

**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 March 31, 2022

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission file number: 001-36361

Aravive, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

2834
(Primary Standard Industrial
Classification Code Number)

26-4106690
(I.R.S. Employer
Identification Number)

River Oaks Tower
3730 Kirby Drive, Suite 1200
Houston, Texas 77098
(Address of principal executive offices)

(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 May 6, 2022, there were 28,825,028 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 MARCH 31, 2022

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2022	December 31, 2021
	(unaudited)	
Assets		
Current Assets		
Cash and cash equivalents	\$ 65,825	\$ 59,424
Prepaid expenses and other current assets	3,227	3,321
Total current assets	<u>69,052</u>	<u>62,745</u>
Restricted cash	2,431	2,431
Property and equipment, net	365	400
Operating lease right-of-use assets	2,020	2,207
Other assets	3	4
Total assets	<u>\$ 73,871</u>	<u>\$ 67,787</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 4,246	\$ 2,657
Accrued liabilities	8,840	8,416
Operating lease obligation, current portion	2,271	2,297
Current portion of deferred revenue	4,423	4,571
Total current liabilities	<u>19,780</u>	<u>17,941</u>
Deferred revenue, net of current portion	2,604	3,548
Operating lease obligation, net of current portion	3,516	4,076
Warrant liability	8,772	—
Total liabilities	<u>34,672</u>	<u>25,565</u>
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, \$0.0001 par value, 100,000,000 shares authorized at March 31, 2022 and December 31, 2021; 24,279,573 and 21,039,594 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	592,059	582,025
Accumulated deficit	(552,862)	(539,805)
Total stockholders' equity	<u>39,199</u>	<u>42,222</u>
Total liabilities and stockholders' equity	<u>\$ 73,871</u>	<u>\$ 67,787</u>

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	
	March 31,	
	2022	2021
Revenue		
Collaboration revenue	\$ 1,092	\$ 256
Total revenue	<u>1,092</u>	<u>256</u>
Operating expenses		
Research and development	13,002	5,884
General and administrative	3,088	2,380
Total operating expenses	<u>16,090</u>	<u>8,264</u>
Loss from operations	(14,998)	(8,008)
Other income (expense), net:		
Interest income	10	9
Change in fair value of warrant liability	1,228	—
Other income (expense), net	703	(5)
Total other income (expense)	<u>1,941</u>	<u>4</u>
Net loss	<u>\$ (13,057)</u>	<u>\$ (8,004)</u>
Net loss per share - basic and diluted	<u>\$ (0.62)</u>	<u>\$ (0.44)</u>
Weighted-average common shares used to compute basic and diluted net loss per share	<u>21,130</u>	<u>18,067</u>

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

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

	Three Months Ended March 31, 2022				
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
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	<u>24,279,573</u>	<u>\$ 2</u>	<u>\$ 592,059</u>	<u>\$ (552,862)</u>	<u>\$ 39,199</u>
	Three Months Ended March 31, 2021				
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at January 1, 2021	16,481,099	\$ 2	\$ 548,707	\$ (500,654)	\$ 48,055
Issuance of common stock upon exercise of options	77,858	—	260	—	260
Issuance of common stock in direct offering, net of issuance costs of \$98	2,875,000	—	20,866	—	20,866
Issuance of common stock in at the market offering	884,695	—	7,034	—	7,034
Stock-based compensation	—	—	505	—	505
Net loss	—	—	—	(8,004)	(8,004)
Balances at March 31, 2021	<u>20,318,652</u>	<u>\$ 2</u>	<u>\$ 577,372</u>	<u>\$ (508,658)</u>	<u>\$ 68,716</u>

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

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

	Three Months Ended	
	March 31,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (13,057)	\$ (8,004)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	222	240
Stock-based compensation expense	620	505
Warrant issuance costs	123	—
Warrant liability fair value adjustment	(1,228)	—
Changes in assets and liabilities		
Prepaid expenses and other assets	95	(1,656)
Accounts payable	1,589	443
Deferred revenue	(1,092)	(256)
Accrued and other liabilities	(162)	(1,291)
Net cash used in operating activities	<u>(12,890)</u>	<u>(10,019)</u>
Cash flows from financing activities		
Proceeds from issuance of common stock in connection with exercise of options	—	260
Proceeds from issuance of common stock and common stock warrants in direct offering, net of issuance costs	19,168	20,866
Proceeds from issuance of common stock in at the market offering	123	7,034
Net cash provided by financing activities	<u>19,291</u>	<u>28,160</u>
Net change in cash, cash equivalents, and restricted cash	6,401	18,141
Cash, cash equivalents, and restricted cash at beginning of period	61,855	62,971
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 68,256</u>	<u>\$ 81,112</u>

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") our wholly owned subsidiary was incorporated in 2007. Aravive is a clinical-stage oncology company developing transformative treatments designed to halt the progression of life-threatening diseases, including cancer and fibrosis.

The Company's lead product candidate, batiraxcept (formerly AVB-500), is an ultrahigh-affinity, decoy protein that targets the GAS6-AXL signaling pathway. By capturing serum GAS6, batiraxcept starves the AXL pathway of its signal, potentially halting the biological programming that promotes disease progression. AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression.

In July 2016, Aravive Biologics was approved for a \$20.0 million Product Development Award from the Cancer Prevention and Research Institute of Texas ("CPRIT Grant"). The CPRIT Grant was expected to allow Aravive Biologics to develop the product candidate referenced above through clinical trials. The CPRIT Grant was effective as of June 1, 2016 and terminated on November 30, 2019. The Company has received all \$20 million of the grant proceeds and has incurred all of the grant award proceeds by the termination date. Aravive Biologics' royalty and other obligations, including its obligation to repay the disbursed grant proceeds under certain circumstances, survive the termination of the grant contract. The CPRIT Grant was subject to customary CPRIT funding conditions including a matching funds requirement where Aravive Biologics matched 50% of funding from the CPRIT Grant. Consequently, Aravive Biologics was required to raise \$10.0 million in matching funds over the three-year project. Aravive Biologics raised all of its required \$10.0 million in matching funds.

Aravive Biologics' award from CPRIT requires it to pay CPRIT a portion of its revenues from sales of certain products, or received from its licensees or sublicensees, at tiered percentages of revenue in the low- to mid-single digits until the aggregate amount of such payments equals 400% of the grant award proceeds, and thereafter at a rate of less than one percent for as long as Aravive Biologics maintains government exclusivity. In addition, the grant contract also contains a provision that provides for repayment to CPRIT of the full amount of the grant proceeds under certain specified circumstances involving relocation of Aravive Biologics' principal place of business outside Texas.

In April 2020, the Company entered into a license and collaboration agreement with WuXi Biologics (Hong Kong) Limited, the objective of which is to identify and develop novel high-affinity bispecific antibodies against CCN2, also known as connective tissue growth factor ("CTGF"), implicated in cancer and fibrosis, and identified from a similar target discovery screen that identified the significance of the AXL/GAS6 pathway in cancer. The goal is to generate a best-in-class therapeutic targeting desmoplasia and tumor growth for initial investigation in the clinic in 2023.

In November 2020, the Company entered into a collaboration and license agreement with 3D Medicines Inc. ("3D Medicines") (the "Agreement or the 3D Medicine 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 mainland China, Taiwan, Hong Kong and Macau (the "Territory") for an upfront cash payment of \$12 million. During the second quarter of 2021, the Company received a \$6 million development milestone from 3D Medicines, for completing our first clinical milestone with 3D Medicines, dosing the first patient in its Phase 3 trial of batiraxcept in PROC.

In August 2021, the Company received a \$3 million development milestone from 3D Medicines based on the Center for Drug Evaluation ("CDE") of the China National Medical Products Administration ("NMPA") approval of the Investigational New Drug application ("IND") submitted by 3D Medicines to participate in the Company's international batiraxcept Phase 3 PROC clinical trial.

As consideration for the rights granted as part of a license agreement that Aravive Biologics entered into in 2012 with Leland Stanford Junior University ("Stanford University") for intellectual and tangible property rights relating to biologic inhibitors for therapeutic targeting the receptor tyrosine kinase AXL, Aravive Biologics is obligated to pay yearly license fees and milestone payments, and a royalty based on net sales of products covered by the patent-related rights. More specifically, Aravive Biologics is obligated to pay Stanford University (i) annual license payments (ii) milestone payments of up to an aggregate of \$1,000,000 upon achievement of clinical and regulatory milestones, and (iii) royalties equal to a percentage (in the low single digits) of net sales of licensed products; provided that the annual license payments made will offset (and be credited against) any royalties due in such license year. In the event of a sublicense to a third party of any rights based on the patents that are solely owned by Stanford University, Aravive Biologics is obligated to pay royalties to Stanford University equal to a percentage of what Aravive Biologics would have been required to pay to Stanford University had it sold the products under sublicense itself. In addition, in such event it is required to pay to Stanford University a percent of sublicensing income. In the event of a termination, Aravive Biologics will be obligated to pay all amounts that accrued prior to such termination.

As the Company advances its clinical programs, the Company is in close contact with its clinical research organizations ("CROs") and clinical sites and is continually assessing the impact of COVID-19 on its planned trials and current timelines and costs as well as the impact of the invasion and military attacks on Ukraine. The Company has experienced delays in patient enrollment due to the COVID-19 pandemic. In addition, the Company has experienced delays in patient enrollment due to the fact that several planned clinical sites in the Ukraine are no longer available for the Company's clinical trials. If the COVID-19 pandemic continues and persists for an extended period of time or increases in severity or the military situation in Ukraine expands into other countries where the Company has or plans to conduct clinical trials, the Company experiences delays in patient enrollment and deems it necessary or advisable to improve patient recruitment by, among other things, opening additional clinical sites, the Company could incur increased clinical program expenses. Any such disruptions or delays would, and any such increased clinical program expenses could, adversely affect the Company's business, financial condition, results of operations and growth prospects.

ARAVIVE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) *(unaudited)****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 March 31, 2022 and, its results of operations for the three months ended March 31, 2022 and 2021, and cash flows for the three months ended March 31, 2022 and 2021. The December 31, 2021 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, 2021 included in the Company's Annual Report on Form 10-K filed by the Company on March 31, 2022, 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 accounting principles generally accepted in the United States of America ("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.

ARAVIVE, INC.

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

The accompanying unaudited condensed consolidated statement of financial position as of March 31, 2022 and the results of operations for the three months ended March 31, 2022 and 2021 and cash flows for the three months ended March 31, 2022 and 2021 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 and negative cash flows from operations. At March 31, 2022, the Company had an accumulated deficit of \$552.9 million and working capital of \$49.3 million. The Company expects to continue to incur losses from costs related to the development of batiraxcept and related administrative activities for the foreseeable future. These factors raised 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 March 31, 2022, the Company had a cash and cash equivalents balance of \$65.8 million consisting of cash and investments in highly liquid U.S. money market funds. The Company intends to seek additional capital through equity and/or debt financings, collaborative or other funding arrangements with partners or through other sources of financing to fulfill its operating and capital requirement for the next 12 months to advance its clinical development program to later stages of development and potentially commercialize its clinical product candidate batiraxcept. Although management has been successful in raising capital in the past, there can be no assurance that the Company will be successful or that any needed financing will be available in the future at terms acceptable to the Company. If the Company is unable to raise additional funds when needed, the Company may be required to delay, reduce, or terminate some or all of its development programs and clinical trials. The Company may also be required to sell or license to others technologies or clinical product candidates or programs that it would prefer to develop and commercialize itself.

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 results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential drug candidates, uncertainty of market acceptance of the Company's products, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers.

Products developed by the Company require clearances from the U.S. Food and Drug Administration ("FDA"), the Pharmaceuticals Medicines and Devices Agency ("PMDA"), or other international regulatory agencies prior to commercial sales. There can be no assurance that the products will receive the necessary clearances. If the Company is denied clearance, clearance is delayed or the Company is unable to maintain clearance, it could have a material adverse impact on the Company.

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to launch and commercialize any product candidates for which it receives regulatory approval.

The Company relies on third-party manufacturers to purchase from their third-party vendors the materials necessary to produce product candidates and manufacture product candidates for clinical studies. The Company also depends on third-party suppliers for key materials and services used in research and development, as well as manufacturing processes, and are subject to certain risks related to the loss of these third-party suppliers or their inability to supply adequate materials and services. The Company does not control the manufacturing processes of the contract development and manufacturing organizations, or CDMOs, with whom it contracts and is dependent on these third parties for the production of its therapeutic candidates in accordance with relevant regulations (such as current Good Manufacturing Practices, or cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. In addition, the Company is dependent upon third-party suppliers for the materials needed to construct its cGMP facility as well as the equipment that will be needed to run the facility.

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 March 31, 2022 and December 31, 2021, 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.

ARAVIVE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) *(unaudited)****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 nonlease 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 January 2022 financing are classified as derivative liabilities on the consolidated balance sheets because the warrants are not indexed to the Company's own common stock. The warrants are presented on our consolidated balance sheets at their fair value on the date of issuance. At the end of each reporting period, changes in estimated fair value during the period are recognized as a component of other income (expense), net in our statement of operations. The Company will continue to adjust the carrying value of the warrants until such time as the warrants are no longer considered derivative liabilities, or until the earlier of the exercise of the warrants or the expiration of the warrants, at which time the liabilities will be reclassified to additional paid-in capital at their fair value.

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. 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.

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 March 31, 2022.

ARAVIVE, INC.

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

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.

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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 March 31, 2022 and Level 1 assets as of December 31, 2021. Level 1 securities are comprised of highly liquid money market funds. The Company's Level 3 warrant liability contains unobservable inputs that reflect the Company's own assumptions in which there is little, if any, market activity at the measurement date, thus the Company's warrant liability is measured at fair value on a recurring basis using unobservable inputs.

Preclinical and 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 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	
	March 31,	
	2022	2021
Operating Expenses		
Research and development	\$ 233	\$ 219
General and administrative	387	286
Total	<u>\$ 620</u>	<u>\$ 505</u>

Net Loss per Share of Common Stock

Basic net loss per common share is calculated by dividing the net 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 loss per share is computed by dividing the net 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 loss per share calculation, stock options and restricted stock units are considered to be potentially dilutive securities. Because the Company has reported a net loss for the three months ended March 31, 2022 and 2021, 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.

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, we have one collaboration agreement with 3D Medicines, see Note 4 for further discussion.

ARAVIVE, INC.

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

Revenue Recognition

The Company's sole source of revenue for 2022 and 2021 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 we satisfy 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.

ARAVIVE, INC.

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

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 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 perform 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 the Company 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.

ARAVIVE, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (unaudited)
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 March 31, 2022 (unaudited)			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	\$ 49,223	\$ 49,223	\$ —	\$ —
Liabilities				
Warrant liability	<u>\$ 8,772</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 8,772</u>

	Fair Value Measurements at December 31, 2021			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	<u>\$ 49,217</u>	<u>\$ 49,217</u>	<u>\$ —</u>	<u>\$ —</u>

Warrant liability

The Company's warrant liability contains unobservable inputs that reflected the Company's own assumptions in which there is little, if any, market activity at the measurement date. Accordingly, the Company's warrant liability is measured at fair value on a recurring basis using unobservable inputs at each reporting period. The warrant liability is classified as a Level 3 input. This liability is shown as a non-current liability on the balance sheet.

The fair value of the warrants is estimated using the Black-Scholes option-pricing model. 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 our 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.

On January 5, 2022, the Company entered into an investment agreement (the "Investment Agreement") with Eshelman Ventures, LLC a related party and, solely for purposes of Article IV and Article V of the Investment Agreement, Dr. Eshelman relating to the issuance of pre-funded warrants (the "January 2022 Warrants") to purchase up to 4,545,455 shares of the Company's common stock, par value \$0.0001 per share, at a price of \$2.20 per share, which was the consolidated closing bid price of the Company's common stock on Nasdaq on December 31, 2021, for an aggregate purchase price of \$10 million. On the issuance date, the January 2022 Warrants were valued at the aggregate purchase price of \$10 million and the Company received \$9.9 million in net proceeds. As of March 31, 2022, the 4,545,455 January 2022 Warrants are exercisable upon shareholder approval, which was obtained on April 1, 2022 (see Note 10), thereafter the January 2022 Warrants are exercisable at any time until all of the January 2022 Warrants are exercised in full and have an exercise price of \$0.0001.

At March 31, 2022, the Company estimated the fair values of the financial liability arising from these warrants using the following assumptions:

Parameter	January 2022 Warrants
Expected term (in years)	0.25
Expected volatility	112%
Risk-free interest rate	1.46%
Expected dividend yield	0.00%
Fair value of common share	\$ 1.93
Exercise price	\$ 0.0001

The warrant liability will increase or decrease each reporting period based on fluctuations of the fair value of the underlying common stock until such time this financial liability is no longer considered a derivative liability, or the earlier of settlement and expiration of warrants. The change in the fair value of the warrant liability for each presented period is recognized as a component of other income (expense), net in the consolidated statements of operations.

The following table provides a summary of changes in the estimated fair values of the Company's Level 3 financial liabilities, which are measured at fair value on a recurring basis using unobservable inputs (in thousands):

**January 2022
Warrants**

Balance at January 1, 2022	\$	—
Issuance of warrants		10,000
Change in fair value		(1,228)
Balance at March 31, 2022	\$	8,772

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 March 31, 2022 or December 31, 2021.

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 \$21 million (inclusive of \$9 million in milestone payments) and is eligible to receive from 3D Medicines cash payments of up to an aggregate of \$207 million (inclusive of \$9 million in milestone payments) 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 the 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.

ARAVIVE, INC.

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 Agreement contemplates that the Company will enter into ancillary arrangements with 3D Medicines, including a clinical supply agreement and a manufacturing technology transfer agreement.

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.

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 \$21.0 million transaction price as such: \$11.3 million to the research and development services performance obligation and \$9.7 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 March 31, 2022, 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 \$1.1 and \$0.3 million related to the research and development services for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, the Company had a contract liability balance of \$7.0 million of which \$4.4 million is classified as current and \$2.6 million is classified as long-term, consisting of deferred revenue related to a portion of the payment received from 3D Medicines. The Company recognized revenue of \$1.1 million for the three months ended March 31, 2022, related to the contract liability balance of \$8.1 million as of December 31, 2021. As of March 31, 2022, the service period for the future research and development services is expected to occur over the next 2.75 years.

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.

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

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 rent expense including both short-term and variable lease components of \$0.1 million associated with the facility leases was \$0.5 million and \$0.4 million for the three months ended March 31, 2022 and 2021, respectively. Cash paid for amounts included in the measurement of lease obligations for operating cash flows from operating leases was \$0.7 million and \$0.3 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, the Company's operating leases had a weighted average remaining lease term of 2.7 years and a weighted average discount rate of 7.64%, which approximates the Company's incremental borrowing rate.

As of March 31, 2022, minimum lease payments under non-cancelable operating leases by period were expected to be as follows (in thousands):

Year Ending December 31,	
2022 (9 months remaining)	\$ 2,222
2023	3,039
2024	2,619
2025	116
2026	31
Total future minimum lease payments	<u>8,027</u>
Less: discount	<u>(2,240)</u>
Total lease liabilities	<u>\$ 5,787</u>

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 has 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 three months ended March 31, 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 March 31, 2022. During the three months ended March 31, 2022, cash received from the Subtenant was \$0.7 million, which amount was included in operating cash flows.

Future base rent the Subtenant shall pay to the Company over the sublease term as of March 31, 2022, are as follows (in thousands):

Year Ending December 31,	
2022 (9 months remaining)	\$ 1,734
2023	2,372
2024	2,029
Total	<u>\$ 6,135</u>

6. Commitments and Contingencies**Purchase Commitments**

The Company conducts 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.

ARAVIVE, INC.

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

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.

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 March 31, 2022.

7. Common Stock and Common Stock Warrants

The Amended and Restated Certificate of Incorporation, authorizes the Company to issue 100,000,000 shares of common stock as of March 31, 2022. Common stockholders are entitled to dividends as and when declared by the Board of Directors, 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. During the three months ended March 31, 2022 and March 31, 2021 the Company sold 54,763 and 884,649 shares, respectively, of common stock that were registered under the Form S-3 and received proceeds net of discounts and offering costs of \$0.1 million and \$7.0 million, respectively, under the Equity Distribution Agreement.

Registered Direct Offerings**Related party transaction**

On February 12, 2021, the Company entered into a Securities Purchase Agreement, with Eshelman Ventures relating to the issuance and sale (the "Offering") of 2,875,000 shares of the Company's common stock at a price per share of \$7.29. The Offering closed on February 18, 2021 and the Company received aggregate proceeds from the Offering of approximately \$20.9 million, net of offering costs. Eshelman Ventures is an entity wholly owned by the Company's chairman of the board.

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 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 common stock warrants are exercisable at any time until all of the pre-funded common stock 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.

8. Stock Based Awards**Equity Incentive Plans**

The Company's Board of Directors (the "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 (Prior Plans). As of March 31, 2022, the total number of shares of common stock available for issuance under the 2019 Plan was 1,566,948. 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, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance awards.

ARAVIVE, INC.

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

Activity under the Company's stock option plan 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, 2022	2,439,253	\$ 3.96		
Options granted	1,543,200	2.14		
Options cancelled	(305,378)	3.70		
Options exercised	—	—		
Balances, March 31, 2022	<u>3,677,075</u>	<u>\$ 3.22</u>	7.8	\$ 1,379
Outstanding and expected to vest as of March 31, 2022	<u>3,176,415</u>	<u>\$ 3.23</u>	7.5	\$ 1,377
Exercisable as of March 31, 2022	<u>1,647,359</u>	<u>\$ 2.89</u>	5.7	\$ 1,371

The intrinsic values of outstanding, vested 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. The intrinsic value of stock options exercised during the three months ended March 31, 2021 was \$0.4 million, and there were no stock options exercised during the three months ended March 31, 2022.

Stock Options Granted to Employees

During the three months ended March 31, 2022 and 2021, 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 \$1.79 and \$5.13 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 March 31, 2022, total unrecognized employee stock-based compensation related to stock options granted was \$4.5 million, which is expected to be recognized over the weighted-average remaining vesting period of 3.2 years.

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

	March 31, 2022	March 31, 2021
Expected volatility	112.0%	113.5%
Risk-free interest rate	1.7%	0.6%
Dividend yield	0.0%	0.0%
Expected life (in years)	6.1	6.1

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 our common stock over the most recent period commensurate with the estimated expected term of our 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.

ARAVIVE, INC.

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

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.

9. Net loss per share of Common Stock

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

	Three Months Ended March 31,	
	2022	2021
Net loss	\$ (13,057)	\$ (8,004)
Basic and diluted net loss per share	\$ (0.62)	\$ (0.44)
Weighted-average shares used to compute basic and diluted net loss per share	21,130	18,067

Basic net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Weighted-average number of common shares outstanding for the period includes the weighted average effect of the Company’s pre-funded warrants issued on March 31, 2022, the exercise of which is not subject to contingencies and requires little or no consideration. Diluted net loss attributable to common stockholders per share is computed by dividing the net 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 each of the three months ended March 31, 2022 and 2021, the Company did not have dilutive common stock equivalents and therefore diluted net loss per common share is the same as basic net loss per common share for those periods.

The following potentially dilutive securities outstanding at the end of the three months ended March 31, 2022 and 2021 have been excluded from the computation of diluted shares outstanding:

	Three Months Ended March 31,	
	2022	2021
Options to purchase common stock	3,677,075	2,540,737
Pre-funded warrants to purchase common stock	4,545,455	—
Common stock warrants	4,850,241	—

10. Subsequent Events

On April 1, 2022, the Company held a Special Meeting of Stockholders at which the Company’s stockholders voted on the proposal and approved for the purposes of Nasdaq Listing Rule 5635(b), of the issuance of up to 4,545,455 shares of the Company’s common stock, par value \$0.0001 per share, in the aggregate (subject to adjustment under certain circumstances), pursuant to the January 2022 Warrants issued to Eshelman Ventures, LLC. On April 1, 2022, Eshelman Ventures, after obtaining the requisite approval from the Company’s stockholders at the Special Meeting, exercised the January 2022 Warrants in full and the Company issued 4,545,455 shares of Common Stock.

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, 2021, included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed on March 31, 2022 (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. (formerly known as Versartis, 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 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.

Overview

We are a clinical-stage oncology company developing transformative treatments designed to halt the progression of life-threatening diseases, including cancer and fibrosis.

Our lead product candidate, batiraxcept (formerly AVB-500), is an ultrahigh-affinity, decoy protein that targets the GAS6-AXL signaling pathway. By capturing serum GAS6, batiraxcept starves the AXL pathway of its signal, potentially halting the biological programming that promotes disease progression. AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression.

Our current development program benefits from the availability of a proprietary serum-based biomarker that has accelerated batiraxcept drug development by allowing us to select a pharmacologically active dose and may potentially identify the cancer patients that have the best chance of responding to batiraxcept.

In our completed Phase 1 clinical trial in healthy volunteers with our lead product candidate, batiraxcept, we have demonstrated proof of mechanism for batiraxcept in neutralizing GAS6. Importantly, batiraxcept had a favorable safety profile preclinically and in the first in human trial and Phase 1b clinical trial in cancer patients.

In August 2018, the FDA designated as a Fast Track development program the investigation of our lead development candidate, batiraxcept, for platinum-resistant recurrent ovarian cancer.

In December 2018, we initiated our Phase 1b clinical trial of batiraxcept combined with standard of care therapies in patients with PROC, for which we reported results in July 2020.

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In April 2020, we entered into a license and collaboration agreement with WuXi, the objective of which is to identify and develop novel high-affinity bispecific antibodies against CCN2, also known as CTGF, implicated in cancer and fibrosis and identified from a similar target discovery screen that identified the significance of the AXL/GAS6 pathway in cancer. The goal is to generate a best-in-class therapeutic targeting desmoplasia and tumor growth for initial investigation in the clinic in 2023.

In November 2020, we entered into 3D Medicines Agreement, whereby we 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 the Territory.

During the fourth quarter of 2020, we initiated our Phase 1b portion of the Phase 1b/2 trial of batiraxcept in ccRCC and we dosed our first patient in the trial in March 2021.

During the first quarter 2021, we initiated our registrational Phase 3 trial of batiraxcept in PROC and we dosed our first patient in the trial in April 2021. This global, randomized, double-blind, placebo-controlled adaptive trial is designed to evaluate efficacy and safety of batiraxcept at a dose of 15 mg/kg in combination with PAC versus PAC alone.

In May 2021, we announced expansion of batiraxcept development programs into first line pancreatic adenocarcinoma ("PA") with the goal of initiating the trial by end of 2021. We dosed our first patient in August 2021.

In June 2021, we announced positive initial safety, pharmacokinetic, and pharmacodynamic results from the batiraxcept Phase 1b portion of the Phase 1b/2 clinical trial in ccRCC.

In October 2021, the EMA granted orphan drug designation for batiraxcept for the treatment of ovarian cancer, following a recommendation from the Committee for Orphan Medicinal Products.

In November 2021, we announced positive preliminary data from our Phase 1b trial evaluating batiraxcept in combination with cabozantinib for treatment of ccRCC.

In January 2022, we announced that we had dosed the first patient in the Phase 2 portion of the Phase 1b/2 study of batiraxcept in combination with cabozantinib for treatment of ccRCC.

In March 2022, we announced updated positive data and new biomarker data from our Phase 1b trial of batiraxcept in ccRCC.

As we advance our clinical programs, we are in close contact with our CROs and clinical sites and are continually assessing the impact of COVID-19 on our planned trials and current timelines and costs as well as the impact of the invasion and military attacks on Ukraine. We have experienced delays in patient enrollment due to the COVID-19 pandemic. In addition, the Company has experienced delays in patient enrollment due to the fact that several planned clinical sites in Ukraine are no longer available for the Company's clinical trials. To date, we are on track to meet all of our recently announced clinical milestones. If the COVID-19 pandemic continues and persists for an extended period of time or increases in severity or the military situation in Ukraine expands into other countries, we could incur increased clinical program expenses. Any such disruptions or delays would, and any such increased clinical program expenses could, adversely affect our business, financial condition, results of operations and growth prospects.

Important Note

This Management's Discussion and Analysis of Financial Condition and Results of Operations includes a discussion of our operations for the three months ended March 31, 2022 and 2021.

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

Recent Clinical Developments

In January 2022, we announced that we had dosed the first patient in the Phase 2 portion of the Phase 1b/2 study of batiraxcept in combination with cabozantinib for treatment of ccRCC.

In March 2022, we announced updated safety and clinical activity data from the 26 patients from the Phase 1b trial evaluating batiraxcept in combination with cabozantinib for treatment of ccRCC. We also announced updated clinical activity for 13 patients in a trial evaluating batiraxcept in combination with gemcitabine and nab-paclitaxel in patients with advanced or metastatic pancreatic adenocarcinoma eligible to receive gemcitabine and nab-paclitaxel as first-line treatment.

On May 11, 2022, we provided updated data and information at our Key Opinion Leader symposium that included the following.

- New unpublished data from Dr. Katherine Fuh showed that biomarker high naïve ovarian cancer patients that had been shown to have a 47% response rate in the Phase 1b platinum-resistant ovarian cancer (PROC) study were poor responders to initial chemotherapy (i.e., treatment that did not contain batiraxcept).
- Updated data as of April 30, 2022 from the ccRCC Phase 1b trial from 26 patients treated with batiraxcept in the Phase 1b portion of the trial at doses of 15 mg/kg (n=16) and 20 mg/kg (n=10), plus cabozantinib 60 mg daily in previously treated (2L+) patients with ccRCC:
 - o There were no dose limiting toxicities observed at either dose;
 - o 14 of the 26 patients remain on study with 9 out of the 12 patients who ended treatment still in survival follow-up;
 - o The best overall response rate (ORR, confirmed + unconfirmed) was 46% across both doses in the ITT population and 50% in patients dosed with 15 mg/kg (the recommended Phase 2 dose);
 - o The best ORR was 60% across both doses in the biomarker high population and 67% in the biomarker high population dosed at 15

mg/kg;

- o The 7-month progression-free survival (PFS) rate was 71% across both doses in the ITT population, 83% across both doses in the biomarker high population, and 91% in the 15 mg/kg biomarker high group; and
- o Eight patients (101-004, 101-005, 102-002, 104-003, 105-002, 105-004, 105-006, and 107-002) experienced resolution of one or more target lesions.
- Updated data as of May 3, 2022 from the 21 patients dosed with 15mg/kg batiraxcept in combination with gemcitabine and nab-paclitaxel as a first-line treatment in patients with advanced or metastatic pancreatic adenocarcinoma in the Phase 1b pancreatic adenocarcinoma trial:
 - o Analysis of all safety data to date demonstrates that batiraxcept has been generally well-tolerated with no unexpected safety signals;
 - o The best ORR (confirmed + unconfirmed) was 29%;
 - o As noted with the other programs, an observable correlation of baseline levels of serum soluble AXL (sAXL)/GAS6 to clinical activity was noted in this trial and the best ORR in that biomarker high population was 40%; and
 - o Five patients (202-004, 202-005, 206-002, 213-002 and 214-001) experienced resolution of one or more target lesions with additional information on these patients:
 - 206-002 and 213-002 have since progressed;
 - 2 patients (213-002 and 214-001) had CA19-9 level that decreased to within normal limits during the study; and
- An outline of a registrational ccRCC study recommended by FDA which involves an integrated P2/P3 study with interim analyses to look at futility in the biomarker low population and ORR for potential accelerated approval with PFS endpoint for full approval. This design provides an opportunity for accelerated approval and full approval in one study. The final PFS analysis will be conducted in the ITT and the biomarker high populations to increase the chance for success. The full protocol and statistical plan are in preparation for submission to FDA.

Recent Financial Developments

In January 2022, we entered into an investment agreement (the “Investment Agreement”) with Eshelman Ventures, LLC and, solely for purposes of Article IV and Article V of the Investment Agreement, Dr. Eshelman, relating to the issuance of a pre-funded warrant to purchase up to 4,545,455 shares of our common stock, par value \$0.0001 per share (“Warrant Shares”), at a price of \$2.20 per share, which was the consolidated closing bid price of our common stock on Nasdaq on December 31, 2021, for an aggregate purchase price of \$10 million. The closing of the transaction occurred on January 5, 2022. Pursuant to the terms of the Investment Agreement, we were required to file a registration statement registering the shares of common stock underlying the pre-funded warrant. The registration statement was filed on January 5, 2022 and declared effective by the SEC on January 18, 2022. The pre-funded warrants issued to Eshelman Ventures, LLC were exercisable upon the approval by our stockholders of the exercise, which approval was obtained on April 1, 2022, at which time the pre-funded warrants were exercised in full.

On March 31, 2022, we closed a registered direct offering of our common stock with a single healthcare-focused institutional investor and Eshelman Ventures, LLC, pursuant to which we issued 3,185,216 shares of common stock, 1,665,025 pre-funded warrants (the “Pre-Funded Warrants”) and common stock warrants (the “Common Stock Warrants”) to purchase up to 4,850,241 shares of common stock in a registered direct offering priced at-the-market under Nasdaq rules. The purchase price per share 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 Warrants and accompanying Common Stock Warrants 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 Common Stock Warrants issued to the institutional investor are exercisable immediately, will expire five years from the exercisable date and will have an exercise price of \$1.88 per share. The Common Stock Warrants issued to Eshelman Ventures, LLC will be exercisable upon the approval by our stockholders of the exercise of previously issued securities, which approval was obtained on April 1, 2022, will expire five years following the exercise date and will have an exercise price of \$2.20 per share. We could receive additional gross proceeds of \$9.4 million, if the Common Stock Warrants are fully exercised.

Financial overview

Revenue

To date, we have not generated any revenue from commercial sales of any of our product candidates. However, for the three months ended March 31, 2022 and March 31, 2021, we generated approximately \$1.1 million and \$0.3 million, respectively, from the 3D Medicine Agreement, which represents a portion of initial signing and milestone payments received from 3D Medicines that is recognized at the time of the receipt and a portion of the payments that is deferred and recognized over the PROC trial period.

In the future, we may generate revenue from a variety of sources, including product sales if we develop products which are approved for sale, license fees, milestones, research and development and royalty payments in connection with strategic collaborations or government contracts, or licenses of our intellectual property.

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 (expense), net

Other income (expense), 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 policies, significant judgments and use of estimates

The Management's Discussion and Analysis of Financial Condition and Results of Operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited consolidated financial statements and in Note 2 to our audited consolidated financial statements contained in the Annual Report. Our significant accounting policies are unchanged from the description contained in Item 7 of our Annual Report filed on Form 10-K, except as related to pre-funded warrants for the purchase of our common stock.

Warrants for the purchase of our common stock are classified as derivative liabilities on our consolidated balance sheets at their fair value on the date of issuance because they are not considered indexed to our common stock. At the end of each reporting period, changes in estimated fair value during the period are recognized as a component of other income (expense), net in our statement of operations. We will continue to adjust the carrying value of the warrants until such time as the warrants are no longer considered derivative liabilities, or until the earlier of the exercise of the warrants or the expiration of the warrants, at which time the liabilities will be reclassified to additional paid-in capital at their fair value.

We estimate the fair value of these liabilities using assumptions that are based on the individual characteristics of the warrants on the valuation date. We use 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.

Results of operations**Comparison of the Three Months Ended March 31, 2022 and 2021**

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

	Three Months Ended March 31,		Increase/ (Decrease)	
	2022	2021		
Revenue:				
Collaboration revenue	\$ 1,092	\$ 256	\$ 836	327%
Operating expenses:				
Research and development	13,002	5,884	7,118	121%
General and administrative	3,088	2,380	708	30%
Total operating expenses	16,090	8,264	7,826	95%
Loss from operations	(14,998)	(8,008)	6,990	87%
Other income (expense), net	1,941	4	1,937	(1)
Net loss	<u>\$ (13,057)</u>	<u>\$ (8,004)</u>	<u>\$ 5,053</u>	<u>63%</u>

(1)Not meaningful

Collaboration revenue

In November 2020, we entered into the 3D Medicines Agreement. Collaboration revenue for the three months ended March 31, 2022 and March 31, 2021 was \$1.1 million and \$0.3 million, respectively.

Research and development expense

Research and development expense increased by \$7.1 million, or 121%, to \$13.0 million in the three months ended March 31, 2022, from \$5.9 million for the same period in 2021. The increase was primarily due to the continued progress of our clinical programs, including our Phase 3 trial of batiraxcept in PROC, our Phase 1b/2 trial of batiraxcept in ccRCC, and our Phase 1b trial of batiraxcept in pancreatic cancer. The advancement of our Phase 3 trial of batiraxcept in PROC is the most significant driver to the increase in expense in 2022 when compared to the same period in 2021. There were also increased manufacturing activities during 2022 due to our ongoing Phase 3 PROC trial.

General and administrative expense

General and administrative expense increased by \$0.7 million, or 30%, to \$3.1 million in the three months ended March 31, 2022 from \$2.4 million for the same period in 2021. The increase was primarily driven by higher stock-based compensation expense along with increased legal fees and rent.

Other income (expense), net

Other income was \$1.9 million for the three months ended March 31, 2022. Other income from the fair value adjustment related to our warrant liability was \$1.2 million, and other income from the sublease income received from our Subtenant was \$0.7 million. Neither the warrant liability nor the sublease with the Subtenant existed for the three months ended March 31, 2021.

Liquidity and capital resources

Since our inception and through March 31, 2022, 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 March 31, 2022, we had an accumulated deficit of approximately \$552.9 million and working capital of approximately \$49.3 million, primarily as a result of research and development and general and administrative expenses. As of March 31, 2022, we had cash and cash equivalents of approximately \$65.8 million, a majority of which is invested in money market funds at several highly rated financial institutions.

During 2020 and 2021, our primary sources of funding have been grant revenue from our CRIT Grant, revenue from 3D Medicines and proceeds from the sale of our common stock, par value \$0.0001 per share. In March 2020, we received approximately \$1.6 million of additional funding from our CPRIT Grant related to a receivable balance recorded as of December 31, 2019. 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 with them. On February 18, 2021, we received approximately \$21 million from the purchase by Eshelman Ventures of 2,875,000 shares of our common stock. In September 2020, we filed a shelf registration statement on Form S-3 with the SEC which was declared effective by the SEC on November 20, 2020. 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, par value \$0.0001 per 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. 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. During the three months ended March 31, 2022, we sold 54,763 shares of common stock for net proceeds of \$0.1 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 Pre-Funded Warrants and Common Stock Warrants to purchase up to 4,850,241 shares of our common stock in a registered direct offering.

As of March 31, 2022, we had cash and cash equivalents of approximately \$65.8 million. We believe that our existing cash and cash equivalents will be sufficient to sustain operations into the first quarter of 2023 and that we will need to obtain additional financing in order to advance our clinical development program to later stages of development, build out our pipeline and fund operations for the foreseeable future and we will continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. These factors raised substantial doubt about our ability to continue as a going concern. 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. Although management has been successful in raising capital in the past, there can be no assurance that we will be successful or that any needed financing will be available in the future at terms acceptable to us. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to complete clinical trials and pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the rate of progress and cost of our clinical studies;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the cost of preparing to manufacture on a larger scale;
- the costs of commercialization activities if any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by us or future partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements; and
- the emergence of competing technologies or other adverse market developments.

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

Cash flows

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

	Three Months Ended March 31,	
	2022	2021
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (12,890)	\$ (10,019)
Financing activities	19,291	28,160
Net increase in cash and cash equivalents	<u>\$ 6,401</u>	<u>\$ 18,141</u>

Cash used in operating activities

Net cash used in operating activities was \$12.9 million and \$10.0 million during the three months ended March 31, 2022 and 2021, 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 three months ended March 31, 2022 increased compared to the same period in 2021 due primarily to the ramp up in our Phase 3 trial of batiraxcept in PROC along with continuing costs related to our trial of our second oncology indication, ccRCC and our new third oncology indication, pancreatic adenocarcinoma.

Cash provided by investing activities

Net cash from investing activities during the three months ended March 31, 2022 and 2021 was zero.

Cash provided by financing activities

Net cash provided by financing activities was \$19.3 million during the three months ended March 31, 2022. Financing activities related to the three months ended March 31, 2022 included a registered direct offering of our securities with proceeds of \$9.3 million, issuance of Pre-Funded Warrants with proceeds of \$9.9 million, along with at the market offering proceeds of \$0.1 million.

Contractual obligations and commitments

During the three months ended March 31, 2022, 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.

Off-balance sheet arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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 March 31, 2022 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 March 31, 2022.

Changes in Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2022, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our 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 Financial Position and Capital Requirements

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 March 31, 2022, we had an accumulated deficit of approximately \$552.9 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 have devoted substantially all of our efforts to research and development, including clinical studies, but have not completed development of any product candidate. We anticipate that our expenses will increase to the extent we:

- continue the research and development of our only product candidate, batiraxcept, and any future product candidates;
- conduct additional clinical studies of batiraxcept in the future, especially later stage trials that involve a larger number of patients;
- seek to discover or in-license additional product candidates;
- seek regulatory approvals for batiraxcept and any future product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize batiraxcept or other future product candidates if they obtain regulatory approval, including process improvements in order to manufacture batiraxcept at commercial scale; and

To be profitable in the future, we must succeed in developing and eventually commercializing batiraxcept as well as other products with significant market potential. This will require us to be successful in a range of activities, including advancing batiraxcept and any future product candidates, completing clinical studies of these product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We may not succeed in these activities and may never generate revenue that is sufficient to be profitable in the future. Even if we are profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product candidates, market our product candidates, if approved, or continue our operations.

We expect our research and development expenses to increase significantly as our product candidates advance in clinical development. Because of numerous risks and uncertainties involved in our business, the timing or amount of increased development expenses cannot be accurately predicted and, our expenses could increase beyond expectations if we are required by the FDA, or comparable non-U.S. regulatory authorities, to perform studies or clinical trials in addition to those we currently anticipate. Even if our product candidate, batiraxcept, is approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of and the related commercial-scale manufacturing requirements for batiraxcept. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. These losses have had and will continue to have an adverse effect on our financial position and working capital.

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.

Our consolidated unaudited financial statements as of March 31, 2022 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our management concluded that our recurring losses from operations and the fact that we have not generated significant revenue or positive cash flows from operations raise substantial doubt about our ability to continue as a going concern for the next twelve months after issuance of our financial statements. 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. At March 31, 2022, we had an accumulated deficit of \$552.9 million and working capital of \$49.3 million. We expect to continue to incur losses from expenses related to the development of batiraxcept and related administrative activities for the foreseeable future. As of March 31, 2022, we had a cash and cash equivalents balance of approximately \$65.8 million consisting of cash and investments in highly liquid U.S. money market funds. We believe that our current cash and cash equivalents will be sufficient to fund our current planned operations into the first quarter of 2023 but that we will need to seek additional capital to fulfill our operating and capital requirement for the next 12 months to advance our clinical development program to later stages of development and commercialize our clinical product candidate. Although management has been successful in raising capital in the past, there can be no assurance that we will be successful or that any needed financing will be available in the future at terms acceptable to the Company. As such, the Company 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 will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates and technologies.

The completion of the development and the potential commercialization of batiraxcept and any future product candidates, should they receive approval, will require substantial funds. As of March 31, 2022, we had approximately \$65.8 million in cash and cash equivalents. We believe that our existing cash and cash equivalents will be sufficient to fund our current planned operations into the first quarter of 2023 based on our existing business plan; however, our existing cash and cash equivalents will not be sufficient to enable us to complete the clinical development and commercialization of batiraxcept. Our future financing requirements will depend on many factors, some of which are beyond our control, including the following:

- the rate of progress and cost of our future clinical studies;
- the number of patients in our clinical trials;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the cost of preparing to manufacture batiraxcept on a larger scale, should we elect to do so;
- the costs of commercialization activities if batiraxcept or any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by us or future partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements;
- the emergence of competing technologies or other adverse market developments; and
- the costs of attracting, hiring and retaining qualified personnel.

We do not have any material committed external source of funds or other support for our development efforts. Although we have entered into an at-the-market facility with Piper Sandler & Co. (“Piper Sandler”), and Cantor Fitzgerald & Co. (“Cantor Fitzgerald”), as sales agents, there can be no assurance that we will meet all of the conditions necessary to continue to use such facility or that we can generate sufficient proceeds from the sale of securities pursuant to such facility to support our operations. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. Additional financing may not be available to us when we need it or it may not be available on favorable terms. In addition, certain SEC and Nasdaq Stock Market Global health limitations with respect to fundraising, including limitations on the use of our shelf registration statement, may make it more difficult to raise additional funds. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one or more of our clinical studies or research and development programs or our commercialization efforts.

Changes in general economic conditions, geopolitical conditions, domestic and foreign trade policies, monetary policies and other factors beyond our control may adversely impact our business and operating results.

Our operations and performance depend on global, regional and U.S. economic and geopolitical conditions. Russia’s invasion and military attacks on Ukraine have triggered significant sanctions from U.S. and European leaders. These events are currently escalating and creating increasingly volatile global economic conditions. Resulting changes in U.S. trade policy could trigger retaliatory actions by Russia, its allies and other affected countries, including

China, resulting in a “trade war.” Furthermore, if the conflict between Russia and Ukraine continues for a long period of time, or if other countries, including the U.S., become further involved in the conflict, we could face significant adverse effects to our business and financial condition.

The above factors, including a number of other economic and geopolitical factors both in the U.S. and abroad, could ultimately have material adverse effects on our business, financial condition, results of operations or cash flows, including the following:

- inability to enroll patients in clinical sites located in affected countries;
- inability or delays in receiving supplies of batiraxcept manufacturing in China;
- effects of significant changes in economic, monetary and fiscal policies in the U.S. and abroad including currency fluctuations, inflationary pressures and significant income tax changes;
- a global or regional economic slowdown in any of our market segments;
- changes in government policies and regulations affecting the Company or its significant customers;
- industrial policies in various countries that favor domestic industries over multinationals or that restrict foreign companies altogether;
- new or stricter trade policies and tariffs enacted by countries, such as China, in response to changes in U.S. trade policies and tariffs;
- postponement of spending, in response to tighter credit, financial market volatility and other factors;
- rapid material escalation of the cost of regulatory compliance and litigation;
- difficulties protecting intellectual property;
- longer payment cycles;
- credit risks and other challenges in collecting accounts receivable; and
- the impact of each of the foregoing on outsourcing and procurement arrangements.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

We intend to seek FDA approval for batiraxcept for ccRCC through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or comparable foreign regulatory authorities may seek to withdraw accelerated approval.

Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. If such post-approval studies fail to confirm the product's clinical benefit, the FDA may withdraw its approval.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA or similar foreign regulatory authorities and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA or similar application for accelerated approval or any other form of expedited development or review. Similarly, there can be no assurance that after subsequent FDA or similar foreign regulatory authorities feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development or review, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or other expedited development or review for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development or review will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development or review for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate, and could harm our competitive position in the marketplace.

Risks Related to the Ownership of Our Common Stock

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future, and as a result, investors in our common stock could incur substantial losses.

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future. From January 1, 2021 through December 31, 2021 the reported sale price of our common stock has fluctuated between \$2.19 and \$9.24 per share. From January 1, 2022 through March 31, 2022 the reported closing price of our common stock has fluctuated between \$1.85 and \$2.75 per share. In addition, the ongoing COVID-19 pandemic has caused broad stock market and industry fluctuations. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price for our common stock may be influenced by many factors, including the following:

- investor reaction to our business strategy;
- the success of competitive products or technologies;
- results of clinical studies of batiraxcept or future product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, results of clinical trials, our commercialization partners, or our competitors, and the timing of these introductions or announcements;

- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- declines in the market prices of stocks generally;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions;
- other events or factors, including those resulting from such events, or the prospect of such events, including war, terrorism and other international conflicts, public health issues including health epidemics or pandemics, such as the ongoing COVID-19 pandemic, and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability; and
- the other risks described in this “Risk factors” section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Since the stock price of our common stock has fluctuated in the past, has been recently volatile and may be volatile in the future, investors in our common stock could incur substantial losses. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management’s attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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 May 5, 2022, our executive officers, directors and entities under their control in the aggregate, beneficially owned shares representing approximately 42.4% of our common stock. Dr. Fredric N. Eshelman, our Executive Chairman beneficially owns 34.0% of our common 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.

Risks Related to the Ownership of the Pre-Funded Warrants or the Common Stock Warrants

There is no public market for the Pre-Funded Warrants or the Common Stock Warrants we have issued.

There is no established public trading market for the Pre-Funded Warrants or Common Stock Warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list any of the warrants on any securities exchange or nationally recognized trading system, including Nasdaq. Without an active market, the liquidity of the Pre-Funded Warrants and Common Stock Warrants will be limited.

The Pre-Funded Warrants and the Common Stock Warrants are speculative in nature.

Holders of the Pre-Funded Warrants may exercise their right to acquire the common stock and pay an exercise price of \$0.001 per share. Following this offering, the market value of the Pre-Funded Warrants is uncertain and there can be no assurance that the market value of the Pre-Funded Warrants will equal or exceed their public offering price.

Furthermore, holders of the Common Stock Warrants that are outstanding may exercise their right to acquire our common stock and pay the applicable exercise price (\$1.88 per share for the investor and \$2.20 for Eshelman Ventures). There can be no assurance that the market price of our common stock will ever equal or exceed the applicable exercise price of the Common Stock Warrants, and consequently, whether it will ever be profitable for holders of the Common Stock Warrants to exercise the Common Stock Warrants.

Except as otherwise provided in the Pre-Funded Warrants and Common Stock Warrants, holders of outstanding Pre-Funded Warrants and Common Stock Warrants will have no rights as stockholders of common stock until such holders exercise their Pre-Funded Warrants and Common Stock Warrants and acquire our common stock.

Our outstanding Pre-Funded Warrants and the Common Stock Warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our common stock at a fixed price, and in the case of the Common Stock Warrants, for a limited period of time. Specifically, a holder of a Common Stock Warrant may exercise the right to acquire a share of common stock and pay the applicable exercise price (\$1.88 per share for the Investor and \$2.20 per share for Eshelman Ventures) prior to the fifth anniversary of the original issuance date, upon which date any unexercised Common Stock Warrants will expire and have no further value. A holder of a

Pre-Funded Warrant may exercise the right to acquire a share of common stock and pay a nominal exercise price of \$0.001 at any time. Upon exercise of the Pre-Funded Warrants and Common Stock Warrants, the holders thereof will be entitled to exercise the rights of a holder of common stock only as to matters for which the record date occurs after the exercise date.

We may not receive any additional funds upon the exercise of the Pre-Funded Warrants or the Common Stock Warrants.

The Pre-Funded Warrants and Common Stock Warrants provide that if we do not maintain a current and effective prospectus relating to the common shares issuable upon exercise of the Pre-Funded Warrants and Common Stock Warrants, it may be exercised by way of a cashless exercise, meaning that the holder may not pay a cash purchase price upon exercise, but instead would receive upon such exercise the net number of shares of our common stock determined according to the formula set forth in the Pre-Funded Warrants or Common Stock Warrants. Accordingly, we may not receive any additional funds upon the exercise of the Pre-Funded Warrants or Common Stock Warrants pre.

Provisions of the Pre-Funded Warrants and Common Stock Warrants could discourage an acquisition of us by a third party.

Certain provisions of the Pre-Funded Warrants and Common Stock Warrants could make it more difficult or expensive for a third party to acquire us. The Pre-Funded Warrants and Common Stock Warrants prohibit us from engaging in certain transactions constituting “fundamental transactions” unless, among other things, the surviving entity assumes our obligations under the Pre-Funded Warrants. Further, the Pre-Funded Warrants provide that, in the event of certain transactions constituting “fundamental transactions,” with some exception, holders of such warrants will have the right, at their option, to require us to repurchase such Pre-Funded Warrants at a price described in such warrants. These and other provisions of the Pre-Funded Warrants offered by this prospectus could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

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
4.1	Form of Eshelman Ventures Pre-Funded Warrant issued January 5, 2022	8-K	001-36361	4.1	01/04/2022
4.2	Form of Investor Warrant issued March 31, 2022	8-K	001-36361	4.1	03/31/2022
4.3	Form of Eshelman Ventures, LLC Warrant issued March 31, 2022	8-K	001-36361	4.2	03/31/2022
4.4	Form of Pre-Funded Warrant issued March 31, 2022	8-K	001-36361	4.3	03/31/2022
10.1	Investment Agreement, dated as of January 3, 2022, by and among Aravive, Inc. Eshelman Ventures, LLC and solely for purposes of Article IV and V of the Investment Agreement Fredric N. Eshelman, Pharm D.	8-K	001-36361	10.1	01/04/2022
10.2#	Offer Letter between Leonard Scott Dove, Ph.D. and Aravive, Inc.	8-K	001-36361	10.1	03/22/2022
10.3	Form of Securities Purchase Agreement, dated March 29, 2022, by and between Aravive, Inc. and the purchaser party thereto	8-K	001-36361	10.1	03/31/2022
10.4	Form of Securities Purchase Agreement, dated March 29, 2022, by and between Aravive, Inc. and Eshelman Ventures, LLC	8-K	001-36361	10.2	03/31/2022
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 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.

Date: May 12, 2022

ARAVIVE, INC.
(Registrant)

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

Date: May 12, 2022

ARAVIVE, INC.
(Registrant)

By: /s/ Vinay Shah
Vinay Shah
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

**Certification of Chief Executive Officer
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: May 12, 2022

By: /s/ Gail McIntyre

Name: Gail McIntyre

Title: Chief Executive Officer
(Principal Executive Officer)

**Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Vinay Shah, 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: May 12, 2022

By: /s/ Vinay Shah

Name: Vinay Shah

Title: Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

**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 March 31, 2022 (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: May 12, 2022

By: /s/ Gail McIntyre

Name: Gail McIntyre

Title: Chief Executive Officer
(Principal Executive Officer)

**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, Vinay Shah, 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 March 31, 2022 (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: May 12, 2022

By: /s/ Vinay Shah

Name: Vinay Shah

Title: Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)