PROSPECTUS SUPPLEMENT

Filed pursuant to Rule 424(b)(3)
Registration Number 333-268934

ZYVERSA THERAPEUTICS, INC.

5,858,714 Shares of Common Stock
723,234 Shares of Common Stock Underlying Series B Preferred Stock
4,878,875 Shares of Common Stock Underlying PIPE Warrants
5,825,358 Shares of Common Stock Underlying Public Warrants
240,204 Shares of Common Stock Underlying Private Placement Warrants
7,121,213 Shares of the Common Stock Underlying the Inducement Warrants

This prospectus supplement updates and supplements the prospectus dated October 20, 2023 (as may be further supplemented or amended from time to time, the "Prospectus"), which forms a part of our Registration Statement on Form S-1 (File No. 333-268934).

This prospectus supplement is not complete without the Prospectus. This prospectus supplement should be read in conjunction with the Prospectus, which is required to be delivered with this prospectus supplement. If there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

Our Common Stock is listed on the Nasdaq Global Market of The Nasdaq Stock Market LLC ("Nasdaq") under the symbol "ZVSA". On November 17, 2023, the last quoted sale price for our Common Stock as reported on Nasdaq was $0.08.

We are an "emerging growth company" and a "smaller reporting company" as such terms are defined under the federal securities laws and, as such, are subject to certain reduced public company reporting requirements.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "*Risk Factors*" beginning on page 12 of the Prospectus, and under similar headings in any amendments or supplements to the Prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the Prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is November 20, 2023.

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

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2023

☐ 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: 001-41184

ZYVERSA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	**86-2685744** (I.R.S. Employer Identification No.)
2200 N. Commerce Parkway, Suite 208 **Weston, FL 33326** (Address of principal executive offices)	**33326** (Zip Code)

(754) 231-1688
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	ZVSA	The Nasdaq Global Market

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: ☒ No: ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes: ☒ No: ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of November 10, 2023, the number of shares outstanding of the registrant's common stock, $0.0001 par value per share, was 43,519,719.

ZYVERSA THERAPEUTICS, INC.
INDEX TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ZYVERSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	Successor	
	September 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current Assets:		
Cash	$ 1,578,721	$ 5,902,199
Prepaid expenses and other current assets	426,519	225,347
Vendor deposits	-	235,000
Total Current Assets	2,005,240	6,362,546
Equipment, net	9,533	17,333
In-process research and development	30,806,158	100,086,329
Goodwill	-	11,895,033
Security deposit	-	46,659
Operating lease right-of-use asset	31,078	98,371
Total Assets	$ 32,852,009	$ 118,506,271
Liabilities, Temporary Equity and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 8,897,534	$ 6,025,645
Accrued expenses and other current liabilities	2,775,485	2,053,559
Operating lease liability	34,349	108,756
Total Current Liabilities	11,707,368	8,187,960
Deferred tax liability	1,440,982	10,323,983
Total Liabilities	13,148,350	18,511,943
Commitments and contingencies (Note 8)		
Successor redeemable common stock, subject to possible redemption, 0 and 65,783 shares outstanding as of September 30, 2023 and December 31, 2022, respectively	-	331,331
Stockholders' Equity:		
Successor preferred stock, $0.0001 par value, 1,000,000 shares authorized: Series A preferred stock, 8,635 shares designated, 50 and 8,635 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	-	1
Series B preferred stock, 5,062 shares designated, 5,062 shares issued and outstanding as of September 30, 2023 and December 31, 2022	1	1
Successor common stock, $0.0001 par value, 110,000,000 shares authorized; 43,517,560 and 9,016,139 shares issued at September 30, 2023 and December 31, 2022, respectively, and 43,515,401 and 9,016,139 shares outstanding as of September 30, 2023 and December 31, 2022, respectively	4,353	902
Additional paid-in-capital	109,587,097	104,583,271
Accumulated deficit	(89,880,624)	(4,921,178)
Treasury stock, at cost, 2,159 and 0 shares at September 30, 2023 and December 31, 2022, respectively	(7,168)	-
Total Stockholders' Equity	19,703,659	99,662,997
Total Liabilities, Temporary Equity and Stockholders' Equity	$ 32,852,009	$ 118,506,271

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

ZYVERSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Successor	Predecessor	Successor	Predecessor
	For the Three Months Ended September 30, 2023	For the Three Months Ended September 30, 2022	For the Nine Months Ended September 30, 2023	For the Nine Months Ended September 30, 2022
Operating Expenses:				
Research and development	$ 673,943	$ 2,334,120	$ 2,950,462	$ 4,120,477
General and administrative	2,228,735	1,061,046	9,694,097	4,526,428
Impairment of in-process research and development	-	-	69,280,171	-
Impairment of goodwill	-	-	11,895,033	-
Total Operating Expenses	2,902,678	3,395,166	93,819,763	8,646,905
Loss From Operations	(2,902,678)	(3,395,166)	(93,819,763)	(8,646,905)
Other (Income) Expense:				
Interest (income) expense	210	69,352	(555)	377,820
Change in fair value of derivative liabilities	-	228,100	-	420,600
Pre-Tax Net Loss	(2,902,888)	(3,692,618)	(93,819,208)	(9,445,325)
Income tax benefit	485	-	8,859,762	-
Net Loss	(2,902,403)	(3,692,618)	(84,959,446)	(9,445,325)
Deemed dividend to preferred stockholders	(32,373)	(9,684,637)	(7,948,209)	(10,015,837)
Net Loss Attributable to Common Stockholders	$ (2,934,776)	$ (13,377,255)	$ (92,907,655)	$ (19,461,162)
Net Loss Per Share				
- Basic and Diluted	$ (0.09)	$ (0.55)	$ (4.79)	$ (0.81)
Weighted Average Number of Common Shares Outstanding				
- Basic and Diluted	30,978,540	24,167,257	19,403,027	24,167,257

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

ZYVERSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

	For the Three and Nine Months Ended September 30, 2023										
	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Successor	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance - January 1, 2023	8,635	$ 1	5,062	$ 1	9,016,139	$ 902	-	$ -	$ 104,583,271	$ (4,921,178)	$ 99,662,997
Reclassification of formerly redeemable common stock	-	-	-	-	65,783	7	-	-	331,324	-	331,331
Issuance of common stock pursuant to vendor agreements	-	-	-	-	130,000	13	-	-	395,187	-	395,200
Registration costs associated with preferred stock issuance	-	-	-	-	-	-	-	-	(34,674)	-	(34,674)
Stock-based compensation	-	-	-	-	-	-	-	-	287,461	-	287,461
Net loss	-	-	-	-	-	-	-	-	-	(3,543,950)	(3,543,950)
Balance - March 31, 2023	8,635	1	5,062	1	9,211,922	922	-	-	105,562,569	(8,465,128)	97,098,365
Registered offering of common stock [1]	-	-	-	-	11,015,500	1,102	-	-	9,829,917	-	9,831,019
Redemption of Series A Preferred Stock	(8,400)	(1)	-	-	-	-	-	-	(10,080,000)	-	(10,080,001)
Conversion of Series A Preferred Stock into common stock	(35)	-	-	-	17,500	2	-	-	(2)	-	-
Shares issued as consideration for extension of lock-up period	-	-	-	-	3,044,152	304	-	-	1,156,474	-	1,156,778
Issuance of common stock pursuant to vendor agreements	-	-	-	-	380,000	38	-	-	209,962	-	210,000
Stock-based compensation	-	-	-	-	-	-	-	-	365,742	-	365,742
Treasury stock acquired, at cost	-	-	-	-	-	-	(2,159)	(7,168)	-	-	(7,168)
Net loss	-	-	-	-	-	-	-	-	-	(78,513,093)	(78,513,093)
Balance - June 30, 2023	200	-	5,062	1	23,669,074	2,368	(2,159)	(7,168)	107,044,662	(86,978,221)	20,061,642
Registered offering of common stock [2]	-	-	-	-	3,256,060	326	-	-	1,575,612	-	1,575,938
Warrant modification	-	-	-	-	-	-	-	-	181,891	-	181,891
Redemption of Series A	(150)	-	-	-	-	-	-	-	(215,048)	-	(215,048)

Preferred Stock											
Exercise of pre-funded warrants	-	-	-	-	9,471,213	947	-	-	-	-	947
Warrant inducement offer - exercise proceeds [3]	-	-	-	-	7,121,213	713	-	-	756,935	-	757,647
Stock-based compensation	-	-	-	-	-	-	-	-	243,045	-	243,045
Net loss	-	-	-	-	-	-	-	-	-	(2,902,403)	(2,902,403)
Balance - September 30, 2023	50	$ -	5,062	$ 1	43,517,560	$ 4,353	(2,159)	$ (7,168)	$ 109,587,097	$ (89,880,624)	$ 19,703,659

	For the Three and Nine Months Ended September 30, 2022						
	Series A Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficiency
Predecessor	Shares	Amount	Shares	Amount			
Balance - January 1, 2022	-	$ -	24,167,257	$ 242	$ 40,065,109	$ (52,896,817)	$ (12,831,466)
Issuance of preferred stock in private placement [4]	133,541	1	-	-	393,300	-	393,301
Stock-based compensation	-	-	-	-	1,941,746	-	1,941,746
Net loss	-	-	-	-	-	(3,748,495)	(3,748,495)
Balance - March 31, 2022	133,541	1	24,167,257	242	42,400,155	(56,645,312)	(14,244,914)
Stock-based compensation	-	-	-	-	695,940	-	695,940
Net loss	-	-	-	-	-	(2,004,212)	(2,004,212)
Balance - June 30, 2022	133,541	1	24,167,257	242	43,096,095	(58,649,524)	(15,553,186)
Issuance of preferred stock in private placement [5]	317,322	4	-	-	959,196	-	959,200
Conversion of convertible notes payable and accrued interest into preferred stock	1,802,193	18	-	-	5,658,870	-	5,658,888
Stock-based compensation:	-	-	-	-	494,022	-	494,022
Net loss	-	-	-	-	-	(3,692,618)	(3,692,618)
Balance - September 30, 2022	2,253,056	$ 23	24,167,257	$ 242	$ 50,208,183	$ (62,342,142)	$ (12,133,694)

[1] Includes gross proceeds of $11,015,500 less issuance costs of $1,184,482

[2] Includes gross proceeds of $2,099,053 less issuance costs of $523,115

[3] Includes gross proceeds of $966,349 less issuance costs of $208,702

[4] Includes gross proceeds of $419,320 less issuance costs of $26,019

[5] Includes gross proceeds of $996,400 less issuance costs of $37,200

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

ZYVERSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Successor For the Nine Months Ended September 30, 2023	Predecessor For the Nine Months Ended September 30, 2022
Cash Flows From Operating Activities:		
Net loss	$ (84,959,446)	$ (9,445,325)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of in-process research and development	69,280,171	-
Impairment of goodwill	11,895,033	-
Stock-based compensation	896,248	3,131,708
Issuance of common stock pursuant to vendor agreements	605,200	-
Shares issued as consideration for extension of lock-up period	1,156,778	-
Amortization of debt discount	-	39,492
Change in fair value of derivative liability	-	420,600
Depreciation of fixed assets	7,800	7,800
Non-cash rent expense	67,293	-
Deferred tax benefit	(8,883,001)	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(201,172)	(57,366)
Security deposit	46,659	(1)
Vendor deposits	235,000	160,000
Accounts payable	2,871,889	3,448,439
Operating lease liability	(74,407)	-
Accrued expenses and other current liabilities	1,122,488	1,216,322
Net Cash Used In Operating Activities	(5,933,467)	(1,078,331)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock in public offering	13,114,555	-
Registration and issuance costs associated with common stock issuance	(1,763,584)	-
Redemption of Series A Preferred Stock	(10,695,610)	-
Proceeds from issuance of preferred stock in private placement	-	1,415,720
Purchase of treasury stock	(7,168)	-
Exercise of pre-funded warrants	947	-
Warrant inducement offer - exercise proceeds	966,349	-
Registration and issuance costs associated with preferred stock issuance	(5,500)	(63,219)
Net Cash Provided By Financing Activities	1,609,989	1,352,501
Net (Decrease) Increase in Cash	(4,323,478)	274,170
Cash - Beginning of Period	5,902,199	328,581
Cash - End of Period	$ 1,578,721	$ 602,751
Supplemental Disclosures of Cash Flow Information:		
Conversion of convertible notes payable and accrued interest into preferred stock	$ -	$ 5,658,888
Reclassification of formerly redeemable common stock	$ 331,331	$ -
Recognition of ROU asset and lease liability upon adoption of ASC 842	$ -	$ 182,732
Accounts payable for deferred offering costs	$ 44,892	$ 1,506,211
Warrant modification - incremental value	$ 181,891	$ -
Warrant inducement offer - incremental value	$ 134,591	$ -

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

Note 1 – Business Organization, Nature of Operations and Basis of Presentation

Organization and Operations

Larkspur Health Acquisition Corp. (“Larkspur”), a blank-check special purpose acquisition company, was incorporated in Delaware on March 17, 2021. On December 12, 2022, Larkspur consummated the Business Combination (as defined below) with ZyVersa Therapeutics, Inc. (“Predecessor”) which was incorporated in the State of Florida on March 11, 2014 as Variant Pharmaceuticals, Inc. Pursuant to the terms of the Business Combination Agreement (the “Business Combination Agreement”) (and upon all other conditions of the Business Combination Agreement being satisfied or waived), on the date of the consummation (the “Closing Date”) of the Business Combination and transactions contemplated thereby (the “Business Combination”), Larkspur (“New Parent”) changed its name to ZyVersa Therapeutics, Inc. and the Predecessor changed its name to ZyVersa Therapeutics Operating, Inc. (the “Operating Company”) after merging with a subsidiary of the New Parent, with the Operating Company being the surviving entity, which resulted in it being incorporated in Delaware and it being a wholly-owned subsidiary of the New Parent (collectively the “Successor”). References to the “Company” or “ZyVersa” refer to the Successor for the three and nine months ended September 30, 2023, and to the Predecessor for the three and nine months ended September 30, 2022.

ZyVersa is a clinical stage biopharmaceutical company leveraging proprietary technologies to develop first-in-class drugs for patients with chronic renal or inflammatory diseases with high unmet medical needs. The Company’s mission is to develop drugs that optimize health outcomes and improve patients’ quality of life.

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”) for interim financial information. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States of America for annual financial statements. In the opinion of management, such statements include all adjustments (consisting only of normal recurring items) which are considered necessary for a fair presentation of the unaudited condensed consolidated financial statements of the Company as of September 30, 2023 and for the nine months ended September 30, 2023 and 2022. The results of operations for the nine months ended September 30, 2023 are not necessarily indicative of the operating results for the full year. It is suggested that these unaudited condensed consolidated financial statements be read in conjunction with the consolidated financial statements and notes thereto included in the Company’s annual report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission (“SEC”) on March 31, 2023.

The accompanying unaudited condensed consolidated financial statements have been derived from the accounting records of the Company and its consolidated subsidiaries. As a result of the Business Combination, for accounting purposes, Larkspur was the acquirer and Predecessor ZyVersa Therapeutics, Inc. was the acquiree and accounting predecessor. Therefore, the financial statement presentation includes the financial statements of the Predecessor for the periods prior to December 13, 2022 and the Successor for the periods including and after December 13, 2022, including the consolidation of the Operating Company. All significant intercompany balances have been eliminated in the unaudited condensed consolidated financial statements. The unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and pursuant to the accounting rules and regulations of the SEC.

Note 2 - Going Concern and Management’s Plans

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

As of September 30, 2023, the Company had cash of approximately $1.6 million and a working capital deficit of approximately $9.7 million. During the nine months ended September 30, 2023, the Company incurred a net loss of approximately $85.0 million and used cash in operations of approximately $5.9 million. The Company has an accumulated deficit of approximately $89.9 million as of September 30, 2023.

The Company has not yet achieved profitability and expects to continue to incur cash outflows from operations. The Company will need substantial cash to complete development of its proprietary technologies and is currently managing costs to maintain cash. It is expected that its research and development and general and administrative expenses will continue to increase and, as a result, the Company will eventually need to generate significant product revenues to achieve profitability.

Consequently, the Company will be required to raise additional funds through equity or debt financing. Management believes that the Company has access to capital resources and continues to evaluate additional financing opportunities; however, there can be no assurance that it will be successful in securing additional capital or that the Company will be able to obtain funds on commercially acceptable terms, if at all. There is also no assurance that the amount of funds the Company might raise will enable the Company to extinguish its working capital deficit, complete its development initiatives or attain profitable operations. The aforementioned conditions raise substantial doubt about the Company's ability to continue as a going concern for at least one year from the issuance date of these financial statements.

Note 3 – Summary of Significant Accounting Policies

Since the date the Company's December 31, 2022 financial statements were issued in its 2022 Annual Report on Form 10-K for the year ended December 31, 2022, there have been no material changes to the Company's significant accounting policies.

Use of Estimates

Preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the financial statements and the amounts disclosed in the related notes to the financial statements. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, fair value calculations for equity securities, derivative liabilities, share based compensation and acquired intangible assets, as well as establishment of valuation allowances for deferred tax assets. Certain of the Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that actual results could differ from those estimates.

Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of vested common shares outstanding during the period. Diluted net income per common share is computed by dividing net income by the weighted average number of common and dilutive common-equivalent shares outstanding during each period.

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to do so would be anti-dilutive:

	Successor	Predecessor
	September 30, 2023	September 30, 2022
Predecessor warrants [1]	-	8,699,397
Successor warrants [1]	36,375,319	-
Predecessor options	-	10,039,348
Successor options	3,559,342	-
Successor Series A Convertible Preferred Stock	25,000	-
Successor Series B Convertible Preferred Stock	723,234	-
Predecessor Series A Convertible Preferred Stock	-	5,945,045
Predecessor convertible notes payable [2]	-	2,977,528
Total potentially dilutive shares	40,682,895	27,661,318

[1] As part of the InflamaCORE, LLC license agreement, warrants to purchase 600,000 Predecessor or 119,125 Successor shares of common stock are to be issued upon the satisfaction of certain milestones and, accordingly, are not included in the amount currently reported. See Note 8 - Commitments and Contingencies - License Agreements for details.

[2] The Company's convertible notes payable have embedded conversion options that result in the automatic issuance of common stock upon the consummation of certain qualifying transactions. The conversion price is a function of the implied common stock price associated with the qualifying transaction. For the purpose of disclosing the potentially dilutive securities in the table above, we used the number of shares of common stock issuable if a qualifying transaction occurred with an implied common stock price equal to the fair value of the common stock of $1.94 per share as of September 30, 2022.

Segment Reporting

The Company operates and manages its business as one reportable and operating segment. All assets and operations are in the U.S. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance.

Note 4 – Business Combination, Goodwill and In-Process Research and Development

On December 12, 2022, Larkspur consummated the Business Combination with ZyVersa Therapeutics, Inc. (see Note 1 – Business Organization, Nature of Operations and Basis of Presentation). The Company accounted for the Business Combination as a forward acquisition of the Operating Company, as it was determined that the Operating Company was a variable interest entity as of the date of the Business Combination. The New Parent was determined to be the primary beneficiary, as its ownership provides the power to direct the activities of the Operating Company and the obligation to absorb the losses and/or receive the benefits of the Operating Company.

Given the non-recurring nature of Larkspur's activities as a SPAC, pro forma financial data combining the pre-Business Combination results of both Larkspur and the Operating Company would not be meaningful and have not been presented.

Purchase Price Allocation

The Business Combination was recorded using the acquisition method of accounting and the initial purchase price allocation was based on the Company's preliminary assessment of the fair value of the purchase consideration and the fair value of the Operating Company's tangible and intangible assets acquired and liabilities assumed at the date of acquisition. At December 31, 2022, the purchase price allocation was not complete due to the proximity of the acquisition date to the calendar year end.

As of June 30, 2023, the preliminary estimates of the acquisition-date fair value of the purchase consideration and the preliminary estimates of the purchase price allocation were confirmed, do not require measurement period adjustments, and were considered final. The acquisition-date fair value of the elements of the purchase consideration were estimated using a market approach with Level 1 inputs (observable inputs) in the case of the fair value of the Successor's common stock and Level 3 inputs (unobservable inputs) in the case of the fair value attributed to the Successor warrants and options. The acquiror was obligated to replace the Operating Company's existing warrants and options pursuant to the Business Combination Agreement. Accordingly, it was necessary to allocate the fair value of the replacement warrants and options between purchase consideration (the fair value attributable to pre-combination services) and compensation for post-combination services. The fair value of the replacement warrants and options attributable to post-combination services was $584,260 and $1,731,237, respectively.

The final estimates of the acquisition-date fair value of the purchase consideration were as follows:

Successor common stock	$	67,197,300
Successor warrants		12,190,015
Successor options		11,864,556
Total fair value of the purchase consideration	$	91,251,871

The final acquisition-date fair values of the assets acquired and liabilities assumed (see the table below) were determined by management, with the assistance of a third-party valuation expert specifically for the in-process research and development ("IPR&D"). The estimated fair value of the IPR&D assets was determined using the "income approach" which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life using Level 3 inputs. Some of the more significant assumptions utilized in the valuations include the estimated net cash flows for each year for each asset, the appropriate discount rate necessary to measure the risk inherent in the future cash flows, the life cycle of each asset, the potential regulatory and commercial success risk, royalties on net sales, as well as other factors. There are inherent uncertainties related to these factors and management's judgment in applying them to arrive at the estimated fair values. The excess of the purchase price over the estimated fair values of the identifiable net assets acquired was recorded as goodwill, which management believes is attributable to the assembled workforce and other intangible assets that do not qualify for separate recognition.

Current assets, including cash of $699,324	$	1,093,223
In-process research and development		100,086,329
Goodwill		11,895,033
Other non-current assets		64,523
Total assets acquired		113,139,108
Current liabilities		10,818,204
Deferred tax liabilities		11,069,033
Total assumed liabilities		21,887,237
Net assets acquired	$	91,251,871

IPR&D recorded for book purposes is considered an indefinite-lived intangible asset until the completion or the abandonment of the research and development efforts. Because the acquisition was structured as a stock sale, the IPR&D and the goodwill do not have any tax basis and will not be deductible for tax purposes.

Impairment

While management did not identify any unfavorable developments related to its IPR&D assets, management did determine that it was more likely than not that the Company's single reporting unit's fair value was below its carrying amount, due to a significant and sustained decline in the Company's market capitalization. Accordingly, it was necessary to perform interim impairment testing as of June 30, 2023.

The fair value of the Company was determined using an income approach. The income approach was based on the present value of the future cash flows, which were derived from financial forecasts and required significant assumptions and judgment, including the estimated net cash flows for each year for each asset, the appropriate discount rate necessary to measure the inherent risk of the future cash flows, the life cycle of each asset, the potential regulatory and commercial success risk, royalties on net sales, as well as other factors. The resulting estimated fair value was reconciled to the Company's market capitalization.

The reconciliation included an estimated implied control premium of approximately 100% above the Company's market capitalization on June 30, 2023.

The summation of the Company's goodwill and IPR&D fair values, as indicated by the Company's discounted cash flow calculations, were compared to the Company's consolidated fair value, as indicated by the Company's market capitalization, to evaluate the reasonableness of the Company's calculations. The Company's determination of a reasonable control premium that an investor would pay, over and above market capitalization for a control position, included a number of factors:

- Market control premium. The identification of recent public market information of comparable peer acquisition transactions. The selection of comparable peer acquisition transactions is subject to judgment and uncertainty.

- Impact of low public float and limited trading activity on market capitalization: A significant portion of the Company's common shares are owned by a concentrated number of investors. The public float of the Company's common shares, calculated as the percentage of common shares freely traded by public investors divided by the Company's total shares outstanding, is significantly lower than that of the Company's publicly traded peers. Based on the Company's evaluation of third-party market data, we believe there is an inherent discount impacting the Company's share price due to the low public float and limited trading volume, thus impacting the Company's market capitalization.

As a result of the Company's analysis, on June 30, 2023, the Company fully impaired its $11.9 million of goodwill and also recorded a $69.3 million impairment charge for its other indefinite-lived intangible assets, namely the IPR&D.

The Company determined that there were no new events or circumstances as of September 30, 2023 that indicate that the fair value of the IPR&D has decreased below its carrying value and intends to perform its annual impairment testing as of October 1, 2023.

Note 5 – Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of September 30, 2023 and December 31, 2022:

	September 30, 2023	December 31, 2022
L&F milestone payment liability	$ 500,000	$ 1,500,000
L&F Note [1]	-	(351,579)
L&F, net	500,000	1,148,421
Payroll accrual	894,416	584,226
Other accrued expenses	31,969	214,229
Federal income tax payable	129,922	106,683
Bonus accrual	1,212,359	-
Registration delay liability [2]	6,819	-
Total accrued expenses and other current liabilities	$ 2,775,485	$ 2,053,559

[1] See Note 8 – "Commitments and Contingencies" for details of the forgiveness of the L&F Note.

[2] See Note 9 – "Stockholders' Permanent and Temporary Equity" for details of the registration delay liability.

Note 6 – Derivative Liabilities

As of January 1, 2022, the Company had Level 3 derivative liabilities that were measured at fair value at issuance, related to the redemption features and put options of certain convertible notes. The redemption features were valued using a combination of a discounted cash flow and a Black-Scholes valuation technique. There were no derivative liabilities as of September 30, 2023 or December 31, 2022.

During the three and nine months ended September 30, 2022, the Predecessor recorded a loss on the change in the fair value of the derivative liabilities of $228,100 and $420,000, respectively.

Note 7 – Income Taxes

The tax provisions for the nine months ended September 30, 2023 and 2022 were computed using the estimated effective tax rates applicable to the taxable jurisdictions for the full year. The Company's tax rate is subject to management's quarterly review and revision, as necessary. The Company's effective tax rate was 9.44% and 0% for the nine months ended September 30, 2023 and 2022, respectively. The increase in the quarterly rates is primarily the result of changes in its valuation allowance. As of September 30, 2022, the Company recorded a full valuation allowance due to historical and projected losses. As of December 31, 2022, the Company recorded a significant deferred tax liability, which was established in connection with the Business Combination on December 12, 2022, which was a source of future taxable income to realize its net deferred tax assets. During the nine months ended September 30, 2023, the Company recorded an impairment on the asset related to the deferred tax liability which decreased the deferred tax liability. Accordingly, the effective tax rate for the nine months ended September 30, 2023 of 9.44% is primarily due to the adjustment to the net deferred tax liability.

Note 8 – Commitments and Contingencies

Litigations, Claims and Assessments

In the ordinary course of business, the Company may be involved in legal proceedings, claims and assessments. The Company records contingent liabilities resulting from such claims, if any, when a loss is assessed to be probable and the amount of the loss is reasonably estimable.

License Agreements

L&F Research LLC

The Company entered into a License Agreement with L&F Research LLC ("L&F Research") effective December 15, 2015, as amended (the "L&F License Agreement") pursuant to which L&F granted us an exclusive royalty-bearing, worldwide, sublicensable license under the patent and intellectual property rights and know-how specific to and for the development and commercialization of VAR 200, for the treatment, inhibition or prevention of kidney disease in humans and symptoms thereof, including focal segmental glomerulosclerosis. On February 28, 2023, the Company and L&F executed an Amendment and Restatement Agreement that waived L&F's right to terminate the L&F License Agreement or any other remedies, for non-payment of the First Milestone Payment, until (a) March 31, 2023 as to $1,000,000 of such milestone payments ("Waiver A") and (b) January 31, 2024 as to $500,000 milestone payments ("Waiver B"). Waiver A was contingent upon (i) forgiveness by the Company of $351,579 in aggregate principal amount outstanding under a certain convertible note, and (ii) a cash payment by the Company to L&F in the amount of $648,421, on or before March 31, 2023. Waiver B is contingent upon a cash payment by the Company to L&F in the amount of $500,000 on or before the earlier of (x) January 31, 2024, and (y) ten business days from the date that the Company receives net proceeds of at least $30,000,000 from the issuance of new equity capital. All other terms of the L&F License remain in effect.

On March 29, 2023, the Company forgave $351,579 in aggregate principal amount outstanding on a certain note and paid $648,421 of cash to L&F, thus meeting the conditions of Waiver A. L&F's put option expired upon meeting the Waiver A conditions, which resulted in a reclassification of 65,783 shares of common stock and $331,331 classified as temporary equity to permanent equity.

Operating Leases

On January 18, 2019, the Predecessor entered into a lease agreement for approximately 3,500 square feet of office space in Weston, Florida for a term of five years. Under the lease agreement, the annual base rent, which excludes the Predecessor's share of taxes and operating costs, is approximately $89,000 for the first year and increases approximately 3% every year thereafter for a total base rent lease commitment of approximately $497,000.

The Successor recognized right-of-use asset amortization of $38,885 and $116,083 in connection with its operating lease for the three and nine months ending September 30, 2023, respectively, and the Predecessor recognized rent expense of $42,225 and $118,519 in connection with its operating lease for the three and nine months ending September 30, 2022, respectively.

A summary of the Company's right-of-use assets and liabilities is as follows:

	Successor	Predecessor
	For the Nine Months Ended September 30, 2023	For the Nine Months Ended September 30, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used in operating activities	$ 74,405	$ 67,567
Right-of-use assets obtained in exchange for lease obligations		
Operating leases	$ -	$ -
Weighted Average Remaining Lease Term		
Operating leases	0.34 Years	1.34 Years
Weighted Average Discount Rate		
Operating leases	6.5%	6.5%

Future minimum payments under these operating lease agreements are as follows:

	Amount
October 1, 2023 to December 31, 2023	$ 34,822
Less: amount representing imputed interest	(472)
Total	$ 34,349

Note 9 – Stockholders' Permanent and Temporary Equity

Common Stock

On June 5, 2023, the Company issued 3,044,152 shares of common stock valued at $1.2 million to certain investors in a private placement (including to certain members of the Company's sponsor) in exchange for increasing the duration of their lockup period until July 31, 2023 with respect to an aggregate of 1,977,749 shares of common stock underlying all securities of the Company held by such investors. The $1,156,778 fair value of the common stock issued was recorded in general and administrative expense in the Statement of Operations during the nine-months ended September 30, 2023.

During the nine months ended September 30, 2023, the Company entered into investor marketing agreements with two vendors in which the Company issued an aggregate of 510,000 shares of common stock and cash in exchange for marketing services. The $605,200 fair value of the common stock was established as a prepaid expense and the Company is recognizing the expense over the terms of the contracts.

Equity Offerings

On April 28, 2023, the Company completed an offering of 11,015,500 shares of common stock and warrants to purchase 11,015,500 shares of common stock for gross proceeds of $11.0 million (the “Registered Offering”). Each share of common stock was sold together with a five-year warrant to purchase one share of common stock at an exercise price of $1.00 per share, which was exercisable upon issuance. The Company determined that the warrant should be equity-classified, primarily because it is indexed to the Company’s own stock and it met the requirements for equity classification. Accordingly, because both the common stock and the warrant are equity-classified, it wasn’t necessary to allocate the proceeds or the issuance costs to the respective securities. Total issuance costs were $1,184,482 including $440,620 of placement fees, $455,332 of legal fees, $259,774 of accounting and professional service costs related to the offering, and $28,756 of other costs.

On July 26, 2023, the Company completed a public offering of 3,256,060 shares of common stock, pre-funded warrants (the “Pre-Funded Warrants”) to purchase 9,471,213 shares of common stock and common warrants (the “July 2023 Warrants”) to purchase 12,727,273 shares of common stock at a combined public offering price of $0.165 per share which resulted in gross proceeds of $2.1 million (the “July 2023 Offering”). The Pre-Funded Warrants are exercisable immediately, may be exercised at any time until all Pre-Funded Warrants are exercised in full, and have an exercise price of $0.0001 per share. The July 2023 Warrants are exercisable immediately for a term of five years and have an exercise price of $0.165 per share. The Company determined that both warrants should be equity-classified, primarily because they are indexed to the Company’s own stock and they met the requirements for equity classification. Accordingly, because the common stock and both warrants are equity-classified, it wasn’t necessary to allocate the proceeds or the issuance costs to the respective securities. Total issuance costs were $523,115 including $125,943 of placement fees, $236,091 of legal fees, $87,037 of accounting and professional service costs related to the offering, $26,744 of other costs, and $47,300 incremental fair value of the modified warrants as compared to the original warrants (see Stock Warrants below).

Redemptions of Series A Preferred Stock

On or about April 28, 2023, cash proceeds from the Registered Offering in the amount of $10.5 million were used to redeem 8,400 shares of Series A Preferred Stock. The loss on the extinguishment of preferred stock is accounted for in a manner similar to the treatment of dividends paid on preferred stock. The loss on extinguishment is calculated as the difference between (a) the fair value of the negotiated $10.5 million of cash transferred to the holders of the Series A Preferred Stock (which also settled the Company’s obligation to make premium and Effectiveness Failure payments), and (b) the $3.8 million net carrying amount of the Series A Preferred Stock. Accordingly, the redemption resulted in the recognition of a $6.7 million deemed dividend for the purposes of calculating the Company’s loss per common share. Because the Company has an accumulated deficit, both the debit and the credit associated with the dividend are to additional paid-in-capital, so there is no balance sheet effect.

On August 3, 2023, the Company entered into a redemption agreement and release with an investor which resulted in the Company, on August 4, 2023, redeeming 150 of the 200 remaining shares of Series A Convertible Preferred Stock and warrants to purchase 86,250 shares of common stock at an exercise price of $2.00 per share for a cash payment of $230,000. The Company recognized an $84,315 deemed dividend during the three months ended September 30, 2023, as a result of the extinguishment accounting associated with the redemption.

Triggering of Down Round Provisions

As a result of the Registered Offering, (a) the exercise price of the Series A Warrants to purchase 863,500 shares of common stock at an exercise price of $11.50 per share that were issued to participants in the original PIPE financing had the exercise price reset to its floor price of $2.00 per share, while becoming exercisable for 4,965,125 shares of common stock (which resulted in the recognition of a $1.4 million deemed dividend); (b) the remaining 235 shares of Series A Preferred Stock had their $10.00 original conversion price reset to the floor conversion price of $2.00 per share of common stock (which resulted in the recognition of a $37,000 deemed dividend); and (c) the $10.00 original conversion price of the 5,062 shares of Series B Preferred Stock issued in connection with the Business Combination reset to its floor price of $7.00 per share of common stock (which resulted in the recognition of a $0.1 million deemed dividend).

Conversion of Series A Preferred Stock

Following the triggering of the down round provision, the holders of 35 shares of Series A Preferred Stock converted into 17,500 shares of common stock at the new conversion price of $2.00 per share.

Temporary Equity

See Note 8 – "Commitments and Contingencies" for discussion of the movement of temporary equity to permanent equity on March 29, 2023.

Stock-Based Compensation

For the three months ended September 30, 2023, the Successor recorded stock-based compensation expense of $243,045 (of which, ($38,224) was included in research and development and $281,269 was included in general and administrative expense) related to options issued to employees and consultants. For the three months ended September 30, 2022, the Predecessor recorded stock-based compensation expense of $494,022 (of which $67,608 was included in research and development and $426,414 was included in general and administrative expense) related to options issued to employees and consultants.

For the nine months ended September 30, 2023, the Successor recorded stock-based compensation expense of $896,249 (of which, $117,320 was included in research and development and $778,929 was included in general and administrative expense) related to options issued to employees and consultants. For the nine months ended September 30, 2022, the Predecessor recorded stock-based compensation expense of $3,131,708 (of which $619,363 was included in research and development and $2,512,345 was included in general and administrative expense) related to options issued to employees and consultants. As of September 30, 2023, there was $1,324,176 of unrecognized stock-based compensation expense, which the Company expects to recognize over a weighted average period of 1.7 years.

Stock Options

On January 27, 2023, the Company granted ten-year stock options to purchase 100,000 shares of Successor common stock, with an aggregate grant date value of $184,426 to its newly appointed Chief Medical Officer and Senior Vice President of Medical Affairs as inducement for entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4) under the 2022 Omnibus Equity Incentive Plan (the "2022 Plan"). The stock options vest annually over three years and have an exercise price of $2.11 per share.

On March 10, 2023, the Company granted ten-year stock options to purchase 13,000 shares of Successor common stock to employees of the Company under the 2022 Plan. The stock options have an aggregate grant date value of $23,770, vest annually over three years and have an exercise price of $2.26 per share. Of the 13,000 shares, 5,000 shares were issued to the son of an executive officer of the Company.

On May 24, 2023, the Company granted ten-year stock options to purchase 1,453,107 shares of Successor common stock to employees and directors of the Company under the 2022 Plan. The stock options have an aggregate grant date value of $555,004, of which $499,660 vest annually over three years and $55,344 vest immediately, and have an exercise price of $0.44 per share.

The grant date fair value of stock options granted during the three and nine months ended September 30, 2023 and 2022 was determined using the Black Scholes method, with the following assumptions used:

	Successor	Predecessor	Successor	Predecessor
	For the Three Months Ended September 30, 2023	For the Three Months Ended September 30, 2022	For the Nine Months Ended September 30, 2023	For the Nine Months Ended September 30, 2022
Fair value of common stock on date of grant	n/a	n/a	$ 0.44 - $2.23	$ 2.27 - $3.00
Risk free interest rate	n/a	n/a	3.53% - 4.27%	1.68% - 3.01%
Expected term (years)	n/a	n/a	6.00	3.53 - 6.00
Expected volatility	n/a	n/a	120% - 123%	111% - 119%
Expected dividends	n/a	n/a	0.00%	0.00%

A summary of the option activity for the nine months ended September 30, 2023 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2023	1,993,235	$ 10.81		
Granted	1,566,107	0.56		
Exercised	-	-		
Forfeited	-	-		
Outstanding, September 30, 2023	3,559,342	$ 6.30	6.6	$ -
Exercisable, September 30, 2023	1,968,166	$ 9.53	5.2	$ -

The following table presents information related to stock options as of September 30, 2023:

Options Outstanding		Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$ 0.44	1,453,107	10	150,000
$ 2.11	100,000	-	-
$ 2.26	13,000	-	-
$ 5.03	662,887	2.3	662,887
$ 11.33	12,186	8.8	12,186
$ 11.58	728,430	5.5	728,430
$ 16.36	589,732	7.7	414,663
	3,559,342	5.2	1,968,166

Stock Warrants

On July 26, 2023, in connection with the July 2023 Offering (see Equity Offerings above), the Company amended the exercise price of certain warrants to purchase 1,377,996 shares of common stock for three investors from $1.00 to $0.165 per share and the expiration date was modified from April 28, 2028 to July 28, 2028. The $47,300 incremental fair value of the modified warrants as compared to the original warrants was recognized as an additional issuance cost of the July 2023 Offering.

On August 2, August 8 and September 8, 2023, a July 2023 Offering investor exercised pre-funded warrants to purchase 9,471,213 shares of common stock at an exercise price of $0.0001 per share for total proceeds of $947.

Between September 13 and September 18, 2023, the Company initiated a limited time program, which at the election of the warrant holder, would permit them to immediately exercise their July 2023 Warrants at a reduced exercise price of $0.1357 per share and they would also be granted new 5.5 year warrants to purchase an equal number of shares of common stock at an exercise price of $0.1357 per share. The new warrants are not exercisable for the first six months. Under the program, warrants to purchase an aggregate of 7,121,213 shares of common stock were exercised on September 14, 2023 for gross proceeds of $966,400 less total issuance costs of $208,702. Issuance costs include placement agent fees of $57,980, legal costs of $16,131, and warrant modification costs of $134,591. Because the modification represented a short-term inducement, modification accounting was only performed on the warrants that were actually exercised under the program. The Company recognized the $134,591 modification date incremental value of the modified warrants and additional warrants issued as compared to the original warrants, as an issuance cost of the warrant exercise.

The issuance date fair value of stock warrants issued during the three and nine months ended September 30, 2023 and 2022 was determined using the Black Scholes method, with the following assumptions used:

	Successor	Predecessor	Successor	Predecessor
	For the Three Months Ended September 30, 2023	**For the Three Months Ended September 30, 2022**	**For the Nine Months Ended September 30, 2023**	**For the Nine Months Ended September 30, 2022**
Fair value of common stock on date of grant	$ 0.14 - $0.17	n/a	$0.14 - $1.00	n/a
Risk free interest rate	4.09% - 4.42%	n/a	3.51% - 4.42%	n/a
Expected term (years)	4.9 - 5.5 years	n/a	5 years	n/a
Expected volatility	121 % - 123%	n/a	121% - 123%	n/a
Expected dividends	n/a	n/a	n/a	n/a

A summary of the warrant activity for the nine months ended September 30, 2023 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2023	8,628,706	$ 10.75		
Issued	40,335,199	0.39		
Exercised	(16,592,426)	0.15		
Forfeited	(97,785)	2.00		
Repriced - Old [1]	(863,500)	11.50		
Repriced - New [1]	4,965,125	2.00		
Repriced - Old [2]	(1,377,996)	1.00		
Repriced - New [2]	1,377,996	0.17		
Repriced - Old [3]	(7,121,213)	0.17		
Repriced - New [3]	7,121,213	0.14		
Outstanding, September 30, 2023	36,375,319	$ 2.87	4.6	$ -
Exercisable, September 30, 2023	29,184,304	$ 3.52	4.4	$ -

[1] Warrants represent the reset of the exercise price of the PIPE Warrants to purchase 863,500 shares of common stock to their floor price of $2.00 per share.

[2] Warrants represent the reset of the exercise price of certain April 28, 2023 offering warrants to purchase 1,377,996 shares of common stock to a price of $0.165 per share.

[3] Warrants represent the reset of the exercise price of certain July 26, 2023 offering warrants to purchase 7,121,213 shares of common stock to a price of $0.1357 per share.

The following table presents information related to stock warrants as of September 30, 2023:

Warrants Outstanding			Warrants Exercisable	
Exercise Price		Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
$	0.14	7,121,213	n/a	-
$	0.17	6,984,056	4.8	6,984,056
$	1.00	9,637,504	4.6	9,637,504
$	2.00	4,878,875	4.2	4,878,875
$	5.03	104,704	1.3	34,901
$	6.90	1,271,904	4.2	1,271,904
$	11.50	6,065,562	4.2	6,065,562
$	11.58	311,502	0.2	311,502
		36,375,319	4.4	29,184,304

Effectiveness Failure

In connection with the Business Combination, the Company issued 8,635 shares of Series A Convertible Preferred Stock (the "PIPE Shares"), and common stock purchase warrants (each, a "PIPE Warrant") to purchase 863,500 shares of common stock, at a purchase price of $1,000 per share and warrant, for an aggregate purchase price of $8,635,000 (the "PIPE Investment") pursuant to subscription agreements dated July 20, 2022 (collectively, the "PIPE Subscription Agreements"). On or about February 20, 2023, the Company failed to have the SEC declare a registration statement effective (the "Effectiveness Failure") which covered the Private Investment in Public Equity ("PIPE") registrable securities within the time period prescribed by the PIPE Securities Purchase Agreement (the "SPA"). The SPA entitles the PIPE investors to receive registration delay payments ("Registration Delay Payments") equal to 1.5% of each investor's purchase price on the date of the Effectiveness Failure and every thirty days thereafter that the Effectiveness Failure persists. Failure to make the Registration Delay Payments on a timely basis result in the accrual of interest at the rate of 2.0% per month. On April 28, 2023, the proceeds from the Registered Offering were used to redeem substantially all of the PIPE Shares. (See Redemption of Series A Preferred Stock above.) As of the filing date of this document, the Company expects to have to make additional Registration Delay Payments of approximately $6,819 in the aggregate subsequent to September 30, 2023 and prior to curing the Effectiveness Failure

Note 10 – Subsequent Events

On September 8, 2023, the Company's Board of Directors approved the Company's Amended and Restated 2022 Omnibus Equity Incentive Plan ("the "A&R Plan"), which the stockholders approved on October 31, 2023. The restated plan increases the number of shares of the Company's common stock reserved for issuance by 4,000,000 shares to 5,453,107.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Unless the context otherwise requires, all references in this section to "we," "us" or "our" refer to the combined business of ZyVersa Therapeutics, Inc., a Florida corporation, prior to the Business Combination and ZyVersa Therapeutics, Inc., a Delaware corporation, and its consolidated subsidiaries after giving effect to the Business Combination.

The following discussion and analysis of the results of operations and financial condition of ZyVersa Therapeutics, Inc. (the "Company") as of September 30, 2023 and for the three and nine months ended September 30, 2023 and 2022 should be read in conjunction with our unaudited condensed consolidated financial statements and the notes to those financial statements that are included elsewhere in this Quarterly Report on Form 10-Q. This discussion and analysis should also be read in conjunction with the Company's audited financial statements and related disclosures as of December 31, 2022 and for the year then ended, which are included in the Form 10-K (the "Annual Report") filed with the Securities and Exchange Commission ("SEC") on March 31, 2023. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains statements that are forward-looking. These statements are based on current expectations and assumptions that are subject to risk, uncertainties and other factors. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," or "continue," and similar expressions or variations. Actual results could differ materially because of the factors discussed in "Risk Factors" in our Annual Report, and other factors that we may not know. Except as otherwise required by applicable law, we disclaim any duty to update any forward-looking statements, all of which are expressly qualified by the statements above, to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q.

Business Overview

We are a clinical stage specialty biopharmaceutical company leveraging advanced proprietary technologies to develop first-in-class drugs for patients with renal or inflammatory diseases with high unmet medical needs.

Our lead renal drug candidate, which we refer to as Cholesterol Efflux Mediator™ VAR 200 (2-hydroxypropyl-beta-cyclodextrin or "2HPβCD") has potential to treat multiple renal diseases. Our lead anti-inflammatory drug candidate, which we refer to as Inflammasome ASC Inhibitor IC 100, is a humanized monoclonal IgG4 antibody inflammasome ASC inhibitor targeting ASC with potential to treat multiple inflammatory diseases.

Business Combination

On December 12, 2022 (the "Closing Date"), we consummated the previously announced Business Combination pursuant to the terms of that certain Business Combination Agreement (the "Business Combination Agreement"), by and among ZyVersa Therapeutics, Inc., a Florida corporation ("Old ZyVersa"), the representative of Old ZyVersa's shareholders named therein (the "Securityholder Representative"), Larkspur Health Acquisition Corp., a Delaware corporation ("Larkspur") and Larkspur Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Larkspur ("Merger Sub"). Pursuant to the terms of the Business Combination Agreement (and upon all other conditions of the Business Combination Agreement being satisfied or waived), on the Closing Date of the Business Combination and transactions contemplated thereby (the "Business Combination"), (i) Larkspur changed its name to "ZyVersa Therapeutics, Inc.", a Delaware corporation (the "Company") and (ii) Merger Sub merged with and into Old ZyVersa (the "Merger"), with Old ZyVersa as the surviving company in the Merger and, after giving effect to such Merger, Old ZyVersa became a wholly-owned subsidiary of the Company (collectively the "Successor").

Prior to the completion of the Business Combination, Larkspur was incorporated in Delaware on March 17, 2021 and ZyVersa Therapeutics, Inc. ("Predecessor") was incorporated in the State of Florida on March 11, 2014 as Variant Pharmaceuticals, Inc. Merger Sub was incorporated in the state of Delaware on July 13, 2022. References to the "Company" or ZyVersa" refer to the Successor for the three and nine months ended September 30, 2023, and to the Predecessor for the three and nine months ended September 30, 2022.

Financial Operations Overview

We have not generated any revenue to date and have incurred significant operating losses. Our net losses were $85.0 million for the period from January 1, 2023 through September 30, 2023 (the "Successor Period") and $9.4 million for the period from January 1, 2022 through September 30, 2022 (the "Predecessor Period"). As of September 30, 2023, we had an accumulated deficit of approximately $89.9 million and cash of $1.6 million. We expect to continue to incur significant expenses for the foreseeable future and to incur operating losses. We expect our expenses will increase in connection with our ongoing activities as we:

- progress development of VAR 200 and IC 100;
- prepare and file regulatory submissions;
- manufacture our product candidates for clinical trials;
- hire additional research and development, finance, and general and administrative personnel;
- protect and defend our intellectual property; and
- meet the requirements of being a public company.

We need additional financing to support our continuing operations. We are seeking to fund our operations through public or private equity or debt financings or other sources, which may include government grants and collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition, ability to pursue our business strategy and ability to continue as a going concern. We will need to raise substantial capital to continue our research and development goals and generate revenues to achieve profitability, and we may never do so.

Components of Operating Results

Revenue

Since inception, we have not generated any revenue and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements.

Operating Expenses

Research and Development Expenses

Research and development expenses consist of costs incurred in the discovery and development of our product candidates, and primarily include:

- expenses incurred under third party agreements with contract research organizations ("CROs"), and investigative sites, that conducted or will conduct our clinical trials and a portion of our pre-clinical activities;
- costs of raw materials, as well as manufacturing cost of our materials used in clinical trials and other development testing;
- expenses, including salaries, stock-based compensation and benefits of employees engaged in research and development activities;
- costs of equipment, depreciation and other allocated expenses; and
- fees paid for contracted regulatory services as well as fees paid to regulatory authorities including the U.S. Food and Drug Administration (the "FDA") for review and approval of our product candidates.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid expenses or accrued expenses.

Research and development activities are central to our business model. We expect that our research and development expenses will increase for the foreseeable future as we continue clinical development for our product candidates. As products enter later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Historically, our research and development costs have primarily related to the development of VAR 200 and IC 100. As we advance VAR 200 and IC 100, as well as identify any other potential product candidates, we will continue to allocate our direct external research and development costs to the products. We expect to fund our research and development expenses partially from our current cash and cash equivalents but primarily from any future equity or debt financings, or other capital sources, including potential collaborations with other companies or other strategic transactions.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the size of patient populations participating in the clinical trials;
- the number of doses a patient receives;
- the duration of patient follow-ups;
- the development state of the product candidates; and
- the efficacy and safety profile of the product candidates.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending, and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving regulatory approval for our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay, or modify clinical trials of our product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years and likely millions of dollars in development costs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, stock-based compensation and related costs for our employees in administrative, executive and finance functions. General and administrative expenses also include professional fees for legal, accounting, audit, tax and consulting services, insurance, human resource, information technology, office, and travel expenses.

We expect that our general and administrative expenses will increase in the future as we increase our general and administrative headcount to support our continued research and development and potential commercialization of our product candidates. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services, director and officer insurance, and investor and public relations costs.

Other (Income) Expense

Interest expense includes interest on indebtedness and accretion of debt discount which are associated with the unsecured convertible promissory notes which bear interest at a rate equal to 6% per annum.

Change in fair value of derivative liability represents the periodic mark-to-market of our derivative liabilities. The Company recorded derivative liabilities that were measured at fair value at issuance, related to the redemption features and put options of certain convertible notes payable.

Results of Operations

Comparison of the three months ended September 30, 2023 (Successor Period) and the three months ended September 30, 2022 (Predecessor Period)

The following table summarizes our results of operations for the Successor for the three months ended September 30, 2023 and for the Predecessor for the three months ended September 30, 2022.

	Successor	Predecessor	Favorable (Unfavorable)	
	For the Three Months Ended September 30,	For the Three Months Ended September 30,		
(in thousands)	2023	2022	$ Change	% Change
Operating expenses:				
Research and development	$ 674	$ 2,334	$ 1,660	71.1%
General and administrative	2,229	1,061	(1,168)	(110.1)%
Total Operating Expenses	2,903	3,395	492	14.5%
Loss from Operations	(2,903)	(3,395)	492	14.5%
Other Income (Expense), Net	-	(298)	298	100.0%
Pre-tax net loss	(2,903)	(3,693)	790	(21.4)%
Income tax benefit	1	-	1	100.0%
Net loss	$ (2,902)	$ (3,693)	$ 791	21.4%

Research and Development Expenses

Research and development expenses were $0.7 million for the three months ended September 30, 2023, a decrease of $1.7 million or 71.1% from the three months ended September 30, 2022. The decrease is primarily attributable to a decrease of $1.7 million in the costs of manufacturing materials of IC 100 for the three months ended September 30, 2022.

General and Administrative Expenses

General and administrative expenses were $2.2 million for the three months ended September 30, 2023, an increase of $1.2 million or 110.1% from the three months ended September 30, 2022. The increase is primarily attributable to an increase of $0.4 million in professional fees associated with being a public company, a $0.3 million increase in director and officer insurance, a $0.2 million increase for bonus accruals, and $0.1 million increase in marketing costs for investor and public relations.

Other Income (Expense)

Total other income (expense), net was zero for the three months ended September 30, 2023, a decrease of $0.3 million or 100.0% from the three months ended September 30, 2022. The change was primarily a result of a decrease in interest and change in fair value of derivative liabilities expense of approximately $0.3 million in the aggregate as a result of convertible debt conversions to equity.

Comparison of the nine months ended September 30, 2023 (Successor Period) and the nine months ended September 30, 2022 (Predecessor Period)

The following table summarizes our results of operations for the Successor for the nine months ended September 30, 2023 and for the Predecessor for the nine months ended September 30, 2022.

	Successor	Predecessor	Favorable (Unfavorable)	
(in thousands)	For the Nine Months Ended September 30, 2023	For the Nine Months Ended September 30, 2022	$ Change	% Change
Operating expenses:				
Research and development	$ 2,951	$ 4,120	$ 1,169	28.4%
General and administrative	9,694	4,526	(5,168)	(114.2)%
Impairment of in-process research and development	69,280	-	(69,280)	(100.0)%
Impairment of goodwill	11,895	-	(11,895)	(100.0)%
Total Operating Expenses	93,820	8,646	(85,174)	(985.1)%
Loss from Operations	(93,820)	(8,646)	(85,174)	(985.1)%
Other Income (Expense), Net	1	(799)	800	100.1%
Pre-tax net loss	(93,819)	(9,445)	(84,374)	893.3%
Income tax benefit	8,860	-	8,860	100.0%
Net loss	$ (84,959)	$ (9,445)	$ (75,514)	(799.5)%

Research and Development Expenses

Research and development expenses were $3.0 million for the nine months ended September 30, 2023, a decrease of $1.2 million or 28.4% from the nine months ended September 30, 2022. The decrease is primarily attributable to an approximately $2.0 million decrease in the costs of manufacturing materials of IC 100. This was partially offset by an approximately $0.8 million increase in the costs of drug manufacturing, formulation and pre-clinical operations.

General and Administrative Expenses

General and administrative expenses were $9.7 million for the nine months ended September 30, 2023, an increase of $5.2 million or 114.2% from the nine months ended September 30, 2022. The increase is primarily attributable to an increase of $2.5 million in professional fees associated with being a public company, a $1.1 million increase in marketing costs for investor and public relations, a $1.0 million increase for director and officer insurance, and $0.4 million in 2023 payments for the Effectiveness Failure related to the PIPE Shares.

Impairment of In-Process Research and Development and Goodwill

Impairment of in-process research and development and impairment of goodwill were $69.3 million and $11.9 million, respectively, compared to none for the nine months ended September 30, 2022. The impairment is a result of the decline in our stock price and the resulting market capitalization of the Company at June 30, 2023.

Other (Income) Expense

Total other income (expense), net was $1,000 of income for the nine months ended September 30, 2023, a decrease of $0.8 million of expense or 100.1% from the nine months ended, September 30, 2022. The change was a result of a decrease in interest expense of approximately $0.4 million and a decrease in the loss from the change in the fair value of the derivative liability of $0.4 million, both as a result of convertible debt conversions to equity.

Cash Flows

The following table summarizes our cash flows from operating and financing activities for the Successor for the nine months ended September 30, 2023 and for the Predecessor for the nine months ended September 30, 2022:

(in thousands)	For the Nine Months Ended September 30, 2023	For the Nine Months Ended September 30, 2022	Increase (decrease)
Net cash provided by (used in)			
Operating activities	$ (5,933)	$ (1,078)	$ (4,855)
Financing activities	1,610	1,352	258
Net (Decrease) Increase in Cash	$ (4,323)	$ 274	$ (4,597)

Cash Flows from Operating Activities

Net cash used in operating activities was $5.9 million and $1.1 million for the nine months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and September 30, 2022, the net cash used in operating activities was primarily attributable to the net loss of approximately $85.0 million and $9.4 million, respectively, offset by $75.0 million and $3.6 million, respectively, of net non-cash expenses, and approximately $4.0 million and $4.8 million, respectively, of cash generated by the levels of operating assets and liabilities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $1.6 million and $1.4 million for the nine months ended September 30, 2023 and 2022, respectively. Cash provided by financing activities during the nine months ended September 30, 2023 primarily represented $13.1 million in cash proceeds from issuance of common stock in a public offering and $1.0 million in exercise proceeds from a warrant inducement offer. This was offset by $1.8 million in registration and issuance costs associated with common stock issuances and $10.7 million in cash paid for the redemption of Series A Preferred Stock. Cash provided by financing activities during the nine months ended September 30, 2022 represented proceeds from the issuance of preferred stock in a private placement of $1.4 million.

Liquidity and Capital Resources

The following table summarizes our total current assets, current liabilities and working capital deficiency at September 30, 2023 and December 31, 2022, respectively:

(in thousands)	September 30, 2023	December 31, 2022
Current Assets	$ 2,005	$ 6,363
Current Liabilities	$ 11,707	$ 8,188
Working Capital Deficiency	$ (9,702)	$ (1,825)

Since our inception in 2014 through September 30, 2023, we have not generated any revenue and have incurred significant operating losses and negative cash flows from our operations. Based on our current operating plan, we have limited our research and development spending and we expect our cash of $1.6 million as of September 30, 2023 will only be sufficient to fund our operating expenses and capital expenditure requirements on a month-to-month basis. However, it is difficult to predict our spending for our product candidates prior to obtaining FDA approval. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control.

Going Concern

Since inception we have been engaged in organizational activities, including raising capital and research and development activities. We have not generated revenues and have not yet achieved profitable operations, nor have we ever generated positive cash flow from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. We are subject to those risks associated with any pre-clinical stage pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, we operate in an environment of rapid technological change and are largely dependent on the services of our employees and consultants. Further, our future operations are dependent on the success of our efforts to raise additional capital. These uncertainties raise substantial doubt about our ability to continue as a going concern for 12 months after the issuance date of our financial statements. The accompanying financial statements have been prepared on a going concern basis. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of us to continue as a going concern, which contemplates the continuation of operations, realization of assets and liquidation of liabilities in the ordinary course of business. We incurred a net loss of $85.0 million for the nine months ended September 30, 2023 and a net loss of $9.4 million for the nine months ended September 30, 2022, and we had an accumulated deficit of $89.9 million at September 30, 2023. We anticipate incurring additional losses until such time, if ever, that we can generate significant revenue from our product candidates currently in development. Our primary source of capital has been the issuance of debt and equity securities. We believe that current cash is only sufficient to fund operations and capital requirements on a month-to-month basis. We will need additional financing to fund our operations, to complete development of and to commercially develop our product candidates and to continue as a going concern. There is no assurance that such financing will be available when needed or on acceptable terms.

Contractual Obligations

The following summarizes our contractual obligations as of September 30, 2023 that will affect our future liquidity. Based on our current operating plan, we plan to satisfy the obligations identified below from our current cash balance and future financing.

Cash requirements for our current liabilities as of September 30, 2023 include approximately $11.7 million for accounts payable, accrued expenses, and our operating lease liability.

Future Capital Requirements

We intend to raise additional capital in the near term in order to meet our current obligations and fund our day-to-day operations and current obligations.

We expect to raise additional capital by issuing equity or equity-linked securities in subsequent offerings. If we are unable to raise additional capital by issuing equity or equity-linked securities on terms favorable to us, we may not have sufficient liquidity to execute our business strategy. We have various warrants outstanding that can be exercised for our common stock, many of which must be exercised in exchange for cash paid to us by the holders of such warrants. If the market price of our common stock is less than the exercise price of a holder’s warrants, it is unlikely that holders will exercise their warrants. As such, we do not expect to receive significant proceeds in the near term from the exercise of most of our warrants based on the current market price of our common stock and the exercise prices of such warrants.

Our policy is to invest any cash in excess of our immediate requirements in investments designed to preserve the principal balance and provide liquidity while producing a modest return on investment. Accordingly, our cash equivalents will be invested primarily in money market funds which are currently providing only a minimal return given the current interest rate environment.

We expect to continue to incur substantial additional operating losses for at least the next several years as we continue to develop our product candidates and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of our product candidates. If we obtain marketing approval for our product candidates, we will incur significant sales, marketing and outsourced manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls, and similar requirements applicable to us as a public company.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the initiation, progress, timing, costs, and results of clinical trials for our product candidates;
- the clinical development plans we establish for each product candidate;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA or other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending, and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the cost and timing of the implementation of commercial scale manufacturing activities; and
- the cost of establishing, or outsourcing, sales, marketing, and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, clinical trials of our product candidates, and other operations and potential product acquisitions and in-licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in-license and develop additional products and product candidates to augment our internal development pipeline. Strategic transaction opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue development, acquisition, or in-licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for general corporate purposes. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could be structured as a collaboration or partnering arrangement. We have no arrangements, agreements, or understandings in place at the present time to enter into any acquisition, in-licensing or similar strategic business transaction. In addition, we continue to evaluate commercial collaborations and strategic relationships with established pharmaceutical companies, which would provide us with more immediate access to marketing, sales, market access and distribution infrastructure.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our existing stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

JOBS Act Accounting Election

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. The JOBS Act permits companies with emerging growth company status to take advantage of an extended transition period to comply with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We expect to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (1) are no longer an emerging growth company or (2) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act.

Off-Balance Sheet Arrangements

There are no off-balance sheet arrangements between us and any other entity that have, or are reasonably likely to have, a current or future effect on financial conditions, changes in financial conditions, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

Critical Accounting Policies and Estimates

Refer to our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 31, 2023 and Note 2 to the condensed consolidated financial statements of this Quarterly Report on Form 10-Q, for a discussion of our critical accounting policies and use of estimates.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act, is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in company reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer (who serve as our Principal Executive Officer and Principal Financial and Accounting Officer, respectively), to allow timely decisions regarding required disclosure.

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2022. Based upon their evaluation and due to the material weakness cited below, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were ineffective.

During the year ended December 31, 2022, our management determined that our internal controls over financial reporting were not effective as of December 31, 2022. Specifically, management's conclusion was based on the following material weakness which existed as of December 31, 2022:

- The Company did not design and implement effective controls over the accounting for significant and complex non-routine transactions.

Our management plans to establish procedures to monitor and evaluate the effectiveness of our internal controls over financial reporting on an ongoing basis and are committed to taking further action and implementing necessary enhancements or improvements, including those necessary to address the material weakness cited above. Management expects to commence its assessment of the design and operating effectiveness of its internal controls over financial reporting, including the development and implementation of its remediation plan, as soon as resources permit. However, the material weakness will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of the Effectiveness of Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. A control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

None.

ITEM 1A. RISK FACTORS.

You should consider the risks and uncertainties described under Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, which we filed with the Securities and Exchange Commission on March 31, 2023, together with all other information contained or incorporated by reference in this Quarterly Report on Form 10-Q, when evaluating our business and our prospects. There are no material changes to the risk factors set forth in Part I, Item 1A, in our Annual Report on Form 10-K for the year ended December 31, 2022.

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

Our common stock is currently listed for trading on The Nasdaq Global Market. We must satisfy the continued listing requirements of Nasdaq, to maintain the listing of our common stock on The Nasdaq Global Market.

On June 9, 2023, the Company received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market, LLC ("Nasdaq") indicating that, based upon the closing bid price of the Company's common stock for the last 30 consecutive business days, the Company is not currently in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Notice").

The Notice has no immediate effect on the continued listing status of our common stock on the Nasdaq Global Market, and, therefore, our listing remains fully effective.

We are provided a compliance period of 180 calendar days from the date of the Notice, or until December 6, 2023, to regain compliance with the minimum closing bid requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). If at any time before December 6, 2023, the closing bid price of our common stock closes at or above $1.00 per share for 10 consecutive business days, Nasdaq will provide written notification that we have achieved compliance with the minimum bid price requirement, and the matter would be resolved. If we do not regain compliance during the compliance period ending December 6, 2023, then Nasdaq may grant us a second 180 calendar day period to regain compliance, provided we (i) meet the continued listing requirement for market value of publicly-held shares and all other initial listing standards for the Nasdaq Global Market, other than the minimum closing bid price requirement and (ii) notify Nasdaq of our intent to cure the deficiency.

We will continue to monitor the closing bid price of our common stock and seek to regain compliance with all applicable Nasdaq requirements within the allotted compliance periods. If we do not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel. Although we intend to engage in efforts to regain compliance, and thus maintain our listing, there can be no assurance that we will regain compliance with the minimum bid price requirement during the 180-day compliance period, secure a second period of 180 days to regain compliance or maintain compliance with the other Nasdaq listing requirements.

If we fail to continue to meet all applicable Nasdaq Global Market requirements in the future and Nasdaq determines to delist our common stock, the delisting could substantially decrease trading of our common stock; adversely affect the market liquidity of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws; adversely affect our ability to obtain financing on acceptable terms, if at all; and may result in the potential loss of confidence by investors, suppliers, customers, and employees, and fewer business development opportunities. Additionally, the market price of our common stock may decline further and shareholders may lose some or all of their investment.

Unless our common stock continues to be listed on a national securities exchange it will become subject to the so-called "penny stock" rules that impose restrictive sales practice requirements.

If we are unable to maintain the listing of our common stock on Nasdaq or another national securities exchange, our common stock could become subject to the so-called "penny stock" rules if the shares have a market value of less than $5.00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than $5.00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and "accredited investors" as defined by relevant SEC rules. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. This means that if we are unable to maintain the listing of our common stock on a national securities exchange, the ability of stockholders to sell their common stock in the secondary market could be adversely affected.

If a transaction involving a penny stock is not exempt from the SEC's rule, a broker-dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker-dealer also must disclose the commissions payable to both the broker-dealer and its registered representative, current quotations for the penny stock, and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer's account and information on the limited market in penny stocks.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES.

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

Exhibit	Description
4.1	Form of Inducement Warrant (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on September 14, 2023).
10.1	Form of Inducement Letter (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 14, 2023).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
32.1**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
101. INS	XBRL Inline Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished, not filed, herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this quarterly report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: November 14, 2023	By: */s/ Stephen C, Glover* Stephen C. Glover Chief Executive Officer (Principal Executive Officer)
Dated: November 14, 2023	By: */s/ Peter Wolfe* Peter Wolfe Chief Financial Officer (Principal Financial and Accounting Officer)