LIPOCINE INC.

FORM 10-Q
(Quarterly Report)

Filed 08/05/25 for the Period Ending 06/30/25

Telephone	801 994 7383
CIK	0001535955
Symbol	LPCN
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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

FORM 10-Q

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

For the quarterly period ended June 30, 2025

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: 001-36357

LIPOCINE INC.
(Exact name of registrant as specified in its charter)

Delaware	**99-0370688**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
675 Arapeen Drive, Suite 202, Salt Lake City, Utah	**84108**
(Address of principal executive offices)	**(Zip Code)**

801-994-7383
(Registrant's telephone number, including area code)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☒

Outstanding Shares

As of August 4, 2025 the registrant had 5,419,047 shares of common stock outstanding.

TABLE OF CONTENTS

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

LIPOCINE INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(Unaudited)

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 6,043,980	$ 6,205,926
Marketable investment securities	11,891,702	15,427,385
Accrued interest income	121,732	120,447
Prepaid and other current assets	362,629	567,915
Total current assets	18,420,043	22,321,673
Property and equipment, net of accumulated depreciation of $1,254,975 and $1,223,297 respectively	133,397	165,075
Other assets	23,753	23,753
Total assets	$ 18,577,193	$ 22,510,501
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 442,994	$ 271,696
Accrued expenses	685,779	921,240
Deferred revenue	320,000	320,000
Total current liabilities	1,448,773	1,512,936
Total liabilities	1,448,773	1,512,936
Commitments and contingencies (notes 8 and 11)		
Stockholders' equity:		
Common stock, par value $0.0001 per share, 75,000,000 shares authorized; 5,374,431 and 5,348,276 issued and 5,374,095 and 5,347,940 outstanding, respectively	8,865	8,863
Additional paid-in capital	221,000,961	220,789,138
Treasury stock at cost, 336 shares	(40,712)	(40,712)
Accumulated other comprehensive income	(1,243)	9,138
Accumulated deficit	(203,839,451)	(199,768,862)
Total stockholders' equity	17,128,420	20,997,565
Total liabilities and stockholders' equity	$ 18,577,193	$ 22,510,501

See accompanying notes to consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenues:				
License revenue	$ 500,000	$ -	$ 500,000	$ 7,500,000
Royalty revenue	122,849	89,565	216,713	206,738
Total revenues	622,849	89,565	716,713	7,706,738
Operating expenses:				
Research and development	2,136,769	1,874,721	3,198,341	4,693,646
General and administrative	890,433	1,507,412	2,012,910	3,083,131
Total operating expenses	3,027,202	3,382,133	5,211,251	7,776,777
Operating loss	(2,404,353)	(3,292,568)	(4,494,538)	(70,039)
Other income (loss):				
Interest and investment income	198,637	308,845	424,149	640,209
Unrealized loss on warrant liability	-	(84,430)	-	(124,502)
Total other income	198,637	224,415	424,149	515,707
Income (loss) before income tax expense	(2,205,716)	(3,068,153)	(4,070,389)	445,668
Income tax expense	-	(481)	(200)	(681)
Net loss attributable to common shareholders Net income (loss) attributable to common shareholders	$ (2,205,716)	$ (3,068,634)	$ (4,070,589)	$ 444,987
Basic earnings (loss) per share attributable to common stock	$ (0.41)	$ (0.57)	$ (0.76)	$ 0.08
Weighted average common shares outstanding, basic	5,351,957	5,343,922	5,350,267	5,329,876
Diluted earnings (loss) per share attributable to common stock	$ (0.41)	$ (0.56)	$ (0.76)	$ 0.10
Weighted average common shares outstanding, diluted	5,351,957	5,343,922	5,350,267	5,459,204
Comprehensive income (loss):				
Net income (loss)	$ (2,205,716)	$ (3,068,634)	$ (4,070,589)	$ 444,987
Net unrealized income (loss) on marketable investment securities	(6,764)	885	(10,381)	(16,978)
Comprehensive income (loss)	$ (2,212,480)	$ (3,067,749)	$ (4,080,970)	$ 428,009

See accompanying notes to consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Changes in Stockholders' Equity
For the Three and Six Months Ended June 30, 2025 and 2024
(Unaudited)

	Stockholder's Equity							
	Common Stock		Treasury Stock			Accumulated		
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balances at March 31, 2024	5,315,830	8,860	336	(40,712)	220,262,456	(10,604)	(196,263,593)	23,956,407
Net loss	-	-	-	-	-	-	(3,068,634)	(3,068,634)
Unrealized net income on marketable investment securities	-	-	-	-	-	885	-	885
Stock-based compensation	-	-	-	-	102,265	-	-	102,265
Costs associated with ATM Offering	32,110	3	-	-	217,437	-	-	217,440
Balances at June 30, 2024	5,347,940	$ 8,863	336	$ (40,712)	$ 220,582,158	$ (9,719)	$ (199,332,227)	$ 21,208,363

	Common Stock		Treasury Stock			Accumulated		
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2023	5,315,830	$ 8,860	336	$ (40,712)	$ 220,171,250	$ 7,259	$ (199,777,214)	$ 20,369,443
Net income	-	-	-	-	-	-	444,987	444,987
Unrealized net loss on marketable investment securities	-	-	-	-	-	(16,978)	-	(16,978)
Stock-based compensation	-	-	-	-	201,571	-	-	201,571
Common stock sold through ATM offering	32,110	3	-	-	209,337	-	-	209,340
Balances at June 30, 2024	5,347,940	$ 8,863	336	$ (40,712)	$ 220,582,158	$ (9,719)	$ (199,332,227)	$ 21,208,363

	Stockholder's Equity							
	Common Stock		Treasury Stock			Accumulated		
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balances at March 31, 2025	5,350,356	8,863	336	(40,712)	220,860,140	5,521	(201,633,735)	19,200,077
Net loss	-	-	-	-	-	-	(2,205,716)	(2,205,716)
Unrealized net loss on marketable investment securities	-	-	-	-	-	(6,764)	-	(6,764)
Stock-based compensation	-	-	-	-	65,205	-	-	65,205
Common stock sold through ATM offering	23,739	2	-	-	75,616	-	-	75,618
Balances at June 30, 2025	5,374,095	$ 8,865	336	$ (40,712)	$ 221,000,961	$ (1,243)	$ (203,839,451)	$ 17,128,420

	Stockholder's Equity							
	Common Stock		Treasury Stock			Accumulated		Total
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Stockholders' Equity
Balances at December 31, 2024	5,347,940	$ 8,863	336	$ (40,712)	$ 220,789,138	$ 9,138	$ (199,768,862)	$ 20,997,565
Net loss	-	-	-	-	-	-	(4,070,589)	(4,070,589)
Unrealized net loss on marketable investment securities	-	-	-	-	-	(10,381)	-	(10,381)
Stock-based compensation	-	-	-	-	136,207	-	-	136,207
Vesting of restricted stock units	2,416	-	-	-	-	-	-	-
Common stock sold through ATM offering	23,739	2	-	-	75,616	-	-	75,618
Balances at June 30, 2025	5,374,095	$ 8,865	336	$ (40,712)	$ 221,000,961	$ (1,243)	$ (203,839,451)	$ 17,128,420

See accompanying notes to condensed consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2025	**2024**
Cash flows from operating activities:		
Net income (loss)	$ (4,070,589)	$ 444,987
Adjustments to reconcile net income (loss) to cash provided by (used in) operating activities:		
Depreciation expense	31,678	17,024
Stock-based compensation expense	136,207	201,571
Non-cash loss on change in fair value of warrant liability	-	124,502
Amortization of discounts on marketable investment securities	(92,625)	(411,145)
Changes in operating assets and liabilities:		
Accrued interest income	(1,285)	(11,382)
Prepaid and other current assets	205,286	476,373
Accounts payable	171,298	(947,179)
Accrued expenses	(235,461)	14,991
Cash used in operating activities	(3,855,491)	(90,258)
Cash flows from investing activities:		
Purchases of marketable investment securities	(5,082,073)	(17,537,469)
Maturities of marketable investment securities	8,700,000	18,200,000
Net cash provided by investing activities	3,617,927	662,531
Cash flows from financing activities:		
Net proceeds from sale of common stock through ATM	75,618	209,340
Cash provided by financing activities	75,618	209,340
Net increase (decrease) in cash and cash equivalents	(161,946)	781,613
Cash and cash equivalents at beginning of period	6,205,926	4,771,758
Cash and cash equivalents at end of period	$ 6,043,980	$ 5,553,371
Supplemental disclosure of cash flow information:		
Income taxes paid	$ -	681
Supplemental disclosure of non-cash investing and financing activity:		
Net unrealized loss on available-for-sale securities	$ (10,381)	$ (16,978)

See accompanying notes to consolidated financial statements

(1) Basis of Presentation

The accompanying unaudited condensed consolidated financial statements included herein have been prepared by Lipocine Inc. ("Lipocine" or the "Company") in accordance with the rules and regulations of the United States Securities and Exchange Commission ("SEC"). The unaudited condensed consolidated financial statements are comprised of the financial statements of Lipocine and its subsidiaries, collectively referred to as the Company. In management's opinion, the interim financial data presented includes all adjustments (consisting solely of normal recurring items) necessary for fair presentation. All intercompany accounts and transactions have been eliminated. Certain information required by U.S. generally accepted accounting principles ("U.S. GAAP") has been condensed or omitted in accordance with rules and regulations of the SEC. Operating results for the three and six months ended June 30, 2025 are not necessarily indicative of the results that may be expected for any future period or for the year ending December 31, 2025.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2024.

The preparation of the unaudited condensed consolidated financial statements requires management to make estimates and assumptions relating to reporting of the assets and liabilities and the disclosure of contingent assets and liabilities to prepare these condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period in conformity with U.S. GAAP. Actual results could differ from these estimates.

The Company believes that its existing capital resources, together with interest thereon, will be sufficient to meet its projected operating requirements through at least August 5, 2026. The Company has based this estimate on assumptions that may prove to be wrong, and the Company could utilize its available capital resources sooner than it currently expects. While the Company believes it has sufficient liquidity and capital resources to fund our projected operating requirements through at least August 5, 2026, the Company will need to raise additional capital through the equity or debt markets or via out-licensing activities to support its operations. If the Company is unsuccessful in raising additional capital, its long-term ability to continue as a going concern will become a risk. Further, the Company's operating plan may change, and the Company may need additional funds to meet operational needs and capital requirements for product development, regulatory compliance and clinical trial activities sooner than planned. In addition, the Company's capital resources may be consumed more rapidly if it pursues additional clinical studies for LPCN 1154, LPCN 2401, LPCN 2101, LPCN 2203, LPCN 1148, LPCN 1144, and/or LPCN 1107. Conversely, the Company's capital resources could last longer if the Company reduces expenses, reduces the number of activities currently contemplated under its operating plan, or terminates, modifies the design of or suspends on-going clinical studies.

On January 12, 2024, the Company entered into a License Agreement (the "Verity License Agreement") with Gordon Silver Limited ("GSL") and Verity Pharmaceuticals, Inc. ("Verity Pharma"), pursuant to which the Company granted to GSL (an affiliate of Verity Pharma) an exclusive, royalty-bearing, sublicensable right and license to commercialize the TLANDO product with respect to testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone, as indicated in a New Drug Application ("NDA") No. 208088, treatment of Klinefelter syndrome, and pediatric indications relating to testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone (the "Field"), in each case within the United States and Canada (the "Licensed Verity Territory"). The Verity License Agreement also provides GSL with a license to develop and commercialize TLANDO XR (LPCN 1111), the Company's potential once-daily oral product candidate for testosterone replacement therapy in the Licensed Verity Territory. The Company retains development and commercialization rights for TLANDO and TLANDO XR (LPCN 1111) outside of the Licensed Verity Territory, and with respect to applications outside of the Field inside or outside the Licensed Verity Territory.

Upon execution of the Verity License Agreement, GSL agreed to pay the Company a license fee of $11.0 million consisting of an initial payment of $2.5 million which was received on signing of the Verity License Agreement, $5.0 million which was received on February 1, 2024, $2.5 million which was received on December 30, 2024, and $1.0 million to be paid no later than January 1, 2026. The Company is also eligible to receive development and sales milestone payments of up to $259 million in the aggregate, depending primarily on the achievement of certain sales milestones in a single calendar year with respect to all products licensed by GSL under the Verity License Agreement. In addition, the Company is eligible to receive tiered royalty payments at rates ranging from 12% up to 18% of net sales of licensed products in the Licensed Verity Territory.

In addition to the Verity License Agreement, the Company entered into a license agreement in the territories of South Korea, the Gulf Corporation Council, or GCC, and Brazil. The Company retains development and commercialization rights for TLANDO outside of the United States, Canada, South Korea, the GCC, and Brazil and retains the development and commercialization rights for TLANDO XR (LPCN 1111) outside the United States and Canada, and with respect to applications outside of the Field inside or outside the Licensed Verity Territory.

(2) Revenue

The Company generates most of its revenue from license and royalty arrangements. At inception of each contract, the Company identifies the goods and services that have been promised to the customer and each of those that represent a distinct performance obligation, determines the transaction price including any variable consideration, allocates the transaction price to the distinct performance obligations and determines whether control transfers to the customer at a point in time or over time. Variable consideration is included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company reassesses its reserves for variable consideration at each reporting date and makes adjustments, if necessary, which may affect revenue and earnings in periods in which any such changes become known.

See Note 7 for a description of the Verity License Agreement, the SPC License Agreement (as defined below), the Pharmalink Distribution Agreement (as defined below), and the Aché License Agreement (as defined below). See Note 11 for a description of the agreement with Spriaso, a related party.

License Fees

For distinct license performance obligations, upfront license fees are recognized when the Company satisfies the underlying performance obligation. Performance obligations under these licenses, which consist of the right to use the Company's proprietary technology, are satisfied at a point in time corresponding with delivery of the underlying technology rights to the licensee, which is generally upon transfer of the licensed technology/product to the customer. In addition, license arrangements may include contingent milestone payments, which are due following achievement by our licensee of specified sales or regulatory milestones and the licensee and/or Company will fulfill its performance obligation prior to achievement of these milestones. Because of the uncertainty of the milestone achievement, and/or the dependence on sales of our licensee, variable consideration for contingent milestones is fully constrained and is not recognized as revenue until the milestone is achieved by our licensee, to the extent collectability is reasonably certain.

Royalties

Royalty revenue consists of sales-based and minimum royalties earned under license agreements for our products. Sales-based royalty revenue represents variable consideration under license agreements and is recognized in the period a customer sells products incorporating the Company's licensed technologies/products. The Company estimates sales-based royalty revenue earned but unpaid at each reporting period using information provided by the licensee. The Company's license arrangements may also provide for minimum royalties, which the Company recognizes upon the satisfaction of the underlying performance obligation, which generally occurs with delivery of the underlying technology rights to the licensee. Sales-based and minimum royalties are generally due within 45 days after the end of each quarter in which they are earned.

Revenue Concentration

A major partner is considered to be one that comprises more than 10% of the Company's total revenues. For the three months ended June 30, 2025, the Company recognized licensing revenue of $500,000 and royalty revenue of approximately $123,000. Revenue recognized in the three months ended June 30, 2025 was 80% and 20%, respectively, from two major customers, Aché Laboratórios Farmacêuticos S.A. ("Aché") and Verity Pharma. For the six months ended June 30, 2025, the Company recognized licensing revenue of $500,000 and royalty revenue of approximately $217,000. Revenue recognized during the six months ended June 30, 2025 was 70% and 30%, respectively, from two major customers, Aché and Verity Pharma. For the three months ended June 30, 2024, the company recognized royalty revenue of approximately $90,000. Revenue recognized in the three months ended June 30, 2024 was 100% from one major customer, Verity Pharma. For the six months ended June 30, 2024, the Company recognized licensing revenue of $7.5 million relating to the Verity License Agreement, approximately $140,000 of royalty revenue from the Verity License Agreement, and $67,000 of royalty revenue from the license agreement with Antares Pharma ("Antares"). Revenue recognized in the six months ended June 30, 2024 was 99% from one major customer, Verity Pharma.

(3) Earnings (Loss) per Share

Basic earnings (loss) per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per share is based on the weighted average number of common shares outstanding plus, where applicable, the additional potential common shares that would have been outstanding related to dilutive options, warrants and unvested restricted stock units to the extent such shares are dilutive.

The following table sets forth the computation of basic and diluted earnings (loss) per share of common stock for the three and six months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Basic earnings (loss) per share attributable to common stock:				
Numerator				
Net income (loss)	$ (2,205,716)	$ (3,068,634)	$ (4,070,589)	$ 444,987
Denominator				
Weighted avg. common shares outstanding	5,351,957	5,343,922	5,350,267	5,329,876
Basic earnings (loss) per share attributable to common stock	$ (0.41)	$ (0.57)	$ (0.76)	$ 0.08
Diluted earnings (loss) per share attributable to common stock:				
Numerator				
Net income (loss)	$ (2,205,716)	$ (3,068,634)	$ (4,070,589)	$ 444,987
Effect of dilutive securities on net earnings (loss):				
Common stock warrants	-	(84,430)	-	(124,502)
Total net income (loss) for purpose of calculating diluted net income (loss) per common share	$ (2,205,716)	$ (2,984,204)	$ (4,070,589)	$ 569,489
Denominator				
Weighted avg. common shares outstanding	5,351,957	5,343,922	5,350,267	5,329,876
Weighted average effect of dilutive securities:				
Stock options	-	-	-	122,074
Warrants	-	-	-	7,254
Total shares for purpose of calculating diluted net earnings (loss) per common share	5,351,957	5,343,922	5,350,267	5,459,204
Diluted earnings (loss) per share attributable to common stock	$ (0.41)	$ (0.56)	$ (0.76)	$ 0.10

The computation of diluted loss per share for the three and six months ended June 30, 2025 and 2024 does not include the following stock options and warrants to purchase shares of common stock or unvested restricted stock units in the computation of diluted earnings (loss) per share because these instruments were antidilutive:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Stock options	354,908	295,517	354,908	173,443
Unvested restricted stock units	19,346	21,762	19,346	14,508
Warrants	-	49,333	-	49,433

(4) Marketable Investment Securities

The Company has classified its marketable investment securities as available-for-sale securities, all of which are debt securities. These securities are carried at fair value with unrealized holding gains and losses, net of the related tax effect, included in accumulated other comprehensive income (loss) in stockholders' equity until realized. Gains and losses on investment security transactions are reported on the specific-identification method. Dividend income is recognized on the ex-dividend date and interest income is recognized on an accrual basis. The amortized cost, gross unrealized holding gains, gross unrealized holding losses, and fair value for available-for-sale securities by major security type and class of security as of June 30, 2025, and December 31, 2024, were as follows:

June 30, 2025	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Government treasury bills	$ 11,892,945	$ 646	$ (1,889)	$ 11,891,702
	$ 11,892,945	$ 646	$ (1,889)	$ 11,891,702

December 31, 2024	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Government treasury bills	$ 15,418,247	$ 9,138	$ -	$ 15,427,385
	$ 15,418,247	$ 9,138	$ -	$ 15,427,385

Maturities of debt securities classified as available-for-sale securities as of June 30, 2025 are as follows:

June 30, 2025	Amortized Cost	Aggregate Fair Value
Due within one year	$ 11,892,945	$ 11,891,702
	$ 11,892,945	$ 11,891,702

There were no sales of marketable investment securities during either the three or six months ended June 30, 2025 or 2024 and therefore no realized gains or losses. Additionally, during the three months ended June 30, 2025 and 2024, $4.5 million and $11.5 million of marketable investment securities matured, respectively, and during the six months ended June 30, 2025 and 2024, $8.7 million and $18.2 million of marketable investment securities matured, respectively. The Company determined there were no other-than-temporary impairments for either the three or six months ended June 30, 2025 or 2024.

(5) Fair Value

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

- Level 1 Inputs: Quoted prices for identical instruments in active markets.
- Level 2 Inputs: Quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuation in which all significant inputs and significant value drivers are observable in active markets.
- Level 3 Inputs: Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

All of the Company's financial instruments are valued using quoted prices in active markets or based on other observable inputs. For accrued interest income, prepaid and other current assets, accounts payable, and accrued expenses, the carrying amounts approximate fair value because of the short maturity of these instruments. The following table presents the placement in the fair value hierarchy of assets and liabilities that are measured at fair value on a recurring basis as of June 30, 2025 and December 31, 2024:

		Fair value measurements at reporting date using		
	June 30, 2025	Level 1 inputs	Level 2 inputs	Level 3 inputs
Assets:				
Cash equivalents - money market funds	$ 5,755,118	$ 5,755,118	$ -	$ -
Government treasury bills	11,891,702	11,891,702	-	-
	$ 17,646,820	$ 17,646,820	$ -	$ -

		Fair value measurements at reporting date using		
	December 31, 2024	Level 1 inputs	Level 2 inputs	Level 3 inputs
Assets:				
Cash equivalents - money market funds	$ 6,155,167	$ 6,155,167	$ -	$ -
Government treasury bills	15,427,385	15,427,385	-	-
	$ 21,582,552	$ 21,582,552	$ -	$ -

The following methods and assumptions were used to determine the fair value of each class of assets and liabilities recorded at fair value in the balance sheets:

Cash equivalents: Cash equivalents primarily consist of highly rated money market funds and treasury bills with original maturities to the Company of three months or less and are purchased daily at par value with specified yield rates. Cash equivalents related to money market funds and treasury bills are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices or broker or dealer quotations for similar assets.

Government treasury bills: The Company uses a third-party pricing service to value these investments. United States treasury bills are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets for identical assets and reportable trades.

The Company's accounting policy is to recognize transfers between levels of the fair value hierarchy on the date of the event or changes in circumstances that caused the transfer. There were no transfers into or out of Level 1, Level 2, or Level 3 for the three and six months ended June 30, 2025.

(6) Income Taxes

The tax provision for interim periods is determined using an estimate of the Company's effective tax rate for the full year adjusted for discrete items, if any, that are taken into account in the relevant period. Each quarter the Company updates its estimate of the annual effective tax rate, and if the estimated tax rate changes, the Company makes a cumulative adjustment.

At June 30, 2025 and December 31, 2024, the Company had a full valuation allowance against its deferred tax assets, net of expected reversals of existing deferred tax liabilities, as it believes it is more likely than not that these benefits will not be realized.

(7) Contractual Agreements

(a) Verity Pharmaceuticals, Inc.

On January 12, 2024, the Company entered into the Verity License Agreement with GSL and Verity Pharma, pursuant to which the Company granted to GSL (an affiliate of Verity Pharma) an exclusive, royalty-bearing, sublicensable right and license to commercialize the Company's TLANDO® product with respect to testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone, as indicated in NDA No. 208088, treatment of Klinefelter syndrome, and pediatric indications relating to testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone, in each case within the Licensed Verity Territory. In June 2025, Verity Pharma filed a New Drug Submission ("NDS") for TLANDO in Canada. The Verity License Agreement also provides GSL with a license to develop and commercialize TLANDO XR (LPCN 1111), the Company's potential once-daily oral product candidate for testosterone replacement therapy in the Licensed Verity Territory. Under the Verity License Agreement, the Company retains rights to TLANDO in applications outside of the Field and to the development and commercialization rights outside of the United States and Canada. The Company retains rights to TLANDO XR in applications outside of the Field and to development and commercialization rights in the field outside of the United States and Canada.

Upon execution of the Verity License Agreement, GSL agreed to pay the Company a license fee of $11.0 million consisting of an initial payment of $2.5 million which was received on signing of the Verity License Agreement, $5.0 million which was received on February 1, 2024, $2.5 which was received on December 30, 2024, and $1.0 million to be paid no later than January 1, 2026. The Company is also eligible to receive development and sales milestone payments of up to $259.0 million in the aggregate, depending primarily on the achievement of certain sales milestones in a single calendar year with respect to all products licensed by GSL under the Verity License Agreement. Under the Verity License Agreement, GSL is generally responsible for expenses relating to the development (including the conduct of any clinical trials) and commercialization of licensed products in the Field in the Licensed Verity Territory, while the Company is generally responsible for expenses relating to development activities outside of the Field and/or the Licensed Verity Territory.

The Company concluded that licensing revenue recognized in conjunction with the Verity License Agreement met the requirements under ASC 606, Revenue from Contracts with Customers. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. License revenue from payments to be received in the future will be recognized when it is probable that we will receive license payments under the terms of the Verity License Agreement.

Under the Verity License Agreement with Verity Pharma, during the three months ended June 30, 2025 and 2024, the Company recognized royalty revenue of $123,000 and $90,000, respectively, and for the six months ended June 30, 2025 and 2024, $217,000 and $140,000, respectively. The Company also recognized $7.5 million in license revenue during the six months ended June 30, 2024 under the Verity License Agreement.

(b) SPC Korea

In September 2024, the Company entered into a Distribution and License Agreement (the "SPC License Agreement") with SPC Korea Limited ("SPC"), pursuant to which the Company granted to SPC a non-transferable, exclusive, royalty-bearing license to commercialize the Company's TLANDO product with respect to the Field, specific to the country of South Korea (the "SPC Territory"). SPC paid the Company a one-time non-refundable, non-creditable upfront fee in October 2024. The Company also received an additional payment for a non-refundable prepayment in consideration for TLANDO product inventory, and is eligible to receive additional payments for various marketing authorization and sales milestones, and the Company will supply TLANDO to SPC and receive a supply price. In addition, the Company will receive royalties on net sales in the SPC Territory.

(c) Pharmalink

In October 2024, the Company entered into a distribution and supply agreement (the "Pharmalink Distribution Agreement") with Pharmalink, pursuant to which the Company granted to Pharmalink a non-transferable, exclusive, license to commercialize the Company's TLANDO product with respect to the Field, specific to the GCC, including Saudi Arabia, Kuwait, the United Arab Emirates ("UAE"), Qatar, Bahrain, and Oman (the "GCC Territory"). Pharmalink paid the Company a one-time non-refundable, non-creditable upfront fee. The Company is eligible to receive additional payments in regulatory authorization milestones related to the marketing approval in countries in the GCC Territory under the Pharmalink Distribution Agreement and the Company will supply TLANDO to Pharmalink at an agreed transfer price.

(d) Aché Laboratórios Farmacêuticos S.A.

In April 2025, the Company entered into a License and Supply Agreement (the "Aché License Agreement") with Aché, pursuant to which the Company granted to Aché an exclusive license to commercialize the Company's TLANDO® product with respect to the Field, specific to Brazil (the "Aché Territory"). Under the agreement, the Company is entitled to receive fees upon the achievement of certain regulatory milestones, royalties on net sales and will supply TLANDO to Aché at an agreed transfer price.

(e) Abbott Products, Inc.

On March 29, 2012, the Company terminated its collaborative agreement with Solvay Pharmaceuticals, Inc. (later acquired by Abbott Products, Inc. ("Abbott")) for TLANDO. As part of the termination, the Company reacquired the rights to the intellectual property from Abbott. All obligations under the prior license agreement have been completed except that the Company will owe Abbott a perpetual 1% royalty on net sales. Such royalties are limited to $1.0 million in the first two calendar years following product launch, after which period there is not a cap on royalties and no maximum aggregate amount. If generic versions of any such product are introduced, then royalties are reduced by 50%. TLANDO was commercially launched on June 7, 2022. The Company incurred royalty expense of approximately $10,000 and $7,000 during the three months ended June 30, 2025 and 2024, respectively. The Company incurred royalty expense of approximately $18,000 and $16,000 during the six months ended June 30, 2025 and 2024, respectively.

(f) Contract Research and Development

The Company has entered into agreements with various contract organizations that conduct pre-clinical, clinical, analytical and manufacturing development work on behalf of the Company as well as a number of independent contractors and primarily clinical researchers who serve as advisors to the Company. The Company incurred expenses of approximately $1.3 million and $1.1 million for the three months ended June 30, 2025 and 2024, respectively, and approximately $1.4 million and $2.9 million for the six months ended June 30, 2025 and 2024, respectively, under these agreements and has recorded these expenses in research and development expenses.

(8) Leases

The Company has a non-cancelable operating lease for office space and laboratory facilities in Salt Lake City, Utah. The term of the lease has been extended through February 28, 2026.

Future minimum lease payments under the non-cancelable operating lease as of June 30, 2025 are:

	Operating Lease
2025	$ 188,639
2026	62,880
Total minimum lease payments	$ 251,519

The Company's rent expense was $94,000 and $92,000 for the three months ended June 30, 2025 and 2024, respectively. The Company's rent expense was $187,000 and $182,000 for the six months ended June 30, 2025 and 2024, respectively.

(9) Stockholders' Equity

On June 4, 2025, the Company held its annual general meeting of shareholders, at which a proposal to amend the Company's Amended and Restated Certificate of Incorporation (the " Restated Certificate") to reduce the number of authorized shares of the Company's common stock from 200,000,000 to 75,000,000 shares was approved. The Company filed the amendment to the Restated Certificate with the Secretary of State of the State of Delaware on June 4, 2025. The amendment to the Restated Certificate became effective upon filing with the Secretary of State of the State of Delaware.

(a) Issuance of Common Stock

On April 26, 2024, the Company entered into a sales agreement with A.G.P./Alliance Global Partners ("A.G.P.") (the "A.G.P. Sales Agreement") pursuant to which the Company may issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to the amount the Company registered on an effective registration statement pursuant to which the offering is being made. The Company currently has registered $10,616,169 shares of common shares for sale under the A.G.P. Sales Agreement, pursuant to the Registration Statement on Form S-3, as amended (File No. 333-275716) (the "Form S-3"), through A.G.P. as the Company's sales agent. A.G.P. may sell the Company's common stock by any method permitted by law deemed to be an "at the market ("ATM") offering" as defined in Rule 415(a)(4) of the Securities Act, including sales made directly on or through the Nasdaq Capital Market or any other existing trade market for our common stock, in negotiated transactions at market prices prevailing at the time of sale or at prices related to prevailing market prices, or any other method permitted by law. A.G.P. will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell shares under the A.G.P. Sales Agreement. The Company will pay A.G.P. 3.0% of the aggregate gross proceeds from each sale of shares under the A.G.P. Sales Agreement. In addition, the Company has also provided A.G.P. with customary indemnification rights.

The shares of the Company's common stock to be sold under the A.G.P. Sales Agreement will be sold and issued pursuant to the Form S-3, as amended, which was previously declared effective by the Securities and Exchange Commission, and the related prospectus and one or more prospectus supplements.

The Company is not obligated to make any sales of its common stock under the A.G.P. Sales Agreement. The offering of common stock pursuant to the A.G.P. Sales Agreement will terminate upon the termination of the A.G.P. Sales Agreement as permitted therein. The Company and A.G.P. may each terminate the A.G.P. Sales Agreement at any time upon ten days' prior notice.

During the three and six month ended June 30, 2025, the Company sold 23,739 shares of common stock pursuant to the A.G.P. Sales Agreement at a weighted average price of $3.29 per share, for aggregate gross proceeds of $78,000, and net proceeds of $76,000, after deducting sales agent commission.

Previously, on March 6, 2017, the Company entered into a sales agreement (the "Cantor Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") pursuant to which the Company could issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to the amount the Company registered on an effective registration statement pursuant to which the offering was made. During the three months and six months ended June 30, 2024, the Company sold 32,110 shares of its common stock pursuant to the Cantor Sales Agreement. On April 24, 2024, the Cantor Sales Agreement was terminated.

(b) Rights Agreement

On November 13, 2015, the Company and American Stock Transfer & Trust Company, LLC, as Rights Agent, entered into a Rights Agreement (the "Rights Agreement"). Also on November 12, 2015, the Board of the Company authorized and the Company declared a dividend of one preferred stock purchase right (each a "Right" and collectively, the "Rights") for each outstanding share of common stock of the Company. The dividend was payable to stockholders of record as of the close of business on November 30, 2015 and entitles the registered holder to purchase from the Company one one-thousandth of a fully paid non-assessable share of Series A Junior Participating Preferred Stock of the Company at a price of $63.96 per one-thousandth share (the "Purchase Price"). The Rights will generally become exercisable upon the earlier to occur of (i) 10 business days following a public announcement that a person or group of affiliated or associated persons has become an Acquiring Person (as defined below) or (ii) 10 business days (or such later date as may be determined by action of the Board prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) following the commencement of, or announcement of an intention to make, a tender offer or exchange offer the consummation of which would result in the beneficial ownership by a person or group of 15% or more of the outstanding common stock of the Company. Except in certain situations, a person or group of affiliated or associated persons becomes an "Acquiring Person" upon acquiring beneficial ownership of 15% or more of the outstanding shares of common stock of the Company.

In general, in the event a person becomes an Acquiring Person, then each Right not owned by such Acquiring Person will entitle its holder to purchase from the Company, at the Right's then current exercise price, in lieu of shares of Series A Junior Participating Preferred Stock, common stock of the Company with a market value of twice the Purchase Price. In addition, if after any person has become an Acquiring Person, (a) the Company is acquired in a merger or other business combination, or (b) 50% or more of the Company's assets, or assets accounting for 50% or more of its earning power, are sold, leased, exchanged or otherwise transferred (in one or more transactions), proper provision shall be made so that each holder of a Right (other than the Acquiring Person, its affiliates and associates and certain transferees thereof, whose Rights became void) shall thereafter have the right to purchase from the acquiring corporation, for the Purchase Price, that number of shares of common stock of the acquiring corporation which at the time of such transaction would have a market value of twice the Purchase Price.

The Company will be entitled to redeem the Rights at $0.001 per Right at any time prior to the time an Acquiring Person becomes such. The terms of the Rights are set forth in the Rights Agreement, which is summarized in the Company's Current Report on Form 8-K dated November 13, 2015. The rights plan was originally set to expire on November 12, 2018; however, on November 5, 2018 our Board approved an Amended and Restated Rights Agreement pursuant to which the expiration date was extended to November 5, 2021, and again on November 2, 2021, the Company adopted a Second Amended and Restated Rights Agreement pursuant to which the expiration date was extended to November 1, 2024. On October 22, 2024, the Company adopted a Third Amended and Restated Rights Agreement pursuant to which the expiration date was extended to October 22, 2027, unless the rights are earlier redeemed or exchanged by the Company.

(c) Share-Based Payments

The Company recognizes stock-based compensation expense for grants of stock option awards, restricted stock units and restricted stock under the Company's Incentive Plan to employees, nonemployees and nonemployee members of the Company's Board based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period. In addition, the Company has granted performance-based stock option awards and restricted stock units, which vest based upon the Company satisfying certain performance conditions. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, the Company estimates that these options or units will vest, which is based on whether the Company considers the performance conditions to be probable of attainment. The Company's estimates of the number of performance-based options or units that will vest will be revised, if necessary, in subsequent periods.

The Company uses the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's common stock price, (ii) the periods of time over which employees and members of the board of directors are expected to hold their options prior to exercise (expected term), (iii) expected dividend yield on the common stock, and (iv) risk-free interest rates. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation cost that has been expensed in the statements of operations amounted to approximately $65,000 and $102,000, respectively, for the three months ended June 30, 2025 and 2024, and approximately $136,000 and $202,000, respectively for the six months ended June 30, 2025 and 2024. The expense is allocated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development	$ 31,016	$ 57,786	$ 66,989	$ 112,866
General and administrative	34,189	44,479	69,218	88,705
	$ 65,205	$ 102,265	$ 136,207	$ 201,571

The Company issued 8,820 stock options during each of the three months ended June 30, 2025 and 2024, and 25,191 and 34,446 stock options during the six months ended June 30, 2025 and 2024, respectively.

Key assumptions used in the determination of the fair value of stock options granted are as follows:

Expected Term: The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term was estimated using the average of the contractual term and the vesting period of the stock option. For awards with performance conditions, and that have the contractual term to satisfy the performance condition, the contractual term was used.

Risk-Free Interest Rate: The risk-free interest rate used was based on the implied yield currently available on U.S. Treasury issues with an equivalent remaining term.

Expected Dividend: The expected dividend assumption is based on management's current expectation about the Company's anticipated dividend policy. The Company does not anticipate declaring dividends in the foreseeable future.

Expected Volatility: The volatility factor is based solely on the Company's trading history.

For options granted during the six months ended June 30, 2025 and 2024, the Company calculated the fair value of each option grant on the respective dates of grant using the following weighted average assumptions:

	2025	2024
Expected term	5.73 years	5.76 years
Risk-free interest rate	4.30%	4.32%
Expected dividend yield	—	—
Expected volatility	94.19%	97.78%

The Company recognizes compensation expense for the portion of options that are expected to vest. Therefore, the Company applied estimated forfeiture rates that were derived from historical employee termination behavior. If the actual number of forfeitures differs from those estimated by management, additional adjustments to compensation expense may be required in future periods.

As of June 30, 2025, there was approximately $320,000 of total unrecognized compensation cost related to unvested stock option compensation granted under the Company's stock option plan. That cost is expected to be recognized over a weighted average period of 1.1 years and will be adjusted for subsequent changes in estimated forfeitures. Additionally, as of June 30, 2025, there was $68,000 of total unrecognized compensation costs related to unvested restricted stock units that have either time-based or performance vesting.

(d) Stock Option Plan

In April 2014, the Board adopted the 2014 Stock and Incentive Plan ("2014 Plan") subject to shareholder approval which was received in June 2014. The 2014 Plan provides for the granting of nonqualified and incentive stock options, stock appreciation rights, restricted stock units, restricted stock and dividend equivalents. An aggregate of 58,823 shares were authorized for issuance under the 2014 Plan. Additionally, 15,994 remaining authorized shares under the 2011 Equity Incentive Plan were issuable under the 2014 Plan at the time of the 2014 Plan adoption. Upon receiving shareholder approval in June 2016, the 2014 Plan was amended and restated to increase the authorized number of shares of common stock of the Company issuable under all awards granted under the 2014 Plan from 74,817 to 145,405. Additionally, upon receiving shareholder approval in June 2018, the 2014 Plan was further amended and restated to increase the authorized number of shares of common stock of the Company issuable under all awards granted under the 2014 Plan from 145,405 to 189,522. Upon receiving shareholder approval in June 2020, the 2014 Plan was further amended and restated to increase the authorized number of shares of common stock of the Company issuable under all awards granted under the 2014 Plan from 189,522 to 336,582. In June 2024, the 2014 Plan was further amended and restated to increase the authorized number of shares of common stock of the Company issuable under all awards granted from 336,582 to 600,000. The Board, on an option-by-option basis, determines the number of shares, exercise price, term, and vesting period for options granted. Options granted generally have a ten-year contractual life. The Company issues shares of common stock upon the exercise of options with the source of those shares of common stock being either newly issued shares or shares held in treasury. An aggregate of 600,000 shares of common stock are authorized for issuance under the 2014 Plan, with 197,655 shares remaining available for grant as of June 30, 2025.

A summary of stock option activity is as follows:

	Outstanding stock options	
	Number of shares	Weighted average exercise price
Balance at December 31, 2023	262,247	$ 34.21
Options granted	84,715	4.79
Options exercised	-	-
Options forfeited	(10,209)	142.99
Options cancelled	(1,495)	5.23
Balance at December 31, 2024	335,258	23.59
Options granted	25,191	4.28
Options exercised	-	-
Options forfeited	(5,541)	85.10
Options cancelled	-	-
Balance at June 30, 2025	354,908	21.26
Options exercisable at June 30, 2025	256,738	27.57

The following table summarizes information about stock options outstanding and exercisable:

As of June 30, 2025

Options outstanding				Options exercisable			
Number outstanding	Weighted average remaining contractual life (Years)	Weighted average exercise price	Aggregate intrinsic value	Number exerciseable	Weighted average remaining contractual life (Years)	Weighted average exercise price	Aggregate intrinsic value
354,908	6.60	$ 21.26	$ -	256,738	5.59	$ 27.57	$ -

As of June 30, 2024

Options outstanding				Options exercisable			
Number outstanding	Weighted average remaining contractual life (Years)	Weighted average exercise price	Aggregate intrinsic value	Number exerciseable	Weighted average remaining contractual life (Years)	Weighted average exercise price	Aggregate intrinsic value
295,517	6.55	$ 30.36	$ 230,307	224,887	5.79	$ 37.54	$ 77,671

The intrinsic value for stock options is defined as the difference between the current market value and the exercise price.

(e) Restricted Stock Units

A summary of restricted stock unit activity is as follows:

	Number of Unvested Restricted Stock Units
Balance at December 31, 2024	21,762
Granted	-
Vested	(2,416)
Cancelled	-
Balance at June 30, 2025	19,346

	Number of Unvested Restricted Stock Units
Balance at December 31, 2023	-
Granted	21,762
Vested	-
Cancelled	-
Balance at June 30, 2024	21,762

The weighted average grant date fair value of restricted stock units awarded during the six months ended June 30, 2024 was $3.61 per share.

(f) Common Stock Warrants

The Company accounts for its common stock warrants under ASC 480, *Distinguishing Liabilities from Equity*, which requires any financial instrument, other than an outstanding share, that, at inception, embodies an obligation to repurchase the issuer's equity shares, or is indexed to such an obligation, and requires or may require the issuer to settle the obligation by transferring assets, to be classified as a liability. In accordance with ASC 480, the Company's outstanding warrants from an offering conducted in 2019 (the "November 2019 Offering") were classified as a liability. The liability was adjusted to fair value at each reporting period, with the changes in fair value recognized as gain (loss) on change in fair value of warrant liability in the Company's consolidated statements of operations. The warrants issued in the November 2019 Offering allowed the warrant holder, if certain change in control events had occurred, the option to receive an amount of cash equal to the value of the warrants as determined in accordance with the Black-Scholes option pricing model with certain defined assumptions upon a fundamental transaction. The warrants expired in November of 2024 and the related warranty liability was extinguished.

During the three and six months ended June 30, 2024, the Company recorded a non-cash loss of approximately $84,000 and $125,000 from the change in fair value of the November 2019 Offering warrants. The fair value of the warrants on June 30, 2024 was determined using the Black Scholes option pricing model with the following Level 3 inputs (as defined in the November 2019 Offering) include (i) volatility of 110.64%, (ii) risk free interest rate of 5.45%, (iii) strike price of $8.50, (iv) fair value of common stock of $8.24, and (v) expected life of 0.4 years.

Additionally, in an offering in February 2020, the Company issued 296,593 common stock warrants. However, because these warrants did not provide the warrant holder the option to put the warrant back to the Company, the warrants were classified as equity. The common stock warrants from the February 2020 offering expired in February 2025 and no warrants were exercised during 2025 prior to their expiration.

No common stock warrants were exercised during either the three or six months ended June 30, 2025 or 2024. As of June 30, 2024, there were 113,795 warrants outstanding, with a weighted average exercise price of $8.72 per share and a remaining life of 0.5 years, with an aggregate intrinsic value of $0. As of June 30, 2025, there are no warrants outstanding.

(10) Commitments and Contingencies

Litigation

The Company is involved in various lawsuits, claims and other legal matters from time to time that arise in the ordinary course of conducting business. The Company records a liability when a particular contingency is probable and estimable.

The Company is not currently aware of any matter, individually or in the aggregate, that could have a material adverse effect on our financial condition, liquidity, or results of operations.

Guarantees and Indemnifications

In the ordinary course of business, the Company enters into agreements, such as lease agreements, licensing agreements, clinical trial agreements, and certain services agreements, containing standard guarantee and / or indemnification provisions. Additionally, the Company has indemnified its directors and officers to the maximum extent permitted under the laws of the State of Delaware.

(11) Agreement with Spriaso, LLC

The Company has a license and a services agreement with Spriaso, a related-party that is majority-owned by certain current and former directors of Lipocine Inc. and their affiliates. Under the license agreement, the Company assigned and transferred to Spriaso all of the Company's rights, title and interest in its intellectual property to develop products for the cough and cold field. In addition, Spriaso received all rights and obligations under the Company's product development agreement with a third-party. In exchange, the Company will receive a royalty of 20 percent of the net proceeds received by Spriaso, up to a maximum of $10.0 million. Spriaso also granted back to the Company an exclusive license to such intellectual property to develop products outside of the cough and cold field. The Company also agreed to continue providing up to 10 percent of the services of certain employees to Spriaso for a period of time. The agreement to provide services expired in 2021; however, it may be extended upon written agreement of Spriaso and the Company. During the three and six months ended June 30, 2025, and 2024, the Company did not receive any revenue from Spriaso. Spriaso filed its first NDA and as an affiliated entity of the Company, using up the one-time waiver for user fees for a small business submitting its first human drug application to the FDA. Spriaso is considered a variable interest entity under the FASB ASC Topic 810-10, Consolidations, however the Company is not the primary beneficiary and has therefore not consolidated Spriaso.

(12) Segment Reporting

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company operates as a single reporting segment, focused on leveraging its proprietary technology platform to augment therapeutics through effective oral delivery of products and product candidates. The Company's measure of segment profit or loss is net income (loss). The CODM is the chief executive officer ("CEO"). The CODM manages and allocates resources to the operations of the Company on a total company basis. Managing and allocating resources on a consolidated basis enables the CEO to assess the overall level of resources available and how to best deploy these resources across functions, therapeutic target areas and research and development projects that are in line with the Company's long-term company-wide strategic goals. Consistent with this decision-making process, the CEO uses consolidated financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets. Operating expenses are used to monitor budget versus actual results. The review of budgeted versus actual results is used in assessing performance of the segment. All the Company's long-lived assets are held in the United States and all the Company's revenues are primarily related to TLANDO.

The following table is representative of the significant expense categories regularly provided to the CODM when managing the Company's single reporting segment. A reconciliation to the consolidated net income (loss) for the three and six months ended June 30, 2025 and 2024 is included in the table below.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Total revenues	$ 622,849	$ 89,565	$ 716,713	$ 7,706,738
Program expenses [1]				
LPCN 1154	1,042,929	1,024,607	1,049,621	2,677,093
Other research and development programs	155,415	(30,916)	176,388	139,101
Non-program expenses [2]	735,511	1,252,539	1,736,128	2,759,176
Personnel costs	1,028,142	1,033,638	2,112,907	1,999,836
Stock-based compensation	65,205	102,265	136,207	201,571
Total segment operating income (loss)	(2,404,353)	(3,292,568)	(4,494,538)	(70,039)
Other income (loss) [3]	198,637	223,934	423,949	515,026
Net income (loss)	$ (2,205,716)	$ (3,068,634)	$ (4,070,589)	$ 444,987

(1) Includes external research and development expenses.
(2) Includes general and administrative expenses, information technology, infrastructure, facilities, and intellectual property, and legal and professional fees.
(3) Includes interest income and loss on warrant liability.

(13) Recent Accounting Pronouncements

Accounting Pronouncements Issued Not Yet Adopted

In November 2024, the FASB issued Accounting Standards Update ("ASU") 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03").* This guidance requires the disaggregation of certain expense captions into specified categories in disclosures within the notes of the financial statements to provide enhanced transparency into the expense captions presented on the statement of earnings. It is effective for annual reporting periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. Adoption may be applied either prospectively to financial statements issued for reporting periods after the effective date of ASU 2024-03 or retrospectively to any or all prior periods presented in financial statements.

The Company is evaluating the impact of this guidance on the Company's related disclosures.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto and other financial information included elsewhere in this report. For additional context with which to understand our financial condition and results of operations, see management's discussion and analysis of financial condition and results of operations included in our annual report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 13, 2025 (the "2024 Form 10-K"), our first quarter report on Form 10-Q filed with the SEC on May 8, 2025, as well as the financial statements and related notes contained therein.

As used in the discussion below, "we," "our," and "us" refers to Lipocine.

Forward-Looking Statements

This section and other parts of this report contain 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"), that involve risks and uncertainties. Forward-looking statements provide current expectations of future events based on certain assumptions and include any statement that does not directly relate to any historical or current fact. Forward-looking statements may refer to such matters as products, product benefits, pre-clinical and clinical development timelines, clinical and regulatory expectations and plans, expected responses to regulatory actions, anticipated financial performance, future revenues or earnings, business prospects, projected ventures, new products and services, anticipated market performance, expected research and development and other expenses, future expectations for liquidity and capital resources needs and similar matters. Such words as "may," "will," "expect," "continue," "estimate," "project," and "intend" and similar terms and expressions are intended to identify forward looking statements. Forward-looking statements are not guarantees of future performance and our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in Part I, Item 1A (Risk Factors) of our 2024 Form 10-K and Item 1A of our Form 10-Q for the quarter ended March 31, 2025 filed with the SEC on May 8, 2025. Except as required by applicable law, we assume no obligation to revise or update any forward-looking statements for any reason.

Overview of Our Business

We are a biopharmaceutical company focused on leveraging our proprietary Lip'ral platform to develop differentiated products through the oral delivery of previously difficult to deliver molecules. Our proprietary delivery technologies are designed to improve patient compliance and safety through orally available treatment options. Our primary development programs are based on oral delivery solutions for poorly bioavailable drugs. We have a portfolio of differentiated innovative product candidates that target high unmet needs for neurological and psychiatric CNS disorders, liver diseases, and hormone supplementation for men and women.

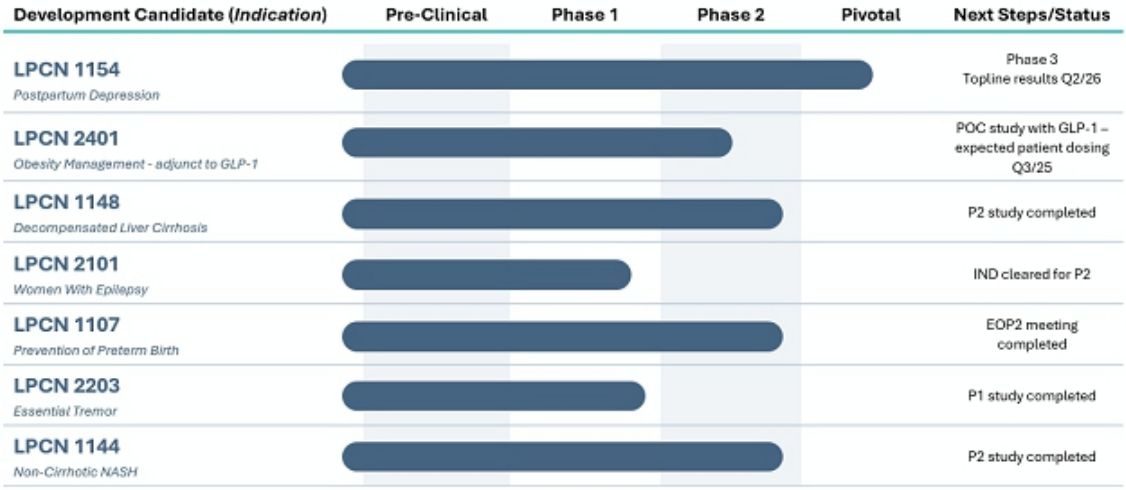
We entered into our first license agreement for the development and commercialization of our product, TLANDO®, an oral testosterone replacement therapy comprised of testosterone undecanoate in October 2021. On March 28, 2022, the FDA approved TLANDO as a testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism and on June 7, 2022, our former commercial partner Antares (a wholly owned subsidiary of Halozyme) announced the commercial launch of TLANDO.

On January 12, 2024, we entered into the Verity License Agreement with Verity Pharma, pursuant to which we granted to Verity Pharma an exclusive, royalty-bearing, sublicensable right and license to develop and commercialize the TLANDO product for TRT in the Licensed Verity Territory. Any FDA post-marketing studies required will also be the responsibility of our licensee, Verity Pharma.

In September 2024, we entered into the SPC License Agreement for the development and commercialization of TLANDO with SPC, pursuant to which the Company granted to SPC a non-transferable, exclusive, royalty-bearing license to commercialize our TLANDO product for TRT in the SPC Territory. In October 2024, we entered into the Pharmalink Distribution Agreement with Pharmalink, granting a non-transferable, exclusive, license to commercialize our TLANDO product specific to the GCC, including Saudi Arabia, Kuwait, UAE, Qatar, Bahrain, and Oman (the "Pharmalink Territory"). In April 2025, we entered into the Aché License Agreement with Aché pursuant to which we granted to Aché an exclusive license to commercialize our TLANDO product with respect to the Field, specific to the Aché Territory. Our ex-U.S. commercialization partners are planning to file marketing approval applications in Canada, one or more of the GCC countries, South Korea and Brazil in 2025 and/or 2026.

Additional clinical development pipeline candidates include: LPCN 1154 for postpartum depression ("PPD"); LPCN 2401 for improved body composition in GLP-1 agonist use such as obesity management; LPCN 2101 for epilepsy; and LPCN 2203 for essential tremor. In addition to our clinical development product candidates, we have assets for which we expect to seek partnerships to enable further development including TLANDO for territories outside of the United States, Canada, South Korea, the GCC and Brazil, LPCN 1148 comprising a novel prodrug of testosterone and testosterone laurate ("TL"), for the management of decompensated cirrhosis, LPCN 1144, an oral prodrug of androgen receptor modulator for the treatment of non-cirrhotic metabolic dysfunction-associated steatohepatitis ("MASH") which has completed Phase 2 testing; and LPCN 1107, potentially the first oral hydroxy progesterone caproate ("HPC") product indicated for the prevention of recurrent preterm birth ("PTB"), which has completed a dose finding clinical study in pregnant women and has been granted orphan drug designation by the FDA.

The following chart summarizes the status of our product candidate development and partnering programs:



Corporate Strategy

The key components of our corporate strategy are to:

Continue to leverage our drug delivery technology platform. Our goal is to become a leading biopharmaceutical company focused on leveraging our Lip'ral drug delivery technology platform to develop and register differentiated products to treat conditions with large unmet medical need through effective oral drug delivery. Our pipeline candidates are based on our Lip'ral drug delivery technology platform, validated through TLANDO, an approved commercial product. Lip'ral technology entails lipidic compositions which form an optimal dispersed phase in the gastrointestinal environment for improved absorption of highly water insoluble drugs. The drug loaded dispersed phase presents the drug efficiently at the absorption site (gastrointestinal tract membrane) thus improving or enabling portal and / or lymphatic absorption post oral administration.

Advance LPCN 1154 and other CNS product candidates. We intend to focus on the development of endogenous neuroactive steroids ("NASs") which have broad applicability in treating various CNS conditions where we can leverage our technology platform to develop highly differentiated oral therapeutics. Our priority is on the development of LPCN 1154, a fast-acting oral antidepressant for postpartum depression ("PPD") with potential for outpatient use.

Support our partners, Verity Pharma, SPC, Pharmalink, and Aché, in commercialization and/or development of our licensed oral TRT option. We believe the TRT market needs a differentiated, convenient oral option. We have exclusively licensed rights to TLANDO to Verity Pharma for commercialization of TLANDO in the Licensed Verity Territory, to SPC for commercialization in the SPC Territory, to Pharmalink the Pharmalink Territory and to Aché in the Aché Territory. We plan to support Verity Pharma's, SPC's, Pharmalink's, and Aché's efforts to effectively enable the availability of TLANDO to patients in a timely manner, in addition to receiving milestone and royalty payments associated with TLANDO commercialization as agreed to in the Verity License Agreement, the SPC License Agreement, the Pharmalink Distribution Agreement and the Aché License Agreement.

Develop partnership(s) to continue the advancement of pipeline assets. We continuously strive to prioritize our resources in seeking partnerships for our pipeline assets. We are currently exploring partnerships for our liver programs including LPCN 1144, our candidate for treatment of non-cirrhotic MASH and LPCN 1148 for the management of decompensated cirrhosis including prevention of the recurrence of overt hepatic encephalopathy ("OHE"), and we are also exploring partnerships for LPCN 2401 for management of incretin mimetics use as an adjunct therapy to or as a monotherapy post cessation of incretin mimetics use and LPCN 1107, our candidate for prevention of pre-term birth. We are also exploring the possibility of licensing LPCN 1021 (known as TLANDO in the United States) to third parties outside of the Licensed Verity Territory, the SPC Territory, the Pharmalink Territory and the Aché Territory, although as of the date of this report, no licensing agreement has been entered into by the Company in any other territories.

Our Pipeline Product Candidates

Our pipeline of clinical development candidates includes LPCN 1154 for PPD, LPCN 2401 as an aid for improved body composition and functionality in the management of GLP-1 agonist use in obese patients, LPCN 2101 for epilepsy, and LPCN 2203 for essential tremor. We will continue to explore other product development candidates targeting CNS indications with a significant unmet need. We will also continue efforts to enter into partnership arrangements for the continued development and/or marketing of all of our products including but not limited to LPCN 1144, LPCN 1148, LPCN 2401, and LPCN 1107 as well as for the TRT assets outside of the Licensed Verity Territory, the SPC Territory, and the Pharmalink Territory.

TRT Franchise – TLANDO and LPCN 1111 (TLANDO XR)

TLANDO: An Oral Product for Testosterone Replacement Therapy

As previously described, under the Verity License Agreement, in January 2024, we granted to Verity Pharma an exclusive, royalty-bearing, sublicensable right and license to develop and commercialize TLANDO, our product for TRT, in the U.S. and Canada effective February 1, 2024. TLANDO received FDA approval on March 28, 2022. Any FDA requirement to conduct certain post-marketing studies will be the responsibility of Verity Pharma. Further, all future development and commercialization of LPCN 1111 in the Licensed Verity Territory will be the responsibility of Verity Pharma. In addition, in September 2024, we granted SPC an exclusive, royalty-bearing license to commercialize TLANDO in South Korea and in October 2024 we granted Pharmalink an exclusive license to commercialize TLANDO in the GCC countries. In April 2025, we granted Aché an exclusive license to commercialize and supply TLANDO in Brazil.

Proof-of-concept for TLANDO was initially established in 2006, and TLANDO was subsequently licensed in 2009 to Solvay Pharmaceuticals, Inc., which was then acquired by Abbott Products, Inc. ("Abbott"). Following a portfolio review associated with the spin-off of AbbVie Inc. by Abbott in 2011, the rights to TLANDO were reacquired by us. All obligations under the prior license agreement have been completed except that Lipocine will owe Abbott a perpetual 1% royalty on net sales of TLANDO. Such royalties are limited to $1 million in the first two calendar years following product launch, after which period there is no cap on royalties and no maximum aggregate amount. If generic versions of any such product are introduced, then royalties are reduced by 50%. TLANDO was commercially launched on June 7, 2022. During the three months ended June 30, 2025 and 2024, we incurred royalty expense of approximately $10,000 and $7,000, respectively, and during the six months ended June 30, 2025 and 2024, we incurred royalty expense of approximately $18,000 and $16,000, respectively.

Since TLANDO received full FDA approval, under the terms of the Verity License Agreement, Verity Pharma will need to assess the safety and effectiveness of TLANDO in pediatric patients, as required by the Pediatric Research Equity Act. The FDA may also require certain post-marketing studies to be conducted which will also be the responsibility of Verity Pharma. Similarly, SPC, Pharmalink, and Aché are responsible for obtaining any regulatory/marketing approvals for TLANDO required for the SPC Territory, the Pharmalink Territory, and the Aché Territory, respectively.

Upon execution of the Verity License Agreement, Verity Pharma paid us an initial payment of $2.5 million which was received on signing of the License Agreement and $5 million which was received on February 1, 2024. Verity Pharma also paid an additional payment of $2.5 million to us on December 30, 2024, and is required to make an additional payment of $1 million to us before January 1, 2026. We are also eligible to receive milestone payments of up to $259 million in the aggregate, depending on the achievement of certain sales milestones in a single calendar year and/or development milestones with respect to products licensed by Verity Pharma under the Verity License Agreement. In addition, we will receive tiered royalty payments at rates ranging from 12% up to 18% of net sales of all products licensed under the Verity License Agreement in the Licensed Verity Territory.

SPC paid us a non-refundable, non-creditable upfront fee in October 2024. We also received additional payments including a non-refundable payment in consideration for TLANDO product inventory, and we are eligible to receive additional payments for marketing authorization and sales milestones, and we will supply TLANDO to SPC and receive a supply price. In addition, we will receive royalties on net sales in South Korea under the SPC License Agreement.

Upon execution of the Pharmalink Distribution Agreement, Pharmalink paid us a non-refundable, non-creditable upfront fee in October 2024. Under the Pharmalink Distribution Agreement, we could receive additional payments in regulatory authorization milestones and we will supply TLANDO to Pharmalink at an agreed transfer price.

Upon execution of the Aché License Agreement, Aché paid us a non-refundable, non-creditable upfront fee in May 2025. Under the Aché License Agreement, we may receive additional payments in regulatory authorization milestones, royalties on net sales and will supply TLANDO to Aché at an agreed transfer price.

We are exploring the possibility of licensing LPCN 1021 (known as TLANDO in the United States) to third parties outside the United States, Canada, South Korea, the GCC countries and Brazil, although no licensing agreement has been entered into by the Company in any other territories. If and when an agreement is made with a partner, the success of any such arrangement would likely be partially contingent upon obtaining local regulatory approval. No assurance can be given that any license agreement will be completed or, if an agreement is completed, that such an agreement would be on terms favorable to us.

Oral Programs for CNS Disorders

Some preferred endogenous or naturally occurring NAS present in the central nervous system act as positive allosteric modulators ("PAMs") of the $GABA_A$ receptor, the major biological target of the inhibitory neurotransmitter γ-aminobutyric acid ("$GABA_A$"). To improve oral delivery of these modulators, several synthetic NAS derivatives of endogenous $GABA_A$ receptor PAMs have been developed for therapeutic use in the past few decades.

In October 2024, we announced positive data from our qEEG study of our oral brexanolone with results indicating robust central nervous system activity of oral brexanolone, with concentration- and time-dependent post-dose changes in qEEG as follows:

- Quantitative Electroencephalogram ("qEEG") in healthy subjects administered single doses of oral brexanolone, a neuroactive steroid, confirmed $GABA_A$ modulation
- Rapid and durable CNS target engagement confirms effective oral delivery of bioidentical brexanolone
- Promising results support continued development of oral brexanolone for the treatment of neuropsychiatric disorders

We believe through utilization of our proprietary technology we may have the ability to enable effective oral delivery of endogenous $GABA_A$ receptor PAMs which historically had been deemed to be not orally bioavailable. As a novel drug class, NASs have received considerable attention because of their potential to treat various neuropsychiatric conditions including depression, movement disorders, epilepsy, anxiety, and neurodegenerative diseases. We have conducted Phase 1 pharmacokinetic ("PK") studies for each of our three lead NAS candidates which have demonstrated promising PK results, safety, and tolerability and we are evaluating additional undisclosed CNS-focused candidates.

LPCN 1154: Product Candidate for PPD

Our most advanced NAS candidate is LPCN 1154, a non-invasive, rapid onset, oral formulation of the neuroactive steroid brexanolone which we are developing for the treatment of PPD. We have completed clinical oral PK studies including a pilot food effect study and a pilot PK bridge study. In addition, as a prelude to a LPCN 1154 definitive PK bridge study, a multi-dose study was done confirming the dosing regimen for the PK bridge study using the scaled up "to be marketed" formulation required for New Drug Application ("NDA") filing. In June 2024, we announced results from the definitive PK study which demonstrated LPCN 1154 meets bioequivalence with comparator, IV brexanolone, meeting standard bioequivalence criteria and C_{trough} criteria. LPCN 1154 treatment was well-tolerated with no sedation nor somnolence events observed in the definitive study.

After completing PK studies and labeling studies such as a food effect study and PK profiling in women with PPD, we met with the FDA in the first quarter of 2025. In the meeting, we were advised that the FDA believes, in addition to the previously completed PK bridge data, an efficacy and safety study of oral LPCN 1154 in the target population will be required for 505(b)(2) NDA submission. Based on observed comparable exposure of LPCN 1154 and the reference drug in the PK bridge study, we have confirmed the target dosing regimen and initiated a phase 3 safety and efficacy study and successfully dosed LPCN 1154 in the first patient in the second quarter of 2025.

We are exploring the possibility of partnering with a third party for the development and/or marketing of LPCN 1154, although no partnering agreement has been entered into by the Company. No assurance can be given that any partnering agreement will be completed, or, if an agreement is completed, that such an agreement would be on terms favorable to us.

PPD

PPD, a type of major depressive disorder with onset either during pregnancy or within four weeks of delivery, refers to depression persisting up to 12 months after childbirth. PPD can be clinically segmented by the severity of symptoms and presence of a comorbidity, including epilepsy. Approximately 1 in 8 mothers suffers from PPD in the United States alone; this equates to approximately 600,000 women being affected by PPD annually.

Disease Overview - PPD

- PPD is distinct from the "baby blues," a condition that up to 70% of all new mother's experience; "baby blues" tend to be short-lived emotional conditions that do not interfere with daily activities.

- Symptoms of PPD include hallmarks of major depression, including, but not limited to, sadness, depressed mood, loss of interest, change in appetite, insomnia, sleeping too much, fatigue, difficulty thinking/concentrating, excessive crying, fear of harming the baby/oneself, and/or thoughts of death or suicide.

- During pregnancy, levels of endogenous NASs increase considerably along with levels of progesterone; however, they drop sharply postpartum. It has been hypothesized that the rapid perinatal decrease in circulating levels of endogenous NASs may be involved in the development of PPD. The first approved treatment option for PPD was an injectable containing endogenous NASs.

- Depression may persist long after child delivery. Additionally, approximately 40% of women relapse in subsequent pregnancies or on other occasions.

- Psychiatric comorbidities are common in patients with epilepsy. Patients with epilepsy are at high risk for major depressive disorders and PPD. Reported PPD rates are higher among women with epilepsy than the general population.

Associated Risk Factors

- Genetic: family history and/or previous experience of depression or other mood disorders

- Physiological: rapid changes in sex hormones, stress hormones, and thyroid hormone levels during and after delivery

- Environmental: stressful life events, changes in relationships at home and at work, and/or lack of familial support

Unmet Medical Need

We believe there is considerable unmet need within women with PPD due to a lack of convenient and fast-acting oral therapies. Selective Serotonin Reuptake Inhibitors ("SSRIs") have been the traditional first-line choice for women with severe PPD and require weeks for onset of efficacy; therefore, a need for an oral treatment option with a faster onset of action remains a significant unmet need in treating PPD, especially in mothers with moderate to severe depression prone to harmful actions.

Injectable brexanolone (Zulresso®, Sage Therapeutics ("Sage")) became the first FDA-approved treatment for postpartum depression. However, numerous factors limited the utilization of injectable brexanolone such as method of administration, cost, and safety concerns and at the end of 2024, Sage withdrew Zulresso from the market. In addition to Zulresso, Sage received FDA approval for zuranolone (brand name ZURZUVAE®) in August 2023 and Zurzuvae was launched commercially in December 2023. Zuranolone, a synthetic neuroactive steroid derivative, is an oral, once daily 14-day treatment for postpartum depression and is the first oral medication approved by the FDA for the treatment of postpartum depression. Per label, besides a long terminal half-life of approximately 19.7 to 24.6 hours and dosage modifications needed for concomitant use with CYP3A4 modulators, warnings and precautions include CNS depressant effects, impaired ability to drive or engage in other potentially hazardous activities and embryo-fetal toxicity. In June 2025, Sage announced the acquisition of Sage by Supernus Pharmaceuticals and Supernus' intention to strengthen their leading presence in neuropsychiatric conditions with Sage's innovative commercial product, ZURZUVAE. The transaction, which has been approved by the boards of directors of both companies, is expected to close in the third quarter of 2025, subject to customary closing conditions.

We believe LPCN 1154 targets the current unmet need for robust, rapid relief with 48-hour dosing duration through a convenient oral therapy candidate comprising bioidentical NASs with good tolerability.

LPCN 2101: NAS for Epilepsy

We are currently evaluating an additional NAS candidate, LPCN 2101, for epilepsy including women with epilepsy ("WWE"). We have completed pre-clinical and Phase 1 studies for LPCN 2101 which demonstrated promising PK results, safety and tolerability. In July 2022 our IND was accepted by the FDA for LPCN 2101 for adults with epilepsy and we plan to initiate a Phase 2 IND opening proof-of-concept study to evaluate the safety, tolerability, and efficacy of LPCN 2101, subject to resource prioritization.

Disease Overview – Epilepsy

Epilepsy is defined by the 1) occurrence of at least two unprovoked seizures more than 24 hours apart, 2) occurrence of one unprovoked seizure and a probability of further seizures occurring over the next 10 years, and/or 3) diagnosis of an epilepsy syndrome. Patients with epilepsy have increased risk of mortality due to direct effects of seizures (e.g., status epilepticus, car accidents) and indirect effects of seizures (e.g., suicide, cardiovascular effects).

Epilepsy is a disorder of the brain that causes seizures, affecting the physical, mental, and social well-being of persons, and is associated with a 2 to 3 times greater mortality rate compared with the general population. About 60-65% of epilepsy is idiopathic and about 30% of patients are refractory (i.e., epilepsy not well managed with currently available Anti-Seizure Medications ("ASMs"). Epilepsy is the most common neurological disorder during pregnancy.

It is estimated that approximately 900,000 childbearing ("CB") aged women suffer from active epilepsy in the U.S. Women of CB age with epilepsy face many additional challenges due to hormonal influences on seizure activity and endocrine function throughout the different phases of their reproductive cycles. Elevated estrogen or decreased progesterone levels can exacerbate seizure frequency. Often, these women experience hormonal and endogenous NAS imbalances, coupled with fluctuations in the blood levels of ASMs that impact control of seizures, efficacy of oral contraceptives, any coexisting anxiety and/or depression and any associated sleep impairment. Epileptic patients are 5-20 times more likely to develop depression.

Clinical segmentation can be categorized by epilepsy type, comorbidities and patient subgroups. Categorization of focal epilepsy, generalized epilepsy, combined focal and generalized epilepsy, and unknown epilepsy can guide the choice of ASM. Special patient subgroups, including WWE of CB age and elderly patients, require special care and management of epilepsy. Comorbidities such as depression and anxiety may be co-treated with therapies that do not aggravate seizures and have no drug interaction with the ASM used for epilepsy. While lowest effective dose and monotherapy are preferred, management of patients with epilepsy is focused on controlling seizures, avoiding adverse events, and maintaining quality of life. Despite a wide range of ASMs available, about 30% of all people with epilepsy still fail to respond to treatment effectively. Women with epilepsy face specific challenges throughout their lifespan because of seizures, ASMs, and hormonal fluctuations.

Women with epilepsy were once counseled to avoid pregnancy, but epilepsy is no longer considered a contraindication to pregnancy. Caregivers for WWE in the preconception phase either intending to start a family (planning pregnancy) or using contraception to prevent an unplanned pregnancy face significant challenges to balance seizure control efficacy with the selection and dosage of ASMs and ASM-related risks such as, among other risks, fetal-neonatal toxicity, contraception failure, and psychiatric side effects.

Several ASMs are known to have teratogenic effects on the developing fetus (converging evidence from registry studies indicates that teratogenic risks are highest with valproate, followed by carbamazepine and topiramate). Other commonly prescribed ASMs, including older generation agents, such as phenobarbital and phenytoin, have been associated with higher risks as compared with lamotrigine, levetiracetam, clonazepam and gabapentin (Vajda et al., 2014; Voinescu and Pennell, 2015). Moreover, risks associated with ASMs are considerable early in pregnancy; therefore, it is necessary that WWE of CB age undergo counseling, monitoring, and adjustment to the most appropriate ASM prior to becoming pregnant. It is preferable that WWE of CB age discuss seizure control with their doctor for at least 6 months before conception and, if possible, cease ASM therapy or use the lowest effective dose of a single anticonvulsant according to the type of epilepsy and the fetal toxicity of the ASM. Anxiety, depression, lack of adherence to ASM, and/or contraception failure may be experienced by women who are worried about unplanned pregnancy or are late in confirming pregnancy, planned or unplanned. ASMs can reduce the efficacy of oral contraceptives, compounding this problem.

Complex, multidirectional interactions between female hormones, seizures, and ASMs exist. Most hormones act as NASs and can thus modulate brain excitability. Any changes in endogenous or exogenous hormone levels can affect the occurrence of seizures, either directly or via PK interactions that modify the plasma levels of ASMs (Harden, 2008). The PK interactions between oral contraceptives and ASMs are bidirectional (Johnston and Crawford, 2014). The efficacy of hormonal contraception may be diminished for women taking CYP-P450 enzyme inducing ASMs. Epilepsy is not a medical condition in which contraceptives are contraindicated. Contraceptive failure, possibly related to ASMs, may be responsible for up to 1 in 4 unplanned pregnancies in WWE (~12.5% of all WWE pregnancies), versus a rate of 1% in healthy women.

Unmet need to treat WWE in CB age

It is estimated that approximately 900,000 CB aged women suffer from active epilepsy in the U.S. Women of CB age with epilepsy face many additional challenges such as hormonal influences on seizure activity and endocrine function throughout the different phases of their reproductive cycles, and approximately 30% of patients with epilepsy cannot be efficiently controlled with available ASMs making consideration of newer pharmacological treatment development options important.

Managing uncontrolled seizures in WWE of CB age is the primary aim during preconception, pregnancy, and postpartum phases. Therefore, uncompromised ASM efficacy with acceptable variability and less or no drug-drug interactions achieved with lowest possible monotherapy dose to address fetal toxicity concerns remain highly unmet needs. Moreover, control of seizures including prevention of breakthrough seizures is critical when planning for pregnancy and also during pregnancy, as it can also lead to undesired falls or auto-accidents and compromise freedom to drive.

Select ASMs have the potential to induce contraception failures, reproductive hormone imbalance, anxiety, and depression. There remains an unmet need for an ASM without the aforementioned downsides, with no to low fetal-neonatal toxicity and without breast-feeding concerns, as well as the potential to treat associated comorbidities.

While over 30 molecules have been approved for the treatment of epilepsy in the U.S., no epilepsy drug has been specifically approved for WWE of CB age. We believe our endogenous NASs as $GABA_A$ PAMs, while targeting the goal of seizure control, also have the potential for additional benefits in psychiatric disorders comorbidities (e.g., anxiety and/or depression) and sleep impairment. Moreover, these oral endogenous NASs could potentially address some of the fetal toxicity concerns related to unplanned or planned pregnancy in WWE. **(1)**

(1) Ref: S.Bangar et al. Functional Neurology 2016; 31(3): 127-134; Reimers et al. Seizure. 2015 May; 28: 66-70.

LPCN 2203: Oral Product for Management of Essential Tremor

LPCN 2203 is an oral candidate for management of essential tremor comprising a bioidentical GABA modulating NAS. We have successfully completed oral pharmacokinetics with bioidentical GABA Modulating NAS and are planning to submit a protocol for a proof-of-concept phase 2 study for ET to the FDA.

Disease Overview - Essential Tremor

Essential Tremor ("ET") is one of the most common movement disorders in the United States, affecting an estimated 7 million in the U.S. For ET patients, uncontrollable shaking of the hands, head, voice, or legs creates difficulty eating, dressing, writing, and pursuing other day-to-day tasks. The etiology of ET is largely unknown, but reduced $GABA_A$ receptor levels and decreased GABAergic activity have been observed in ET.

While ET is often associated with aging populations, ET can begin much earlier in life, with a progressive disease course that can eventually necessitate a care partner. Social anxiety and depressive symptoms can manifest in patients with ET as tremor severity increases, and may negatively impact a patient's ability to work and engage in hobbies. In an interview study of ET patients and care partners, the most common impacts on activities of daily living are pouring liquids and writing/typing (100%) and grooming/hygiene, drinking, dressing, eating, and reading (80-85%). Overall, 90% of participants noted the emotional impact of ET, with 75% reporting tremor-related worry or anxiety.

The only FDA approved pharmacological treatment for ET was approved more than 50 years ago, and the majority of patients with ET experience a sub-optimal response with standard-of-care treatments, highlighting numerous and compelling unmet needs in care such as daytime efficacy and improved tolerability, a PRN (pro re nata) or "as needed" option, and a superior benefit-to-risk profile.[(1) (2)]

(1) Ref: Louis ED, Ottman R. Tremor Other Kyperkinet Mov (NY). 2014;4:259.

(2) Ref: Gerbasi et.al. Patient experiences in essential tremor: Mapping functional impacts to existing measures using qualitative research. MDS 2023.

Other Pipeline Candidates

We continue to pursue opportunities for partnering and/or development arrangements for the continued development and/or marketing of LPCN 2401, LPCN 1148, LPCN 1144, and LPCN 1107. We are planning a POC study with LPCN 2401, but otherwise we do not currently anticipate conducting any further significant development activities with respect to these products and product candidates without the participation of a partner. There can be no guarantee that we will be able to identify or enter into partnering arrangements on terms that are beneficial to us or at all. Even if we do enter into partnering arrangements, such arrangements may not be sufficient to successfully develop and commercialize these products.

LPCN 2401: Management of Incretin Mimetic Use in Obesity Management

LPCN 2401 is targeted to be a once daily oral formulation comprising a proprietary anabolic androgen receptor agonist. LPCN 2401 is expected to have a favorable benefit to risk profile as a non-invasive option for use as an adjunct to GLP-1 chronic weight management therapies for quality weight loss and/or as a monotherapy post cessation of GLP-1 chronic weight management therapies for weight and glycemic status maintenance with demonstrated benefits to the liver.

LPCN 2401 has potential for use as an adjunct to incretin mimetics (GLP-1/GIP agonists) including amplification of GLP-1 insulinotropic actions which is supported by studies demonstrating the role of androgen receptor agonist in regulation of GLP-1 through:

- Enhancement of GLP-1-mediated insulin release from β cells through genomic- and non-genomic mechanisms
- Increase in GLP-1 Receptor Expression in diabetics and non-diabetics
- Promoting proliferation of β cells and improving insulin sensitivity

Target benefits of LPCN 2401 in combination with GLP-1 agonists include inducing quality weight loss by attenuation of functionality loss through improved body composition, entailing majority of weight loss through fat mass loss, amplification/acceleration of fat mass loss while lessening lean mass loss, a serious unmet need, especially for elderly and sarcopenic adult GLP-1 agonist users who are most vulnerable to accelerated lean mass loss and functional decline. In a recent study with 16 weeks of GLP-1 agonist use for weight management in elderly (60 yr and above) patients, a rapid loss of lean mass was observed with a median percentage of total body weight loss that is due to lean mass of 32% in 16 weeks. In addition, 43% of GLP-1 users lost ≥10% Stair Climb Power from baseline; the equivalent of almost eight years of expected age-related stair climb power loss was observed in just 4 months of GLP-1 use.

Moreover, as an adjunct to incretin mimetics, LPCN 2401 may help maintain or increase weight loss, particularly in diabetics, through increased expression activity of GLP1R and increased effectiveness of GIP1 therapies secondary to actions at GLP1R (glucose lowering). LPCN 2401 could also be potentially used as monotherapy post discontinuation of GLP-1 agonist to manage weight/fat regain and durability of diabetes remission.

Data from preclinical and clinical studies support the potential of LPCN 2401 and LPCN 2401+E in improving body composition. In April 2024, Lipocine announced results from a multi-center prospective, blinded Phase 2 study, which demonstrated increases in lean mass of 4.4%, decreases in fat mass of 6.7%, reduction in android fat of 4.1% and increased bone mineral content of 2.8% in a population consistent with GLP-1 use for weight management. LPCN 2401 was well tolerated with minimal GI or androgenic adverse events and no reports of muscle spasms.

Per FDA Guidance (2025), for efficacy claims related to changes in body composition, trial design should include appropriate choice of population and selection of endpoints that measure how a patient feels, functions, or survives, to potentially support such a claim. Consistent with regulatory guidance, we plan to conduct a proof-of-concept phase 2 study for LPCN 2401 in elderly obese and overweight GLP-1 eligible patients, with appropriate body composition and functional end points such as stair climb performance measure

We plan to initiate a proof-of-concept study evaluating LPCN 2401 as an adjunct to GLP-1 agonist use in the third quarter of 2025. We may explore the possibility of partnering LPCN 2401 with a third party, although no partnering agreement has been entered into by us. No assurance can be given that any license agreement will be completed, or, if an agreement is completed, that such an agreement would be on terms favorable to us.

Disease and Market Overview – GLP-1 Agonist Use and Obesity Management

Approximately 74% of U.S. adults aged 20 and older are either obese or overweight, and an estimated 30% of the U.S. adult population has a BMI ≥ 30 kg/m^2. Elderly and sarcopenic GLP-1 agonist users are the population of GLP-1 users who are most vulnerable to accelerated lean mass loss and functional decline. Obesity is a chronic, relapsing health risk defined by excess body fat. Excess body fat increases the risk of death and major comorbidities such as type 2 diabetes, hypertension, dyslipidemia, cardiovascular disease, osteoarthritis of the knee, sleep apnea, and some cancers[1]. About 30% of overweight (BMI ≥ 25 $kg/m^{2)}$ adults [2] have type 2 diabetes, 50%[3] have dyslipidemia, and 67%[4] have hypertension. In the US alone, ~34M older adults aged 60+ years are obese (BMI at or above 30.0) and ~31M older adults aged 60+ years are overweight (BMI between 25.0 to 30).

It is estimated that the total GLP-1 users in the U.S. may reach 30 million (around 9% of the overall population) by 2030**[5].** Reportedly, ~24M[6] obese elderly are most vulnerable to losing muscle mass. The rapid weight loss observed with the currently approved chronic weight management GLP-1 receptor agonist medications includes unwanted lean mass loss, up to 40% of the patient's total weight lost. Moreover, discontinuation of these therapies frequently results in a rapid regain in weight. Loss of lean mass has multiple negative health implications including weakness/fatigue, lowered metabolism which can cause a regain in fat mass, declines in neuromuscular function, potential effects on emotion and psychological states, and increased risk of injury.

Several recent studies showed that body composition, especially lean body mass (muscle) may play an independent role in survival of patients with diseases such as cancer and cardiovascular diseases (DH Lee and EL Giovannucci, Exp Biol Med. 2018). Therefore, a focus on body composition in obesity management to sustainably lose fat mass while maintaining lean mass should be an essential goal.

There is a significant unmet need for an oral, efficacious, muscle preserving/gaining option for chronic obesity/weight management that ameliorates the loss of lean mass associated with GLP-1/GIP agonist treatment, resulting in a higher quality weight loss. Moreover, there is a need for a chronic long-term pharmacotherapy option to maintain weight upon cessation of incretin mimetic therapy, prevent fat/weight rebound "overshoot" and minimize lag in muscle recovery to prevent collateral fattening as well as improve the durability of any achieved diabetes remission while on GLP-1.

(1) Ref: Caterson and Hubbard et al. 2004; Calle and Thun et al. 1999
(2) https://news.harvard.edu/gazette/story/2012/03/the-big-setup/
(3) https://www.ncbi.nlm.nih.gov/books/NBK305895/
(4) https://pmc.ncbi.nlm.nih.gov/articles/PMC6316192/#sec3-nutrients-10-01976
(5) https://www.jpmorgan.com/insights/global-research/current-events/obesity-drugs
(6) Ref: Flynn et al. Morgan Stanley, February 27, 2024

LPCN 1148: Oral Product Candidate for the Management of Decompensated Cirrhosis

We studied LPCN 1148 comprising testosterone laurate ("TL") for the management of decompensated cirrhosis. We believe LPCN 1148 targets unmet needs for cirrhosis subjects including improvement in the quality of life of patients while on the liver transplant waiting list, prevention or reduction in the occurrence of new decompensation events such as OHE, and improvement in post liver transplant survival, including outcomes and costs. We are exploring the possibility of partnering with a third party for the development and/or marketing of LPCN 1148, although no partnering agreement has been entered into by the Company. No assurance can be given that any partnering agreement will be completed, or, if an agreement is completed, that such an agreement would be on terms favorable to us.

We conducted a Phase 2 proof of concept ("POC") study (NCT04874350) in male subjects with cirrhosis to evaluate the therapeutic potential of LPCN 1148 for the management of sarcopenia. The Phase 2 POC study was a prospective, multi-center, randomized, placebo-controlled study in male sarcopenic cirrhotic patients. Subjects were initially randomized 1:1 to 1 of 2 arms.

The treatment arm was an oral dose of LPCN 1148, and the second arm was a matching placebo. There were no restrictions on patients with respect to background therapies, including current standard of care, diet or exercise. The primary endpoint was a change in skeletal muscle index at week 24 with key secondary endpoints including change in liver frailty index, rates of breakthrough OHE, and number of waitlist events, including all-cause mortality. Total treatment was 52 weeks, with 24-week placebo-controlled treatment subjects receiving LPCN 1148 in the 28-week open-label extension ("OLE") phase of the study for the duration of the study through week 52.

In July 2023 we announced that the Phase 2 study met the study primary endpoint, increased skeletal muscle index (L3-SMI) relative to placebo (P<.01), in patients with cirrhosis. The study also demonstrated improvements in clinical outcomes such as prevention of new decompensation events including OHE, rates of hospitalizations, and patient reported outcomes ("PROs"). LPCN 1148 was well-tolerated, with adverse event ("AE") rates and severities similar to placebo and no mortality was noted in the LPCN 1148 treatment group, nor were there any cases of drug-induced liver injury.

In March 2024 we announced that 24-week L3-SMI increases were maintained through 52 weeks of LPCN 1148 intervention and that placebo patients who switched to LPCN 1148 in the open label extension period of the study had increases in L3-SMI. Furthermore, fewer OHE events were observed in LPCN 1148 treated patients and time to first recurrent OHE event was longer for treated patients. LPCN 1148 was well-tolerated, with AE rates and severities similar to placebo and fewer participants experienced serious or severe adverse events when switched from placebo to LPCN 1148 and patients on therapy were hospitalized for fewer days. We plan to request a Type C meeting with the FDA to discuss the clinical development plan for LPCN 1148.

Disease Overview – Cirrhosis

Annually, cirrhosis has caused more than 1 million deaths worldwide, and there are over 500,000 people living with decompensated cirrhosis in the U.S. Non-alcoholic fatty liver disease is the most rapidly increasing indication for liver transplant. 62% of those on the liver transplant ("LT") waitlist are male and the economic burden (approximately $812,500/transplant) is high and continues to increase. Each year about half of the approximately 17,000 people in U.S. on the LT waitlist undergo transplant, while nearly 3,000 patients either die or are removed from the list because they were "too sick to transplant."

Liver cirrhosis is defined as the histological development of regenerative nodules surrounded by fibrous bands. Patients with cirrhosis typically have a year-long silent, asymptomatic phase (compensated cirrhosis) until decreasing liver function and increasing portal pressure move the patient into the symptomatic phase (decompensated cirrhosis). Transition to decompensated cirrhosis is marked by clinical events including ascites, encephalopathy, jaundice, and/or variceal hemorrhage. Decompensated subjects survive on average less than 2 years. Common causes of liver cirrhosis include alcoholic liver disease, non-alcoholic fatty liver disease ("NAFLD"), chronic hepatitis B and C, primary biliary cirrhosis, and primary sclerosing cholangitis and some patients have liver disease of unknown cause (cryptogenic).

Common complications in patients with cirrhosis may include: compromised liver function, portal hypertension, varices in GI tract with internal bleeding, edema, ascites, hepatic encephalopathy ("HE"), compromised immunity with post-transplant acute rejection risk, high sodium levels, increased bilirubin, low albumin level, insulin resistance with impaired peripheral uptake of glucose, depression, accelerated muscle disorder in the form of sarcopenia, myosteatosis, and frailty with compromised energetics, bone diseases (e.g., osteoporosis), high alkaline phosphatase, cachexia, malnutrition, weight loss (>5%), symptoms of hypogonadism such as abnormal hair distribution, anemia, sexual dysfunction, testicular atrophy, muscle wasting, fatigue, osteoporosis, gynecomastia, inflammation with elevated cytokines, and infection risk leading to hospital admissions and possibly death.

HE, a significant decompensation event in patients with cirrhosis, is a brain dysfunction caused by liver insufficiency and/or portal systemic shunting. Because the damaged liver cannot function normally (as in cirrhosis), neurotoxins such as ammonia are inadequately removed from systemic circulation and travel to the brain, where they affect neurotransmission. This can cause episodes of HE, which may present as alterations in consciousness, cognition, and behavior that range from minimal to severe. Overt HE occurs in 30% to 40% of patients with cirrhosis at some point during the clinical course of their disease. As the burden of chronic liver disease and cirrhosis is increasing, the frequency of HE is also increasing.

LPCN 1144: An Oral Prodrug of Bioidentical Testosterone Product Candidate for the Treatment of MASH

We are exploring the possibility of partnering with a third party for LPCN 1144, although no partnering agreement has been entered into by the Company. No assurance can be given that any license agreement will be completed, or, if an agreement is completed, that such an agreement would be on terms favorable to us.

Disease Overview – MASH

MASH is an advanced state of non-alcoholic fatty liver disease ("NAFLD") that can progress to a cirrhotic liver or liver failure, require liver transplant, and can result in hepatocellular carcinoma/ liver cancer, and death. Progression of MASH to end stage liver disease is one of the leading causes of liver failure requiring liver transplantation. Importantly, beyond these critical conditions, MASH and NAFLD patients additionally suffer heightened cardiovascular risk and die more frequently from cardiovascular events than from liver disease. NAFLD/MASH is becoming more common due to its strong correlation with obesity and metabolic syndrome, including components of metabolic syndrome such as diabetes, cardiovascular disease and high blood pressure. 20% to 30% of the U.S. population is estimated to suffer from NAFLD, with a large proportion of that group, 15% to 20%, progressing to MASH, which lacks an effective therapy. MASH is a silent killer that affects millions in the U.S. Diagnoses have been on the rise and are expected to increase dramatically in the next decade. Approximately 50% of MASH patients are adult males. In men, especially with comorbidities associated with NAFLD/MASH, testosterone deficiency has been associated with an increased accumulation of visceral adipose tissue and insulin resistance, which could be factors contributing to NAFLD/MASH. There is currently no approved therapy for the treatment of MASH although there are several drug candidates currently under development with many having clinical failures to date.

The critical pathophysiologic mechanisms underlying the development and progression of MASH include reduced ability to handle lipids, increased insulin resistance, injury to hepatocytes and liver fibrosis in response to hepatocyte injury. MASH patients have an excessive accumulation of fat in the liver resulting primarily from a caloric intake above and beyond energy needs. A healthy liver contains less than 5% fat, but a liver in someone with MASH can contain more than 20% fat. This abnormal liver fat contributes to the progression to MASH, a liver necro-inflammatory state that can lead to scarring, also known as fibrosis, and, for some, can progress to cirrhosis and liver failure.

Current Status

We have completed the *LiFT* Phase 2 clinical study in biopsy-confirmed non-cirrhotic MASH subjects. The *LiFT* clinical study was a prospective, multi-center, randomized, double-blind, placebo-controlled multiple-arm study in biopsy-confirmed hypogonadal and eugonadal male MASH subjects with grade F1-F3 fibrosis and a target NAFLD Activity Score ≥ 4 with a 36-week treatment period. The *LiFT* clinical study enrolled 56 biopsy confirmed MASH male subjects. Subjects were randomized 1:1:1 to one of three arms (Treatment A was a twice daily oral dose of 142 mg testosterone equivalent, Treatment B was a twice daily oral dose of 142 mg testosterone equivalent formulated with 217 mg of d-alpha tocopherol equivalent, and the third arm was a twice daily matching placebo).

The primary endpoint of the *LiFT* clinical study was change in hepatic fat fraction via MRI-PDFF and exploratory liver fat/marker end points post 12 weeks of treatment. Additionally, key secondary endpoints post 36 weeks of treatment included assessment of histological change for MASH resolution and/or fibrosis improvement (biopsy) as well as liver fat data (MRI-PDFF). The *LiFT* clinical study was not powered to assess statistical significance of any of the secondary endpoints. Other important endpoints included the following: change in liver injury markers, anthropomorphic measurements, body composition including lean mass, fat mass, and bone mineral density, lipids, insulin resistance and inflammatory/fibrosis markers; as well as PROs.

Treatments with LPCN 1144 post 12 weeks of treatment in the *LiFT* study resulted in robust liver fat reduction, assessed by MRI-PDFF, and showed improvement of liver injury markers with no observed tolerability issues.

Liver biopsies were performed at baseline ("BL") and after 36 weeks of treatment ("EOS"). Pre-specified biopsy analyses included MASH Clinical Research Network ("CRN") scoring as well as a continuous paired and digital technique ("Digital Technique-Fibronest"). All biopsy analyses were performed on the same slides and the reads for the three techniques were done independently. Analysis sets included the MASH Resolution Set (all subjects that have BL and EOS biopsy with MASH at BL [NAS ≥4 with lobular inflammation score ≥ 1 and hepatocyte ballooning score ≥1 at BL] (n=37)), the Biopsy Set (all subjects with baseline and EOS biopsies (n=44)), and the Safety Set (all randomized subjects (n=56)).

Both LPCN 1144 treatment arms met with statistical significance the pre-specified accelerated approval regulatory endpoint of MASH resolution with no worsening of fibrosis based on MASH CRN scoring. Additionally, both treatment arms showed substantial improvement of the observed MASH activity in steatosis, inflammation, and ballooning.

During the 36 weeks of treatment, LPCN 1144 was well tolerated with an overall safety profile comparable to placebo. Additionally, subjects were given the option to have access to LPCN 1144 through an open label extension ("OLE") study.

The extension study enabled the collection of additional data on LPCN 1144 for up to a total of 72 weeks of therapy, as well as data for 36 weeks of therapy for those subjects on placebo in the *LiFT* study. Key results from the OLE study are as follows:

- LPCN 1144 was well tolerated over 72-week exposure with no observed safety signals;
- Liver injury markers were reduced and maintained with extended LPCN 1144 treatment; and
- Observed liver histology improvements support further development.

In November 2021, the FDA granted Fast Track Designation to LPCN 1144 as a treatment for non-cirrhotic MASH. The Fast Track program is designed to accelerate the development and expedite the review of products, such as LPCN 1144, which are intended to treat serious diseases and for which there is an unmet medical need.

We had a written only response from the FDA for a LPCN 1144 Type C meeting with the FDA in January 2022 to discuss the development path forward with LPCN 1144. The FDA acknowledged that the NDA submission of LPCN 1144 would be via the 505(b)2 regulatory pathway and agreed that no additional non-clinical studies are needed to support an NDA submission. The FDA acknowledged that subjects in the LiFT study achieved improvements in key components associated with MASH histopathology after 36-weeks of treatment with LPCN 1144 in adult males and agreed that the proposed multicomponent primary surrogate endpoint is acceptable for seeking approval under the accelerated approval pathway. The FDA agreed that the proposed primary multicomponent surrogate endpoint, MASH resolution with no worsening of fibrosis, is acceptable for seeking approval under the accelerated approval pathway and the FDA recommended a Phase 3 trial with a study duration of 72 weeks. In July 2022, Lipocine held an End of Phase 2 meeting with the FDA for LPCN 1144 for MASH. The FDA recommended a Phase 2 dose ranging study be conducted to identify the optimal dose prior to conducting a pivotal study. The FDA agreed to the proposed unique testosterone ester, testosterone laurate, for future clinical studies.

LPCN 1107: An Oral Product Candidate for the Prevention of Preterm Birth ("PTB")

We are exploring the possibility of partnering with a third party for the development and/or marketing of LPCN 1107, although no partnering agreement has been entered into by us. No assurance can be given that any partnering agreement will be completed, or, if an agreement is completed, that such an agreement would be on terms favorable to us.

We believe LPCN 1107 has the potential to become the first oral hydroxyprogesterone caproate ("HPC") product indicated for the reduction of risk of PTB (delivery less than 37 weeks) in women with singleton pregnancy who have a history of singleton spontaneous PTB. Prevention of PTB is a significant unmet need as approximately 11% of all U.S. pregnancies result in PTB, a leading cause of neonatal mortality and morbidity.

Current Status

We have completed a multi-dose PK dose selection study in pregnant women. The objective of the multi-dose PK selection study was to assess HPC blood levels in order to identify the appropriate LPCN 1107 Phase 3 dose. The multi-dose PK dose selection study was an open-label, 4-period, 4-treatment, randomized, single and multiple dose PK study in pregnant women with 3 dose levels of LPCN 1107 and the IM HPC (Makena®). The study enrolled 12 healthy pregnant women (average age of 27 years) with a gestational age of approximately 16 to 19 weeks. Subjects received three dose levels of LPCN 1107 (400 mg BID, 600 mg BID, or 800 mg BID) in a randomized, crossover manner during the first 3 treatment periods and then received 5 weekly injections of HPC during the fourth treatment period. During each of the LPCN 1107 treatment periods, subjects received a single dose of LPCN 1107 on Day 1 followed by twice daily administration from Day 2 to Day 8. Following completion of the 3 LPCN 1107 treatment periods and a washout period, all subjects received 5 weekly injections of HPC. Results from this study demonstrated that average steady state HPC levels (Cavg0-24) were comparable or higher for all 3 LPCN 1107 doses than for injectable HPC. Additionally, HPC levels as a function of daily dose were linear for the 3 LPCN 1107 doses. Also, unlike the injectable HPC, steady state exposure was achieved for all 3 LPCN 1107 doses within 7 days.

A traditional PK/PD based Phase 2 clinical study in the intended patient population is not expected to be required prior to entering into Phase 3. Therefore, based on the results of our multi-dose PK study we had an End-of-Phase 2 meeting and subsequent guidance meetings with the FDA to define a pivotal Phase 2b/3 development plan for LPCN 1107. We have completed a food effect study to characterize the dosing regimen for the pivotal study and we have submitted a pivotal clinical study protocol to the FDA.

The FDA has granted orphan drug designation to LPCN 1107 based on a major contribution to patient care. Orphan designation qualifies Lipocine for various development incentives, including tax credits for qualified clinical testing, and a waiver of the prescription drug user fee when we file our NDA.

Recent Competition Update

On October 5, 2020, the FDA's Center for Drug Evaluation and Research ("CDER") proposed that Makena be withdrawn from the market because the PROLONG trial failed to verify the clinical benefit of Makena and concluded that the available evidence does not show Makena is effective for its approved use and on April 6, 2023, the FDA withdrew its approval of Makena and ordered the immediate withdrawal of Makena and several approved generic versions of the drug, making it unlawful for the drug to be distributed in the U.S. The FDA stated that in light of the unmet need for a treatment for preventing preterm birth and improving neonatal outcomes, it is imperative that the medical and scientific communities increase their efforts to find effective treatments and stated their hope that the decision to withdraw Makena will help galvanize further research. The FDA further stated their commitment to working together with patients, researchers, and drug developers to advance the development of safe and effective therapies that are urgently needed as a treatment for the prevention of preterm birth.

Financial Operations Overview

Revenue

To date, we have not generated any revenues from product sales and do not expect to do so until our FDA approved product receives regulatory approval outside the U.S. and Canada or until one of our product candidates receives approval from the FDA. Revenues to date have been generated substantially from license fees, royalty and milestone payments and research support from our licensees. Since our inception through June 30, 2025, we have generated $53.8 million in revenue under our various license and collaboration arrangements and from government grants. We have entered into the Verity License Agreement, the SPC License Agreement, the Pharmalink Distribution Agreement, and the Aché License Agreement with the potential for revenue from future milestones, royalties and/or product sales, but we may never generate revenues from any of our clinical or preclinical development programs or licensed products as we may never succeed in obtaining regulatory approval or commercializing any of these product candidates.

Research and Development Expenses

Research and development expenses consist primarily of salaries, benefits, stock-based compensation and related personnel costs, fees paid to external service providers such as contract research organizations and contract manufacturing organizations, contractual obligations for clinical development, clinical sites, manufacturing and scale-up for late stage clinical trials, formulation of clinical drug supplies, and expenses associated with regulatory submissions. Research and development expenses also include an allocation of indirect costs, such as those for facilities, office expense, and depreciation of equipment based on the ratio of direct labor hours for research and development personnel to total direct labor hours for all personnel. We expense research and development expenses as incurred. Since our inception, we have spent approximately $157.8 million in research and development expenses through June 30, 2025.

We expect to continue to incur significant costs as we develop our other product candidates, including our CNS product candidates, as well as the development of any future pipeline product candidates.

In general, the cost of clinical trials may vary significantly over the life of a project as a result of uncertainties in clinical development, including, among others:

- the number of sites included in the trials;
- the length of time required to enroll suitable subjects;
- the duration of subject follow-ups;
- the length of time required to collect, analyze and report trial results;
- the cost, timing and outcome of regulatory review; and
- potential changes by the FDA in clinical trial and NDA filing requirements.

Future research and development expenditures are subject to numerous uncertainties regarding timing and cost to completion, including, among others:

- the timing and outcome of regulatory filings and FDA reviews and actions for product candidates;
- our dependence on third-party manufacturers for the production of satisfactory finished products for registration and launch should regulatory approval be obtained on any of our product candidates;
- the potential for future license or co-promote arrangements for our product candidates, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our future plans and capital requirements; and
- the effect on our product development activities of actions taken by the FDA or other regulatory authorities.

A change of outcome for any of these variables with respect to the development of our product development candidates could mean a substantial change in the costs and timing associated with these efforts, could require us to raise additional capital, and may require us to reduce operations.

Given the stage of clinical development and the significant risks and uncertainties inherent in the clinical development, manufacturing, and regulatory approval process, we are unable to estimate with any certainty the time or cost to complete the development of LPCN 1154, LPCN 2401, LPCN 2101, LPCN 2203, LPCN 1148, LPCN 1144, LPCN 1111, LPCN 1107 and other product candidates. Clinical development timelines, the probability of success, and development costs can differ materially from expectations and results from our clinical trials may not be favorable. If we are successful in progressing LPCN 1154, LPCN 2401. LPCN 2101, LPCN 2203 or other future product candidates into later stage development, we will require additional capital. The amount and timing of our future research and development expenses for these product candidates will depend on the pre-clinical and clinical success of both our current development activities and potential development of new product candidates, as well as ongoing assessments of the commercial potential of such activities. We will continue efforts to enter into partnership arrangements for the continued development and/or marketing of LPCN 1154, LPCN 1144, LPCN 1148, LPCN 2401, LPCN 1107, for the development and commercialization of TLANDO outside of the United States, Canada, South Korea, the GCC countries and Brazil, and LPCN 1111 outside of the United States and Canada.

We expect to continue to incur significant research and development expenses in the future as we complete on-going clinical studies, including studies for our CNS product candidates, including a Phase 3 study for LPCN 1154, and as we conduct future clinical studies, including when and if we conduct Phase 2 clinical studies with LPCN 2401 or our development product candidates and when and if we conduct clinical studies for LPCN 2101 or LPCN 2203 and/or Phase 3 clinical studies with LPCN 1144, LPCN 1148, and LPCN 1107. We are also exploring the possibility of licensing all of our product candidates, although we have not entered into a licensing agreement and no assurance can be given that any license agreement will be completed, or, if an agreement is completed, that such agreement would be on terms favorable to us. If we are unable to raise additional capital or obtain non-dilutive financing, we may need to reduce research and development expenses in order to extend our ability to continue as a going concern.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, and outside consulting services related to our executive, finance, business development and administrative support functions. Other general and administrative expenses include rent and utilities, travel expenses, and professional fees for auditing, tax, legal, and various other services.

General and administrative expenses also include expenses for the cost of preparing, filling and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims.

We expect that general and administrative expenses will increase in the future as we continue as a public company. These fees include legal and consulting fees, accounting and audit fees, director fees, directors' and officers' insurance premiums, fees for investor relations services and enhanced business and accounting systems, litigation costs, professional fees and other costs. However, if we are unable to raise additional capital, we may need to reduce general and administrative expenses in order to extend our ability to continue as a going concern.

Other Income and Expense

Other income and expense consists primarily of interest income earned on our cash, cash equivalents and marketable investment securities and losses on our warrant liability in 2024.

Results of Operations

Comparison of the Three Months Ended June 30, 2025 and 2024

The following table summarizes our results of operations for the three months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		
	2025	2024	Variance
Revenue	$ 622,849	$ 89,565	$ 533,284
Research and development expenses	2,136,769	1,874,721	262,048
General and administrative expenses	890,433	1,507,412	(616,979)
Interest and investment income	198,637	308,845	(110,208)
Unrealized loss on warrant liability	-	(84,430)	84,430
Income tax expense	-	(481)	481

Revenue

We recognized royalty revenue from TLANDO sales of $123,000 during the three months ended June 30, 2025, compared to royalty revenue of $90,000 during the three months ended June 30, 2024. License revenue of $500,000 and $0 was recognized in the three months ended June 30, 2025, and 2024, respectively.

Research and Development Expenses

The increase in research and development expenses during the three months ended June 30, 2025, as compared to the three months ended June 30, 2024 consists of a $153,000 increase in costs related to the initiation of our LPCN 2401 clinical studies, an $81,000 increase in other research and development costs, and a $28,000 increase in personnel related costs.

General and Administrative Expenses

The decrease in general and administrative expenses during the three months ended June 30, 2025 as compared to the three months ended June 30, 2024 primarily consists of a $350,000 decrease in business development fees and consulting expenses incurred in 2024, a $184,000 decrease in legal fees, a $40,000 decrease in Delaware franchise tax as a result of the reduction in authorized common stock from 200,000,000 down to 75,000,000 shares, a $25,000 decrease in other professional fees and general and administrative related costs, and an $18,000 decrease in corporate insurance premiums.

Interest and Investment Income

The decrease in interest and investment income during the three months ended June 30, 2025 compared to interest and investment income during the three months ended June 30, 2024 was due to lower interest rates and lower cash and marketable investment securities balances in 2025 as compared to 2024.

Gain (Loss) on Warrant Liability

There were no outstanding common stock warrants from the November 2019 Offering in 2025 as the liability was extinguished when the November 2019 warrants expired in November 2024.

We recorded a loss of approximately $84,000 on warrant liability during the three months ended June 30, 2024, related to the change in the fair value of outstanding common stock warrants issued in the November 2019 Offering. The loss in 2024 resulted from an increase in the fair value of warrants mainly due to a higher stock price at the end of the second quarter of 2024 compared to the stock price at the end of the first quarter of 2024. There were also no warrants exercised during the three months ended June 30, 2024. The warrants were classified as a liability due to a provision contained within the warrant agreement which allowed the warrant holder the option to elect to receive an amount of cash equal to the value of the warrants as determined in accordance with the Black-Scholes option pricing model with certain defined assumptions upon a change of control.

Comparison of the Six Months Ended June 30, 2025 and 2024

The following table summarizes our results of operations for the six months ended June 30, 2025 and 2024:

	Six Months Ended June 30,		
	2025	**2024**	**Variance**
Revenue	$ 716,713	$ 7,706,738	$ (6,990,025)
Research and development expenses	3,198,341	4,693,646	(1,495,305)
General and administrative expenses	2,012,910	3,083,131	(1,070,221)
Interest and investment income	424,149	640,209	(216,060)
Unrealized loss on warrant liability	-	(124,502)	124,502
Income tax expense	(200)	(681)	481

Revenue

We recognized revenue of $717,000 and $7.7 million during the six months ended June 30, 2025 and 2024, respectively. Revenue during the six months ended June 30, 2025, consists of license revenue of $500,000 compared to license revenue of $7.5 million resulting from our Verity Licensing Agreement during the same period in 2024. During the six months ended June 30, 2025, and 2024, we recognized royalty revenue from TLANDO sales of $217,000 and $207,000, respectively.

Research and Development Expenses

The decrease in research and development expenses during the six months ended June 30, 2025, as compared to the six months ended June 30, 2024 consists of a $1.6 million decrease resulting from lower costs related to our LPCN 1154 Phase III clinical study in 2025 as compared to LPCN 1154 studies which occurred in 2024 and a $22,000 decrease in other research and development related costs and supplies in 2025, offset by a $126,000 increase in costs related to the initiation of our LPCN 2401 clinical studies and a $28,000 increase in personnel related costs.

General and Administrative Expenses

The decrease in general and administrative expenses during the six months ended June 30, 2025 as compared to the six months ended June 30, 2024 primarily consists of a $512,000 decrease related to the one-time business development fees incurred in 2024 in conjunction with the Verity License Agreement, a $410,000 decrease in other business development expense, a $110,000 decrease in legal fees, a $36,000 decrease in corporate insurance premiums, and a $22,000 decrease in professional fees and other general and administrative costs, offset by a $20,000 increase in personnel related costs.

Interest and Investment Income

The decrease in interest and investment income during the six months ended June 30, 2025 compared to interest and investment income during the six months ended June 30, 2024 was due to lower interest rates and lower cash and marketable investment securities balances in 2025 as compared to 2024.

Gain (Loss) on Warrant Liability

There were no outstanding common stock warrants from the November 2019 Offering in 2025 as the liability had been extinguished when the November 2019 warrants expired in November 2024.

We recorded a loss of approximately $125,000 on warrant liability during the six months ended June 30, 2024, related to the change in the fair value of outstanding common stock warrants issued in the November 2019 Offering. The loss in 2024 resulted from an increase in the fair value of warrants mainly due to a higher stock price at the end of the second quarter of 2024 compared to the stock price at the end of the fourth quarter of 2023. No warrants were exercised during the six months ended June 30, 2024. The warrants were classified as a liability due to a provision contained within the warrant agreement which allowed the warrant holder the option to elect to receive an amount of cash equal to the value of the warrants as determined in accordance with the Black-Scholes option pricing model with certain defined assumptions upon a change of control.

Liquidity and Capital Resources

Since our inception, our operations have been primarily financed through sales of our equity securities, issuances of debt and payments received under our license and collaboration arrangements. We have devoted our resources to funding research and development programs, including discovery research, and preclinical and clinical development activities. We have incurred operating losses in most years since our inception and we expect to continue to incur operating losses into the foreseeable future as we advance the clinical development of LPCN 1154, LPCN 2401, LPCN 2101, LPCN 2203, and any other future product candidates, including continued research efforts.

As of June 30, 2025, we had $17.9 million of unrestricted cash, cash equivalents and marketable investment securities compared to $21.6 million at December 31, 2024.

In April 2025, we entered into the Aché License and Supply Agreement with Aché pursuant to which we granted to Aché an exclusive license to commercialize our TLANDO® product with respect to the Field, specific to Brazil. Under the agreement, we are entitled to receive fees upon the achievement of certain regulatory milestones, royalties on net sales and will supply TLANDO to Aché at an agreed transfer price.

In October 2024, we entered into the Pharmalink Distribution Agreement with Pharmalink, pursuant to which we granted to Pharmalink a non-transferable, exclusive, license to commercialize our TLANDO product in the Pharmalink Territory. Pharmalink paid us a one-time non-refundable, non-creditable upfront fee. We are eligible to receive additional payments in regulatory authorization milestones related to the marketing approval in countries in the Pharmalink Territory under the Pharmalink Distribution Agreement and we have agreed to supply TLANDO to Pharmalink at a specified transfer price.

In September 2024, we entered into the SPC License Agreement with SPC, pursuant to which we granted to SPC a non-transferable, exclusive, royalty-bearing license to develop and commercialize our TLANDO product with respect to TRT in South Korea. Under the terms of the SPC License Agreement, SPC paid us a non-refundable, non-creditable upfront fee in October 2024. We also received a non-refundable payment in consideration for certain TLANDO product inventory, and are eligible to receive additional payments upon the receipt of marketing authorization and achievement of sales milestones, and we will supply TLANDO to SPC and receive a supply price. In addition, we will receive royalties on net sales in the SPC Territory under the SPC License Agreement. Our ability to realize benefits from the SPC License Agreement, including milestone, product sale and royalty payments, is subject to a number of risks. We may not realize milestone, product sale or royalty payments in anticipated amounts, or at all.

On January 12, 2024, we entered into the Verity License Agreement with Verity Pharma, pursuant to which we granted to Verity Pharma an exclusive, royalty-bearing, sublicensable right and license to develop and commercialize our TLANDO product with respect to TRT in the Licensed Verity Territory. Upon execution of the Verity License Agreement in January 2024 and upon transition of the commercialization of TLANDO from Antares to Verity Pharma in February 2024, Verity Pharma paid us initial payments of $2.5 million and $5 million, respectively. Verity Pharma also paid us of $2.5 million on December 30, 2024, has agreed to make additional payments to us of $1 million before January 1, 2026. The Verity License Agreement also provides Verity Pharma with a license to develop and commercialize TLANDO XR (LPCN 1111), our potential next generation, once daily oral product candidate for testosterone replacement therapy comprised of TT in the U.S. and Canada. We are eligible to receive milestone payments of up to $259 million in the aggregate, depending on the achievement of certain development milestones and sales milestones in a single calendar year with respect to all products licensed by Verity Pharma under the Verity License Agreement. In addition, we receive tiered royalty payments at rates ranging from 12% up to 18% of net sales of all products licensed to Verity Pharma in the Licensed Verity Territory. Our ability to realize benefits from the Verity License Agreement, including milestone and royalty payments, is subject to a number of risks. We may not realize milestone or royalty payments in anticipated amounts, or at all.

Previously on March 6, 2017, we entered into the Cantor Sales Agreement with Cantor under which we agreed to sell shares of our common stock, having registered up to $50.0 million for sale under the Cantor Sales Agreement. During the year ended December 31, 2024, we sold 32,110 shares of our common stock under the Cantor Sales Agreement at a weighted-average sales price of $6.77 per share, resulting in net proceeds of approximately $209,000, which is net of approximately $8,000 in expenses. On April 24, 2024, we terminated the Cantor Sales Agreement. From the inception to the termination of the Cantor Sales Agreement, we sold, in aggregate, 996,821 shares of our common stock for $33.5 million.

On April 26, 2024, we entered into the A.G.P. Sales Agreement with A.G.P. pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to the amount we registered on an effective registration statement pursuant to which the offering is being made. We currently have registered up to $10,616,169 of shares of common stock for sale under the A.G.P. Sales Agreement, pursuant to the Form S-3, through A.G.P. as sales agent. A.G.P. may sell our common stock by any method permitted by law deemed to be an ATM offering as defined in Rule 415(a)(4) of the Securities Act, including sales made directly on or through the Nasdaq Capital Market or any other existing trade market for our common stock, in negotiated transactions at market prices prevailing at the time of sale or at prices related to prevailing market prices, or any other method permitted by law. A.G.P. will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell shares under the A.G.P. Sales Agreement. We will pay A.G.P. 3.0% of the aggregate gross proceeds from each sale of shares under the A.G.P. Sales Agreement. In addition, we have also provided A.G.P. with customary indemnification rights.

Our shares of common stock to be sold under the A.G.P. Sales Agreement will be sold and issued pursuant to the Form S-3, as amended, which was previously declared effective by the SEC, and the related prospectus and one or more prospectus supplements.

We are not obligated to make any sales of our common stock under the A.G.P. Sales Agreement. The offering of common stock pursuant to the A.G.P. Sales Agreement will terminate upon the termination of the A.G.P. Sales Agreement as permitted therein. We and A.G.P. may each terminate the A.G.P. Sales Agreement at any time upon ten days' prior notice.

During the three and six months ended June 30, 2025, we sold 23,739 shares of common stock at a weighted average price of $3.29 per share pursuant to the A.G.P. Sales Agreement for aggregate net proceeds of approximately $76,000, after paying commissions of approximately $2,000 to A.G.P, as sales agent.

We believe that our existing capital resources, together with interest thereon, will be sufficient to meet our projected operating requirements through at least August 5, 2026, which include a Phase 3 clinical study for LPCN 1154 and a POC study for LPCN 2401, research and development activities, and compliance with regulatory requirements. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect if additional activities are performed by us including new clinical studies for LPCN 2401, LPCN 2101, LPCN 2203, LPCN 1148, LPCN 1144, and/or LPCN 1107. While we believe we have sufficient liquidity and capital resources to fund our projected operating requirements through at least August 5, 2026, we will need to raise additional capital at some point through the equity or debt markets or through additional out-licensing activities, either before or after August 5, 2026, to support our operations. If we are unsuccessful in raising additional capital as necessary, our ability to continue as a going concern will be limited. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development, regulatory compliance and clinical trial activities sooner than planned. In addition, our capital resources may be consumed more rapidly if we pursue additional clinical studies for LPCN 1154, LPCN 2401, LPCN 2101, LPCN 2203, LPCN 1148, LPCN 1144, and/or LPCN 1107. Conversely, our capital resources could last longer if we reduce expenses, reduce the number of activities currently contemplated under our operating plan or if we terminate, modify or suspend on-going clinical studies. We can raise capital pursuant to the A.G.P. Sales Agreement but may choose not to issue common stock if our market price is too low to justify such sales in our discretion. There are numerous risks and uncertainties associated with the development and, subject to approval by the FDA, commercialization of our product candidates. There are numerous risks and uncertainties impacting our ability to enter into collaborations with third parties to participate in the development and potential commercialization of our product candidates. We are unable to precisely estimate the amounts of increased capital outlays and operating expenditures associated with our anticipated or unanticipated clinical studies and ongoing development efforts. All of these factors affect our need for additional capital resources. To fund future operations, we will need to ultimately raise additional capital and our requirements will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our clinical studies, pre-clinical testing and other related activities for all of our product candidates, including LPCN 1154, LPCN 2401, LPCN 2101, LPCN 2203, LPCN 1148, LPCN 1144, and LPCN 1107;
- the cost of manufacturing clinical supplies and establishing commercial supplies, of our product candidates and any products that we may develop;
- the cost and timing of establishing sales, marketing and distribution capabilities, if any;
- the terms and timing of any collaborative, licensing, settlement and other arrangements that we may establish;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the timing, receipt and amount of sales, profit sharing, milestones or royalties, if any, from our potential products;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions; and
- the extent to which we grow significantly in the number of employees or the scope of our operations.

Funding may not be available to us on favorable terms, or at all. Also, market conditions may prevent us from accessing the debt and equity capital markets, including sales of our common stock through the A.G.P. Sales Agreement. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical studies, research and development programs or, if any of our product candidates receive approval from the FDA, commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, including the Sales Agreement, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. These arrangements may not be available to us or available on terms favorable to us. To the extent that we raise additional capital through marketing and distribution arrangements, other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences, warrants or other terms that adversely affect our stockholders' rights or further complicate raising additional capital in the future. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable, for any reason, to raise needed capital, we will have to reduce costs, delay research and development programs, liquidate assets, dispose of rights, commercialize products or product candidates earlier than planned or on less favorable terms than desired or reduce or cease operations.

Sources and Uses of Cash

The following table provides a summary of our cash flows for the six months ended June 30, 2025 and 2024:

	Six Months Ended June 30,	
	2025	**2024**
Cash used in operating activities	$ (3,855,491)	$ (90,258)
Cash used in investing activities	3,617,927	662,531
Cash used in financing activities	75,618	209,340

Net Cash from Operating Activities

During the six months ended June 30, 2025 and 2024, net cash used in operating activities was $3.9 million and $90,000, respectively.

Net cash used in operating activities during the six months ended June 30, 2025, was primarily attributable to cash required to support ongoing operations, including research and development activities related to the commencement of our LPCN 1154 Phase III clinical trial, offset by the licensing fee received. Net cash used in operating activities during the six months ended June 30, 2024, was primarily attributable to cash outlays to support ongoing operations, including research and development expenses and general and administrative expenses, offset by the cash provided by the Verity License Agreement of $7.5 million.

Net Cash from Investing Activities

During the six months ended June 30, 2025 and 2024, net cash provided by investing activities was $3.6 million and $663,000, respectively.

Net cash provided by investing activities during the six months ended June 30, 2025 and 2024, was primarily the result of the maturities of marketable investments securities, net. There were no capital expenditures during either the six months ended June 30, 2025 or 2024.

Net Cash from Financing Activities

During the six months ended June 30, 2025 and 2024, net cash provided by financing activities was approximately $76,000 and $209,000, respectively.

Net cash provided by financing activities during the six months ended June 30, 2025 primarily resulted from the sale of 23,739 shares of common stock at a weighted average price of $3.29 per share pursuant to the A.G.P. Sales Agreement. Net cash provided by financing activities during the six months ended June 30, 2024, primarily resulted from the sale of 32,110 shares of common stock at a weighted average price of $6.77 per share pursuant to the Cantor Sales Agreement.

Contractual Commitments and Contingencies

Purchase Obligations

We enter into contracts and issue purchase orders in the normal course of business with clinical research organizations for clinical trials and clinical and commercial supply manufacturing and with vendors for pre-clinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice and are cancellable obligations.

Operating Leases

In August 2004, we entered into an agreement to lease our facility in Salt Lake City, Utah consisting of office and laboratory space which serves as our corporate headquarters. On December 2, 2024, we modified and extended the lease through February 28, 2026.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements which we have prepared in accordance with U.S. GAAP. In preparing our financial statements, we are required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We concluded that licensing revenue recognized in conjunction with the Verity License Agreement met the requirements under ASC 606, Revenue from Contracts with Customers. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. License revenue from payments to be received in the future will be recognized when it is probable that we will receive license payments under the terms of the Verity License Agreement, the SPC License Agreement or the Pharmalink Distribution Agreement (see Footnote 7 – Contractual Agreements for disclosure regarding the SPC License Agreement and the Pharmalink Distribution Agreement).

There have been no significant and material changes in our critical accounting policies during the six months ended June 30, 2025, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations-Critical Accounting Policies and Significant Judgments and Estimates" in our 2024 Form 10-K.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to various market risks, which include potential losses arising from adverse changes in market rates and prices, such as interest rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes.

There have been no material changes to the Company's market risk during the first six months of 2025. For a discussion of the Company's exposure to market risk, refer to the Company's market risk disclosures set forth in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" of the 2024 Form 10-K.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures" within the meaning of Rule 13a-15(e) of the Exchange Act. Our disclosure controls and procedures, ("Disclosure Controls") are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, such as this Quarterly Report on Form 10-Q, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our Disclosure Controls include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

As of the end of the period covered by this Quarterly Report on Form 10-Q, we evaluated the effectiveness of the design and operation of our Disclosure Controls, which was done under the supervision and with the participation of our management, including our Chief Executive Officer and our Principal Financial Officer. Based on the controls evaluation, our Chief Executive Officer and Principal Financial Officer have concluded that our Disclosure Controls were effective as of June 30, 2025.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the most recent fiscal quarter covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Please refer to Note 10 – *Commitments and Contingences* to the unaudited condensed consolidated financial statements contained in this report for certain information regarding our legal proceedings. We are not currently a party to any material litigation or other material legal proceedings. We may, from time to time, be involved in various legal proceedings arising from the normal course of business activities, and, while the Company has insurance that covers

claims of this nature, unfavorable resolution of any of these matters could materially affect our future results of operations, cash flows, or financial position.

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this Quarterly Report on Form 10-Q, consider the risk factors discussed in Part 1, "Item 1A. Risk Factors" in the Company's 2024 Form 10-K, filed with the SEC on March 13, 2025, and the risk factors discussed in Item 1A of the Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, filed with the SEC on May 8, 2025, and in this Quarterly Report on Form 10-Q, which could materially affect our business, financial condition or future results. The risks described in the aforementioned reports are not the only risks facing the Company. Additional risks and uncertainties not currently known to the Company or that it currently deems to be not material also may materially adversely affect the Company's business, financial condition, and/or operating results.

The following are the risk factors that have materially changed from our risk factors included in our 2024 Form 10-K:

Risks Related to Our Business and Industry

LPCN 1154 is in development and an NDA submission may not be filed, or if filed, may not be accepted by the FDA.

LPCN 1154 is currently in development. There can be no assurance as to whether the results of the clinical trials in LPCN 1154 for postpartum depression will support an NDA submission or whether an NDA submission will be accepted for review or approved by the FDA, including the oral route related brexanolone or its metabolites exposure profile relative to injectable brexanolone. A safety and efficacy study in the patient population is ongoing, however there can be no assurance that the safety and efficacy study will be completed, or that the results from the study will meet the primary endpoint. Further, there can be no assurance that additional studies will not be required, and if they are required that we will have sufficient resources to conduct such additional studies to enable an NDA submission.

LPCN 1154 may not achieve planned commercialization or commercialization objectives for a variety of reasons.

Commercialization of LPCN 1154 is likely dependent on us finding a partner to market and sell LPCN 1154, if approved. We are exploring the possibility of partnering LPCN 1154 to a third party for commercialization, however we may not be able to identify potential partners or successfully enter into partnership arrangements on terms favorable to us, if at all. We cannot be certain as to whether label language required by the FDA will require warnings, blackbox or otherwise, as to the safety or efficacy of LPCN 1154 which could negatively affect the commercialization of LPCN 1154, if approved. If we are unable to successfully partner or otherwise develop and get regulatory approval for LPCN 1154, LPCN 1154 may never be commercialized.

There can be no assurance there will not be any third-party patent infringement proceedings against us. Such proceedings could delay or prevent further development of LPCN 1154.

In addition, we rely on third party vendors for our supply of brexanolone, the active pharmaceutical in LPCN 1154. If our third party suppliers are not able to supply brexanolone on a timely basis, or if the cost of obtaining brexanolone increases, our ability to successfully develop and commercialize LPCN 1154 will be adversely affected.

Risks Related to Ownership of Our Common Stock

Our management and directors will be able to exert influence over our affairs.

As of June 30, 2025, our executive officers and directors beneficially owned approximately 6.5% of our common stock. These stockholders, if they act together, may be able to influence our management and affairs and all matters requiring stockholder approval, including significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might affect the market price of our common stock.

The market price of our common stock has been volatile over the past year and may continue to be volatile.

The market price and trading volume of our common stock has been volatile over the past year and it may continue to be volatile. Over the past year, our common stock has traded as low as $2.83 and as high as $7.83 per share. We cannot predict the price at which our common stock will trade in the future and it may decline. The price at which our common stock trades may fluctuate significantly and may be influenced by many factors, including our financial results; developments generally affecting our industry; general economic, industry and market conditions, and our customers; the depth and liquidity of the market for our common stock; investor perceptions of our business; reports by industry analysts; announcements by other market participants, including, among others, investors, our competitors, and our customers; regulatory action affecting our business; and the impact of other “Risk Factors” discussed herein and in our 2024 Form 10-K. In addition, changes in the trading price of our common stock may be inconsistent with our operating results and outlook. The volatility of the market price of our common stock may be inconsistent with our operating results and outlook. The volatility of the market price of our common stock may adversely affect investors’ ability to purchase or sell shares of our common stock.

Risks Relating to Our Financial Position and Capital Requirements

We have incurred significant operating losses in most years since our inception and anticipate that we will incur continued losses for the foreseeable future.

We have focused a significant portion of our efforts on developing TLANDO and more recently on LPCN 1154, LPCN 1148, and LPCN 1144. We have funded our operations to date through sales of our equity securities, debt and payments received under our license and collaboration arrangements. We have incurred losses in most years since our inception. As of June 30, 2025, we had an accumulated deficit of approximately $203.8 million. Substantially all of our operating losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. These losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders’ equity. We expect to continue to incur significant research and development expenses in connection with clinical trials associated with LPCN 1154 and LPCN 2401, and potentially with LPCN 2101, LPCN 2203, LPCN 1148, LPCN 1144 and LPCN 1107, if further clinical trials are initiated. As a result, we expect to continue to incur significant operating losses for the foreseeable future as we evaluate further clinical development of LPCN 1154, LPCN 2401, LPCN 2101, LPCN 2203, and possibly LPCN 1148, LPCN 1144, and LPCN 1107, in addition to our other programs and continued research efforts. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

ITEM 5. OTHER INFORMATION

10b5-1 Trading Plans

During the second quarter of 2025, none of our directors or executive officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (as each term is defined in Item 408(a) of Regulation S-K).

ITEM 6. EXHIBITS

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation	8-K	333-178230	3.2	7/25/2013
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Lipocine Inc.	8-K	333-178230	3.4	6/28/2022
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Lipocine Inc.	8-K	333-178230	3.2	5/11/2023
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Lipocine Inc.	8-K	333-178230	3.4	6/4/2025
3.5	Certificate of Designation of Series A Junior Participating Preferred Stock.	8-K	333-178230	3.1	12/1/2015
3.6	Certificate of Increase of Series A Junior Participating Preferred Stock	8-K	333-178230	3.1	11/1/2021
3.7	Certificate of Amendment to Certificate of Designation of Series A Junior Participating Preferred Stock.	8-K	333-178230	3.1	10/22/2024
3.8	Certificate of Designation of Series B Preferred Stock	8-K	333-178230	3.2	3/10/2023
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 Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350 (1)				
32.2**	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350 (1)				
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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 Labels 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)				

* Filed herewith

** Furnished herewith

(1) This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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.

	Lipocine Inc.
	(Registrant)
Dated: August 5, 2025	*/s/ Mahesh V. Patel*
	Mahesh V. Patel, President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)
Dated: August 5, 2025	*/s/ Krista Fogarty*
	Krista Fogarty, Corporate Controller (Principal Accounting Officer)

EXHIBIT 31.1

CERTIFICATIONS

I, Mahesh V. Patel, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Lipocine 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.

Dated: August 5, 2025

/s/ Mahesh V. Patel

Mahesh V. Patel, President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATIONS

I, Mahesh V. Patel, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Lipocine 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.

Dated: August 5, 2025

/s/ Mahesh V. Patel

Mahesh V. Patel
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION

In connection with the Quarterly Report on Form 10-Q of Lipocine Inc. (the "Corporation") for the quarter ended June 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mahesh V. Patel, President and Chief Executive Officer of the Corporation, hereby certifies, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

Dated: August 5, 2025

/s/ Mahesh V. Patel

Mahesh V. Patel, President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION

In connection with the Quarterly Report on Form 10-Q of Lipocine Inc. (the "Corporation") for the quarter ended June 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mahesh V. Patel, Principal Financial Officer of the Corporation, hereby certifies, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

Dated: August 5, 2025

/s/ Mahesh V. Patel
Mahesh V. Patel
(Principal Financial Officer)