UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

☐ **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: 001-37990

LEAP THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware State or other jurisdiction of incorporation or organization	**27-4412575** (I.R.S. Employer Identification No.)
47 Thorndike St, Suite B1-1, Cambridge, MA Address of Principal Executive Offices	**02141** Zip Code

(617) 714-0360

Registrant's Telephone Number, Including Area Code

N/A

Former Name, Former Address and Former Fiscal Year, if Changed Since

Last Report 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 $0.001 per share	LPTX	Nasdaq Capital Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company.

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

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

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

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

As of November 8, 2024, there were 38,317,897 shares of the registrant's common stock, par value $0.001 per share, outstanding.

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward-looking statements which reflect our current views with respect to, among other things, our operations and financial performance. Such statements are based upon our current plans, estimates and expectations that are subject to various risks and uncertainties that could cause actual results to differ materially from such statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as "anticipate," "expect," "project," "intend," "believe," "may," "will," "should," "plan," "could," "continue," "target," "contemplate," "estimate," "forecast," "guidance," "predict," "possible," "potential," "pursue," "likely," and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts, including statements regarding estimations of projected cash runway; our future product development plans; the potential, safety, efficacy, and regulatory and clinical progress of our product candidates, including the anticipated timing for initiation of clinical trials and release of clinical trial data and the expectations surrounding potential regulatory submissions, approvals and timing thereof; and any assumptions underlying any of the foregoing, are forward-looking statements. Important factors that could cause actual results to differ materially from our plans, estimates or expectations could include, but are not limited to: (i) our ability and plan to develop and commercialize DKN-01 and our other programs; (ii) status, timing and results of our preclinical studies and clinical trials; (iii) the potential benefits of DKN-01 and our other programs; (iv) the timing of our development programs and seeking regulatory approval of DKN-01 and our other programs; (v) our ability to obtain and maintain regulatory approval; (vi) our estimates of expenses and future revenues and profitability; (vii) our estimates regarding our capital requirements and our needs for additional financing; (viii) our estimates of the size of the potential markets for DKN-01 and our other programs; (ix) the benefits to be derived from any collaborations, license agreements, or other acquisition efforts, including the ongoing collaborations with BeiGene, NovaRock and Adimab; (x) sources of revenues and anticipated revenues, including contributions from any collaborations or license agreements for the development and commercialization of products; (xi) the rate and degree of market acceptance of DKN-01 or our other products; (xii) the success of other competing therapies that may become available; (xiii) the manufacturing capacity for our products; (xiv) our intellectual property position; (xv) our ability to maintain and protect our intellectual property rights; (xvi) our results of operations, financial condition, liquidity, prospects, and growth and strategies; (xvii) the industry in which we operate; (xviii) the trends that may affect the industry or us and (xix) the effect of inflation, currency rate and interest rate fluctuations, as well as fluctuations in the market price of our traded securities.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods. You should carefully and completely read this Quarterly Report and any documents that we have filed as exhibits to this Quarterly Report.

You should refer to Part II, Item 1A, Risk Factors in this Quarterly Report and Part I, Item 1A, Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on March 18, 2024, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard any such statement as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. Any forward-looking statement that we make in this Quarterly Report speaks only as of the date of such statement, and, except to the extent required by applicable law, we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report or to reflect the occurrence of unanticipated events. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

DKN-01 is an investigational drug undergoing clinical development and has not been approved by the U.S. Food and Drug Administration (the "FDA"), nor has it been submitted to the FDA for approval. DKN-01 has not been, and may never be, approved by any regulatory agency or marketed anywhere in the world. Statements contained in this Quarterly Report should not be deemed to be promotional.

INTRODUCTORY COMMENT

References to Leap

Throughout this Quarterly Report on Form 10-Q, the "Company," "Leap," "Leap Therapeutics," "we," "us," and "our," except where the context requires otherwise, refer to Leap Therapeutics, Inc. and its consolidated subsidiaries, and "Board of Directors" refers to the board of directors of Leap Therapeutics, Inc.

Part I – FINANCIAL INFORMATION

Item 1. Financial Statements

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	September 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 62,823	$ 70,643
Research and development incentive receivable	780	771
Prepaid expenses and other current assets	209	183
Total current assets	63,812	71,597
Property and equipment, net	—	5
Right of use assets, net	370	257
Deposits	865	966
Total assets	$ 65,047	$ 72,825
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,946	$ 6,465
Accrued expenses	9,049	5,957
Income tax payable	722	—
Lease liability - current portion	376	262
Total current liabilities	16,093	12,684
Total liabilities	16,093	12,684
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding	—	—
Common stock, $0.001 par value; 240,000,000 shares authorized; 38,264,464 and 25,565,414 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	38	26
Additional paid-in capital	500,850	459,591
Accumulated other comprehensive income	6	106
Accumulated deficit	(451,940)	(399,582)
Total stockholders' equity	48,954	60,141
Total liabilities and stockholders' equity	$ 65,047	$ 72,825

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 14,915	$ 11,503	$ 44,099	$ 61,549
General and administrative	2,940	3,330	9,833	10,672
Total operating expenses	17,855	14,833	53,932	72,221
Loss from operations	(17,855)	(14,833)	(53,932)	(72,221)
Interest income	894	1,084	2,534	3,089
Australian research and development incentives	(499)	554	—	1,124
Foreign currency loss	(8)	(501)	(18)	(953)
Change in fair value of Series X preferred stock warrant liability	—	—	—	12
Loss before income taxes	(17,468)	(13,696)	(51,416)	(68,949)
Provision for income taxes	(708)	—	(708)	—
Net loss	(18,176)	(13,696)	(52,124)	(68,949)
Dividend attributable to down round feature of warrants	—	—	(234)	—
Net loss attributable to common stockholders	$ (18,176)	$ (13,696)	$ (52,358)	$ (68,949)
Net loss per share				
Basic and diluted	$ (0.44)	$ (0.51)	$ (1.44)	$ (3.78)
Weighted average common shares outstanding				
Basic and diluted	41,209,639	26,987,182	36,307,890	18,240,455

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	$ (18,176)	$ (13,696)	$ (52,124)	$ (68,949)
Other comprehensive income (loss):				
Foreign currency translation adjustments	3	346	(100)	632
Comprehensive loss	$ (18,173)	$ (13,350)	$ (52,224)	$ (68,317)

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY
For the Three and Nine Months Ended September 30, 2023

(In thousands, except share amounts)

(Unaudited)

	Mezzanine Equity		Stockholders Equity					
	Series X Non Voting Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at June 30, 2023	—	$ —	25,565,414	$ 26	$ 457,038	$ 414	$ (373,421)	$ 84,057
Fractional shares paid in cash	—	—	—	—	1	—	—	1
Foreign currency translation adjustment	—	—	—	—	—	346	—	346
Stock-based compensation	—	—	—	—	1,300	—	—	1,300
Net loss	—	—	—	—	—	—	(13,696)	(13,696)
Balances at September 30, 2023	—	$ —	25,565,414	$ 26	$ 458,339	$ 760	$ (387,117)	$ 72,008

	Mezzanine Equity		Stockholders Equity					
	Series X Non Voting Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount	Shares	Amount				
Balances at December 31, 2022	—	$ —	9,902,137	$ 10	$376,896	$ 128	$ (318,168)	$ 58,866
Issuance of Series X Preferred Stock in connection with Flame merger	136,248	67,715	—	—	—	—	—	—
Issuance of common stock in connection with Flame merger	—	—	1,972,901	2	9,803	—	—	9,805
Issuance of common stock warrants in connection with Flame merger	—	—	—	—	13	—	—	13
Redemption of 2019 Warrants	—	—	—	—	(29)	—	—	(29
Issuance of common stock upon vest of restricted stock units	—	—	66,061	—	—	—	—	—
Conversion of Series X preferred stock to common stock	(136,248)	(67,715)	13,624,800	14	67,701	—	—	67,715
Reclassification of Series X preferred stock warrants to equity	—	—	—	—	78	—	—	78
Fractional shares paid in cash	—	—	(485)	—	2	—	—	2
Foreign currency translation adjustment	—	—	—	—	—	632	—	632
Stock-based compensation	—	—	—	—	3,875	—	—	3,875
Net loss	—	—	—	—	—	—	(68,949)	(68,949
Balances at September 30, 2023	—	$ —	25,565,414	$ 26	$458,339	$ 760	$ (387,117)	$ 72,008

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Three and Nine Months Ended September 30, 2024

(In thousands, except share amounts)

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at June 30, 2024	38,264,464	$ 38	$ 499,511	$ 3	$ (433,764)	$ 65,788
Foreign currency translation adjustment	—	—	—	3	—	3
Stock-based compensation	—	—	1,339	—	—	1,339
Net loss	—	—	—	—	(18,176)	(18,176)
Balances at September 30, 2024	38,264,464	$ 38	$ 500,850	$ 6	$ (451,940)	$ 48,954

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2023	25,565,414	$ 26	$ 459,591	$ 106	$ (399,582)	$ 60,141
Issuance of common stock upon vest of restricted stock units	27,500	—	—	—	—	—
Issuance of common stock upon exercise of stock options	10,557	—	29	—	—	29
April 2024 Private Placement (net of issuance costs of $2,948)	12,660,993	12	37,039	—	—	37,051
Dividend attributable to the down round feature of 2017 Warrants	—	—	234	—	(234)	—
Foreign currency translation adjustment	—	—	—	(100)	—	(100)
Stock-based compensation	—	—	3,957	—	—	3,957
Net loss	—	—	—	—	(52,124)	(52,124)
Balances at September 30, 2024	38,264,464	$ 38	$ 500,850	$ 6	$ (451,940)	$ 48,954

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (52,124)	$ (68,949)
Adjustments to reconcile net loss to net cash used in operating activities:		
In-process research and development costs acquired in connection with the acquisition of Flame	—	29,582
Depreciation expense	5	11
Stock-based compensation expense	3,957	3,875
Foreign currency transaction loss	18	953
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(24)	83
Research and development incentive receivable	—	1,279
Accounts payable and accrued expenses	2,573	(1,006)
Right-of-use asset	307	306
Income tax payable	708	—
Lease liability	(307)	(308)
Other assets	100	801
Net cash used in operating activities	(44,787)	(33,373)
Cash flows from investing activities:		
Cash acquired in connection with the acquistion of Flame	—	50,362
Payment of direct and incremental costs of the asset acquisition	—	(1,393)
Net cash provided by investing activities	—	48,969
Cash flows from financing activities:		
Proceeds from April 2024 Private Placement	39,999	—
Payment of deferred offering costs	(2,948)	—
Payment of redemption of 2019 warrants	—	(29)
Payment of fractional shares	—	(1)
Proceeds from the exercise of stock options	29	—
Net cash providided by (used in) financing activities	37,080	(30)
Effect of exchange rate changes on cash and cash equivalents	(113)	(323)
Net (decrease) increase in cash and cash equivalents	(7,820)	15,243
Cash and cash equivalents at beginning of period	70,643	65,500
Cash and cash equivalents at end of period	$ 62,823	$ 80,743
Supplemental disclosure of non-cash financing activities:		
Remeasurement of right-of-use asset and lease liability	$ 420	$ —
Dividend attributable to the down round feature of 2017 Warrants	$ 234	$ —
Issuance and conversion of Series X Preferred Stock issued in connection with the acquisition of Flame to common stock	$ —	$ 67,715
Reclassification of Series X Preferred Stock Warrants from liability to equity	$ —	$ 78
Issuance of common stock in connection with the acquisition of Flame	$ —	$ 9,805
Issuance of warrants for the purchase of common stock in connection with the acquisition of Flame	$ —	$ 13
Net liabilities assumed from acquistion of Flame	$ —	$ 928

See notes to condensed consolidated financial statements.

Leap Therapeutics, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(In thousands, except share and per share amounts)

(Unaudited)

1. Nature of Business, Basis of Presentation and Liquidity

Nature of Business

Leap Therapeutics, Inc. was incorporated in the state of Delaware on January 3, 2011. During 2015, HealthCare Pharmaceuticals Pty Ltd. was formed and is a wholly owned subsidiary of the Company.

On December 10, 2015, the Company entered into a merger agreement with GITR Inc. ("GITR"), an entity under common control, whereby a wholly owned subsidiary of the Company was merged with GITR and the surviving name of the wholly owned subsidiary was GITR Inc.

On August 29, 2016, the Company entered into a merger agreement with Macrocure Ltd. ("Macrocure"), a publicly held, clinical stage biotechnology company based in Petach Tikva, Israel. In connection with the merger, Macrocure became a wholly owned Subsidiary of the Company, and the Company applied to be listed on the Nasdaq Global Market. Nasdaq approved the listing, and trading in the Company's common stock commenced on January 24, 2017, under the trading symbol "LPTX." On February 1, 2017, Macrocure's name was changed to Leap Therapeutics Ltd. In 2020, Leap Therapeutics Ltd. was dissolved.

On December 15, 2021, Leap Securities Corp. was formed and is a wholly owned subsidiary of the Company.

On January 17, 2023, the Company entered into a merger agreement with Flame Biosciences, Inc., a privately held, biotechnology corporation ("Flame"), whereby Flame became a wholly owned subsidiary of the Company under the name Flame Biosciences LLC.

The Company is a biopharmaceutical company developing novel biomarker-targeted antibody therapies designed to treat patients with cancer by inhibiting fundamental tumor-promoting pathways, targeting cancer-specific cell surface molecules, and harnessing the immune system to attack cancer cells. The Company's strategy is to identify, acquire, and develop molecules that translate into therapeutics that generate durable clinical benefit and enhanced patient outcomes. The Company's lead clinical stage program is DKN-01, a monoclonal antibody that inhibits Dickkopf-related protein 1, or DKK1. The Company is currently studying DKN-01 in multiple ongoing clinical trials in patients with esophagogastric cancer, gynecologic cancers, or colorectal cancer. The Company also has two other antibody programs, FL-301 and FL-501.

In January 2020, the Company entered into an Option and License Agreement with BeiGene, Ltd., or BeiGene, which granted BeiGene an option to obtain an exclusive license from the Company that would grant to BeiGene the right to develop and commercialize DKN-01 in Asia (excluding Japan), Australia, and New Zealand. In March 2023, BeiGene notified the Company that it did not intend to exercise its option, and the agreement is continuing as a clinical collaboration.

The Company intends to apply its experience in identifying and developing products to build a pipeline of programs relating to the practice of cancer medicine.

Basis of Presentation

The December 31, 2023 year-end condensed consolidated balance sheet data in the accompanying interim condensed consolidated financial statements was derived from audited consolidated financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These 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, 2023, included in the Company's Annual Report on Form 10-K filed with the SEC on March 18, 2024.

The accompanying interim condensed consolidated financial statements are unaudited and have been prepared on the same basis as the audited consolidated financial statements as of and for the year ended December 31, 2023. In the opinion of management, the accompanying condensed consolidated financial statements contain all adjustments which are necessary for the fair presentation of the Company's financial position as of September 30, 2024, statements of operations and statements of comprehensive loss for the three and nine months ended September 30, 2024 and 2023 and statements of cash flows for the nine months ended September 30, 2024 and 2023. Such adjustments are of a normal and recurring nature. The results of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2024.

Liquidity

Since inception, the Company has been engaged in organizational activities, including raising capital, and research and development activities. The Company does not yet have a product that has been approved by the FDA, has not generated any product sales revenues and has not yet achieved profitable operations, nor has it ever generated positive cash flows from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. Further, the Company's future operations are dependent on the success of the Company's efforts to raise additional capital, its research and commercialization efforts, regulatory approval, and, ultimately, the market acceptance of the Company's products.

In accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. As of September 30, 2024, the Company had cash and cash equivalents of $62,823. Additionally, the Company had an accumulated deficit of $451,940 as of September 30, 2024, and during the nine months ended September 30, 2024, the Company incurred a net loss attributable to common stockholders of $52,358. The Company expects to continue to generate operating losses for the foreseeable future. The Company believes that its cash and cash equivalents of $62,823 as of September 30, 2024 will be sufficient to fund its operating expenses for at least the next 12 months from issuance of these financial statements.

In addition, to support its future operations, the Company will likely seek additional funding through public or private equity financings or government programs and will seek funding or development program cost-sharing through collaboration agreements or licenses with larger pharmaceutical or biotechnology companies. If the Company does not obtain additional funding or development program cost-sharing, or exceeds its current spending forecasts or fails to receive the research and development tax incentive payment, the Company has the ability and would be forced to delay, reduce or eliminate certain clinical trials or research and development programs, reduce or eliminate discretionary operating expenses, and delay company and pipeline expansion, any of which could adversely affect its business prospects. The inability to obtain funding, as and when needed, could have a negative impact on the Company's financial condition and ability to pursue its business strategies.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions are eliminated upon consolidation.

Use of Estimates

The presentation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Research and development incentive income and receivable

The Company recognizes other income from Australian research and development incentives when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. The research and development incentive is one of the key elements of the Australian government's support for Australia's innovation system and is supported by legislative law primarily in the form of the Australian Income Tax Assessment Act 1997, as long as eligibility criteria are met.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive regime described above. At each period end, management estimates the refundable tax offset available to the Company based on available information at the time.

Under the program, a percentage of eligible research and development expenses incurred by the Company through its subsidiary in Australia are reimbursed. The percentage was 43.5% for the year ended December 31, 2023 and for the nine months ended September 30, 2024.

The research and development incentive receivable represents an amount due in connection with the above program. The Company recorded a research and development incentive receivable of $780 and $771 as of September 30, 2024 and December 31, 2023, respectively, in the condensed consolidated balance sheets and other income (expense) from Australian research and development incentives of ($499) and $554, respectively, for the three months ended September 30, 2024 and 2023 and $1,124 for the nine months ended September 30, 2023, in the condensed consolidated statements of operations related to refundable research and development incentive program payments in Australia. The Company did not record Australian research and development income during the nine months ended September 30, 2024.

The following table shows the change in the research and development incentive receivable from January 1, 2023 to September 30, 2024 (in thousands):

Balance at January 1, 2023	$	2,099
Cash received for 2022 eligible expenses		(2,333)
Australian research and development incentive income		1,101
Foreign currency translation		(96)
Balance at December 31, 2023	$	771
Australian research and development incentive income		—
Foreign currency translation		9
Balance at September 30, 2024	$	780

Foreign Currency Translation

The financial statements of the Company's Australian subsidiary are measured using the local currency as the functional currency. The assets and liabilities of this subsidiary are translated into U.S. dollars at an exchange rate as of the consolidated balance sheet date. Equity is translated at historical exchange rates. Revenues and expenses are translated into U.S. dollars at average rates of exchange in effect during the period. The resulting cumulative translation adjustments have been recorded as a separate component of stockholders' equity. Realized and unrealized foreign currency transaction gains and losses are included in the results of operations.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents. All cash and cash equivalents are held in United States or Australian financial institutions and money market funds. At times, the Company may maintain cash balances in excess of the federally insured amount of $250 per depositor, per insured bank, for each account ownership category. Although the Company currently believes that the financial institutions with whom it does business will be able to fulfill their commitments to the Company, there is no assurance that those institutions will be able to continue to do so. The Company has not experienced any credit losses associated with its balances in such accounts for the year ended December 31, 2023 or for the nine months ended September 30, 2024.

Deposits

As of September 30, 2024 and December 31, 2023, there were $865 and $966, respectively, of deposits made by the Company with certain service providers that are to be applied to future payments due under the service agreements or returned to the Company if not utilized, which were recorded in the condensed consolidated balance sheets.

Warrants

The Company will recognize on a prospective basis the value of the effect of the down round feature in the warrants to purchase shares of common stock that were issued in a private placement in November 2017 (the "2017 Warrants") and in the warrants that

were issued in a private placement in March 2020 (the "March 2020 Coverage Warrants") when it is triggered (i.e., when the exercise price is adjusted downward). This value is measured as the difference between (1) the financial instrument's fair value (without the down round feature) using the pre-trigger exercise price and (2) the financial instrument's fair value (with the down round feature) using the reduced exercise price. The value of the effect of the down round feature will be treated as a dividend and a reduction to income available to common stockholders in the basic earnings per share ("EPS") calculation. In connection with the private placement of common stock and prefunded warrants completed in April 2024 (the "April 2024 Private Placement"), when the 2017 Warrants were repriced from $10.55 to $2.82 as a result of a down round, the Company recorded a dividend of $234 during the nine months ended September 30, 2024.

The Company initially classified the warrants that were exercisable for shares for Series X Non-Voting Convertible Preferred Stock (the "January 2023 Series X Preferred Stock Warrants") as a liability on its condensed consolidated balance sheet on January 17, 2023 and subsequently remeasured the warrant liability to fair value at each reporting date until the conversion of Series X Non-Voting Convertible Preferred Stock (the "Series X Preferred Stock") into common stock, which occurred on June 21, 2023. Changes in the fair value of the warrant liability were recognized as gains (losses) in the Company's condensed consolidated statement of operations.

In June 2023, in connection with obtaining Stockholder Approval to convert shares of Series X Preferred Stock into shares of common stock ("Stockholder Approval"), the January 2023 Series X Preferred Stock Warrants were reclassified from liability to equity.

Fair Value of Financial Instruments

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

A summary of the assets carried at fair value in accordance with the hierarchy defined above is as follows (in thousands):

	Total	Level 1	Level 2	Level 3
September 30, 2024				
Assets:				
Cash equivalents	$ 25,018	$ 25,018	$ —	$ —
Total assets	$ 25,018	$ 25,018	$ —	$ —
December 31, 2023				
Assets:				
Cash equivalents	$ 39,065	$ 39,065	$ —	$ —
Total assets	$ 39,065	$ 39,065	$ —	$ —

Cash equivalents of $25,018 and $39,065 as of September 30, 2024 and December 31, 2023, respectively, consisted of overnight investments and money market funds which are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets.

The carrying values of the research and development incentive receivable, accounts payable and accrued liabilities approximate their fair value due to the short-term nature of these assets and liabilities.

Leases

The Company accounts for leases in accordance with Accounting Standards Codification, or ASC, Topic 842, *Leases*.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. The Company has determined that the rate implicit in the lease is not determinable and the Company does not have borrowings with similar terms and collateral. Therefore, the Company considered a variety of factors, including observable debt yields from comparable companies and the volatility in the debt market for securities with similar terms, in determining that 8% was reasonable to use as the incremental borrowing rate for purposes of the calculation of lease liabilities.

In accordance with the guidance in Topic 842, components of a lease should be split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, maintenance, consumables, etc.), and non-components (e.g., property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components.

Although separation of lease and non-lease components is required, certain practical expedients are available. Entities may elect the practical expedient to not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company has elected to account for the lease and non-lease components of each of its operating leases as a single lease component and allocate all of the contract consideration to the lease component only. The lease component results in an operating right-of-use asset being recorded on the consolidated balance sheets and amortized such that lease expense is recorded on a straight line basis over the term of the lease.

Net Loss per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and warrants.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required.

Recently issued accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies that the Company adopts as of the specified effective date. In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. ASU 2023-07 will improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses on an interim and annual basis. The ASU is effective for fiscal years beginning after December 15, 2023, and interim periods after December 15, 2024, with early adoption permitted. The adoption of this standard is not expected to have a material impact on the Company’s financial statements at adoption date.

3. Acquisition of Flame Biosciences

Merger

On January 17, 2023 (the "Effective Date"), Leap acquired 100% of the outstanding equity of Flame, in accordance with the terms of the Agreement and Plan of Merger, dated as of the Effective Date (the "Merger Agreement"), by and among Leap, Fire Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Leap ("First Merger Sub"), Flame Biosciences LLC, a Delaware limited liability company and wholly owned subsidiary of Leap ("Second Merger Sub"), Flame, and the Stockholder Representative named therein. Pursuant to the Merger Agreement, First Merger Sub merged with and into Flame, and Flame was the surviving corporation of such merger and became a wholly owned subsidiary of Leap (the "First Merger"). Immediately following the First Merger, Flame merged with and into Second Merger Sub, and Second Merger Sub was the surviving entity of such merger (together with the First Merger, the "Merger").

Pursuant to the Merger, Leap agreed to issue to the stockholders of Flame (the "Flame Stockholders") 1,972,901 shares of common stock, and 136,248 shares of Series X Preferred Stock, which was a newly designated series of preferred stock that was intended to have economic rights equivalent to the common stock, but with limited voting rights, and issued to the warrant holders of Flame (the "Flame Warrant Holders") the right to acquire 6,530 shares of common stock (the "January 2023 Common Stock Warrants") and 443 shares of Series X Preferred Stock (the "January 2023 Series X Preferred Stock Warrants"). Each share of Series X Preferred Stock converted into 100 shares of common stock during the three months ended June 30, 2023, as a result of the one-for-ten reverse stock split approved by the stockholders and effected by the Board of Directors. Under the terms of the Merger Agreement, Leap held back approximately 15,604 Series X Preferred shares (the "Holdback Shares"), which converted into 1,560,400 shares of common stock out of the aggregate number of shares that the Flame Stockholders otherwise would be entitled to receive pursuant to the Merger so that Leap can have recourse to the Holdback Shares for purposes of satisfying certain claims for indemnification that Leap may have against the Flame Stockholders in connection with the Merger. In January 2024, Leap released the Holdback Shares to the Flame Shareholders.

On June 16, 2023, the Company obtained Stockholder Approval to convert the Series X Preferred Stock into shares of its common stock, which occurred on June 21, 2023.

The Company accounted for the acquisition of Flame as an asset acquisition allocating the purchase price under GAAP of $79,016 to net assets acquired. Although there is a presumption under SEC Rule 11-01(d) ("11-01(d)") that when a legal entity is acquired, it represents a business acquisition, the Company concluded that, in this case, the transaction did not represent the acquisition of a business. After considering the criteria set forth in 11-01(d), the Company concluded that the acquisition of Flame by the Company was an acquisition of assets and not an acquisition of a business in accordance with 11-01(d). Specifically, the Company concluded that 1) the entity did not generate revenue and 2) there was not sufficient continuity of Flame's operations prior to and following the transaction, in that no facilities, employees, sales force, distribution system, customer base, trade names or production techniques remained with the entity after the acquisition.

Leap primarily acquired cash of $50,362, certain working capital items ($928) and a portfolio of clinical- and pre-clinical-stage intellectual property, in connection with the acquisition of Flame. The Company accounted for the acquisition of Flame by recording the cash and any other assets and liabilities of Flame on its condensed consolidated balance sheet at their historical carrying values, which approximates fair values. The remaining fair value of the consideration transferred was allocated to the in-process research and development ("IPR&D") assets acquired. Certain transaction costs that were not deemed to meet the criteria of costs directly attributable to the issuance of securities were capitalized in accordance with ASC 805-50-30-1 and recognized as part of the fair value of assets acquired. As the Company concluded that such IPR&D does not have an alternative future use, the relative fair value allocated to acquired IPR&D of $29,582 was expensed in research and development expenses within the Company's condensed consolidated statement of operations during the nine months ended September 30, 2023.

In addition, subject to and upon the terms and conditions set forth in the Merger Agreement, the Company may also (i) pay Contingent Merger Consideration (as defined in the Merger Agreement) that may become payable if, and only if, certain assets of Flame related to Flame's FL-101 program and/or FL-103 program are sold after the consummation of the Merger pursuant to the FL-101/103 Disposition Agreement (as defined in the Merger Agreement), which Contingent Merger Consideration shall be 80% of the after-tax net proceeds of such sale, if any, and the payment thereof is subject to the terms and conditions set forth in the Merger Agreement and (ii) issue pursuant to the Merger additional shares of Series X Preferred Stock or common stock as a result of any applicable post-closing purchase price adjustment in the event that Flame's actual Company Net Cash (as defined in the Merger Agreement) as of the Effective Date is determined to be greater than Flame's estimated Company Net Cash as of the closing.

Sale of FL - 101/FL - 103 to AlmataBio, Inc.

On December 6, 2023 the Company sold certain IPR&D assets previously acquired from Flame related to Flame's FL - 101/FL - 103 program, including permits, clinical trial material, clinical data, and related identified contracts, such as licensing, research, clinical trials, and various other agreements. The Company received total consideration in the form of a non - refundable closing date cash payment of $500.

Pursuant to the terms of the asset purchase agreement, the Company is entitled to receive milestone payments of up to $70,000 upon achievement of certain regulatory approval and sales milestones specified in the asset purchase agreement.

The IPR&D assets sold related to Flame's FL - 101/FL - 103 program did not meet the definition of a business and had a carrying value of $0 at the time of the sale. In addition, the Company estimated the likelihood of receiving any milestone payments to be remote. As such, management elected the most likely amount method to determine the transaction price of the sale, which included the non - refundable closing date cash payment of $500 and future milestone payments of $0. Therefore, the Company recognized a non - operating gain in other income for the difference between the amount of non - refundable consideration received of $500 and the carrying value of $0 during the year ended December 31, 2023. In the event of a change in circumstances, such that it becomes likely that the Company will receive milestone payments, the Company will recognize income for the change in transaction price in the period in which the transaction price changes.

In addition, during the year ended December 31, 2023, the Company incurred various qualified expenses, such as legal fees, consulting and general and administrative expenses in connection with the sale of Flame's FL - 101 program. Such expenses exceeded the non - refundable consideration received of $500, and therefore, the Company was not obligated to pay Contingent Merger Consideration to the Flame Stockholders.

Series X Preferred Stock

Pursuant to the Merger, the Company agreed to issue 136,248 shares of Series X Preferred Stock to Flame Stockholders and January 2023 Series X Preferred Stock Warrants for 443 shares of Series X Preferred Stock to Flame Warrant Holders. The Company obtained Stockholder Approval during the three months ended June 30, 2023 to convert each issued share of Series X Preferred Stock and each share of Series X Preferred Stock issuable pursuant to the January 2023 Series X Preferred Stock Warrants into 100 shares of its common stock. The Series X Preferred Stock was converted to common stock on June 21, 2023.

January 2023 Common Stock Warrants and January 2023 Series X Preferred Stock Warrants

In January 2023, pursuant to the Merger, the warrants held by the Flame Warrant Holders became exercisable for 6,530 shares of Leap's common stock (the "January 2023 Common Stock Warrants"). The January 2023 Common Stock Warrants have an exercise price of $6.78 per share and expire in February 2025. The January 2023 Common Stock Warrants qualify for equity classification.

Also in January 2023, pursuant to the Merger, the warrants held by the Flame Warrant Holders became exercisable for 443 shares of Series X Preferred Stock (the "January 2023 Series X Preferred Stock Warrants"). Upon obtaining Stockholder Approval for the conversion of the Series X Preferred Stock and the one-for-ten reverse stock split, each share of Series X Preferred Stock converted into 100 shares of Common Stock. The January 2023 Series X Preferred Stock Warrants have an exercise price of $6.78 per share and expire in February 2025.

The Company initially recorded the January 2023 Series X Preferred Stock Warrants as a liability on the Effective Date and the warrant liability was subsequently remeasured to fair value at each reporting date and on the date on which Stockholder Approval to convert shares of Series X Preferred Stock into shares of common stock was obtained. On June 21, 2023, after obtaining stockholder approval for the conversion of the Series X Preferred Stock into common stock, the January 2023 Series X Preferred Stock Warrants were reclassified from liability to equity.

Changes in the fair value of the warrant liability are recognized as gains (losses) in the Company's consolidated statement of operations. During the nine months ended September, 2023, the Company recorded a gain of $12 in its condensed consolidated statement of operations.

4. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2024	December 31, 2023
Clinical trials	$ 6,193	$ 2,522
Professional fees	138	254
Payroll and related expenses	2,718	3,181
Accrued expenses	$ 9,049	$ 5,957

5. Leases

The Company has an operating lease for real estate in the United States and does not have any finance leases. The Company's leases may contain options to renew and extend lease terms and options to terminate leases early. Reflected in the right-of-use asset and lease liability on the Company's consolidated balance sheets are the periods provided by renewal and extension options that the Company is reasonably certain to exercise, as well as the periods provided by termination options that the Company is reasonably certain to not exercise.

The Company's existing lease expires in July 2025 and includes variable lease and non-lease components that are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. Such payments primarily include common area maintenance charges.

In calculating the present value of future lease payments, the Company utilized its incremental borrowing rate based on the lease term. The Company has an existing net lease in which the non-lease components (e.g. common area maintenance, maintenance, consumables, etc.) are paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. During the nine months ended September 30, 2024, the Company extended the term of its operating lease to July 31, 2025 and recorded an additional right-of-use asset and lease liability of $420. As of September 30, 2024, a right-of-use asset of $370 and lease liability of $376 are reflected on the condensed consolidated balance sheet. The Company recorded rent expense of $115 and $113, respectively, during the three months ended September 30, 2024 and 2023, and $340 and $341, respectively, during the nine months ended September 30, 2024 and 2023. Cash paid for amounts included in the measurement of lease liabilities was $346 and $339, respectively, during the three months ended September 30, 2024 and 2023, and $117 and $113, respectively, during the nine months ended September 30, 2024 and 2023.

Future lease payments under non-cancelable operating leases as of September 30, 2024 are detailed as follows:

Future Operating Lease Payments	
2024	117
2025	273
Total Lease Payments	**390**
Less: imputed interest	(14)
Total operating lease liabilities	**$ 376**

6. Warrants

As of September 30, 2024, the number of shares of common stock issuable upon the exercise of outstanding warrants, consisted of the following:

	September 30, 2024		
Description	Number of Common Shares Issuable	Exercise Price	Expiration Date
January 23 2017 Warrants	5,450	$ 0.10	Upon M&A Event
2017 Warrants	250,227	$ 2.82	November 2024
2019 Warrants	690,813	$ 19.50	February 2026
March 2020 Pre-funded Warrants	824,718	$ 0.01	No Expiry
March 2020 Coverage Warrants	2,594,503	$ 21.10	Jan - March 2027
September 2021 Pre-funded Warrants	591,603	$ 0.01	No Expiry
January 2023 Common Stock Warrants	50,830	$ 6.78	February 2025
April 2024 Pre-funded Warrants	1,523,404	$ 0.001	No Expiry
	6,531,548		

2017 Warrants

The 2017 Warrants contain full ratchet anti-dilution protection provisions. The Company will recognize on a prospective basis the value of the effect of the down round feature in the warrant when it is triggered (i.e., when the exercise price is adjusted downward). This value is measured as the difference between (1) the financial instrument's fair value (without the down round feature) using the pre-trigger exercise price and (2) the financial instrument's fair value (with the down round feature) using the reduced exercise price. The value of the effect of the down round feature will be treated as a dividend and a reduction to income available to common stockholders in the basic EPS calculation. In connection with the April 2024 Private Placement, when the 2017 Warrants were repriced from $10.55 to $2.82, the Company recorded a dividend of $234 during the nine months ended September 30, 2024.

2019 Warrants

During the three months ended March 31, 2023, the Company redeemed 10,000 of the 2019 Warrants at a purchase price of $2.90 per share.

January 2023 Common Stock Warrants

In January 2023, pursuant to the Merger, the warrants held by the Flame Warrant Holders became exercisable for 6,530 shares of Leap's common stock (the "January 2023 Common Stock Warrants"). The January 2023 Common Stock Warrants have an exercise price of $6.78 per share and expire in February 2025. The January 2023 Common Stock Warrants qualify for equity classification.

January 2023 Series X Preferred Stock Warrants

In January 2023, pursuant to the Merger, the warrants held by the Flame Warrant Holders also became exercisable for 443 shares of Series X Preferred Stock (the "January 2023 Series X Preferred Stock Warrants"). Following Stockholder Approval, each share of Series X Preferred Stock converted into 100 shares of common stock during the three months ended June 30, 2023. The January 2023 Series X Preferred Stock Warrants have an exercise price of $6.78 per share and expire in February 2025.

The Company initially recorded the January 2023 Series X Preferred Stock Warrants as a liability on its condensed consolidated balance sheet as of the Effective Date and subsequently remeasured the warrant liability to fair value at each reporting date and on the date Stockholder Approval was obtained to convert shares of Series X Preferred Stock into shares of common stock. Changes in the fair value of the warrant liability were recognized as gains (losses) in the Company's consolidated statement of operations. During the nine months ended September, 2023, the Company recorded a gain of $12 in its condensed consolidated statement of operations.

During the three months ended June 30, 2023, upon obtaining Stockholder Approval, the January 2023 Series X Preferred Stock Warrants were converted into common stock warrants and reclassified from liability to equity.

7. Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Board of Directors, if any, subject to the preferential dividend rights of the preferred stockholders. Through September 30, 2024, no dividends have been declared for shares of common stock.

Acquisition of Flame – January 2023

On January 17, 2023 Leap acquired 100% of the outstanding equity of Flame. Pursuant to the Merger, Leap issued to Flame Stockholders 1,972,901 shares of common stock. The Company also issued Series X Preferred Stock to Flame Stockholders pursuant to the Merger (see Note 3).

Private Placement - April 2024

On April 15, 2024, the Company completed a private placement whereby the Company issued 12,660,993 shares of its common stock at a purchase price of $2.82 per share, and 1,523,404 prefunded warrants at a purchase price of $2.819 per share (which is equal to the price per share less the $0.001 exercise price per warrant share). The aggregate net proceeds received by the Company from the offering was $37,051, net of $2,948 of underwriting discounts and commissions and offering expenses payable by the Company.

8. Equity Incentive Plans

Equity Incentive Plans

On January 20, 2017, the Company's stockholders approved the 2016 Equity Incentive Plan (the "2016 Plan"). Beginning on January 1, 2018, the number of shares of common stock authorized for issuance pursuant to the 2016 Plan was increased each January 1 by an amount equal to 4% of the Company's outstanding common stock as of the end of the immediately preceding calendar year or such lesser amount as determined by the compensation committee of the Company's Board of Directors.

On June 16, 2022, the Company's stockholders approved the 2022 Equity Incentive Plan (the "2022 Plan"), which provides for a total of 750,000 new shares of the Company's common stock to be granted. In addition, on June 16, 2023, and July 2, 2024, stockholders approved new shares of the Company's common stock to be added to the 2022 Plan for future issuance of 2,250,000 and 2,000,000, respectively.

As of September 30, 2024, there were 2,573,313 shares available for grant under the Company's equity incentive plans.

A summary of stock option activity under the Equity Plans is as follows:

	Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Life in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2023	3,384,366	$ 13.97	8.40	$ 3,431
Granted	1,727,500	$ 2.67		
Exercised	(10,557)	$ 2.77		
Forfeited	(254,674)	$ 5.69		
Outstanding at September 30, 2024	4,846,635	$ 10.40	8.24	$ 527
Options exercisable at September 30, 2024	2,396,563	$ 17.90	7.40	
Options vested and expected to vest at September 30, 2024	4,846,635	$ 10.40	8.24	$ 527

The grant date fair value of the options granted during the nine months ended September 30, 2024 and 2023 was estimated at the date of grant using the Black-Scholes option valuation model. The expected life was estimated using the "simplified" method as defined by the SEC's Staff Accounting Bulletin 107, Share-Based Payment. The expected volatility was based on the historical volatility of the Company. The risk-free interest rate was based on the continuous rates provided by the U.S. Treasury with a term approximating the expected life of the option. The expected dividend yield was 0% because the Company does not expect to pay any

dividends for the foreseeable future. The Company elected the straight-line attribution method in recognizing the grant date fair value of options issued over the requisite service periods of the awards, which are generally the vesting periods.

The weighted average grant date fair value for the stock options granted during the nine months ended September 30, 2024 and 2023 was $2.12 and $2.09 per share, respectively.

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors during the nine months ended September 30, 2024 and 2023 were as follows, presented on a weighted average basis:

	Nine Months Ended September 30,	
	2024	2023
Expected volatility	92.99 %	90.37 %
Weighted average risk-free interest rate	3.98 %	4.05 %
Expected dividend yield	0.00 %	0.00 %
Expected term (in years)	6.46	6.48

Stock options generally vest over a three or four year period, as determined by the compensation committee of the Board of Directors at the time of grant. The options expire 10 years from the grant date. As of September 30, 2024, there was approximately $5,633 of unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining weighted-average period of approximately 1.93 years.

Restricted Stock Units ("RSUs")

The Company did not grant any RSUs during the nine months ended September 30, 2024 and 2023.

The following table presents RSU activity under the 2016 Plan during the nine months ended September 30, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2023	262,500	$ 19.97
Vested	(27,500)	$ 25.70
Forfeited	(7,500)	$ 19.40
Outstanding at September 30, 2024	227,500	$ 19.29

As of September 30, 2024, there were 227,500 shares outstanding covered by RSUs that are expected to vest with a weighted average grant date fair value of $19.29 per share and an aggregate grant date fair value of approximately $4,388. As of September 30, 2024, there was approximately $516 of unrecognized compensation costs related to RSUs granted to employees, which are expected to be recognized as expense over a remaining weighted average period of 0.38 years.

The Company recognized stock-based compensation expense related to the issuance of stock option awards and RSUs to employees and non-employees in the condensed consolidated statements of operations during the three and nine months ended September 30, 2024 and 2023 as follows:

Stock Based Compensation Expense

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 720	$ 737	$ 2,076	$ 2,086
General and administrative	619	563	1,881	1,789
Total	$ 1,339	$ 1,300	$ 3,957	$ 3,875

9. Net Loss Per Share

Basic and diluted net loss per share for the three and nine months ended September 30, 2024 and 2023 was calculated as follows (in thousands except share and per share amounts).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	$ (18,176)	$ (13,696)	$ (52,124)	$ (68,949)
Dividend attributable to down round feature of warrants	—	—	(234)	—
Net loss attributable to common stockholders for basic and diluted loss per share	$ (18,176)	$ (13,696)	$ (52,358)	$ (68,949)
Denominator:				
Weighted average number of common shares outstanding – basic and diluted	41,209,639	26,987,182	36,307,890	18,240,455
Net loss per share attributable to common stockholders – basic and diluted	$ (0.44)	$ (0.51)	$ (1.44)	$ (3.78)

Included within weighted average common shares outstanding for the three and nine months ended September 30, 2024 and 2023 are 2,945,175 common shares issuable upon the exercise of certain warrants, which are exercisable at any time for nominal consideration, and as such, the shares are considered outstanding for the purpose of calculating basic and diluted net loss per share attributable to common stockholders.

All warrants exercisable for common stock participate on a one-for-one basis and shares and warrants exercisable for Series X Preferred Stock issued participate on an as converted basis with common stock in the distribution of dividends, if and when declared by the board of directors, on the Company's common stock. For purposes of computing EPS, these securities are considered to participate with common stock in earnings of the Company. Therefore, the Company calculates basic and diluted EPS using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. No income was allocated to the warrants and Series X Preferred Stock for the nine months ended September 30, 2024 and 2023, as results of operations were a loss for the period.

The Company's potentially dilutive securities include RSUs, stock options and warrants. These securities were excluded from the computations of diluted net loss per share for the three and nine months ended September 30, 2024 and 2023, as the effect would be to reduce the net loss per share. The following table includes the potential shares of common stock, presented based on amounts outstanding at each period end, that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Restricted stock units to purchase common stock	227,500	285,000	227,500	285,000
Options to purchase common stock	4,846,635	3,425,647	4,846,635	3,425,647
Warrants to purchase common stock	3,586,373	3,586,371	3,586,373	3,586,371
	8,660,508	7,297,018	8,660,508	7,297,018

10. Commitments and Contingencies

Manufacturing Agreements—The Company is party to manufacturing agreements with vendors to manufacture DKN-01, its lead product candidate, for use in clinical trials. As of September 30, 2024, there were $65 noncancelable commitments under these agreements.

License and Service Agreement—On January 3, 2011, the Company entered into a license agreement with Eli Lilly and Company ("Lilly"), a shareholder, to grant a license to the Company for certain intellectual property rights relating to pharmaceutically active compounds that may be useful in the treatment of bone healing, cancer and, potentially, other medical conditions. As defined in the license agreement, the Company would be required to pay royalties to Lilly based upon a percentage in

the low single digits of net sales of developed products, if and when achieved. However, there can be no assurance that clinical or commercialization success of developed products will occur, and no royalties have been paid or accrued through September 30, 2024.

License Agreement—On May 28, 2015, the Company entered into a license agreement with Lonza Sales AG ("Lonza"), pursuant to which Lonza granted the Company a world-wide, non-exclusive license for certain intellectual property relating to a gene expression system for manufacturing DKN-01. As defined in the license agreement, the Company would be required to pay royalties to Lonza based on a percentage in the low single digits of net sales of DKN-01, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur, and no royalties have been paid or accrued through September 30, 2024.

Collaboration Agreement—On April 2, 2024, the Company amended and restated its existing collaboration agreement with Adimab, LLC (the "Adimab Agreement"), pursuant to which Adimab will conduct research programs to develop monoclonal antibodies to certain targets identified by the Company and provide it with an option to acquire exclusive rights to such antibodies. Upon payment of an option fee, on a product-by-product basis, Adimab will grant the Company a world-wide, exclusive license for, or assign ownership to the Company of, certain intellectual property rights and grant the Company a non-exclusive license with respect to the Adimab platform technology. As defined in the Adimab Agreement, after exercising an option and making the option payment, the Company would be required to pay Adimab milestones upon the completion of clinical development and regulatory milestones, along with a royalty in the low-single digits of net sales of each product, if and when achieved. However, there can be no assurance that clinical, or commercialization success will occur, and no royalties have been paid or accrued through September 30, 2024.

License Agreement—On August 13, 2021, the Company entered into a strategic partnership and license agreement with NovaRock Biopharmaceuticals, Inc. (the "NovaRock Agreement"), pursuant to which NovaRock granted the Company a world-wide, excluding the People's Republic of China, Hong Kong, Macau, and Taiwan, exclusive license for certain intellectual property rights relating to FL-301 and FL-302. As defined in the license agreement, the Company would be required to pay NovaRock milestones upon the completion of development, regulatory and sales milestones for up to three different products (FL-301, FL-302 and potentially one additional target), along with a royalty in the mid-single digits of net sales of each product in the territory, if and when achieved. However, there can be no assurance that clinical, or commercialization success will occur, and no royalties have been paid or accrued through September 30, 2024.

Legal Proceedings—At each reporting date, the Company evaluates whether a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to its legal proceedings. As of the date of this report, the Company is not currently a party to any material legal proceedings.

Indemnification Agreements—In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of September 30, 2024 or December 31, 2023.

11. Income Taxes

During the three and nine months ended September 30, 2024, the Company recorded a provision for income taxes of $708 related to the Company's operations in Australia.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to help the reader understand our results of operations and financial condition. This MD&A is provided as a supplement to, and should be read in conjunction with, our condensed consolidated financial statements and the accompanying notes thereto and other disclosures included in this Quarterly Report on Form 10-Q, including the disclosures under Part II, Item IA "Risk Factors," and our audited condensed consolidated financial statements and the accompanying notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the Securities and Exchange Commission, or the SEC, on March 18, 2024. Our condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and, unless otherwise indicated, amounts are presented in U.S. dollars.

Company Overview

We are a biopharmaceutical company developing biomarker-targeted antibody therapies designed to treat patients with cancer by inhibiting fundamental tumor-promoting pathways, targeting cancer-specific cell surface molecules, and harnessing the immune system to attack cancer cells. Our strategy is to identify, acquire, and develop molecules that will rapidly translate into high impact therapeutics that generate durable clinical benefit and enhanced patient outcomes.

Our lead clinical stage program is DKN-01, a monoclonal antibody that inhibits Dickkopf-related protein 1, or DKK1. We are currently studying DKN-01 in multiple ongoing clinical trials in patients with esophagogastric cancer, gynecologic cancers, or colorectal cancer. We also have two other antibody programs, FL-301 and FL-501.

We intend to apply our extensive experience in identifying and developing transformational products to build a pipeline of programs that have the potential to change the practice of cancer medicine.

We have devoted substantially all of our resources to development efforts relating to our product candidates, including manufacturing and conducting clinical trials of our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through proceeds from our sales of common stock and preferred stock and proceeds from the issuance of notes payable.

Recent Developments

Since June 30, 2024, we have continued to make progress with the development of DKN-01 and our business strategy.

DKN-01 Development Update

- ***Enrollment completed in the expanded randomized controlled Part B of the DeFianCe study evaluating DKN-01 in combination with standard of care bevacizumab and chemotherapy as a second-line treatment for patients with advanced colorectal cancer ("CRC").*** Part B of the DeFianCe study is a Phase 2, randomized, controlled, open-label study of DKN-01 in combination with standard of care bevacizumab and chemotherapy in patients with advanced CRC who have received one prior systemic therapy. Part B of the study enrolled 188 patients. We expect to report initial data in mid-2025.

- ***Patient follow-up continuing in the randomized controlled Part C of the DisTinGuish study evaluating DKN-01 in combination with tislelizumab and chemotherapy in patients with gastroesophageal junction ("GEJ") and gastric cancer, with initial data expected in late 2024 or early 2025.*** Part C of the DisTinGuish study is a Phase 2, randomized, controlled, open-label study of DKN-01 in combination with tislelizumab and chemotherapy in first-line, HER-2 negative patients with GEJ and gastric cancer. Part C of the study enrolled 170 patients. We expect to report initial data in late 2024 or early 2025.

Pipeline Update:

- ***Advancing FL-501 into development as a potential best-in-class anti-GDF-15 antibody with promising preclinical data.*** FL-501 is a potential best in class monoclonal antibody designed to neutralize GDF-15 to treat patients with cachexia and other GDF-15-driven diseases. FL-501 may also enhance the activity of the immune system in the tumor micro-environment. FL-501 was engineered for higher target affinity and a longer plasma half-life compared to competing therapies. In preclinical cachexia models, FL-501 increased body weight and restored muscle mass.

Financial Overview

Research and Development Expenses

Our research and development activities have included conducting nonclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates, primarily DKN-01. We recognize research and development expenses as they are incurred. Our research and development expenses during the three and nine months ended September 30, 2024 consisted primarily of:

- salaries and related overhead expenses for personnel in research and development functions, including costs related to stock-based compensation;
- fees paid to consultants and CROs for our nonclinical and clinical trials, and other related clinical trial fees, including but not limited to laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- costs related to acquiring and manufacturing clinical trial material; and
- costs related to compliance with regulatory requirements.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of DKN-01 and any other product candidates, subject to the availability of additional funding.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of internal and external costs, such as employee costs, including salaries and stock-based compensation, other internal costs, fees paid to consultants, central laboratories, contractors and CROs in connection with our clinical and preclinical trial development activities. We use internal resources to manage our clinical and preclinical trial development activities and perform data analysis for such activities.

We participate, through our subsidiary in Australia, in the Australian government's research and development ("R&D") Incentive program ("R&D Incentive Program"), such that a percentage of our eligible research and development expenses are reimbursed by the Australian government as a refundable tax offset and such incentives are reflected as other income.

The table below summarizes our research and development expenses incurred by development program and the R&D Incentive income for the three and nine months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(in thousands)		(in thousands)	
Direct research and development by program:				
DKN-01 program	$ 14,776	$ 11,016	$ 43,765	$ 31,153
TRX518 program	—	—	9	22
FL-301 program	—	137	31	137
FL-302 program	11	—	63	—
FL-501 program	128	109	231	109
FL-101 program	—	241	—	546
In-process research and development acquired from Flame	—	—	—	29,582
Total research and development expenses	$ 14,915	$ 11,503	$ 44,099	$ 61,549
Australian research and development incentives	$ (499)	$ 554	$ —	$ 1,124

The successful development of our clinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could result in a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, accounting and audit services.

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

Interest income

Interest income consists primarily of interest income earned on cash and cash equivalents.

Research and development incentive income

Research and development incentive income includes payments under the R&D Incentive Program from the government of Australia. The R&D Incentive Program is one of the key elements of the Australian government's support for Australia's innovation system. It was developed to assist businesses in recovering some of the costs of undertaking research and development. The research and development tax incentive provides a tax offset to eligible companies that engage in research and development activities.

Companies engaged in research and development may be eligible for either:

- a refundable tax offset at a rate of 18.5% above the company's tax rate for entities with income of less than A$20 million per annum; or
- a non-refundable tax offset for all other entities which is a progressive marginal tiered R&D intensity threshold. Increasing rates of benefit apply for incremental research and development expenditure by intensity:
    - 0 to 2% intensity: an 8.5% premium to the company's tax rate
    - Greater than 2% intensity: a 16.5% premium to the company's tax rate;

We recognize as income the amount we expect to be reimbursed for qualified expenses.

Foreign currency translation adjustment

Foreign currency translation adjustment consists of gains (losses) due to the revaluation of foreign currency transactions attributable to changes in foreign currency exchange rates associated with our Australian subsidiary.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K filed with the SEC on March 18, 2024, and the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- accrued research and development expenses;
- research and development incentive receivable; and
- stock-based compensation.

Results of Operations

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

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		
	2024	2023	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 14,915	$ 11,503	$ 3,412
General and administrative	2,940	3,330	(390)
Total operating expenses	17,855	14,833	3,022
Loss from operations	(17,855)	(14,833)	(3,022)
Interest income	894	1,084	(190)
Australian research and development incentives	(499)	554	(1,053)
Foreign currency loss	(8)	(501)	493
Loss before income taxes	(17,468)	(13,696)	(3,772)
Provision for income taxes	(708)	—	(708)
Net loss	$ (18,176)	$ (13,696)	$ (4,480)

Research and Development Expenses

	Three Months Ended September 30,		
	2024	2023	Increase (Decrease)
	(in thousands)		
Direct research and development by program:			
DKN-01 program	$ 14,776	$ 11,016	$ 3,760
TRX518 program	—	—	—
FL-301 program	—	137	(137)
FL-302 program	11	—	11
FL-501 program	128	109	19
FL-101 program	—	241	(241)
Total research and development expenses	$ 14,915	$ 11,503	$ 3,412

Research and development expenses were $14.9 million for the three months ended September 30, 2024, compared to $11.5 million for the three months ended September 30, 2023. The increase of $3.4 million in research and development expenses during the three months ended September 30, 2024 as compared to the same period in 2023, was primarily due to an increase of $1.7 million in manufacturing costs related to clinical trial material and manufacturing campaigns, and an increase of $0.8 million in clinical trial costs due to patient enrollment, the duration of patients on study, the enhancement of correlative studies, the increase in site activity associated with Part C of the DisTinGuish study, and the expansion of the size of Part B of the DeFianCe study. There was also an increase of $0.5 million in consulting fees associated with research and development activities and an increase of $0.4 million in payroll and other related expenses due to an increase in headcount of our R&D full-time employees.

General and Administrative Expenses

General and administrative expenses were $2.9 million for the three months ended September 30, 2024, compared to $3.3 million for the three months ended September 30, 2023. The decrease of $0.4 million in general and administrative expenses during the three months ended September 30, 2024 as compared to the same period in 2023, was due to a $0.4 million decrease in professional fees.

Interest Income

During the three months ended September 30, 2024, we recorded interest income of $0.9 million. During the three months ended September 30, 2023, we recorded interest income of $1.1 million. The decrease was due to a higher average cash and cash equivalent balance during the three months ended September 30, 2023.

Australian Research and Development Incentives

We recorded R&D incentive income of $0.6 million during the three months ended September 30, 2023, based upon the applicable percentage of eligible research and development activities under the R&D Incentive Program, which expenses included the cost of manufacturing clinical trial material. During the three months ended September 30, 2024, we expensed $0.5 million of R&D incentive income recognized during the six months ended June 30, 2024, in connection with our estimated 2024 Australian tax liability.

The R&D incentive receivable has been recorded as "Research and development incentive receivable" in the condensed consolidated balance sheets.

Foreign Currency Gain/Loss

During the three months ended September 30, 2023, we recorded foreign currency transaction losses of $0.5 million. During the three months ended September 30, 2024, we recorded an immaterial amount of foreign currency transaction losses. Foreign currency transaction gains and losses are due to changes in the Australian dollar exchange rate related to activities of the Australian entity.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		
	2024	2023	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 44,099	$ 61,549	$ (17,450)
General and administrative	9,833	10,672	(839)
Total operating expenses	53,932	72,221	(18,289)
Loss from operations	(53,932)	(72,221)	18,289
Interest income	2,534	3,089	(555)
Australian research and development incentives	—	1,124	(1,124)
Foreign currency loss	(18)	(953)	935
Change in fair value of Series X preferred stock warrant liability	—	12	(12)
Loss before income taxes	(51,416)	(68,949)	17,533
Provision for income taxes	(708)	—	(708)
Net loss	$ (52,124)	$ (68,949)	$ 16,825

Research and Development Expenses

	Nine Months Ended September 30,		Increase (Decrease)
	2024	2023	
	(in thousands)		
Direct research and development by program:			
DKN-01 program	$ 43,765	$ 31,153	$ 12,612
TRX518 program	9	22	(13)
FL-301 program	31	137	(106)
FL-302 program	63	—	63
FL-501 program	231	109	122
FL-101 program	—	546	(546)
In-process research and development acquired from Flame	—	29,582	(29,582)
Total research and development expenses	$ 44,099	$ 61,549	$ (17,450)

Research and development expenses were $44.1 million for the nine months ended September 30, 2024, compared to $61.5 million for the nine months ended September 30, 2023. The decrease of $17.5 million in research and development expenses during the nine months ended September 30, 2024 as compared to the same period in 2023, was primarily due to $29.6 million of in-process research and development ("IPR&D") acquired in the Flame merger which we expensed during the nine months ended September 30, 2023. This decrease was partially offset by an increase of $8.7 million in clinical trial costs due to patient enrollment, the duration of patients on study, the enhancement of correlative studies, the increase in site activity associated with Part C of the DisTinGuish study, and the expansion of the size of Part B of the DeFianCe study. There was also an increase of $1.9 million in manufacturing costs related to clinical trial material and manufacturing campaigns, an increase of $1.5 million in payroll and other related expenses due to an increase in headcount of our R&D full-time employees and an increase of $0.1 million in consulting fees associated with research and development activities.

General and Administrative Expenses

General and administrative expenses were $9.8 million for the nine months ended September 30, 2024, compared to $10.7 million for the nine months ended September 30, 2023. The decrease of $0.9 million in general and administrative expenses during the nine months ended September 30, 2024 as compared to the same period in 2023, was due to a decrease of $1.2 million in professional fees associated with our business development activities, partially offset by an increase of $0.3 million in payroll and other related expenses.

Interest Income

During the nine months ended September 30, 2024, we recorded interest income of $2.5 million. During the nine months ended September 30, 2023, we recorded interest income of $3.1 million. The decrease was due to a higher average cash and cash equivalent balance during the nine months ended September 30, 2023.

Australian Research and Development Incentives

We recorded R&D incentive income of $1.1 million during the nine months ended September 30, 2023, based upon the applicable percentage of eligible research and development activities under the R&D Incentive Program, which expenses included the cost of manufacturing clinical trial material. We did not record R&D incentive income during the nine months ended September 30, 2024.

The R&D incentive receivable has been recorded as "Research and development incentive receivable" in the condensed consolidated balance sheets.

Foreign Currency Loss

During the nine months ended September 30, 2023, we recorded foreign currency transaction losses of $1.0 million. During the nine months ended September 30, 2024, we recorded an immaterial amount of foreign currency transaction losses. Foreign currency transaction gains and losses are due to changes in the Australian dollar exchange rate related to activities of the Australian entity.

Financial Position, Liquidity and Capital Resources

Since our inception, we have been engaged in organizational activities, including raising capital, and research and development activities. We do not yet have a product that has been approved by the Food and Drug Administration (the "FDA"), have not yet achieved profitable operations, nor have we ever generated positive cash flows from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. Further, our future operations are dependent on the success of efforts to raise additional capital, our research and commercialization efforts, regulatory approval, and, ultimately, the market acceptance of our products.

In accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, we have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. As of September 30, 2024, we had cash and cash equivalents of $62.8 million. Additionally, we had an accumulated deficit of $451.9 million at September 30, 2024, and during the nine months ended September 30, 2024, we incurred a net loss of $52.4 million. We expect to continue to generate operating losses in the foreseeable future. We believe that our cash and cash equivalents of $62.8 million as of September 30, 2024, will be sufficient to fund our operating expenses for at least the next 12 months from the issuance of this report on Form 10-Q.

In addition, to support our future operations, we will seek additional funding through public or private equity financings or government programs and will seek funding or development program cost-sharing through collaboration agreements or licenses with larger pharmaceutical or biotechnology companies. If we do not obtain additional funding or development program cost-sharing, we could be forced to delay, reduce or eliminate certain clinical trials or research and development programs, reduce or eliminate discretionary operating expenses, and delay company and pipeline expansion, which could adversely affect our business prospects. The inability to obtain funding, as and when needed, could have a negative impact on Leap's financial condition and our ability to pursue our business strategies.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Cash used in operating activities	$ (44,787)	$ (33,373)
Cash provided by investing activities	—	48,969
Cash provided by (used in) financing activities	37,080	(30)
Effect of exchange rate changes on cash and cash equivalents	(113)	(323)
Net increase (decrease) in cash and cash equivalents	$ (7,820)	$ 15,243

*Operating activities***.** Net cash used in operating activities for the nine months ended September 30, 2024 was primarily related to our net loss from the operation of our business of $52.1 million and net changes in working capital, including a decrease in lease liabilities of $0.3 million. These changes were partially offset by an increase in accounts payable and accrued expenses of $2.6 million, an increase in taxes payable of $0.7 million, a decrease of $0.3 million in right-of-use asset, a decrease of $0.1 million in other assets and noncash stock-based compensation expense of $4.0 million.

Net cash used in operating activities for the nine months ended September 30, 2023 was primarily related to our net loss from the operation of our business of $68.9 million and net changes in working capital, including a decrease in accounts payable and accrued expenses of $1.0 million and a decrease in lease liabilities of $0.3 million. These changes were partially offset by a decrease in research and development incentive receivable of $1.3 million, a decrease of $0.8 million in other assets, a decrease of $0.1 million in prepaid expenses and other assets, noncash IPR&D expense of $29.6 million, noncash stock based compensation expense of $3.9 million, foreign currency transaction losses of $1.0 million and change in a right-of-use asset of $0.3 million.

Investing Activities. Net cash provided by investing activities for the nine months ended September 30, 2023 was related to cash acquired in connection with the acquisition of Flame of $50.4 million and payment of direct and incremental costs of $1.4 million associated with the acquisition of Flame. There were no investing activities during the nine months ended September 30, 2024.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2024 consisted of $40.0 million in gross proceeds from the April 2024 Private Placement and an immaterial amount of proceeds upon the exercise of

stock options, partially offset by $2.9 million of offering costs paid. Net cash used in financing activities for the nine months ended September 30, 2023 consisted of an immaterial amount we paid for the redemption of 10,000 of the 2019 warrants.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not Applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our President and Chief Executive Officer, who is also serving as Chief Financial Officer and therefore currently serves as both our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of September 30, 2024, our management, with the participation of our Chief Executive Officer, who is also serving as Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (2013 Framework). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer has concluded, based upon the evaluation described above, that, as of September 30, 2024, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such material information is accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

During the three months ended September 30, 2024, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that materially affected, or are reasonably likely to affect, internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

An investment in our ordinary shares involves a high degree of risk. You should carefully consider the risk factors discussed in Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 as filed with the SEC on March 18, 2024, which could materially affect our business, financial condition, operating results or cash flows.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

(c) Rule 10b5-1 Trading Plan

During the three months ended September 30, 2024, no director or officer of the Company adopted or terminated a "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

See the Exhibit Index immediately prior to the signature page to this Quarterly Report on Form 10-Q for a list of exhibits filed or furnished with this report, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

31.1*	Certification of Chief Executive Officer and Chief Financial Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from Leap Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at September 30, 2024 and December 31, 2023, (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2024 and 2023, (iii) Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2024 and 2023, (iv) Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2024 and 2023, (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2024 and 2023, and (vi) Notes to the Condensed Consolidated Financial Statements, tagged as blocks of text.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

**Furnished with this report.

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.

LEAP THERAPEUTICS, INC.

Date: November 12, 2024

By: /s/ Douglas E. Onsi
Douglas E. Onsi
President, Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Duly Authorized Signatory)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Douglas E. Onsi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Leap Therapeutics, 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my 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.

November 12, 2024
Date

/s/ DOUGLAS E. ONSI
Douglas E. Onsi
President, Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Leap Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas E. Onsi, as Chief Executive Officer, President and Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my 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 Company.

Date: November 12, 2024

By: /s/ DOUGLAS E. ONSI
Douglas E. Onsi
President, Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

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 Leap Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing.