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: June 30, 2024
or

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

For the transition period from _____to _____

Commission File Number: 001-41575

Lipella Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-2388040**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

7800 Susquehanna St., Suite 505
Pittsburgh, PA 15208
(Address of principal executive offices) (Zip Code)

(412) 894-1853
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

As of August 12, 2024, there were 8,004,636 shares of common stock, par value $0.0001 per share ("Common Stock"), of the registrant outstanding.

Lipella Pharmaceuticals Inc.
Form 10-Q
June 30, 2024

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References in this Quarterly Report on Form 10-Q to the "Company," "Lipella," "we," "us," or "our" mean Lipella Pharmaceuticals Inc. unless otherwise expressly stated or the context indicates otherwise.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

Lipella Pharmaceuticals Inc.
CONDENSED BALANCE SHEETS

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current Assets		
Cash and cash equivalents	$ 1,186,506	$ 3,293,738
Grants receivable	35,332	32,286
Prepaid expenses	858,989	103,256
Total Current Assets	2,080,827	3,429,280
Property and Equipment		
Furniture, fixtures and equipment	140,294	140,294
Furniture, fixtures and equipment (accumulated depreciation)	(128,987)	(127,544)
Furniture and fixtures, net	11,307	12,750
Other Assets		
Operating lease right of use asset	91,978	135,144
Total Assets	2,184,112	3,577,174
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	178,361	138,016
Accrued expenses	126,999	77,280
Operating lease liability	93,679	89,223
Payroll liability	81,274	80,836
Total Current Liabilities	480,313	385,355
Operating lease liability, net of current portion	—	47,371
Total Liabilities	480,313	432,726
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 shares authorized; -0- shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	$ —	$ —
Common stock, $.0001 par value; 200,000,000 shares authorized, 7,605,636 shares issued and outstanding at June 30, 2024 and 6,053,956 shares issued and outstanding at December 31, 2023	761	605
Subscription receivable	—	—
Additional paid-in capital	14,156,836	13,467,686
Accumulated deficit	(12,453,799)	(10,323,843)
Total stockholders' equity	1,703,798	3,144,448
Total liabilities and stockholders' equity	$ 2,184,111	$ 3,577,174

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

Lipella Pharmaceuticals Inc.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2024	**June 30, 2023**	**June 30, 2024**	**June 30, 2023**
Grant revenues	$ 136,431	$ 106,676	$ 282,311	$ 224,724
Total revenues	136,431	106,676	282,311	224,724
Cost and expenses				
Research and development	$ 661,558	1,057,645	$ 1,504,158	1,751,376
General and administrative	$ 427,062	624,231	$ 947,988	1,132,980
Total costs and expenses	1,088,620	1,681,876	2,452,146	2,884,356
Loss from operations	(952,189)	(1,575,200)	(2,169,835)	(2,659,632)
Other income (expense)				
Interest income, net	14,043	41,968	39,880	63,969
Interest expense related party	—	(5,454)	—	(10,848)
Total other income(expense)	14,043	36,514	39,880	53,121
Loss before income taxes	(938,146)	(1,538,686)	(2,129,955)	(2,606,511)
Provision for income taxes	—	—	—	—
Net Loss	$ (938,146)	$ (1,538,686)	$ (2,129,955)	$ (2,606,511)
Loss per share of Common Stock				
Basic	$ (0.12)	$ (0.27)	$ (0.29)	$ (0.45)
Dilutive	$ (0.12)	$ (0.27)	$ (0.29)	$ (0.45)
Weighted average of shares of Common Stock outstanding:				
Basic	7,605,636	5,743,945	7,449,016	5,743,945
Dilutive	7,605,636	5,743,945	7,449,016	5,743,945

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

Lipella Pharmaceuticals Inc.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

	Series A Convertible Preferred Stock		*Common Stock*		*Additional paid-in capital*	*Accumulated Deficit*	*Total*
	Shares	*Amount*	*Shares*	*Amount*			
Balances, December 31, 2022	—	$ —	5,743,945	$ 574	$ 10,379,900	$ (5,704,878)	$ 4,675,596
Net loss	—	—	—	—	—	(1,067,825)	(1,067,825)
Stock-based compensation	—	—	—	—	208,639	—	208,639
Balances, March 31, 2023	—	—	5,743,945	574	10,588,539	(6,772,703)	3,816,410
Net loss	—	—	—	—	—	(1,538,686)	(1,538,686)
Stock-based compensation	—	—	—	—	847,618	—	847,618
Balances, June 30, 2023	—	—	5,743,945	574	11,436,157	(8,311,389)	3,125,342
Balances, December 31, 2023	—	—	6,053,956	605	13,467,686	(10,323,843)	3,144,448
Net loss	—	—	—	—	—	(1,191,809)	(1,191,809)
Stock-based compensation	—	—	—	—	208,639	—	208,639
Warrants exercised for shares of Common Stock	—	—	500,000	50	(50)	—	—
Issuance of Common Stock	—	—	289,812	29	199,971	—	200,000
Shares issued for services	—	—	196,078	20	199,980	—	200,000
Balances, March 31, 2024	—	—	**7,039,846**	**704**	**14,076,227**	**(11,515,652)**	**2,561,278**
Net loss	—	—	—		—	(938,146)	(938,146)
Stock-based compensation	—	—	—		80,666	—	80,666
Warrants exercised for share of Common Stock	—	—	565,790	57	(57)	—	—
Balances, June 30, 2024	**—**	**$ —**	**7,605,636**	**$ 761**	**$ 14,156,836**	**$ (12,453,799)**	**$ 1,703,798**

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

Lipella Pharmaceuticals Inc.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	For the Six Months Ended June 30,	
	2024	**2023**
Cash flow from operating activities:		
Net loss	$ (2,129,955)	$ (2,606,511)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,443	—
Shares issued for services	200,000	—
Non-cash stock option expense	289,305	1,056,257
Interest expense related party net (non-cash)	—	—
Changes in operating assets and liabilities:		
Operating right of use asset	252	(67)
Grants receivable	(3,046)	85,611
Prepaid expense	(755,732)	338,589
Accounts payable	40,345	(362,300)
Accrued expenses	49,719	(254,101)
Payroll liability	438	9,423
Net cash used in operating activities	(2,307,231)	(1,733,099)
Cash flow from financing activities:		
Proceeds from issuance of Common Stock, net of issuance costs	200,000	—
Repayment of notes payable	—	(275,000)
Net cash provided by financing activities	200,000	(275,000)
Net decrease in cash, cash equivalents	(2,107,232)	(2,008,099)
Cash, and cash equivalents at beginning of period	3,293,738	5,121,743
Cash, and cash equivalents at end of period	$ 1,186,505	$ 3,113,644
Supplemental disclosure of cash flow information:		
Interest paid	$ (1,457)	$ (10,338)
Income taxes paid	—	—
Supplemental disclosure of cash flow information:		
Issuance of Common Stock for forgiveness of related party note	—	—
Issuance of Common Stock options for consulting services	—	—

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

Note 1. Description of Business and Basis of Presentation

Nature of Business

Lipella Pharmaceuticals Inc. (the "Company", "we", "us" or "our") is a clinical-stage biotechnology company focused on developing new drugs by reformulating the active agents in existing generic drugs and optimizing these reformulations for new applications. Our operations consist of research, preclinical development and clinical development activities, and our most advanced program is in Phase 2 clinical development. Since our inception in 2005, we have historically financed our operations through a combination of federal grant revenue, licensing revenue, manufacturing revenue, as well as equity and debt financing.

Basis of Presentation

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

In the opinion of management, the accompanying unaudited condensed financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations, and cash flows. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to instructions, rules, and regulations prescribed by the U.S. Securities and Exchange Commission ("SEC"). The unaudited condensed interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2023 that was filed with the SEC on February 27, 2024 (our "Annual Report").

Note 2. Going Concern

The accompanying condensed financial statements have been prepared in conformity with GAAP, which contemplate continuation of the Company as a going concern. The Company has not established a source of revenues sufficient to cover its operating costs and will require significant additional capital to continue its research and development programs, including progressing clinical product candidates to commercialization and preparing for commercial-scale manufacturing and sales.

The Company's net loss for the six months ended June 30, 2024 and fiscal year ended December 31, 2023 was $ 2,129,955 and $4,618,965, respectively. Since inception, the Company has incurred historical losses and has an accumulated deficit of $12,453,799 at June 30, 2024 and $10,323,843 at December 31, 2023, respectively. At June 30, 2024, the Company had available cash and cash equivalents of $ 1,186,506 and net working capital of $1,600,513. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to: research, development of product candidates, conducting preclinical studies and clinical trials, and administrative organization. These funds, and our funds available under existing government contracts, may not be sufficient to enable us to meet our obligations as they come due at least for the next twelve months from the issuance date of these financial statements.

If we are unable to obtain additional capital (which is not assured at this time), our long-term business plan may not be accomplished, and we may be forced to curtail or cease operations. These factors individually and collectively raise substantial doubt about our ability to continue as a going concern. The accompanying unaudited condensed financial statements do not include any adjustments that may result from this uncertainty.

Note 3. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 3, "Accounting Policies," in the Company's Annual Report on Form 10-K filed with the SEC on February 27, 2024. There have been no material changes to the significant accounting policies during the three-month period ended June 30, 2024, except for items mentioned below.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of these financial statements. Actual results could differ from those estimates.

Adoption of New Accounting Pronouncements

During the three months ended June 30, 2024, no new accounting pronouncement was issued or became effective, that had or is expected to have, a material impact on our Financial Statements.

Concentration of Credit Risk

The Company's grant revenues and grant receivables are from the National Institute of Health (the "NIH"). The NIH is an agency of the United States Department of Health & Human Services, and the Company believes amounts are fully collectible from this agency. Contract revenues were $282,311 for the six months ended June 30, 2024, and $ 136,431 for the three months ended June 30, 2024.

Earnings Per Share

Basic net loss per share of Common Stock is computed by dividing the net loss for the period by the weighted-average number of shares of Common Stock outstanding during the period. Diluted net loss per share of Common Stock is computed giving effect to all dilutive Common Stock equivalents, consisting of stock options and warrants. Diluted net loss per share of Common Stock for the six months ended June 30, 2024 and 2023 is the same as basic net loss per share, as the Common Stock equivalents were anti-dilutive due to the net loss.

At June 30, 2024 and 2023 the Common Stock equivalent shares were, as follows:

	June 30,	
	2024	2023
Shares of Common Stock issuable under equity incentive plans outstanding	2,893,000	2,478,000
Shares of Common Stock issuable upon exercise of warrants	1,558,467	143,994
Shares of Common Stock issuable upon conversion of Series A Preferred Stock	—	—
Common Stock equivalent shares excluded from diluted net loss per share	4,451,467	2,621,994

Note 4. Fair Value Measurements and Marketable Debt Securities

In accordance with ASC 820, "*Fair Value Measurements and Disclosures"* ("ASC 820"), the Company measures its assets and liabilities at fair value. We apply the three-level valuation hierarchy as described in ASC 820, which is based upon the transparency of input as of the measurement date. The three levels of inputs as defined are:

Level 1 - Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 - Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instruments.

Level 3 - Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

At June 30, 2024 and December 31, 2023, the Company's financial instruments consist primarily of: cash and cash equivalents, accounts payable and accrued liabilities. For cash equivalents, accounts payable and accrued liabilities, the carrying amounts of these financial instruments as of June 30, 2024 and December 31, 2023 were considered representative of their fair values due to their short term to maturity.

The Company held no marketable securities at June 30, 2024 and December 31, 2023. For cash equivalents at June 30, 2024 and December 31, 2023, the fair value input levels are summarized below:

June 30, 2024	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash Equivalents (maturity less than 90 days)				
Commercial Paper	$ —	$ —	$ —	$ —
U.S. Government	—	—	—	—
Money market funds	871,203	—	—	871,203
Total Cash equivalents	871,203	—	—	871,203
Marketable Securities	—	—	—	—
Total Cash Equivalents and Marketable Securities	$ 871,203	**$ —**	**$ —**	$ 871,203

December 31, 2023	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash Equivalents (maturity less than 90 days)				
Commercial Paper	$ —	$ —	$ —	$ —
U.S. Government	—	—	—	—
Money market funds	3,052,648	—	—	3,052,648
Total Cash equivalents	3,052,648	—	—	3,052,648
Marketable Securities	—	—	—	—
Total Cash Equivalents and Marketable Securities	$ 3,052,648	$ —	$ —	$ 3,052,648

Note 5. Prepaid Expenses

At June 30, 2024, prepaid expenses were $858,989, and consisted primarily of prepaid insurance of $ 87,490, prepaid costs of issuance of $241,835, an advance deposit with our clinical trial management partner of $ 346,671, and $182,993 in other prepaid expenses related primarily to professional services. At December 31, 2023, prepaid expenses consisted of $88,554 of prepaid insurance, and $ 14,702 of prepaid expenses.

Note 6. Accrued Expenses

At June 30, 2024, accrued expenses were $126,999, consisting of $19,575 of accrued clinical expenses and $ 107,424 of unbilled legal and professional expenses. At December 31, 2023, accrued expenses totaled $77,280 and consisted of $ 19,575 in clinical expenses, $52,050 in franchise tax expenses, and $5,655 in unbilled professional services expenses.

Note 7. Notes Payable – Related Party

There were no notes payable outstanding at June 30, 2024 or December 31, 2023.

Note 8. Letter of Credit

The Company has a letter of credit with a bank for an aggregate available amount of $ 50,000 due upon demand. The letter of credit is collateralized by substantially all of the Company's assets and personally guaranteed by Dr. Jonathan Kaufman, the Company's Chief Executive Officer. The outstanding advances under the line of credit bear interest at the lending bank's prime rate plus 3.10%. The outstanding balance was $0 at June 30, 2024 and December 31, 2023, respectively.

Note 9. Stock Options

The Company has two stock incentive plans (each, a "Stock Option Plan" and collectively, the "Stock Option Plans"), each of which provides for the grant of both incentive stock options and non-qualified stock options. Under the terms of the Stock Option Plans, the maximum number of shares of Common Stock for which incentive and/or non-qualified stock options may be issued is 3,478,000 shares. This number comprises 1,078,000 stock options already issued and outstanding (non-expired) from the 2008 stock option plan, and 2,400,000 shares of Common Stock underlying option awards that may be issuable under the 2020 stock option plan. Incentive stock options are granted with an exercise price determined by the Company's board of directors (the "Board"). The terms of the vesting of such options, including termination, are as set forth in the Stock Option Plans and their respective award agreements. Such stock options generally expire 10 years from the date of the grant. Subject to certain exceptions for grants made to employees who are large stockholders, stock options granted under the Stock Option Plans have an exercise price not less than the fair market value of the underlying Common Stock on the date of such grant. If an employee leaves the Company prior to fully vesting their option awards and the remaining unvested portion is considered forfeited, the earlier recognition of the unvested shares is reversed during the period of forfeiture. As of June 30, 2024, there were $460,092 in unrecognized compensation costs related to non-vested share-based compensation arrangements granted, to be recognized over the remaining vesting period of less than one year.

The Company recognized $80,667 and $847,618 of compensation costs related to stock option vesting for the three months ended June 30, 2024 and 2023, respectively. The Company recognized $289,306 of compensation costs for the six months ended June 30, 2024, and $ 1,056,257 of compensation costs for the six months ended June 30, 2023.

The following is an analysis of options to purchase shares of Common Stock issued and outstanding as of June 30, 2024 and December 31, 2023:

	Shares	***Weighted Average Exercise Price Per Share ($)***	***Weighted Average Remaining Contractual Term (in Years)***	***Aggregate intrinsic value ($)***
Outstanding as of December 31, 2022	2,054,000	$ 2.84	5.51	$ 605,687
Granted	424,000	$ 2.19	9.96	$ —
Expired	—			
Cancelled	(25,000)	$ 2.19		
Exercised	—			
Outstanding as of December 31, 2023	2,453,000	$ 2.73	5.19	$ —
Granted	440,000	$ 0.77	9.96	$ —
Expired	—			
Cancelled	—			
Exercised	—			
Outstanding as of March 31, 2024	2,893,000	$ 2.43	5.70	$ —
Granted	—			
Expired	—			
Cancelled	—			
Exercised	—			
Outstanding as of June 30, 2024	2,893,000	$ 2.43	5.45	$ —
Vested as of June 30, 2024	2,493,000			
Exercisable as of June 30, 2024	2,493,000			
Exercisable as of December 31, 2023	2,272,333			

A summary of status of the Company's non-vested stock options (exercisable for shares of Common Stock on a one-to-one basis) as of, and changes during, the six months ended June 30, 2024 and 2023 is presented below:

	Number of Stock Options	Weighted-Average Fair Value Grant Date
Nonvested at December 31, 2022	434,667	$ 2.82
Granted	424,000	2.84
Vested	(423,334)	2.83
Expired	—	—
Nonvested at June 30, 2023	435,333	$ 2.81
Nonvested at December 31, 2023	180,667	$ 2.81
Granted	440,000	0.55
Vested	(220,667)	1.13
Expired	—	—
Nonvested at June 30, 2024	400,000	$ 0.70

In the six months ended June 30, 2024 and June 30, 2023, the Company granted options as described below.

Stock Option Grants - On March 15, 2024, the Company granted 440,000 stock options at a $0.77 strike price, vesting as follows: one third of such grant vests on April 1, 2024, one third of such grant vests on July 1, 2024, and one third of such grant vests on October 1, 2024.

On June 16, 2023, the Company issued 424,000 stock options at a $2.19 strike price, vesting immediately upon issuance.

The weighted-average fair value of stock options on the date of grant and the assumptions used to estimate the fair value of stock options granted during the six months ended June 30, 2024 and June 30, 2023 using the Black-Scholes option-pricing model are as follows:

Six months ended June 30,	**2024**	**2023**
Weighted-average fair value of options granted	$ 0.55	$ 1.50
Expected volatility	86.17%	83.47%
Expected life (in years)	5.17	5.04
Risk-free interest rate (range)	4.33%	3.99%
Expected dividend yield	$ —	$ —

Note 10. Preferred Stock

The Company's Series A Convertible Preferred Stock, par value $0.0001 per share (the "Series A Preferred Stock"), ranks prior, with respect to dividend rights and rights upon a liquidation event, to all Common Stock and any other series of preferred stock which is junior to Series A Preferred Stock. Upon any matter submitted to the shareholders of the Company for a vote, each holder of Series A Preferred Stock is entitled to the number of votes as is equal to the number of shares of Common Stock into which such shares of Series A Preferred Stock are convertible at the time of such vote. The Series A Preferred Stock is not entitled to any mandatory dividends.

The Company issued 1,592,447 shares of Series A Preferred Stock at $ 0.60 per share over a period beginning September 2008 through June 2013, for gross proceeds of $833,188. The implied price of the Series A Preferred Stock issuance, $0.5232 per share, is $ 0.0768 per share less than the $0.60 offering price. This difference is associated with the conversion terms of three debt instruments issued from June 2006 through April 2008 that had a total face value of $351,500, and converted into a total of 789,634 of the 1,592,447 shares, which imputes the additional $ 122,280 to interest and/or conversion discounts. In addition, $351,500 in face value of the debt instruments had associated warrants. All consideration upon the issuance of convertible debt plus warrants was imputed to the debt component leaving the associated warrants having no value. All note-associated warrants have expired.

In the year ended December 31, 2022, all 636,979 outstanding shares of Series A Preferred Stock were converted to Common Stock on a 1:1 basis. There were no shares of Series A Preferred Stock outstanding at December 31, 2023 or June 30, 2024. The Series A Preferred Stock was cancelled and eliminated by the Company on April 11, 2024.

Note 11. Common Stock

The Company's second amended and restated certificate of incorporation, as amended, authorizes the issuance of 200,000,000 shares of Common Stock. There were 7,605,636 shares of Common Stock outstanding as of June 30, 2024 and 6,053,956 shares outstanding as of December 31, 2023.

On May 3, 2024, 565,790 shares of Common Stock were issued for the exercise of the same number of pre-funded warrants.

Notice of Failure to Satisfy Nasdaq Minimum Bid Price Requirement

As disclosed in our Current Report on Form 8-K filed with the SEC on April 19, 2024, on April 17, 2024, we received a written notification (the "Nasdaq Letter") from The Nasdaq Stock Market LLC ("Nasdaq") notifying us that, based upon the closing bid price of the Common Stock for the last 30 consecutive business days, the Company was not in compliance with the requirement to maintain a minimum bid price of $1.00 per share of its Common Stock, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Nasdaq Letter had no immediate effect on the listing of the Common Stock, which continues to trade on the Nasdaq Capital Market under the symbol "LIPO" at this time.

Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company has been given 180 calendar days, or until October 14, 2024, to regain compliance with the Minimum Bid Price Requirement. If at any time before October 14, 2024, the bid price of the Common Stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, the Nasdaq staff will provide written confirmation that the Company has regained compliance with the Minimum Bid Price Requirement and the matter will be closed.

If the Company does not regain compliance with the Minimum Bid Price Requirement, the Company may be eligible for an additional 180-calendar day grace period. To qualify, the Company will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and will need to provide written notice of its intention to cure the deficiency during the second compliance period. If the Company does not regain compliance with the Minimum Bid Price Requirement by October 14, 2024, and is otherwise not eligible for such additional 180-day grace period to regain such compliance, the Nasdaq staff will provide written notice to the Company that the Common Stock will be subject to delisting. At that time, the Company may appeal any such delisting determination to a Nasdaq hearings panel.

Note 12. Warrants

No warrants were issued in the three months and six months ended June 30, 2024. On October 23, 2023, the Company entered into a securities purchase agreement (the "Purchase Agreement") with an institutional investor for the issuance and sale in a private placement (the "Private Placement") of pre-funded common stock purchase warrants ("Pre-Funded Warrants") to purchase up to 1,315,790 shares of Common Stock, with an exercise price of $0.001 per share, and common stock purchase warrants (the "Warrants") to purchase up to 1,315,790 shares of Common Stock, with an exercise price of $1.40 per share. The gross proceeds to the Company from the Private Placement were approximately $ 2.0 million, before deducting placement agent fees and expenses and offering expenses payable by the Company. The Warrants and the Pre-Funded Warrants are immediately exercisable for three years from issuance and are subject to 4.99% and 9.99% beneficial ownership limitations (as applicable). The combined purchase price for one Pre-Funded Warrant and one accompanying Warrant was $1.519. The closing of the Private Placement contemplated by the Purchase Agreement occurred on October 25, 2023. The Company had no warrant liabilities at June 30, 2024 and December 31, 2023.

Note 13. Commitment and Contingencies

Operating Leases

Operating leases are recorded as right of use ("ROU") assets and lease liabilities on the balance sheet. ROU assets represent our right to use the leased assets for the lease term, and lease liabilities represent our obligation to make lease payments. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its estimated incremental borrowing rate at the commencement date to determine the present value of lease payments. The operating lease ROU assets also include any lease payments made and exclude lease incentives.

The Company entered into a lease agreement beginning July 1, 2020, for the Company's principal headquarters on the fifth floor of 7800 Susquehanna Street, Pittsburgh, Pennsylvania, which includes office space and sterile manufacturing operations (the "Lease"). The Lease has a five-year term and includes an option for renewal, which is not reasonably certain and is excluded from the right of use calculation. On July 26, 2023, the Company entered a second lease for additional space on the fourth floor of the same building (the "Fourth Floor Lease"), commencing August 1, 2023 and co-terminating with the existing Lease on June 30, 2025. Subsequently effective January 1, 2024, the Company terminated the Fourth Floor Lease early at no penalty upon mutual agreement with the landlord and replaced it with a lease of additional space that had become available immediately adjacent to our existing offices (the "Suite 504 Lease", and together with the "Lease", "the Leases"). The Suite 504 Lease term co-terminates with the Lease. Future minimum rent payments under the Leases as of June 30, 2024 are as follows:

Year ending		
2024 (six months remaining)	$	48,519
2025	$	48,519
Total minimum lease payments	$	97,037
Less: amount representing interest	$	(3,358)
Present value of minimum lease payments	$	93,679

The Leases are accounted for as a ROU asset and liability. As of June 30, 2024, the Company had $ 91,979 of an operating lease ROU asset, and $93,679 of current lease liabilities, respectively, recorded on the balance sheets. There was no long term lease liability at June 30, 2024, as the existing leases end 12 months from the balance sheet date. As of December 31, 2023, the Company had an ROU asset of $135,144 and current and non-current operating lease liabilities of $89,223 and $47,371, respectively.

The lease expense for the three months ended June 30, 2024 and June 30, 2023 was $ 23,834 and $16,368, respectively. The lease expense for the six months ended June 30, 2024 and June 30, 2023 was $47,845 and $32,737, respectively. Cash paid for the amounts included in the measurement of lease liabilities for the three months ended June 30, 2024 and 2023 was $23,797 and $16,402, respectively, and for the six months ended June 30, 2024 and 2023 was $47,594 and $32,804, respectively. The payments are included in the operating activities in the accompanying statement of cash flows. The discount rates used for our right-of-use leases range from 6.25% to 7.25%.

Contract Commitments

The Company enters into contracts in the normal course of business with contract research organizations ("CROs"), contract manufacturing organizations, universities, and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. These contracts generally do not contain minimum purchase commitments and are cancellable by us upon prior written notice although, purchase orders for clinical materials are generally non-cancellable. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation or upon the completion of a manufacturing run.

Note 14. Income Taxes

The provision for income taxes for the three and six months ended June 30, 2024 and 2023 was $0, resulting in an effective income tax rate of 0% for each period. The Company's effective tax rate for the six months ended June 30, 2024 and 2023 was primarily due to the full valuation allowance against the Company's net deferred tax assets.

The Company regularly evaluates the realizability of its deferred tax assets and establishes a valuation allowance if it is more likely than not that some or all of the deferred tax assets will not be utilized. Because of our cumulative losses, substantially all of the deferred tax assets have been fully offset by a valuation allowance as of June 30, 2024 and December 31, 2023. We have not paid income taxes for the year ended December 31, 2023. The income tax provision attributable to loss before income tax benefit for the three and six months ended June 30, 2024 differed from the amounts computed by applying the U.S. federal statutory rate of 21% as a result of the following:

Statutory federal income tax rate	21.00%
State taxes, net of federal benefit	7.11%
Change in valuation allowance	-28.11%
Effective tax rate	0.00%

The Company's 2019 through 2023 tax years remain subject to examination by the Internal Revenue Service for federal tax purposes and the Commonwealth of Pennsylvania for state tax purposes.

Note 15. Subsequent Events

Subsequent events have been evaluated through the date on which the unaudited condensed financial statements were issued, and no material events were identified, except as disclosed below.

On August 1, 2024, the Company, in a registered direct offering and pursuant to a securities purchase agreement, issued 399,000 shares of Common Stock to an institutional investor at an offering price of $0.62 per share, along with pre-funded warrants to purchase 1,667,000 shares of Common Stock at an offering price of $0.619 per pre-funded warrant (the "August 2024 Offering"). The per share exercise price for the pre-funded warrants is $0.001, and the pre-funded warrants are immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. Such shares and pre-funded warrants were issued pursuant to a prospectus supplement, dated July 31, 2024, to the registration statement on Form S-3 (File No. 333-276815), declared effective by the SEC on February 8, 2024. In connection with the August 2024 Offering and pursuant to an engagement letter with H.C. Wainwright & Co. LLC (the "Placement Agent"), who served as the placement agent for the August 2024 Offering, the Company agreed to pay the Placement Agent aggregate cash fees of 8.5% of the gross proceeds received by the Company from the August 2024 Offering, and an aggregate of $60,950 in reimbursements, non-accountable expenses and clearing expenses. The Company also agreed to issue to the Placement Agent warrants to purchase up to 154,950 shares of Common Stock under Section 4(a)(2) of the Securities Act of 1933, as amended, which are exercisable immediately following issuance, expire on July 31, 2029, and have an exercise price equal to $0.775 per share. The net proceeds of the August 2024 Offering were approximately $1.0 million, after fees and expenses.

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

The following discussion and analysis of our financial condition and results of operations for the three and six months ended June 30, 2024 should be read together with our unaudited condensed financial statements and related notes included in Item 1 of Part I of this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2024 (this "Form 10-Q"), as well as the audited financial statements, the related notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2023 contained in our Annual Report on Form 10-K for the year ended December 31, 2023, that was filed with the SEC on February 27, 2024 (our "Annual Report"), and all risk factors disclosed herein and therein. Such discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as well as information relating to our business that reflect our management's current views, expectations and assumptions concerning our business, strategies, products, future results and events and financial performance, which are subject to risks and uncertainties that may cause our, or our industry's, actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. Such forward-looking statements speak only as of the date of this Form 10-Q. Although we believe that the expectations reflected in such forward-looking statements are reasonable, we cannot guarantee future results, levels of activity or achievements or that our underlying assumptions will prove to be correct. Except as required by applicable law, including the securities laws of the United States, we expressly disclaim any obligation or undertaking to disseminate any update or revisions to any such forward-looking statement to reflect any change in our expectations with regard thereto or to conform such forward-looking statements to actual results. Statements made in this Form 10-Q, other than statements of historical fact, addressing operating performance, events, or developments which our management expects or anticipates will or may occur in the future, and also statements related to expected or anticipated growth, revenues, profitability, new products, adequacy of funds from operations, statements expressing general optimism about future operating results, and other non-historical information, are forward-looking statements. In particular, the words "may," "will," "expects," "anticipates," "aims," "potential," "future," "intends," "plans," believes," "estimates," "continue," "likely to," and variations of such words and similar expressions identify forward-looking statements, but such words are not the exclusive means of identifying such forward-looking statements, and their absence does not necessarily mean that such statement is not forward-looking.

Overview

We are a clinical-stage biotechnology company focused on developing new drugs by reformulating the active agents in existing generic drugs and optimizing these reformulations for new applications. We believe that this strategy combines many of the cost efficiencies and risk abatements derived from using existing generic drugs with potential patent protections for our proprietary formulations; this strategy allows us to expedite, protect, and monetize our product candidates. Additionally, we maintain a therapeutic focus on diseases with significant, unaddressed morbidity and mortality where no approved drug therapy currently exists. We believe that this focus can potentially help reduce the cost, time and risk associated with obtaining marketing approval.

LP-10 is the development name of our reformulation of tacrolimus (an approved generic active agent) specifically optimized for topical deposition to the internal surface of the urinary bladder lumen using a proprietary drug delivery platform that we have developed and that we refer to as our metastable liposome drug delivery platform (our "Platform"). We are developing LP-10 and our Platform to be, to our knowledge, the first drug candidate and drug delivery technology that could be successful in treating cancer survivors who acquire hemorrhagic cystitis. We have received U.S. Food and Drug Administration ("FDA") "orphan drug" designation covering LP-10 and plan to apply for additional regulatory designations in the event we achieve qualifying results in clinical trials for LP-10. Market data exclusivity may be available in the U.S. and other jurisdictions in which regulatory approval is obtained for the Company's product, regardless of patent status.

The safety and efficacy of LP-10 was evaluated in a 13-subject, open-label, multi-center, dose-escalation, phase 2a clinical trial in patients experiencing complications associated with a rare but highly morbid disease called "radiation-induced hemorrhagic cystitis" or "radiation cystitis." This phase 2a clinical trial commenced on February 15, 2021, and we reported the trial's summary results in the first quarter of 2023. We met with the FDA in the fourth quarter of 2023 regarding the LP-10 clinical trial results, and on April 3, 2024, the FDA granted a Type C meeting request to discuss our proposed Phase-2b clinical trial design for the evaluation of LP-10. We received a response from the FDA on May 15, 2024, and based on our communication with the FDA, we are currently preparing a full Phase 2b protocol for submission to the FDA in the third quarter of 2024.

There is currently no FDA approved drug therapy available for radiation cystitis patients, who are all cancer survivors who received pelvic radiation therapy to treat solid pelvic tumors, including prostate and ovarian cancers, and who are now dealing with therapy-associated complications, including urinary bleeding (a radiation cystitis symptom). LP-10's active ingredient, tacrolimus, which has a well-known pharmacology and toxicology, addresses a reduction (or cessation) of uncontrolled urinary bleeding.

In the fourth quarter of 2023, we received IND approval from the FDA for LP-310, our product for the treatment of oral lichen planus ("OLP"). We have begun the clinical trial process for LP-310, and initiated the first clinical site in the second quarter of 2024, and expect to treat the first patient by the third quarter of 2024. OLP is a chronic, T-cell-mediated, autoimmune oral mucosal disease, and LP-310 contains tacrolimus which inhibits T-lymphocyte activation. To date, upon review of relevant FDA public data resources on approved drugs and biologics, we are not aware of any other liposomal products developed to treat such disease.

In the first quarter of 2024, we received IND approval from the FDA for LP-410, our phase-1/2a product, for the treatment of oral graft-versus-host disease ("GVHD"). LP-410 is an oral rinse, similar to LP-310, but will have a different containment system. Hematopoietic cell transplantation ("HCT") is used to treat a wide range of malignancies, hematologic and immune deficiency states, and autoimmune diseases. GVHD is a clinical syndrome where donor-derived immunocompetent T-cells react against patient tissues directly or through exaggerated inflammatory responses following HCT. Lipella has developed LP-410 for the topical delivery directly to the mouth surface. LP-410 targets the underlying mechanisms of oral GVHD, potentially providing a safe and effective treatment option for affected individuals. Lipella received "orphan drug" designation approval on November 11, 2023 for tacrolimus for the treatment of oral GVHD. An IND application for LP-410's treatment of oral GVHD was submitted to the FDA on January 30, 2024.

Since our inception in 2005, we have focused primarily on business planning and progressing our lead product candidates, including progressing LP-10 through clinical development, raising capital, organizing and staffing the Company. On December 22, 2022, we completed our initial public offering (the "IPO") and issued an aggregate of 1,217,391 shares of Common Stock at a price of $5.75 per share. The aggregate net proceeds from the IPO were approximately $5.0 million after deducting underwriting discounts and commissions of approximately $630,000 and offering expenses of approximately $1.16 million.

Recent Developments

In July 2024, the Company enrolled the first patients in a multi-center Phase 2a clinical trial evaluating LP-310 for the treatment of OLP, and is actively screening additional subjects with symptomatic OLP.

On August 1, 2024, the Company completed the August 2024 Offering and received net proceeds of approximately $1.0 million, after fees and expenses. See "Note 15 – Subsequent Events" of the notes to the Company's unaudited condenses financial statements in this Form 10-Q as well as the Current Report on Form 8-K filed by the Company with the SEC on August 1, 2024 for more information regarding the August 2024 Offering.

Results of Operations

Comparison of the Three Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended June 30, 2024 and 2023 (in thousands):

	For the three months ended June 30,		Increase
	2024	2023	(Decrease)
(in thousands)			
Revenue	$ 136	$ 107	$ 30
Operating expenses:			
Research and development ("R&D")	662	1,058	(396)
General and administrative	427	624	(197)
Total operating expenses	1,089	1,682	(593)
Loss from operations	(952)	(1,575)	623
Other income	14	37	(23)
Net loss	$ (938)	$ (1,539)	$ 600

Grants and Other Revenue

We have not yet commercialized any products and we do not expect to generate revenue from sales of any product candidates for several years. For the three months ended June 30, 2024 and 2023, we recognized revenue from a grant awarded by the National Institutes of Health ("NIH") in September of 2022 (the "2022 NIH Grant"), which was an award of an aggregate of $673,000. NIH approved an additional year of funding under the 2022 NIH Grant in June 2023, increasing the total funding provided under the 2022 NIH Grant to $1,353,000.

We recognize revenue from grants when the related costs are incurred and the right to payment is realized. For the three months ended June 30, 2024, we earned $136,000 in connection with the 2022 NIH Grant, recognized as revenue, compared with $107,000 revenue in the three months ended June 30, 2023. The increase in annual grant revenue from 2023 to 2024 is driven by increased salaries and time spent on the grant work.

Operating Expenses

Our operating expenses consist of (i) R&D expenses and (ii) general and administrative expenses.

Research and Development Expenses

R&D costs primarily consist of direct costs associated with consultants and materials, biologic storage, third party CRO costs and contract development and manufacturing expenses, salaries and other personnel-related expenses. R&D costs are expensed as incurred. More specifically, these costs include:

- costs of funding research performed by third parties that conduct research and development and nonclinical and clinical activities on our behalf;
- costs of manufacturing drug supply and drug product;
- costs of conducting nonclinical studies and clinical trials of our product candidates;
- consulting and professional fees related to research and development activities, including equity-based compensation to non-employees;
- costs related to compliance with clinical regulatory requirements; and
- employee-related expenses, including salaries, benefits and stock-based compensation expense for our research and development personnel.

Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data, such as information provided to us by our vendors, and analyzing the progress of our nonclinical and clinical studies or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period. Advance payments that we make for goods or services to be received in the future for use in R&D activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

We expect that our R&D expenses will increase substantially in connection with our clinical development activities for our LP-10 and LP-310 programs. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of, or obtain regulatory approval for, any of our current or future product candidates. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the specific factors set forth in the section of our Annual Report titled "Risk Factors." If any events described in the applicable risk factors included in the section of our Annual Report titled "Risk Factors" occur, then the costs and timing associated with the development of any of our product candidates could significantly change. We may never succeed in obtaining regulatory approval for, of commercialization of, LP-10, LP-310, or any of our other product candidates.

R&D expenses decreased by approximately $396,000, from $1,058,000 for the three months ended June 30, 2023 to $662,000 for the three months ended June 30, 2024. The decrease in R&D expenses was primarily attributable to a decrease in stock option expense of $468,000 related to a June 2023 stock option grant issuance that vested immediately. This was offset by an increase in outside services of $44,000 for clinical study trials. Indirect costs related to operational overhead and employee benefits increased $28,000.

General and Administrative Expenses

General and administrative expenses consist primarily of management and business consultants and other related costs, including stock-based compensation. General and administrative expenses also include board of directors' expenses and professional fees for legal, patent, consulting, accounting, auditing, tax services and insurance costs.

General and administrative expenses were $427,000 for the three months ended June 30, 2024, compared to $624,000 for the three months ended June 30, 2023, a decrease of $197,000. These decreases were primarily related to a decrease in stock option expense of $299,000 and related to a June 2023 stock option grant that was fully vested upon issuance. This was offset by an increase in outside services spend of $102,000, including investor relations expense.

Net Other Income (Expense)

Net other income for the three months ended June 30, 2024 was $14,000, as compared to $37,000 for the three months ended June 30, 2023. There was a $28,000 decrease in interest income on the Company's short term investment portfolio, driven by lower investment balances. It was offset by a reduction in interest expense of $5,000. There was no interest expense on related party notes during the three months ended June 30, 2024, as the Company had no outstanding debt during such period, as compared to the same period for the prior year, when the Company had $250,000 of notes outstanding. See Note 7 of the notes to our financial statements in our Annual Report for details of such related party notes and accrued interest at the prior period.

Comparison of the Six Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the six months ended June 30, 2024 and 2023 (in thousands):

	Six Months Ended June 30,		Increase
(in thousands)	**2024**	**2023**	**(Decrease)**
Revenue	$ 282	$ 225	$ 57
Operating expenses:			
R&D	1,504	1,751	(247)
General and administrative	948	1,133	(185)
Total operating expenses	2,452	2,884	(432)
Loss from operations	(2,170)	(2,659)	489
Other income (expense)	40	53	(13)
Net loss	$ (2,130)	$ (2,606)	$ 476

Grants and Other Revenue

For the six months ended June 30, 2024, we earned $282,000 in connection with a grant from the NIH, recognized as revenue. We received $225,000 in revenue for the six months ended June 30, 2023. The increase in annual grant revenue from 2023 to 2024 is related to the increased time spent on the grant project, as well as increased salaries and overhead costs associated with the project.

Operating Expenses

Research and Development Expenses

The following table summarizes our R&D expenses for the six months ended June 30, 2024 and 2023 (in thousands):

	Six Months Ended June 30,		Increase
(in thousands)	**2024**	**2023**	**(Decrease)**
Direct R&D expenses for the LP-10 product candidate program:			
Employee-related costs	$ 34,000	$ 81,000	$ (47,000)
Employee stock option expense	22,000	142,000	(120,000)
Outsourced R&D	52,000	82,000	(30,000)
Facility-related costs	25,000	43,000	(18,000)
Platform development, early-stage research and unallocated expenses:			
Employee-related costs	415,000	292,000	123,000
Employee stock option expense	225,000	574,000	(349,000)
Outsourced R&D	477,000	354,000	123,000
Facility-related costs	254,000	183,000	71,000
Total research and development expenses	$ 1,504,000	$ 1,751,000	$ (247,000)

R&D expenses decreased by approximately $247,000, to $1,504,000 for the six months ended June 30, 2024, from $1,751,000 for the six months ended June 30, 2023. The decrease in R&D expenses was primarily attributable to a decrease in stock option expense versus the prior year by $469,000. This was offset by increases in 2024 of personnel costs (including employee benefits) of $76,000, and overhead and facility related costs, including supplies, of $53,000. There was also an increase in outside services of $93,000 in 2024, compared to the same period in the prior year, related to planning and launching our clinical trial for LP-310.

General and Administrative Expenses

General and administrative expenses were $948,000 for the six months ended June 30, 2024, compared to $1,133,000 for the six months ended June 30, 2023. General and administrative expenses decreased by approximately $185,000. including a decrease in stock option expense $297,000, with higher costs in the prior year related to our June 2023 option grants to employees and directors. Simultaneously, other personnel costs (including payroll taxes and benefits) decreased $13,000, and there was an increase in outside services of $121,000, which includes legal, investor relations, accounting and tax services, and others.

Net Other Income (Expense)

Net other income for the six months ended June 30, 2024 was $40,000, as compared to $53,000 for the six months ended June 30, 2023. This balance primarily included (i) cash interest income, (ii) unrealized loss on investments, and (iii) non-cash interest expense on related party notes in 2023. A higher cash investment balance in 2023 resulted in a decrease of $24,000 in interest on short term investments in the six months ended June 30, 2024

compared to the same period in the prior year. Meanwhile, interest expense on related party notes decreased by $11,000 due to an pay off of notes outstanding from $275,000 during the six months ended June 30, 2023 to $0 during the six months ended June 30, 2024. See Note 7 of the notes to our unaudited condensed financial statements in this Form 10-Q as well as Note 7 of the notes to our financial statements in our Annual Report for details of such related party notes and accrued interest at the respective periods.

Liquidity and Capital Resources

Sources of Liquidity

We have not yet commercialized any products, and we do not expect to generate revenue from sales of any product candidates for several years, if at all. Cash and cash equivalents totaled $1.2 million as of June 30, 2024. We consider all highly liquid investments that mature in 90 days or less when purchased to be cash equivalents.

We have incurred operating losses and experienced negative operating cash flows for the six months ended June 30, 2024 and the year ended December 31, 2023, and we anticipate that we will continue to incur losses for the foreseeable future. Our net loss totaled $2,129,955 and $2,606,511 for the six months ended June 30, 2024 and 2023 respectively, and $4,618,965 for the year ended December 31, 2023.

Historically, we have financed our operations through a combination of grant revenue and equity financing, however our goals for the foreseeable future will likely require significant equity financing. Our ability to achieve significant profitability depends on our ability to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, LP-10 and/or our other product candidates, which may not occur for several years, if ever. The net losses we incur may fluctuate significantly from quarter to quarter.

Cash Flows

The following table provides information regarding our cash flows for each of the periods presented (in thousands):

	For the Six Months Ended June 30,	
Dollars in thousands	**2024**	**2023**
Net cash (used) provided in operating activities	$ (2,307)	$ (1,733)
Net cash provided in financing activities	200	(275)
Net increase(decrease) in cash and cash equivalents	$ (2,107)	$ (2,008)

Net Cash (Used) Provided in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2024 was approximately $2,307,000. This comprised a net loss for the period of approximately $2,130,000, and increased prepaid expenses (primarily insurance policies, outside services, and clinical trial operations services) of $758,000, offset by increased operating liabilities of $90,000. There were also noncash adjustments reducing the net loss by $289,000 in stock option expense and $200,000 in shares of Common Stock issued for services.

Net cash used in operating activities for the six months ended June 30, 2023 was approximately $1,733,000. This comprised a net loss for the period of approximately $2,606,000, and decreased operating liabilities of $607,000, offset by decreases in the following assets: grants receivable of $86,000 and prepaid expenses (primarily insurance policies and consulting services) of $339,000. There were also and noncash adjustments to net loss of $1,056,000 in stock option expense.

Net Cash Used in Investing Activities

There was no cash used in investing activities for the six month periods ended June 30, 2024 and 2023.

Net Cash Used in Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2024 was $200,000, received for the issuance of Common Stock. Net cash used in financing activities for the six months ended June 30, 2023 was $275,000 in cash, of which $25,000 was used to fully repay a line of credit and $250,000 was used to fully repay a related party note.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing R&D activities, particularly as we continue R&D, advance clinical trials of LP-10 and advance the preclinical development of our other programs, including LP-310. In addition, we expect to incur additional costs associated with operating as a public company. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our operations and capital expenses through the end of 2024. However, we have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of LP-10, LP-310 and our other and future product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on, and could increase significantly as a result of, many factors, including, but not limited to, those referenced above in "*— Results of Operations — Operating Expenses — Research and Development Expenses*".

Going Concern

The unaudited condensed financial statements of the Company have been prepared on a going concern basis, which contemplates the realization of assets and the discharge of liabilities in the normal course of business. We have generated losses from operations since inception. The Company expects operating losses to continue in the foreseeable future because of additional costs and expenses related to research and development activities, plans to expand its product portfolio, and increasing its market share. The Company's ability to transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support its cost structure. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business.

Management of the Company may raise additional funds through the issuance of equity securities or debt. There can be no assurance that such financing will be available at terms acceptable to the Company, if at all. Failure to generate sufficient cash flows from operations and raise additional capital could have a material adverse effect on the Company's ability to achieve its intended business objectives. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying unaudited condensed financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Off-Balance Sheet Arrangements

We did not have during the six months ended June 30, 2024, or the year ended December 31, 2023, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Contractual Obligations

We did not have during the six months ended June 30, 2024 or the year ended December 31, 2023, and we do not currently have, any material contractual obligations, such as license agreements or similar arrangements, other than as described below and in the financial notes to our unaudited condensed financial statements included in this Form 10-Q and in our Annual Report.

Employment Agreements

We are party to employment agreements with each of Drs. Kaufman and Chancellor and Mr. Johnston, executive officers of the Company, the material terms of each of which are described in the section entitled "*Executive Compensation – Executive Employment Agreements*" of our Annual Report, which descriptions are supplemented by the disclosure of the August 2023 amendments to our agreements with Drs. Kaufman and Chancellor contained in our Current Report on Form 8-K filed with the SEC on August 8, 2023, and as described in our Annual Report.

Lease Agreement

We are party to a lease agreement, dated June 1, 2019, with Bridgeway Development Corporation ("Bridgeway"), as amended, for the lease of 2,690 square feet of office and lab and manufacturing space in Pittsburgh, Pennsylvania commencing on July 1, 2020 (the "Lease"). The Lease term expires on June 30, 2025 and we have the right to exercise a one-time option to extend the Lease term for an additional five-year term. The annual base rent under the Lease is approximately $66,000. On July 26, 2023, the Company entered into a second lease for additional space on the fourth floor of the same building (the "Fourth Floor Lease," and together with the Lease, the "Leases"), commencing August 1, 2023 and co-terminating with the Lease on June 30, 2025. Annual rent under the Fourth Floor Lease was approximately $28,000. As space became available in the immediate proximity to our existing offices at the beginning of 2024, we terminated the Fourth Floor Lease upon mutual agreement with the landlord and replaced it with a lease for Suite 504 ("the Suite 504 Lease"). The Suite 504 Lease is effective January 1, 2024 and the term co-terminates with the Lease. The annual base rent for the current year for the Suite 504 Lease is approximately $29,000. See Note 13 of the notes to our unaudited condensed financial statements included in this Form 10-Q.

Service Agreements

We enter into service agreements in the normal course of business with CROs and for clinical trials, preclinical research studies and testing, manufacturing, and other services and products for operating purposes. These contracts do not contain any minimum purchase commitments. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly to reimburse them for their unrecoverable outlays incurred prior to cancellation. The exact amounts of such obligations are dependent on the timing of termination, and the exact terms of the relevant agreement and cannot be reasonably estimated. The expense we incurred pursuant to these agreements for the six months ended June 30, 2024 was approximately $421,000, which was consistent with the approximately $430,000 expense incurred for the six months ended June 30, 2023. The spending was primarily attributable to expenses relating to our ongoing research and development work, and costs related to our clinical trials for LP-10 in 2023 and LP-310 in 2024.

Critical Accounting Policies and Significant Judgments and Estimates

This management's discussion and analysis is based on our unaudited condensed financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make judgments and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the unaudited condensed financial statements and the reported amounts of expenses during the reported periods. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the financial statements prospectively from the date of change in estimates.

While our accounting policies are described in more detail in the notes to our financial statements included in our Annual Report, we believe the following accounting policies used in the preparation of our financial statements require the most significant judgments and estimates. See Note 3 of the notes to our financial statements in our Annual Report for a description of our other significant accounting policies.

Accrued Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued third-party R&D expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued R&D expenses include the costs incurred for services performed by our vendors in connection with R&D activities for which we have not yet been invoiced.

We base our expenses related to R&D activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct R&D activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the R&D expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future R&D activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts incurred.

Stock-Based Compensation

We measure stock-based compensation based on the grant date fair value of the stock-based awards and recognize stock-based compensation expense on a straight-line basis over the requisite service period of the awards, which is generally the vesting period of the respective award. For non-employee awards, compensation expense is recognized as the services are provided, which is generally ratably over the vesting period. We account for forfeitures as they occur. On January 1, 2018, we adopted, using the modified retroactive approach, the guidance of *Accounting Standard Update 2018-07, Compensation — Stock Compensation (Topic 718) — Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), and account for awards to non-employees using the grant date fair value without subsequent periodic remeasurement. The adoption of ASU 2018-07 did not have a material effect on our financial statements.

We classify stock-based compensation expense in our statements of operations in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified. In future periods, we expect stock-based compensation expense to increase, due in part to our existing unrecognized stock-based compensation expense and as we grant additional stock-based awards to continue to attract and retain our employees.

We determine the fair value of restricted Common Stock awards granted based on the fair value of our Common Stock. We have historically determined the fair value of the underlying Common Stock based on input from management and the board of directors and the Company's enterprise value determined utilizing various methods, including the "back-solve" method. The total enterprise value, determined from the back-solve method, is historically then allocated to the various outstanding equity instruments, including the underlying Common Stock, utilizing the option pricing method ("OPM") or a hybrid of the probability-weighted expected return method ("PWERM") and the OPM.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. As the public market for our Common Stock has been limited and prior to the IPO there was no such public market, we have historically determined the volatility for awards granted based on an analysis of reported data for a group of guideline companies that issued options with substantially similar terms. The expected volatility has been determined using a weighted-average of the historical volatility measures of this group of guideline companies along with our own. We expect to continue estimating expected volatility based on the group of guideline companies until we have adequate historical data regarding the volatility of our own traded stock price. The expected term of our stock options granted to employees and non-employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. We have not paid, and do not anticipate paying, dividends on our Common Stock; therefore, the expected dividend yield is assumed to be zero.

As there was no public market for our Common Stock prior to the IPO, the estimated fair value of our Common Stock prior to our IPO had been approved by our board of directors, with input from management, as of the date of each award grant, considering our most recently available independent third-party valuations of our Common Stock and any additional objective and subjective factors that we believed were relevant and which may have changed from the date of the most recent valuation through the date of each award grant. We estimated the value of our equity using the market approach and a precedent transaction method which "back-solves" the equity value that yielded a specific value for our Series A Stock. We allocated the equity value to our Common Stock and shares of our Series A Stock using either an OPM or a hybrid method, which is a hybrid between the OPM and the PWERM. The hybrid method we utilized estimated the probability-weighted value across multiple scenarios but used the OPM to estimate the allocation of value within at least one of the scenarios. In addition to the OPM, the hybrid method considered the IPO scenario in which the shares of our Series A Preferred Stock converted to Common Stock. The future value of the Common Stock in the IPO scenario was discounted back to the valuation date at an appropriate risk adjusted discount rate. In the hybrid method, the present value indicated for each scenario was probability weighted to arrive at an indication of value for our Common Stock.

In addition to considering the results of the valuations, management considered various objective and subjective factors to determine the fair value of our Common Stock as of each grant date, which may be a date later than the most recent third-party valuation date, including:

- the prices of our Series A Preferred Stock sold to or exchanged between outside investors in arm's length transactions, if any, and the rights, preferences and privileges of our Series A Preferred Stock as compared to those of our Common Stock, including the liquidation preferences of our Series A Preferred Stock;
- the progress of our R&D efforts, including the status of preclinical studies;
- the lack of liquidity of our equity as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- the achievement of enterprise milestones;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- the likelihood of achieving a liquidity event for the holders of our Series A Preferred Stock and Common Stock, such as an IPO, or a sale of the Company, given prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

There are significant judgments and estimates inherent in these valuations. These judgments and estimates included assumptions regarding our future operating performance, the stage of development of our programs, the timing of a potential offering, or other liquidity event, and the determination of the appropriate valuation methodology at each valuation date. The assumptions underlying these valuations represented management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different. Subsequent to the completion of the IPO, the fair value of our Common Stock is determined based on the market price of our Common Stock on Nasdaq.

With respect to stock options granted during the six months ended June 30, 2024 and 2023, the following table sets forth by grant date the (i) number of shares of our Common Stock issuable upon exercise of such stock options, (ii) per share exercise price of such options and (iii) estimated fair value per share of our Common Stock on each such date. We did not grant any shares of restricted Common Stock during this period.

Grant date	Number of shares of Common Stock issuable upon exercise of stock options granted	Exercise price per share of Common Stock	Estimated fair value per share of Common Stock at grant date
03/15/24	440,000	$ 0.77	$ 0.55
06/16/23	424,000	$ 2.19	$ 1.50

The per share values at each such grant date, which we applied to determine the per share estimated fair value of the respective awards for accounting purposes, were based upon the calculations described above used to determine the fair value of our Common Stock as of each grant date.

Emerging Growth Company Status

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this extended transition period and, as a result, we will not be required to adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

In addition, as an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include, among other things:

- reduced disclosure about the compensation paid to our executive officers;
- not being required to submit to our stockholders' advisory votes on executive compensation or golden parachute arrangements;
- an exemption from the auditor attestation requirement in the pursuant to the Sarbanes-Oxley Act of 2002; and
- an exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation.

We may take advantage of these exemptions until such time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earliest of

- the last day of the fiscal year on which we have $1.235 billion or more in annual revenue;
- the date on which we become a "large accelerated filer" (i.e., as of our fiscal year end, the total market value of our common equity securities held by non-affiliates is $700 million or more as of June 30);
- the date on which we issue more than $1.0 billion of non-convertible debt over a three-year period; or
- the last day of our fiscal year following the fifth anniversary of the date of the completion of the IPO.

We may choose to take advantage of some but not all of these exemptions.

Recent Accounting Pronouncements

We have reviewed all recently issued accounting pronouncements and have determined that, other than as disclosed in Note 3 to our unaudited condensed financial statements included in this Report, such standards will not have a material impact on our financial statements or do not otherwise apply to our operations.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

As a smaller reporting company, as defined in Item 10(f)(1) of Regulation S-K, we are not required to provide the information required by this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this report. Disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on this evaluation, the Company's management, including the Chief Executive Officer and Chief Financial Officer, concluded that its disclosure controls and procedures were effective as of June 30, 2024.

Changes in Internal Controls

There were no changes in the Company's internal control over financial reporting that occurred during the three months ended June 30, 2024, that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

Limitations of the Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include, but are not limited to, the realities that judgments in decision making can be faulty and that breakdowns can occur because of simple errors. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become subject to legal proceedings, claims or litigation arising in the ordinary course of business. We are not presently a party to any legal proceedings that in the opinion of our management, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows.

Item 1A. Risk Factors.

As a smaller reporting company, we are not required to provide the information required by this item.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

In accordance with SEC Release 33-8238, Exhibits 32.1 and 32.2 are being furnished and not filed.

* Filed herewith.

SIGNATURES

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

Lipella Pharmaceuticals Inc.

Date: August 13, 2024

By: /s/ Jonathan Kaufman
Jonathan Kaufman
President and Chief Executive Officer
(Duly Authorized Officer and Principal Executive Officer)

Date: August 13, 2024

By: /s/ Douglas Johnston
Douglas Johnston
Chief Financial Officer
(Duly Authorized Officer and Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION
OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Jonathan Kaufman, as the principal executive officer of the registrant, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended June 30, 2024, of Lipella Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 13, 2024

By:/s/ Jonathan Kaufman
Jonathan Kaufman
Chief Executive Officer
(Duly Authorized Officer and Principal Executive Officer)

Exhibit 31.2

CERTIFICATION
OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Douglas Johnston, as the principal financial officer of the registrant, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended June 30, 2024, of Lipella Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 13, 2024

By:/s/ Douglas Johnston
Douglas Johnston
Chief Financial Officer
(Duly Authorized Officer and Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Lipella Pharmaceuticals Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan Kaufman, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 13, 2024

By: /s/ Jonathan Kaufman
Jonathan Kaufman
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of Lipella Pharmaceuticals Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas Johnston, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 13, 2024

By: /s/ Douglas Johnston
Douglas Johnston
Chief Financial Officer
(Principal Financial and Accounting Officer)