inc. and its subsidiaries, including Aravive Biologics.

Financial Overview

Revenue

To date, we have not generated any revenue from commercial sales of any of our product candidates. However, for the three and nine months ended September 30, 2023, we generated approximately $2.8 million and $5.5 million in collaboration revenue, respectively, from the 3D Medicine Agreements and other income.

In the future, we do not anticipate generating revenue from research and development activities as we have terminated our P3 PROC trial and the PROC program and terminated our P1b/P2 trials of batiraxcept in ccRCC and pancreatic adenocarcinoma and will not continue either the ccRCC or the pancreatic adenocarcinoma programs unless we raise additional capital, which to date we have been unable to do. Although we are seeking strategic alternatives it is unlikely that any strategic alternative, will provide additional funding sufficient to continue our research and development of batiraxcept.

Research and Development Expenses

We recognize both internal and external research and development expenses as incurred. Our external research and development expenses consist primarily of:

- the cost of acquiring and manufacturing clinical trial and other materials, including expenses incurred under agreements with contract manufacturing organizations;
- expenses incurred under agreements with contract research organizations, investigative sites, and consultants that conduct our clinical trials; and
- other costs associated with development activities, including additional studies;

Internal research and development costs consist primarily of salaries and related fringe benefit costs for our employees (such as workers' compensation and health insurance premiums), stock-based compensation charges and travel costs.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not included in research and development.

Other Income, Net

Other income, net is primarily comprised of sublease income for our 1020 Marsh Facility lease, gains and losses on foreign currency transactions related to third party contracts with foreign-based contract manufacturing organizations and change in fair value of the warrant liability.

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that we have prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to revenue recognition and estimated future research and development expenses, warrant liabilities and stock-based compensation. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Historically, revisions to our estimates have not resulted in a material change to the financial statements.

Clinical Trial Accruals

Our clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and Clinical Research Organization (“CROs”) that conduct and manage clinical trials on our behalf.

Our estimates of preclinical and clinical trial expenses are based on the services performed, pursuant to contracts with research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. In accruing service fees, we estimate the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

The preceding estimates and judgment materially affect our research and development expenses. Changes in our estimates of patient enrollment and related costs could have a material effect on our research and development expenses.

Stock-Based Compensation

For purposes of calculating stock-based compensation, we estimate the fair value of share-based compensation awards using a Black-Scholes option-pricing model. The determination of the fair value of stock-based compensation awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including but not limited to expected stock price volatility over the term of the awards and the expected term of stock options.

If factors change and we employ different assumptions, share-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining stock-based compensation expense and the actual factors which become known over time, we may change the input factors used in determining stock-based compensation expense for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made. For actual forfeitures, we recognize the adjustment to compensation expense in the period the forfeitures occur.

Warrant Liability

The Company estimates the fair value of these liabilities using assumptions that are based on the individual characteristics of the warrants on the valuation date and reporting date. The Company uses the Black-Scholes option-pricing model and the fair value of the underlying stock to determine the fair value of these liabilities. The valuation model is based on inputs as of the valuation dates, including the estimated volatility of our stock, the remaining contractual term of the warrants and the risk-free interest rates and various other factors.

If factors change and we employ different assumptions, the warrant liability and other income/expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining the warrant liability and the actual factors which become known over time, we might change our inputs used in the valuation model. These changes, if any, may materially impact our results of operations in the period such changes are made.

Additional Information

Refer to Note 2 to the condensed consolidated financial statements for more information on accounting pronouncements that have impacted or are expected to materially impact our consolidated financial condition, results of operations, or cash flows.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2023 and 2022

The following table summarizes our net loss during the periods indicated (in thousands, except percentages):

	Three Months Ended September 30,		Increase/ (Decrease)		Nine Months Ended September 30,		Increase/ (Decrease)	
	2023	2022			2023	2022		
Revenue:								
Collaboration revenue	$ 2,756	$ 4,956	$ (2,200)	-44%	$ 5,520	$ 7,663	$ (2,143)	-28%
Operating expenses:								
Research and development	8,730	18,668	(9,938)	-53%	35,435	48,985	(13,550)	-28%
General and administrative	2,940	2,836	104	4%	9,499	9,651	(152)	-2%
Total operating expenses	11,670	21,504	(9,834)	-46%	44,934	58,636	(13,702)	-23%
Loss from operations	(8,914)	(16,548)	(7,634)	-46%	(39,414)	(50,973)	(11,559)	-23%
Total other income (expense), net	30,140	885	(29,255)	(A)	28,692	3,776	(24,916)	(A)
Net income (loss)	$ 21,226	$ (15,663)	$ (36,889)	-236%	$ (10,722)	$ (47,197)	$ (36,475)	-77%

(A) Not meaningful

Collaboration Revenue

In November 2020, we entered into the 3D Medicines Agreement. Collaboration revenue for the three and nine months ended September 30, 2023 was $2.8 million and $5.5 million, respectively, compared to collaboration revenue for the three and nine months ended September 30, 2022 of $5.0 million and $7.7 million, respectively. The decrease in revenue for the three and nine months ended September 30, 2023 relative to the same period in 2022 is a result of recognition of revenue related to a milestone achieved in 2022, as compared to no milestones achieved in 2023.

Research and Development Expense

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development expenses				
PROC	$ 4,503	$ 6,348	$ 15,184	$ 19,556
ccRCC	905	1,585	3,169	3,964
PDAC	668	609	2,169	2,531
CMC (1)	480	7,689	6,577	15,194
Other personnel and unallocated (2)	2,174	2,437	8,336	7,740
Total research and development expense	$ 8,730	$ 18,668	$ 35,435	$ 48,985

(1) As of September 30, 2023, we had one product candidate, batiraxcept, being investigated in our clinical trials across all indications. Costs related to production and testing for CMC activities are not allocated on a program-by-program basis.
(2) Costs (primarily personnel) are related to all research and development programs and are not allocated on a program-by-program basis.

Research and development expense decreased by $9.9 million, or 53%, to $8.7 million for the three months ended September 30, 2023, from $18.7 million for the same period in 2022. The most significant driver of this decrease in research and development expense was a decrease in expenditures related to our Phase 3 PROC trial. The decrease in PROC expenses to $4.5 million in the three months ended September 30, 2023 from $6.3 million for the same period in 2022 was driven primarily by decreased CRO costs as the study was terminated in August of 2023. Research and development costs associated with our Phase 1b/2 ccRCC trial decreased to $0.9 million for the three months ended September 30, 2023 from $1.6 million for the same period in 2022. The decrease was driven primarily by decreased CRO costs as the study was terminated in August of 2023. Research and development costs associated with our Phase 1 PDAC trial were $0.7 million for the three months ended September 30, 2023 from $0.6 million for the same period in 2022. Research and development costs associated with CMC activities decreased to $0.5 million for the three months ended September 30, 2023 from $7.7 million for the same period in 2022. The decrease was primarily driven by decreased drug product manufacturing and quality testing expenses, as all of our studies were terminated in August of 2023. Other research and development expense decreased to $2.2 million for the three months ended September 30, 2023 from $2.4 million for the same period in 2022. The decrease was driven primarily by decrease employee costs allocated to research and development activities due to the reduction in force in August 2023.

Research and development expense decreased by $13.6 million, or 28%, to $35.4 million for the nine months ended September 30, 2023, from $49.0 million for the same period in 2022. The most significant driver of this decrease in research and development expense was a decrease in expenditures related to our Phase 3 PROC trial. The decrease in PROC expenses to $15.2 million in the nine months ended September 30, 2023 from $19.6 million for the same period in 2022 was driven primarily by decreased CRO costs due to the study ramping up in 2022, while the study was terminated in August of 2023. Research and development costs associated with our Phase 1b/2 ccRCC trial decreased to $3.2 million for the nine months ended September 30, 2023 from $4.0 million for the same period in 2022. Research and development costs associated with our Phase 1 PDAC trial decreased to $2.2 million for the nine months ended September 30, 2023 from $2.5 million for the same period in 2022. The decrease was driven primarily by decreased CRO costs as the study was terminated in August of 2023. Research and development costs associated with CMC activities decreased to $6.6 million for the nine months ended September 30, 2023 from $15.2 million for the same period in 2022. The decrease was primarily driven by decreased drug product manufacturing, as all of our studies were terminated in August of 2023. Other research and development expense increased to $8.3 million for the nine months ended September 30, 2023 from $7.7 million for the same period in 2022. The increase was driven primarily by increased employee headcount allocated to research and development activities.

General and Administrative Expense

General and administrative expense increased by $0.1 million, or 4%, to $2.9 million in the three months ended September 30, 2023 from $2.8 million for the same period in 2022. The slight increase in general and administrative expense during the three months ended September 30, 2023 compared to the same periods in 2022 was primarily driven by commercial activity in 2023 which was not incurred in 2022. General and administrative expense decreased by $0.2 million, or 2%, to $9.5 million in the nine months ended September 30, 2023 from $9.7 million for the same period in 2022. The decrease in general and administrative expense during the nine months ended September 30, 2023 compared to the same periods in 2022 was primarily driven by lower consulting, legal and insurance expenses.

Other Income (Expense), Net

Total other income (expense), net increased by $29.3 million to $30.1 million for three months ended September 30, 2023 compared to $0.9 million for the same period in 2022. This increase was primarily driven by the change in fair value of our warrant liabilities of $29.2 million for the three months ended September 30, 2023. The gain on the fair value of our warrant liabilities is primarily due to a decrease in our stock price in relation to the exercise price of the warrants and the related increase in volatility. Total other income (expense), net increased by $24.9 million to $28.7 million for nine months ended September 30, 2023 compared to $3.8 million for the same period in 2022. This increase was primarily driven by the change in fair value of our warrant liabilities of $25.6 million for the nine months ended September 30, 2023.

Liquidity and Capital Resources

Since our inception and through September 30, 2023, we have financed our operations through private placements of our equity securities, public offerings of our equity securities, debt financing, CPRIT grant proceeds, sales of common stock through our at-the-market facility as well as payments received from license agreements. As of September 30, 2023, we had an accumulated deficit of approximately $626.8 million, primarily as a result of research and development and general and administrative expenses, and a working capital deficit of approximately $0.2 million. As of October 31, 2023, we had cash and cash equivalents of approximately $5.1 million, a majority of which is invested in money market funds at several highly rated financial institutions. We expect our cash and cash equivalents will not be sufficient to sustain operations beyond the fourth quarter of 2023. Although management has been successful in raising capital in the past, we may not be successful in raising sufficient cash to continue our operations, especially in light of the recent results from the Phase 3 AXLerate-OC trial and the discontinuance of our other clinical trials. The announcement in August 2023 that our Phase 3 AXLerate-OC trial evaluating the safety and efficacy of batiraxcept in platinum-resistant ovarian cancer did not meet its primary endpoint and the resulting decline in the trading price of our common stock and has negatively impact our ability to raise capital. In order to preserve cash, we have terminated our P1b/P2 trials of batiraxcept in ccRCC and pancreatic adenocarcinoma and will not continue either the ccRCC or the pancreatic adenocarcinoma programs unless we raise additional capital. We would need to conduct additional trials in the future to continue to pursue regulatory approval of batiraxcept in the United States, which we believe will be unlikely.

We are currently exploring various strategic alternatives, including strategic partnerships and financing opportunities related and unrelated to historical operations. If we do not raise capital or successfully engage a strategic partner, we will be forced to cease operations, liquidate its assets and possibly seek bankruptcy protection or engage in a similar process. On October 2, 2023, our stockholders approved the transfer of all or substantially all of our assets through an assignment for the benefit of creditors if our Board of Directors deems such transfer to be in the best interests of our stockholders and the voluntary dissolution and liquidation of the Company pursuant to a plan of dissolution. The consolidated financial statements included in this Quarterly Report on Form 10-Q do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should we be unable to continue as a going concern.

During 2021 and 2022, our primary sources of funding have been milestone payments from 3D Medicines and proceeds from the sale of our common stock and other securities. In November 2020, June 2021 and August 2021, we received $12 million, $6 million and $3 million, respectively, in upfront and milestone payments from 3D Medicines pursuant to the 3D Medicines Agreement we entered into with them. In October 2022, we received a $6 million milestone payment from 3D Medicines. On February 18, 2021, we received approximately $21 million from the purchase by Eshelman Ventures of 2,875,000 shares of our common stock. On September 4, 2020, we entered into an equity distribution agreement (the "Equity Distribution Agreement") with Piper Sandler and Cantor Fitzgerald to sell shares of our common stock, from time to time, through an “at the market offering” program having an aggregate offering price of up to $60,000,000 through which Piper Sandler and Cantor Fitzgerald will act as sales agents. During the year ended December 31, 2021, we sold 1,432,627 shares of common stock for net proceeds of $9.8 million under the Equity Distribution Agreement. On January 5, 2022, we received approximately $9.9 million in net proceeds from the purchase by Eshelman Ventures, LLC of pre-funded warrants to purchase up to 4,545,455 shares of our common stock. In March 2022, we received approximately $9.3 million in net proceeds, in the aggregate, from the purchase by Eshelman Ventures, LLC and a single healthcare-focused institutional investor of 3,185,216 shares of our common stock, 1,665,025 March Pre-Funded Warrants and March Common Stock Warrants to purchase up to 4,850,241 shares of our common stock in a registered direct offering. In October 2022, we received approximately $40 million in net proceeds from a private placement offering from new biotechnology investors, existing investors, our management and certain of our Directors for the issuance and sale of an aggregate of 45,178,811 shares of our common stock (or October Pre-Funded Warrants in lieu thereof) and October Common Warrants to purchase up to an aggregate of 45,178,811 shares of common stock in a private placement offering priced at-the-market under Nasdaq rules. The purchase price per share and accompanying October Common Warrant was $0.9199 for all investors who participated in the deal (or $0.9198 per October Pre-Funded Warrant and accompanying October Common Warrant). During the year ended December 31, 2022, we sold 54,763 shares of common stock for net proceeds of $0.1 million under the Equity Distribution Agreement. We sold no shares of common stock and received no net proceeds under the Equity Distribution Agreement during the three and nine months ended September 30, 2023. Due to our stock price as of the date of the filing of this Quarterly Report on Form 10-Q, our trading volume and the number of shares of common stock held by affiliates, it is unlikely we will be able to generate significant, if any, funding from the Equity Distribution Agreement or our registration statements on Form S-3.

Cash Flows

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

	Nine Months Ended September 30,	
	2023	2022
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$ (45,216)	$ (50,843)
Financing activities	25	19,320
Net (decrease) in cash and cash equivalents	$ (45,191)	$ (31,523)

Cash Used in Operating Activities

Net cash used in operating activities was $45.2 million and $50.8 million during the nine months ended September 30, 2023 and 2022, respectively, which was primarily due to the use of funds in our operations related to the development of batiraxcept, our product candidate. Cash used in operating activities for the nine months ended September 30, 2023 decreased compared to the same period in 2022 due primarily to a decrease in CRO costs due to all of our trials terminated in August of 2023, and a decrease in manufacturing costs in 2023 as compared to the same period in 2022.

Cash Provided by Financing Activities

Cash provided by financing activities of $25 thousand during the nine months ended September 30, 2023 related to share purchases through our employee stock purchase plan. Financing activities related to the nine months ended September 30, 2022 included a registered direct offering of our securities with proceeds of $19.2 million along with at the market offering proceeds of $0.1 million.

Contractual Obligations and Commitments

During the nine months ended September 30, 2023, there were no other material changes to our contractual obligations and commitments described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Annual Report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

An evaluation as of September 30, 2023 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our “disclosure controls and procedures.” Rule 13a-15(e) under the Exchange Act defines “disclosure controls and procedures” as controls and other procedures of a company that are designed to ensure that the 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, and that such information is accumulated and communicated to a company’s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level at September 30, 2023.

Changes in Internal Control Over Financial Reporting

During the quarter ended September 30, 2023, there were no changes in the Company’s internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. As set forth above, our Chief Executive Officer and Chief Financial Officer have concluded, based on the evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. You should consider carefully the following risks, together with all the other information in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and notes thereto. If any of the following risks actually materializes, our operating results, financial condition and liquidity could be materially adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment. The following information updates, and should be read in conjunction with, the information disclosed in Part I, Item 1A, "Risk Factors," contained in the Annual Report. Except as disclosed below, there have been no material changes from the risk factors disclosed in the Annual Report.

Risks Related To Our Clinical Trials

We are in the process of evaluating strategic alternatives and assessing our clinical programs in renal and pancreatic cancer following the failure of the Phase 3 clinical trial for our only product candidate, batiraxcept, for the treatment of PROC, to meet its primary endpoint.

We do not have any products that have gained regulatory approval. Our only clinical-stage product candidate is batiraxcept. On August 2, 2023, we announced that the Phase 3 clinical trial of batiraxcept for the treatment of PROC failed to meet its primary endpoint. Based on the Phase 3 clinical data, we have terminated the Phase 3 PROC trial and the PROC program. The Company's existing cash and cash equivalents will not be sufficient to complete the clinical development and commercialization of batiraxcept for clear cell renal cell cancer (ccRCC) or pancreatic cancer. In order to preserve cash, the Company has also discontinued the P1b/P2 trials in ccRCC and pancreatic ductal adenocarcinoma and will not continue either the ccRCC or pancreatic programs unless we raise additional capital from investors supporting such a use of proceeds, which based upon our current stock price is unlikely.

We are currently exploring various strategic alternatives, including strategic partnerships, the sale of its assets and financing opportunities related and unrelated to historical operations. If we do not raise capital or successfully engage a strategic partner, we will be forced to cease operations, liquidate its assets and possibly seek bankruptcy protection or engage in a similar process. On October 2, 2023, our stockholders approved the transfer of all or substantially all of our assets through an assignment for the benefit of creditors if our Board of Directors deems such transfer to be in the best interests of our stockholders and the voluntary dissolution and liquidation of the Company pursuant to a plan of dissolution.

We currently have only one product candidate, batiraxcept and are dependent on the success of batiraxcept.

Presently we have been developing one clinical product candidate, batiraxcept, as a potential treatment for several types of cancer. Based on the topline results of our Phase 3 AXLerate-OC trial evaluating the safety and efficacy of batiraxcept in platinum-resistant ovarian cancer, we are no longer developing batiraxcept for the treatment of PROC and will no longer submit the planned BLA to the FDA at the end of 2023. In order to preserve cash, the Company has also discontinued the P1b/P2 trials in ccRCC and pancreatic ductal adenocarcinoma and will not continue either the ccRCC or pancreatic programs unless we raise additional capital. Accordingly, we no longer have any product candidate being developed. We estimated that a Phase 2 clinical trial of batiraxcept in renal cancer patients will require funding of between $30 and $50 million and that a Phase 3 clinical trial of batiraxcept in ccRCC patients will require funding of between $80 and $100 million. We do not have sufficient resources to fund any additional trials of batiraxcept, have not received any offers from collaborators or partners to support financing necessary to conduct additional trials and it is unlikely that we will be able to raise sufficient funds to support additional clinical trials prior to our cash position getting to the point that we will need to pursue the winding down and dissolution of the Company.

Our License Agreement with Stanford University provides Stanford University with the right to terminate the license if we are not diligently developing and commercializing batiraxcept. We have terminated all clinical trials of batiraxcept and do not currently have sufficient funds to commence additional clinical trials. If the license agreement with Stanford University were terminated, we would no longer have any rights to develop our only product candidate.

We may not be successful in identifying and implementing any strategic business combination or other transaction.

We continue to evaluate various potential strategic options, including a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction. To date, we have been unable to secure additional equity, debt or other financing and have been unsuccessful in our efforts to successfully consummate any particular strategic transaction. The biotech industry is a competitive industry and thus there are numerous competitors for strategic transactions with a limited number of parties seeking a transaction on terms that would be beneficial to our shareholders. The process of evaluating these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business. Any delays in identifying a potential counterparty will cause our cash balance to continue to deplete, which will make us less attractive as a strategic counterparty. This termination of all clinical trials creates continued uncertainty for our employees and this uncertainty may adversely affect our ability to retain key employees necessary to maintain our ongoing operations or to execute any potential strategic options, which could have a material adverse effect on our business. Further, our market capitalization is below the value of our cash and cash equivalents. Potential counterparties in a strategic transaction involving our company may place minimal or no value on our remaining assets. As a result, we may not be able to execute on a strategic transaction before our cash position gets reduced, as a result of running a public company, to the point that we will need to pursue the winding down and dissolution of the Company.

Any strategic transactions that we may consummate could have negative consequences.

Any strategic business combination or other transactions that we may consummate could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affect our business and decrease the value of the Company. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be successfully consummated, lead to increased stockholder value, or achieve the results hoped for. Any failure of such potential transaction to achieve the anticipated results could significantly impair the ability of a shareholder to realize any benefit from any future strategic transaction.

If we are successful in completing any strategic transaction, we may be exposed to other operational and financial risks.

The negotiation and consummation of any strategic transaction may require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our Company or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If a strategic transaction is not consummated, including a financing, our Board may decide to pursue a dissolution and liquidation of our remaining assets. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for current debts and commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed prior to our cash position getting to the point that we will need to pursue the winding down and dissolution of the Company. To date, we have been unable to secure additional equity, debt or other financing and have been unsuccessful in our efforts to consummate a strategic transaction. If a strategic transaction is not completed, our Board may decide to pursue an assignment for the benefit of creditors (which the stockholders have authorized), a reorganization or a dissolution of the Company and liquidation of all our remaining assets (which the stockholders have authorized). In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. The process of liquidation may be lengthy and we cannot make any assurances regarding the timing of completing such a process. If our Board were to approve and effect a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. It is unlikely that the amount of available cash that will be available to distribute to stockholders after paying our debts and other obligations and setting aside funds for reserves, nor as to the timing of any such distribution. Our financial commitments and contingent liabilities would include: (i) personnel costs, including severance; (ii) contractual obligations to vendors and clinical study sites; (iii) non-cancelable lease obligations; and (iv) potential litigation against us.

As a result of the requirement to reserve for contingencies, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

We may become involved in securities class action litigation that could divert management's attention and harm the Company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as discontinuations of clinical programs. These events may also result in investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Risks Related to Our Financial Position and Capital Requirements

We do not currently have sufficient working capital to fund our planned operations for the next twelve months and may not be able to continue as a going concern. There is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

As of November 9, 2023, the issuance date of the consolidated financial statements, there is substantial doubt about our ability to continue as a going concern, as we currently do not have adequate financial resources to fund our forecasted operating costs for at least twelve months from the filing of this Quarterly Report on Form 10-Q. As of October 31, 2023, we had a cash and cash equivalents balance of approximately $5.1 million consisting of cash and investments in highly liquid U.S. money market funds. As of September 30, 2023, we have incurred a accumulated deficit of $626.8 million. At December 31, 2022, we had a cash and cash equivalents balance of approximately $53.7 million consisting of cash and investments in highly liquid U.S. money market funds. At December 31, 2022, we had an accumulated deficit of $616.1 million. For the nine months ended September 30, 2023, we reported net losses of $10.7 million and for the years ended December 31, 2022 and 2021, we reported net losses of $76.3 million and $39.2 million, respectively. As a result, our existing cash resources are not sufficient to meet our anticipated needs over the next twelve months from the date hereof or past the fourth quarter, even after taking into account our significantly reduced operations, and we would need to raise additional capital to continue our operations.

Our operating history and near-term forecast of incurring net losses and negative operating cash flows raise substantial doubt about our ability to continue as a going concern. We believe that our current cash and cash equivalents will not be sufficient to fund our operations beyond the fourth quarter of 2023 and that we will need to raise additional capital in order to avoid a wind down and dissolution of the Company. Our auditors also included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2022 with respect to this uncertainty. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Since inception, we have incurred net losses and negative cash flows from operations. We may not be successful or needed financing may not be available. In light of the failure to meet the primary endpoint of our Phase 3 AXLerate-OC trial evaluating the safety and efficacy of batiraxcept in platinum-resistant ovarian cancer, we believe our ability to attract investors willing to fund our company will be difficult. In addition, the resulting decline in the trading price of our common stock negatively impacted our ability to raise capital. Our existing cash and cash equivalents will not be sufficient to enable us to complete the clinical development and commercialization of batiraxcept for any indications or to in license any other product candidates and develop them. If are unable to raise capital or engage a strategic partner, we will be forced to cease operations and liquidate our assets and possibly seek bankruptcy protection or engage in a similar process. As such, we cannot conclude that such plans will be effectively implemented within one year after the date that the financial statements included in this Quarterly Report on Form 10-Q are filed with the SEC and there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

We have a limited operating history and have incurred significant losses since our inception, we do not have sufficient cash to continue our research and development efforts and we anticipate that we will continue to incur substantial and increasing losses for the foreseeable future. We have only one product candidate, batiraxcept, which is no longer under development and has no commercial sales, and we have to raise new capital, making our future viability uncertain.

Historically, we operated as a clinical-stage biopharmaceutical company with a limited operating history. We have never generated any product revenue and do not have any products currently in development or approved for sale.

In August 2023, we announced the Phase 3 AXLerate-OC ("AXLerate") trial evaluating the safety and efficacy of batiraxcept in PROC did not meet its primary endpoint. As a result, we have terminated the Phase 3 PROC trial and the PROC program. Our existing cash and cash equivalents will not be sufficient to complete the clinical development and commercialization of batiraxcept for clear cell renal cell cancer (ccRCC) or pancreatic cancer. In order to preserve cash, we have also discontinued the P1b/P2 trials in ccRCC and pancreatic ductal adenocarcinoma and will not continue either the ccRCC or pancreatic programs unless we raise additional capital. We are currently exploring various strategic alternatives, including strategic partnerships and financing opportunities. If we do not raise capital or successfully engage a strategic partner, it will be forced to cease operations, liquidate its assets and possibly seek bankruptcy protection or engage in a similar process.

We have incurred significant losses since inception and expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred significant operating losses in each year since our inception and expect to incur substantial and increasing losses for the foreseeable future. As of September 30, 2023, we had an accumulated deficit of approximately $626.8 million.

To date, we have financed our operations primarily through private placements of our equity securities, debt financing, CPRIT grant proceeds, at-the-market offerings of our common stock, public offerings of our securities as well as upfront and milestone payments received from license agreements. We do not have any revenue generated from operations and will need to raise capital in order to avoid a wind down and dissolution of the Company. We have devoted substantially all of our efforts to research and development, including clinical studies, but have not completed development of any product candidate. The announcement in August 2023 that our Phase 3 AXLerate-OC trial evaluating the safety and efficacy of batiraxcept in platinum-resistant ovarian cancer did not meet its primary endpoint and the resulting decline in the trading price of our common stock is further expected to negatively impact our ability to raise capital. We also anticipate that our stock price will continue to decline based upon the discontinuance of our other two programs, making it more difficult to raise money or find a strategic partner. Our existing cash and cash equivalents will not be sufficient to enable us to continue operations beyond the fourth quarter of 2023.

Our failure to meet the continued listing requirements of The Nasdaq Global Select Market could result in a de-listing of our common stock.

Our shares of common stock are listed for trading on The Nasdaq Global Select Market under the symbol "ARAV." If we fail to satisfy the continued listing requirements of The Nasdaq Global Select Market, Nasdaq may take steps to de-list our common stock or warrants.

On September 15, 2023, we received a letter from Nasdaq notifying us that for the preceding 30 consecutive business days (August 3, 2023 through September 14, 2023), the market value of our listed securities ("MVLS") did not maintain a minimum market value of $50,000,000 (the "Minimum MVLS Requirement") as required by Nasdaq Listing Rule 5450(b)(2)(A). On September 15, 2023, we also received a letter from Nasdaq notifying us that for the preceding 30 consecutive business days (August 3, 2023 through September 14, 2023), the market value of our publicly held shares ("MVPHS") did not maintain a minimum market value of $15,000,000 (the "Minimum MVPHS Requirement") as required by Nasdaq Listing Rule 5450(b)(2)(C). On

September 15, 2023, we also received a letter from Nasdaq notifying us that for the preceding 30 consecutive business days (August 3, 2023 through September 14, 2023), our common stock did not maintain a minimum closing bid price of $1.00 (“Minimum Bid Price Requirement”) per share as required by Nasdaq Listing Rule 5450(a)(1). In accordance with Nasdaq Listing Rules we have a compliance period of 180 calendar days, or until March 13, 2024, to regain compliance with the Nasdaq Listing Rules.

We intend to attempt to take actions to restore our compliance with Nasdaq’s listing requirements, but we can provide no assurance that that we will be able to do so. Any perception that we may not regain compliance or a delisting of our common stock by Nasdaq could adversely affect our ability to attract new investors, decrease the liquidity of the outstanding shares of our common stock, reduce the price at which such shares trade and increase the transaction costs inherent in trading such shares with overall negative effects for our stockholder. In addition, delisting of our common stock from Nasdaq could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, and might deter certain institutions and persons from investing in our common stock.

In the event of a de-listing, we would take actions to restore our compliance with The Nasdaq listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below The Nasdaq listing requirements.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as “covered securities.” Because our common stock is listed on Nasdaq, our common stock is covered securities. Although the states are preempted from regulating the sale of covered securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were to be delisted from Nasdaq, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities.

Our executive officers, directors, and entities under our control, and principal stockholders will continue to maintain the ability to control or significantly influence all matters submitted to stockholders for approval.

As of November 3, 2023, our current executive officers, directors and entities under their control, and principal stockholders, in the aggregate, beneficially owned shares representing approximately 51.6% of our common stock. Dr. Fredric N. Eshelman, our Executive Chairman beneficially owns 47.1% of our common stock and owns 34.7% of our outstanding voting stock. As a result, Dr. Eshelman acting on his own, would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, Dr. Eshelman will control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation by Reference Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Bylaws	S-1/A	333-193997	3.4	03/06/2014
3.2	Amended and Restated Certificate of Incorporation	8-K	001-36361	3.1	03/26/2014
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	8-K	001-36361	3.1	06/01/2017
3.4	Certificate of Amendment of Amended to the Amended and Restated Certificate of Incorporation, as amended	8-K	001-36361	3.1	09/12/2017
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation, as amended	8-K	001-36361	3.1	10/16/2018
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation, as amended	8-K	001-36361	3.2	10/16/2018
3.7	Certificate of Correction to Certificate of Amendment to the Amended and Restated Certificate of Incorporation, as amended	10-K	001-36361	3.6	03/15/2019
3.8	Certificate of Amendment of amended and restated certificate of incorporation of Aravive, Inc.	8-K	001-36361	3.1	01/18/2023
3.9	Amendment to Amended and Restated Bylaws	8-K	001-36361	3.1	11/03/2023
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act.				
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act.				
32.1*+	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act.				
32.2*+	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.				
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
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	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101)				

* Filed Herewith.

\+ This certification accompanies the Quarterly Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

\# Indicated management contract or compensatory plan

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.

	ARAVIVE, INC. (Registrant)
Date: November 9, 2023	By:/s/ Gail McIntyre
	Gail McIntyre Chief Executive Officer (Principal Executive Officer)
	ARAVIVE, INC. (Registrant)
Date: November 9, 2023	By:/s/ Rudy Howard
	Rudy Howard Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Gail McIntyre, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aravive, 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 Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 9, 2023

By: /s/ Gail McIntyre
Name: Gail McIntyre
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Rudy Howard, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Aravive, 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 Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 9, 2023

By: /s/ Rudy Howard
Name: Rudy Howard
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

I, Gail McIntyre, Chief Executive Officer (Principal Executive Officer) of Aravive, Inc. (the “Company”), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2023 (the “Form 10-Q”) fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented.

Dated: November 9, 2023

By: /s/ Gail McIntyre
Name: Gail McIntyre
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

I, Rudy Howard, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) of Aravive, Inc. (the “Company”), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2023 (the “Form 10-Q”) fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented.

Dated: November 9, 2023

By: /s/ Rudy Howard
Name: Rudy Howard
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)