

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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

OR

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

For the transition period from to

Commission File Number: 001-38942



ARCTURUS THERAPEUTICS HOLDINGS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

10628 Science Center Drive, Suite 250
San Diego, California
(Address of principal executive offices)

32-0595345
(I.R.S. Employer
Identification No.)

92121
(Zip Code)

(858) 900-2660

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	ARCT	The NASDAQ Stock Market LLC

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 5, 2024, the registrant had 27,087,359 shares of voting common stock outstanding.

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (this “Quarterly Report”), including the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and the documents incorporated by reference herein may contain express or implied “forward-looking statements” within the meaning of the federal securities laws, Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part II, Item 1A, “Risk Factors” in this Quarterly Report. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise. These statements, which represent our current expectations or beliefs concerning various future events, may contain words such as “may,” “will,” “expect,” “anticipate,” “intend,” “plan,” “believe,” “estimate” or other words indicating future results, though not all forward-looking statements necessarily contain these identifying words. Such statements may include, but are not limited to, statements concerning the following:

- our compliance, and ability to remain in compliance, with the requirements of our collaboration agreements, including our collaboration with Seqirus Inc. (“CSL Seqirus”);
- the anticipated benefits and success of our collaboration agreement with CSL Seqirus related to the licensure of our STARR[®] mRNA technology and LUNAR[®] lipid-mediated delivery, including our timely receipt of upfront and potential royalty and other payments thereunder;
- the continued development activities of the LUNAR-COV19 and LUNAR-FLU programs under our collaboration with CSL Seqirus;
- the status, success and benefits of our arrangements with private and governmental entities, some of which are subject to termination for convenience by our counterparties;
- our compliance, and ability to remain in compliance, with the stringent requirements of our current and potential government contracts, including our arrangements with the Biomedical Advanced Research and Development Authority, a division of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services and the Department of Defense;
- our plans to conduct and advance any of our research programs;
- the initiation, design, cost, timing, progress, enrollment and results of, and our expected ability to undertake certain activities and accomplish certain goals with respect to, our research and development activities, preclinical studies and clinical trials, including those related to our therapeutics pipeline candidates ARCT-810 and ARCT-032;
- the potential safety, immunogenicity, efficacy or regulatory approval of any of our product candidates;
- the potential safety, immunogenicity, efficacy or regulatory approval of any of our COVID-19 vaccine candidates as a booster or primary vaccination series;
- the potential effects, efficacy and benefits of our technologies and product candidates on their own and in comparison to technologies, drugs or courses of treatment currently available or that may be developed by competitors;
- the likelihood that preclinical or clinical data will be predictive of future clinical results or efficacy or safety of a product candidate;
- the anticipated timing of enrollment, duration, milestones and announcements of results of clinical trials, and the submission of applications to conduct clinical trials;
- the likelihood that clinical data will be sufficient for regulatory approval or completed in time to submit an application for regulatory approval within a particular timeframe;
- the likelihood or timing of any regulatory approval, and the likelihood that the marketing approval of ARCT-154 in Japan will be predictive of any future marketing approvals in other countries or for other versions of our LUNAR-COV19 or other product candidates or of any commercial sales;
- the potential administration regimen or dosage, or ability to administer multiple doses of, any of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our plans to develop and commercialize our product candidates;
- our ability, and the ability of our partners, to successfully commercialize, and our expectations regarding future therapeutic and commercial potential with respect to, our product candidates;
- the rate and degree of market acceptance of our product candidates;

- the success of competing therapies that are or may become available;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets and address unmet medical needs;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- interactions with regulatory authorities in the United States and foreign countries;
- our ability to attract and retain experienced and seasoned scientific and management professionals;
- the performance of our third-party suppliers and manufacturers, including the ability to implement and scale-up manufacturing levels as necessary;
- the receipt of relevant approvals related to the manufacture and distribution of our product candidates;
- our strategic alliance partners' election to pursue development and commercialization of any programs or product candidates that are subject to our collaboration and license agreements with such partners;
- our ability to attract collaborators with relevant development, regulatory and commercialization expertise;
- future activities to be undertaken by our strategic alliance partners, collaborators and other third parties;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- our ability to avoid, settle or be victorious at costly litigation with shareholders, former executives or others, should these situations arise;
- our ability to obtain and deploy funding for our operations and to efficiently use our financial and other resources;
- our ability to continue as a going concern; and
- the accuracy of our estimates regarding future expenses, future revenues, cash flows, capital requirements need for additional financing, and possible sources of revenue.

These and other forward-looking statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. In addition, historic results of scientific research, preclinical and clinical trials do not guarantee that future research or trials will suggest the same conclusions, nor that historic results referred to herein will be interpreted in the same manner due to additional research, preclinical and clinical trial results or otherwise. The forward-looking statements contained in this Quarterly Report are subject to risks and uncertainties, including those discussed in our other filings with the United States Securities and Exchange Commission (the "Commission"). Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof unless specifically stated otherwise. Although we currently believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

**ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except par value information)	September 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 237,178	\$ 292,005
Restricted cash	55,000	55,000
Accounts receivable	30,199	32,064
Prepaid expenses and other current assets	8,444	7,521
Total current assets	330,821	386,590
Property and equipment, net	10,350	12,427
Operating lease right-of-use assets, net	27,598	28,500
Non-current restricted cash	1,885	1,885
Total assets	\$ 370,654	\$ 429,402
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 10,131	\$ 5,279
Accrued liabilities	32,396	31,881
Deferred revenue	26,936	44,829
Total current liabilities	69,463	81,989
Deferred revenue, net of current portion	13,338	42,496
Operating lease liability, net of current portion	25,987	25,907
Other non-current liabilities	—	497
Total liabilities	108,788	150,889
Stockholders' equity		
Common stock, \$0.001 par value; 60,000 shares authorized; issued and outstanding shares were 27,084 at September 30, 2024 and 26,828 at December 31, 2023	27	27
Additional paid-in capital	680,641	646,352
Accumulated deficit	(418,802)	(367,866)
Total stockholders' equity	261,866	278,513
Total liabilities and stockholders' equity	\$ 370,654	\$ 429,402

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

(in thousands, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
Collaboration revenue	\$ 38,815	\$ 43,376	\$ 117,389	\$ 132,670
Grant revenue	2,858	1,764	12,155	3,274
Total revenue	41,673	45,140	129,544	135,944
Operating expenses:				
Research and development, net	39,134	51,077	151,376	155,513
General and administrative	13,276	13,377	40,443	40,364
Total operating expenses	52,410	64,454	191,819	195,877
Loss from operations	(10,737)	(19,314)	(62,275)	(59,933)
(Loss) gain from foreign currency	(201)	4	(642)	(175)
Gain on debt extinguishment	—	—	—	33,953
Finance income, net	3,818	3,981	11,981	9,710
Net loss before income taxes	(7,120)	(15,329)	(50,936)	(16,445)
Provision for income taxes	(217)	893	—	1,573
Net loss	\$ (6,903)	\$ (16,222)	\$ (50,936)	\$ (18,018)
Net loss per share, basic and diluted	\$ (0.26)	\$ (0.61)	\$ (1.89)	\$ (0.68)
Weighted-average shares outstanding, basic and diluted	27,062	26,574	26,970	26,559
Comprehensive loss:				
Net loss	\$ (6,903)	\$ (16,222)	\$ (50,936)	\$ (18,018)
Comprehensive loss	\$ (6,903)	\$ (16,222)	\$ (50,936)	\$ (18,018)

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)

(in thousands)	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2023	26,828	\$ 27	\$ 646,352	\$ (367,866)	\$ 278,513
Net loss	—	—	—	(26,817)	(26,817)
Share-based compensation expense	—	—	10,088	—	10,088
Issuance of common stock upon exercise of stock options	89	—	2,188	—	2,188
Balance at March 31, 2024	26,917	\$ 27	\$ 658,628	\$ (394,683)	\$ 263,972
Net loss	—	—	—	(17,216)	(17,216)
Share-based compensation expense	—	—	9,424	—	9,424
Issuance of common stock upon exercise of stock options	125	—	2,403	—	2,403
Balance at June 30, 2024	27,042	\$ 27	\$ 670,455	\$ (411,899)	\$ 258,583
Net loss	—	—	—	(6,903)	(6,903)
Share-based compensation expense	—	—	9,493	—	9,493
Issuance of common stock upon exercise of stock options	2	—	11	—	11
Issuance of common stock under equity plans	40	—	682	—	682
BALANCE – September 30, 2024	27,084	\$ 27	\$ 680,641	\$ (418,802)	\$ 261,866

(in thousands)	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2022	26,555	\$ 27	\$ 608,426	\$ (338,141)	\$ 270,312
Net income	—	—	—	50,754	50,754
Share-based compensation expense	—	—	8,182	—	8,182
Balance at March 31, 2023	26,555	\$ 27	\$ 616,608	\$ (287,387)	\$ 329,248
Net loss	—	—	—	(52,550)	(52,550)
Share-based compensation expense	—	—	8,383	—	8,383
Issuance of common stock upon exercise of stock options	19	—	94	—	94
Balance at June 30, 2023	26,574	\$ 27	\$ 625,085	\$ (339,937)	\$ 285,175
Net loss	—	—	—	(16,222)	(16,222)
Share-based compensation expense	—	—	9,269	—	9,269
Issuance of common stock upon exercise of stock options	114	—	1,231	—	1,231
Issuance of common stock under equity plans	35	—	609	—	609
BALANCE – September 30, 2023	26,723	\$ 27	\$ 636,194	\$ (356,159)	\$ 280,062

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

(in thousands)	Nine Months Ended September 30,	
	2024	2023
Operating activities		
Net loss	\$ (50,936)	\$ (18,018)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,725	2,142
Share-based compensation expense	29,005	25,834
Foreign currency transaction loss	643	90
Gain on debt extinguishment	—	(33,953)
Other non-cash expenses	—	502
Changes in assets and liabilities:		
Accounts receivable	1,865	(35,456)
Prepaid expense and other assets	(923)	556
Right-of-use assets	3,638	3,011
Accounts payable	4,852	10,497
Accrued liabilities	(625)	(3,437)
Deferred revenue	(47,051)	33,960
Lease liabilities	(2,656)	(3,198)
Net cash used in operating activities	(59,463)	(17,470)
Investing activities		
Acquisition of property and equipment	(648)	(2,026)
Net cash used in investing activities	(648)	(2,026)
Financing activities		
Proceeds from exercise of stock options	4,602	1,325
Proceeds from the issuance of common stock under equity plans	682	609
Proceeds from debt	—	20,000
Payments on debt obligations	—	(27,364)
Net cash provided by (used in) financing activities	5,284	(5,430)
Net decrease in cash, cash equivalents and restricted cash	(54,827)	(24,926)
Cash, cash equivalents and restricted cash at beginning of the period	348,890	393,977
Cash, cash equivalents and restricted cash at end of the period	\$ 294,063	\$ 369,051
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ —	\$ 2,102
Non-cash investing activities		
Non-cash asset disposal	\$ 473	\$ —
Right-of-use assets acquired through operating leases	\$ 2,736	\$ —
Purchase of property and equipment in accounts payable	\$ —	\$ 416

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

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1. Description of Business, Basis of Presentation and Summary of Significant Accounting Policies

Description of Business

Arcturus Therapeutics Holdings Inc. (the “Company” or “Arcturus”) is a commercial messenger RNA medicines company focused on the development of infectious disease vaccines and opportunities within liver and respiratory rare diseases. Arcturus became a clinical stage company in 2020 when it announced that its Investigational New Drug (“IND”) application for ornithine transcarbamylase (“OTC”) deficiency and its Clinical Trial Application (“CTA”) for candidate LUNAR-COV19 were approved by applicable health authorities. In 2023, our COVID-19 vaccine, ARCT-154 (also referred to as KOSTAIVE[®]), received marketing authorization approval in Japan for adults 18 years and older, and in September 2024 KOSTAIVE became the world’s first approved and commercially available self-amplifying RNA (sa-mRNA) vaccine.

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of Arcturus and its subsidiaries and are unaudited. All intercompany accounts and transactions have been eliminated in consolidation. These condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In management’s opinion, the accompanying condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of the results for the interim periods presented.

Interim financial results are not necessarily indicative of results anticipated for the full year. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023.

These condensed consolidated financial statements are prepared in accordance with GAAP, which requires management to make estimates and assumptions regarding the valuation of certain debt and equity instruments, share-based compensation, accruals for liabilities, income taxes, revenue and deferred revenue, leases, and other matters that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Although these estimates are based on management’s knowledge of current events and actions the Company may undertake in the future, actual results may ultimately differ from these estimates and assumptions.

Joint Ventures, Equity Method Investments and Variable Interest Entities

Investments for which the Company exercises significant influence but does not have control are accounted for under the equity method. Equity method investment activity is related to the Company’s joint venture in ARCALIS, Inc. with Axcelead, Inc. (“Axcelead”). The Company’s share of the investee’s results is presented as either income or loss from equity-method investment in the accompanying condensed consolidated statements of operations and comprehensive loss.

Liquidity

The Company has incurred significant operating losses since its inception. As of September 30, 2024 and December 31, 2023, the Company had an accumulated deficit of \$418.8 million and \$367.9 million, respectively.

The Company’s activities since inception have consisted principally of research and development activities, general and administrative activities, and raising capital. The Company’s activities are subject to significant risks and uncertainties, including failing to secure additional funding before the Company achieves sustainable revenues and profit from operations. From the Company’s inception through September 30, 2024, the Company has funded its operations principally with the proceeds from revenues earned through collaboration agreements, the sale of capital stock, expense reimbursements from government contracts and proceeds from long-term debt. At September 30, 2024, the Company’s balance of cash and cash equivalents, including restricted cash, was \$294.1 million.

Management believes that it has sufficient working capital on hand to fund operations through at least the next twelve months from the date these condensed consolidated financial statements were available to be issued. There can be no assurance that the Company will be successful in securing additional funding, that the Company’s projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company and its chief operating decision-maker view the Company's operations and manage its business in one operating segment, which is the research and development of medical applications for the Company's nucleic acid-focused technology.

Revenue Recognition

At contract inception, the Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of Accounting Standards Codification ("ASC") Topic 808, Collaborative Arrangements ("ASC 808"). For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration reflect a vendor-customer relationship and are therefore within the scope of ASC 606.

The Company determines revenue recognition for arrangements within the scope of ASC 606 by performing the following five steps: (i) identify the contract; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when, or as, the company satisfies a performance obligation.

The terms of the Company's revenue agreements include license fees, upfront payments, development and regulatory milestone payments, profit-sharing arrangements, reimbursement for research and development activities, option exercise fees, drug substance and drug product supply fees, consulting and related technology transfer fees and royalties on sales of commercialized products. The event-based milestone payments represent variable consideration, and the Company uses the most likely amount method to estimate this variable consideration because the Company will either receive the milestone payment or will not, which makes the potential milestone payment a binary event. The most likely amount method requires the Company to determine the likelihood of earning the milestone payment. Given the high degree of uncertainty around achievement of these milestones, the Company determines the milestone amounts to be fully constrained and does not recognize revenue until the uncertainty associated with these payments is resolved. The Company will recognize revenue from sales-based royalty payments when or as the sales occur. The Company will re-evaluate the transaction price in each reporting period as uncertain events are resolved and other changes in circumstances occur.

A performance obligation is a promise in a contract to transfer a distinct good or service to the collaborative partner and is the unit of account in ASC 606. A contract's transaction price is allocated to each distinct performance obligation based on relative standalone selling price and recognized as revenue when, or as, the performance obligation is satisfied.

For performance obligations that are recognized over time, the Company measures the progress using an input method. The input methods used are based on the effort expended or costs incurred toward the satisfaction of the performance obligation. The Company estimates the amount of effort expended, including the time estimated it will take to complete the activities, or costs incurred in a given period, relative to the estimated total effort or costs to satisfy the performance obligation. This approach requires the Company to make numerous estimates and use significant judgment. If estimates or judgments change over the course of the collaboration, a cumulative catch up of revenue is recognized in the period such changes are identified.

See "Note 2, Revenue" for specific details surrounding the Company's arrangements.

Leases

The Company determines if an arrangement is a lease at inception. Lease right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. For operating leases with an initial term greater than 12 months, the Company recognizes operating lease right-of-use assets and operating lease liabilities based on the present value of lease payments over the lease term at the commencement date. Operating lease right-of-use assets are comprised of the lease liability plus any lease payments made and excludes lease incentives. Lease terms include options to renew or terminate the lease when the Company is reasonably certain that the renewal option will be exercised or when it is reasonably certain that the termination option will not be exercised. For the Company's operating leases, if the interest rate used to determine the present value of future lease payments is not readily determinable, the Company estimates its incremental borrowing rate as the discount rate for the lease. The Company's incremental borrowing rate is estimated to approximate the interest rate on a collateralized basis with similar terms and payments, and in similar economic environments. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company has elected the practical expedient to not separate lease and non-lease components.

See "Note 9, Commitments and Contingencies" for specific details surrounding the Company's leases.

Research and Development Costs, Net

All research and development costs are expensed as incurred. Research and development costs consist primarily of salaries, employee benefits, costs associated with preclinical studies and clinical trials (including amounts paid to clinical research organizations and other professional services), in-process research and development expenses, pre-launch inventory and license agreement expenses. Research and development expenses are presented net of any grants. Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods are received or the services are performed.

The Company records accruals for estimated research and development costs, comprising payments for work performed by third party contractors, laboratories, participating clinical trial sites, and others. Some of these contractors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. For the latter, the Company accrues the expenses as goods or services are used or rendered.

Clinical trial activities performed by third parties are accrued and expensed based upon estimates of the proportion of work completed over the life of the individual clinical trial and patient enrollment rates in accordance with agreements established with Clinical Research Organizations ("CROs") and clinical trial sites. Estimates are determined by reviewing contracts, vendor agreements and purchase orders, and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

Pre-Launch Inventory

Prior to obtaining initial regulatory approval for an investigational product candidate, the Company expenses costs relating to production of inventory as research and development expense in its condensed consolidated statements of operations and comprehensive loss, in the period incurred. When the Company believes regulatory approval and subsequent commercialization of an investigational product candidate is probable, and the Company also expects future economic benefit from the sales of the investigational product candidate to be realized, it will then capitalize the costs of production as inventory.

Restricted Cash

Restricted cash includes collateral pledged and held in the Company's securities accounts pursuant to a security agreement with Wells Fargo Bank, National Association ("Wells Fargo") (Note 5). At September 30, 2024, such collateral amounted to \$55.0 million.

Restricted cash also includes cash required to be set aside as security for lease payments and to maintain a letter of credit for the benefit of the landlord for the Company's offices. At September 30, 2024 and 2023, the Company had restricted cash of \$1.9 million and \$2.1 million, respectively, in conjunction with property leases in San Diego, California, and such restriction is expected to be removed at the end of the lease term. At September 30, 2023, non-current restricted cash also includes \$20.0 million related to the Wells Fargo Loan (Note 5).

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the unaudited condensed consolidated balance sheets that sum to the total of the same such amounts shown in the unaudited condensed consolidated statement of cash flows as of September 30, 2024 and 2023:

(in thousands)	September 30, 2024	September 30, 2023
Cash and cash equivalents	\$ 237,178	\$ 311,918
Restricted cash	55,000	35,000
Non-current restricted cash	1,885	22,133
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	<u>\$ 294,063</u>	<u>\$ 369,051</u>

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury-stock method. Dilutive shares of common stock for the three and nine months ended September 30, 2024 were comprised of stock options and restricted stock units. Dilutive shares of common stock for the three and nine months ended September 30, 2023 were comprised of stock options.

No dividends were declared or paid during the reported periods.

Recently Issued Accounting Standards Not Yet Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the condensed consolidated financial statements and disclosures.

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. ASU 2023-07 is effective for annual reporting periods beginning after December 15, 2023, and for interim reporting periods beginning January 1, 2025, with early adoption permitted. We are currently evaluating the impact that adoption of ASU 2023-07 will have on our financial statement disclosures.

Note 2. Revenue

The Company has entered into license agreements and collaborative research and development arrangements with pharmaceutical and biotechnology companies, as well as consulting, related technology transfer, product revenue and government grant agreements. Under these arrangements, the Company is entitled to receive license fees, consulting fees, product fees, technological transfer fees, upfront payments, milestone payments if and when certain research and development milestones, technology transfer milestones or success-based milestones are achieved, royalties on approved product sales and reimbursement for research and development activities. The Company's costs of performing these services are included within research and development expenses. The Company's milestone payments are typically defined by achievement of certain preclinical, clinical, and commercial success criteria. Preclinical milestones may include in vivo proof of concept in disease animal models, lead candidate identification, and completion of IND-enabling toxicology studies. Clinical milestones may, for example, include successful enrollment of the first patient in or completion of Phase 1, 2 and 3 clinical trials, and commercial milestones are often tiered based on net or aggregate sale amounts. The Company cannot guarantee the achievement of these milestones due to risks associated with preclinical and clinical activities required for development of nucleic acid medicine-based therapeutics and vaccines.

The following table presents changes during the nine months ended September 30, 2024 in the balances of contract assets and liabilities as compared to what was disclosed in the Company's Annual Report.

(in thousands)	December 31, 2023	Additions	Deductions	September 30, 2024
Contract Assets:				
Accounts receivable	\$ 32,064	\$ 83,375	\$ (85,240)	\$ 30,199
Contract Liabilities:				
Deferred revenue	\$ 87,325	\$ 82,493	\$ (129,544)	\$ 40,274

The following table summarizes the Company's revenues for the periods indicated.

(in thousands)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Collaboration Revenue:				
CSL Seqirus	\$ 38,786	\$ 43,433	\$ 117,078	\$ 129,257
Other collaboration revenue	29	(57)	311	3,413
Total collaboration revenue	\$ 38,815	\$ 43,376	\$ 117,389	\$ 132,670
Grant revenue:				
BARDA	\$ 2,858	\$ 1,764	\$ 12,155	\$ 3,274
Total grant revenue	\$ 2,858	\$ 1,764	\$ 12,155	\$ 3,274

The following paragraphs provide information regarding the nature and purpose of the Company's most significant collaboration and grant arrangements.

CSL Seqirus

On November 1, 2022, the Company entered into a Collaboration and License Agreement (as amended, the “CSL Collaboration Agreement”) with Seqirus, Inc., a part of CSL Limited (“CSL Seqirus”), for the global exclusive rights to research, develop, manufacture, and commercialize vaccines. Under the terms of the CSL Collaboration Agreement, the Company provides CSL Seqirus with an exclusive global license to its mRNA technology (including STARR[®]) and LUNAR[®] lipid-mediated delivery, along with mRNA drug substance and drug product manufacturing process. CSL Seqirus will lead development and commercialization of vaccines under the collaboration. The collaboration plans to advance vaccines against SARS-CoV-2 (COVID-19), influenza, pandemic preparedness as well as three other respiratory infectious diseases. In September 2024, our COVID-19 vaccine KOSTAIVE[®] became the world’s first approved and commercially available self-amplifying RNA (sa-mRNA) vaccine.

The Company received a \$200.0 million upfront payment and is eligible to receive over \$1.3 billion in development milestones if all products are registered in the licensed fields and entitled to potentially receive up to \$3.0 billion in commercial milestones based on “net sale” of vaccines in the various fields. In addition, the Company is eligible to receive a 40% net profit share for COVID-19 vaccine products and up to low double-digit royalties for vaccines against flu, pandemic preparedness and three other respiratory pathogens. During the third quarter of 2024, upon the first commercial sale of KOSTAIVE following regulatory approval in Japan, the Company achieved a \$25.0 million development milestone related to the CSL Collaboration Agreement which was included in accounts receivable as of September 30, 2024.

In evaluating the CSL Collaboration Agreement in accordance with ASC 606, the Company concluded that CSL Seqirus is a customer. The Company identified all promised goods/services within the CSL Collaboration Agreement, and when combining certain promised goods/services, the Company concluded that there are five distinct performance obligations. The nature of the performance obligations consists of delivery of the vaccine license, research and development services for COVID and non-COVID vaccines and regulatory activities for COVID vaccines. For each performance obligation, the Company estimated the standalone selling price based on 1) in the case of the license, the fair value using costs to recreate plus margin method and 2) in the case of research and development services and regulatory activities, cost plus margin for estimated full-time equivalent (“FTE”) costs, direct costs including laboratory supplies, contractors, and other out-of-pocket expenses for research and development services and regulatory activities.

As of September 30, 2024, the transaction price consisted of upfront consideration received and milestones achieved. Additional variable consideration was not included in the transaction price at September 30, 2024 because the Company could not conclude that it is probable that including the variable consideration will not result in a significant revenue reversal.

The Company allocated the transaction price to the performance obligations in proportion to their standalone selling price. The vaccine license was recognized at the point in time it was transferred in 2022. The research and development and regulatory activities performance obligations are recognized over a period of time based on the percentage of services rendered using the input method, meaning actual costs incurred divided by total costs budgeted to satisfy the performance obligation. Any consideration related to sales-based royalties will be recognized when the amounts are probable of non-reversal, provided that the reported sales are reliably measurable and the Company has no remaining promised goods/services, as they are constrained and therefore have also been excluded from the transaction price. The revenue recognized in the third quarter of 2024 relates to the license delivered, milestones achieved and services performed through September 30, 2024.

Total deferred revenue as of September 30, 2024 and December 31, 2023 for the CSL Collaboration Agreement was \$40.3 million and \$87.1 million, respectively.

During 2023, the Company also received an advance payment of \$23.6 million for the manufacturing and supply of ARCT-154 drug product. The advance payment was for specified manufacturing runs of ARCT-154 which include the drug substance utilized, as well as the reservation fees and related manufacturing requirements. The Company concluded that the promise to manufacture and supply ARCT-154 drug product is a customer option as part of the CSL Collaboration Agreement and is accounted for as a separate contract. The Company recognized \$18.0 million in revenue related to this customer option during the second quarter of 2024. No amount related to this customer option remained in deferred revenue as of September 30, 2024.

During 2023, the Company entered into an amendment to the CSL Collaboration Agreement, pursuant to which the Company agreed to sponsor and conduct a Phase 1 clinical study in the influenza field. As part of the amendment, the Company received \$17.5 million from CSL Seqirus. The amendment also provides for up to \$1.5 million in additional payments which are achievable upon meeting certain clinical milestones relating to the Phase 1 clinical study in the influenza field. The Company previously concluded that the expansion of research and development support services under the CSL Collaboration Agreement represented an option that was not a material right. Therefore the Company concluded the promise to sponsor and conduct the Phase 1 clinical study is a separate contract and the sole performance obligation under the new arrangement. During the quarter ended September 30, 2024, the Company recognized \$4.0 million related to the performance obligation and the remaining amount of \$5.9 million is included in deferred revenue.

During the fourth quarter of 2023, the Company received an advance payment of \$5.3 million from CSL Seqirus for manufacturing activities related to COVID-19 vaccine product. During the first quarter of 2024, the Company received an additional advance payment of \$5.1 million from CSL Seqirus for manufacturing activities related to COVID-19 vaccine product. The Company concluded that the promise to perform manufacturing activities is a customer option as part of the CSL Collaboration Agreement and is accounted for as a separate contract. The Company recognized \$5.3 million in revenue related to this customer option during the third quarter of 2024 upon the transfer of vaccine product to CSL Seqirus. The remaining \$5.1 million is included in deferred revenue as of September 30, 2024 and will be recognized as revenue when the remaining vaccine product is transferred to CSL Seqirus.

In March 2024, the Company entered into an amendment to the CSL Collaboration Agreement, pursuant to which the parties agreed to, among other things, adjust (i) the development plans for certain product candidates, (ii) various development milestones related to such product candidates, (iii) provisions of the CSL Collaboration Agreement related to specific royalty payments, (iii) provisions of the CSL Collaboration Agreement related to distributors, and (iv) proprietary payment calculations related to the foregoing.

BARDA Grant

In August 2022, the Company entered into a cost reimbursement contract (the "BARDA Contract") with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS) for an award of up to \$63.2 million for the development of a pandemic influenza vaccine using the Company's STARR[®] self-amplifying mRNA vaccine platform technology. The Company earns grant revenue for performing tasks under the agreement.

The Company determined that the BARDA Contract is not in the scope of ASC 808 or ASC 606. Applying International Accounting Standards No. 20 ("IAS 20"), Accounting for Government Grants and Disclosure of Government Assistance, by analogy, the Company recognizes grant revenue from the reimbursement of direct out-of-pocket expenses, overhead allocations and fringe benefits for research costs associated with the grant. The costs associated with these reimbursements are reflected as a component of research and development expense in the Company's condensed consolidated statements of operations and comprehensive income (loss).

As of September 30, 2024, the remaining available funding net of revenue earned was \$41.6 million.

Note 3. Fair Value Measurements

The Company establishes the fair value of its assets and liabilities using the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company established a fair value hierarchy based on the inputs used to measure fair value.

The three levels of the fair value hierarchy are as follows:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3: Unobservable inputs in which little or no market data exists and are therefore determined using estimates and assumptions developed by the Company, which reflect those that a market participant would use.

The carrying value of cash, restricted cash, accounts receivable, accounts payable and accrued liabilities approximate their respective fair values due to their relatively short maturities.

As of September 30, 2024 and December 31, 2023, all assets measured at fair value on a recurring basis consisted of cash equivalents and money market funds, which were classified within Level 1 of the fair value hierarchy. The fair value of these financial instruments was measured based on quoted prices.

Note 4. Balance Sheet Details

Property and equipment, net balances consisted of the following:

(in thousands)	September 30, 2024	December 31, 2023
Research equipment	\$ 16,864	\$ 16,046
Computers and software	1,131	1,275
Office equipment and furniture	703	958
Leasehold improvements	2,644	2,655
Construction in progress	—	233
Total	21,342	21,167
Less accumulated depreciation and amortization	(10,992)	(8,740)
Property and equipment, net	\$ 10,350	\$ 12,427

Depreciation and amortization expenses were \$0.9 million and \$2.7 million for the three and nine months ended September 30, 2024, respectively, and \$0.8 million and \$2.1 million for the three and nine months ended September 30, 2023, respectively. Construction in progress is primarily comprised of research equipment not yet placed in service.

Accrued liabilities consisted of the following:

(in thousands)	September 30, 2024	December 31, 2023
Accrued compensation	\$ 10,846	\$ 5,918
Cystic Fibrosis Foundation liability	7,109	7,633
Income tax payable	—	641
Current portion of operating lease liability	3,435	4,309
Clinical trial accruals	2,039	2,333
Vinbiocare contractual liabilities	2,036	2,514
Other accrued research and development expenses	6,931	8,533
Total	\$ 32,396	\$ 31,881

Note 5. Debt

Wells Fargo Credit Agreement

The Company's wholly-owned subsidiary, Arcturus Therapeutics, Inc. ("Arcturus Therapeutics") entered into a credit agreement with Wells Fargo Bank on April 21, 2023, and amended on June 26, 2024, whereby Wells Fargo will make a \$50.0 million revolving credit line available to the Company (the "Loan") and each draw on the Loan evidenced by a revolving line of credit note (the "Note").

Borrowings under the agreement will bear interest at a rate of 1.00% above either the Daily Simple SOFR or Term SOFR (as such terms are defined in the Note), with "SOFR" being the rate per annum equal to the secured overnight financing rate as administered by the Federal Reserve Bank of New York. If an Event of Default (as defined in the agreement) occurs, then all Loans shall bear interest at a rate equal to 2.00% above the interest rate applicable immediately prior to the occurrence of the Event of Default.

The term of the agreement was originally two years, with an option for one-year renewals subject to Wells Fargo approval and Arcturus Therapeutics furnishing to Wells Fargo a non-refundable commitment fee equal to 0.25% of the Loan amount for each such renewal. There is no penalty for terminating the facility prior to the maturity date of the Note. As collateral, the Company has agreed to pledge \$55.0 million in cash to be held in the Company's securities accounts with Wells Fargo Securities, LLC, an affiliate of Wells Fargo, pursuant to a security agreement. In June 2024, Arcturus Therapeutics and Wells Fargo entered into an amendment to the Note, whereby the term of the Note was extended by one year to April 2026. No borrowings were outstanding as of September 30, 2024.

Note 6. Stockholders' Equity

Net Loss per Share

Potentially dilutive securities that were not included in the calculation of diluted net loss per share for the three and nine months ended September 30, 2024 as they were anti-dilutive totaled 0.7 million and 1.1 million, respectively, and 1.2 million and 0.8 million for the three and nine months ended September 30, 2023, respectively.

Sales Agreement

On December 23, 2022, the Company entered into a Controlled Equity OfferingSM Sales Agreement, which was amended on August 7, 2023 (as amended, the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"), Wells Fargo Securities, LLC ("Wells Fargo Securities"), and William Blair & Company, L.L.C. ("William Blair") relating to shares of the Company's common stock. In accordance with the terms of the Sales Agreement, the Company may offer and sell shares of its common stock having an aggregate offering price of up to \$200,000,000 from time to time through Cantor, Wells Fargo Securities, or William Blair, each acting as the Company's sales agent. During the period ended September 30, 2024 the Company did not offer or sell any shares of common stock pursuant to the Sales Agreement.

Note 7. Share-Based Compensation Expense

In June 2024 at the Company's 2024 Annual Meeting of Stockholders (the "2024 Annual Meeting"), the stockholders of the Company approved an amendment to the Company's 2019 Omnibus Equity Incentive Plan (as amended, the "2019 Plan") which, among other things, increased the aggregate number of shares authorized for use in making awards to eligible persons under the 2019 Plan by 2,000,000 shares, for a total of up to 10,750,000 shares available for issuance. As of September 30, 2024, a total of 2,203,234 shares remain available for future issuance under the 2019 Plan, subject to the terms of the 2019 Plan.

In October 2021, the Company adopted the 2021 Inducement Equity Incentive Plan which covers the award of up to 1,000,000 shares of common stock (the "2021 Plan") effective as of October 15, 2021. Approval of the Company's stockholders is not required as a condition to the effectiveness of the 2021 Plan for so long as the plan is in compliance with applicable Nasdaq inducement plan rules. In April 2022, the compensation committee of the Company's board of directors approved a proposal to reduce the total number of shares available for future issuance under the 2021 Plan to 130,000. As of September 30, 2024, a total of 124,697 shares remain available for future issuance under the 2021 Plan, subject to the terms of the 2021 Plan.

Stock Options

Share-based compensation expense included in the Company's condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023 was as follows:

(in thousands)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 4,395	\$ 3,863	\$ 13,575	\$ 11,112
General and administrative	5,098	5,406	15,430	14,722
Total	<u>\$ 9,493</u>	<u>\$ 9,269</u>	<u>\$ 29,005</u>	<u>\$ 25,834</u>

Note 8. Income Taxes

The Company is subject to taxation in the United States and various states. The Company computes its quarterly income tax provision by using a forecasted annual effective tax rate and adjusts for any discrete items arising during the quarter. The primary difference between the effective tax rate and the federal statutory tax rate is due to federal and state income tax expense offset by valuation allowance on the Company's deferred tax assets.

For the three months ended September 30, 2024, the Company recorded \$0.2 million of income tax benefit and for the nine months ended September 30, 2024, the Company recorded no income tax benefit. For the three and nine months ended September 30, 2023, the Company recorded \$0.9 million and \$1.6 million of income tax expense, respectively.

Note 9. Commitments and Contingencies

Cystic Fibrosis Foundation Agreement

On September 25, 2023, the Company amended its Development Program Letter Agreement, dated May 16, 2017 and as amended July 13, 2018 and August 1, 2019, with the Cystic Fibrosis Foundation ("CFF"). Pursuant to the amendment, CFF increased the amount it will award to advance LUNAR-CF to \$24.6 million from approximately \$15.6 million and the Company agreed to incur at least \$15.0 million toward activities under the research plan. Total expense of \$0.3 million was recognized during the three months ended September 30, 2024. Total contra expense of \$0.5 million was recognized during the nine months ended September 30, 2024. For both the three and nine months ended September 30, 2023, the Company recognized contra expense of \$1.8 million. As of September 30, 2024 and December 31, 2023, \$7.1 million and \$7.6 million, respectively, remained in accrued liabilities.

Leases

In October 2017, the Company entered into a non-cancellable operating lease agreement for office space adjacent to its previously occupied headquarters. The commencement of the lease began in March 2018 and the lease extends for approximately 84 months from the commencement date with a remaining lease term through March 2025. Monthly rental payments are due under the lease and there are escalating rent payments during the term of the lease. The Company is also responsible for its proportional share of operating expenses of the building and common areas. In conjunction with the new lease, the Company received free rent for four months and received a tenant improvement allowance of \$0.1 million. In March 2024, the Company negotiated with the lessor to extend the lease through March 2027.

The Company entered into an irrevocable standby letter of credit with the landlord for a security deposit of \$0.1 million upon executing the lease which is included (along with additional funds required to secure the letter of credit) in the balance of non-current restricted cash.

In February 2020, the Company entered into a second non-cancellable operating lease agreement for office space near its current headquarters. The lease extended for 13 months from the commencement date and included a right to extend the lease for one twelve-month period. In February 2021, the Company opted to extend the lease through March 2025 to coincide with the lease term of the Company's headquarters. In January 2024, the Company vacated this office space with no intention of operating out of the location in the future. The Company was still engaged in the lease for the property and obligated to make the remaining lease payments through March 31, 2025, and therefore recorded an impairment loss in the amount of \$1.3 million during the three months ended March 31, 2024, as there was no future economic benefit from the lease. In July 2024, the Company terminated the existing lease agreement, in accordance with its terms, thereby ending their contractual obligation to pay for the premises. As a result, no lease liability remains as of September 30, 2024.

In September 2021, the Company entered into a third non-cancellable lease agreement for office, research and development, engineering and laboratory space near its current headquarters, and such lease term commenced during the second quarter of 2022. The initial term of this lease extends ten years and eight months from the date of possession, and the Company has the right to extend the term of the lease for an additional five-year period. When the lease term was determined for the operating lease right-of-use assets and lease liabilities, the extension option for the lease was not included. The lease has a monthly base rent ranging from \$0.3 million to \$0.4 million which escalates over the lease term. The Company received a free rent period of four months and also pays for various operating costs, including utilities and real property taxes. The Company entered into an irrevocable standby letter of credit with the landlord for a security deposit of \$2.0 million upon executing the lease which is included (along with additional funds required to secure the letter of credit) in the balance of non-current restricted cash.

Operating lease right-of-use asset and liability on the condensed consolidated balance sheets represent the present value of remaining lease payments over the remaining lease terms. The Company does not allocate lease payments to non-lease components; therefore, payments for common-area-maintenance and administrative services are not included in the operating lease right-of-use asset and liability. The Company uses its incremental borrowing rate to calculate the present value of the lease payments, as the implicit rate in the lease is not readily determinable.

As of September 30, 2024, the remaining payments of the operating lease liability were as follows:

(in thousands)	<u>Remaining Lease Payments</u>
2024 (remainder of year)	\$ 1,213
2025	4,811
2026	5,274
2027	4,132
2028	3,822
Thereafter	15,750
Total remaining lease payments	<u>35,002</u>
Less: imputed interest	(5,580)
Total operating lease liabilities	<u>\$ 29,422</u>
Weighted-average remaining lease term	7.4
Weighted-average discount rate	4.7%

Operating lease costs consist of the fixed lease payments included in operating lease liability and are recorded on a straight-line basis over the lease terms. Operating lease costs were \$1.3 million and \$4.1 million for the three and nine months ended September 30, 2024, respectively, and \$1.4 million and \$4.2 million for the three and nine months ended September 30, 2023, respectively.

Note 10. Related Party Transactions

See “Note 1, Joint Ventures, Equity Method Investments and Variable Interest Entities” for specific details surrounding the Company’s agreement with Axcelead to form the joint venture entity, ARCALIS, Inc.

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

The following is a discussion of the financial condition and results of operations of Arcturus Therapeutics Holdings Inc. for the three- and nine-month periods ended September 30, 2024. Unless otherwise specified herein, references to the “Company,” “Arcturus,” “we,” “our” and “us” mean Arcturus Therapeutics Holdings Inc. and its consolidated subsidiaries. You should read the following discussion and analysis together with the interim condensed consolidated financial statements and related notes included elsewhere herein. For additional information relating to our management’s discussion and analysis of financial conditions and results of operations, please see our Annual Report on Form 10-K for the year ended December 31, 2023 (the “2023 Annual Report”), which was filed with the U.S. Securities and Exchange Commission (the “Commission”) on March 14, 2024. Unless otherwise defined herein, capitalized words and expressions used herein shall have the same meanings ascribed to them in the 2023 Annual Report.

This report includes forward-looking statements which, although based on assumptions that we consider reasonable, are subject to risks and uncertainties which could cause actual events or conditions to differ materially from those currently anticipated and expressed or implied by such forward-looking statements. This report also includes certain statements based solely on information, reports and studies provided by or conducted by Seqirus, Inc. and Meiji Holdings Co., Ltd or their respective affiliates.

You should read this report and the documents that we reference in this report and have filed as exhibits to this report completely and with the understanding that our actual future results may be materially different from what we expect. You should also review the factors and risks we describe in the reports we will file or submit from time to time with the Commission after the date of this report.

Overview

We are a commercial messenger RNA medicines company focused on the development of infectious disease vaccines and opportunities within liver and respiratory rare diseases. In addition to our messenger RNA (“mRNA”) platform, our proprietary lipid nanoparticle (“LNP”) delivery system, LUNAR[®], may enable multiple nucleic acid medicines. Our proprietary self-amplifying mRNA technology (STARR[®] technology) has been demonstrated to be longer lasting and broader response at lower dose levels than conventional mRNA. In 2023, our COVID-19 vaccine, ARCT-154 (also referred to as KOSTAIVE[®]), received marketing authorization approval in Japan, and in September 2024 KOSTAIVE became the world’s first approved and commercially available self-amplifying RNA (sa-mRNA) vaccine.

We are leveraging our proprietary LUNAR platform and our nucleic acid technologies to develop and advance a pipeline of mRNA-based vaccines and therapeutics for infectious diseases and rare genetic disorders with significant unmet medical needs. We continue to expand this platform by adding new innovative delivery solutions that allow us to expand our discovery efforts. Our proprietary LUNAR technology is intended to address the major hurdles in RNA drug development, namely the effective and safe delivery of RNA therapeutics to disease-relevant target tissues. We believe the versatility of our platform to target multiple tissues, its compatibility with various nucleic acid therapeutics, and our expertise in developing scalable manufacturing processes can allow us to deliver on the next generation of nucleic acid medicines.

Business Updates

Vaccine Collaboration with CSL Seqirus

In November 2022, we entered into a Collaboration and License Agreement (as amended, the “CSL Collaboration Agreement”) with Seqirus, Inc. (“CSL Seqirus”), a part of CSL Limited, and one of the world’s leading influenza vaccine providers, for global exclusive rights to research, develop, manufacture and commercialize self-amplifying mRNA vaccines against COVID-19, influenza and three other respiratory infectious diseases and global non-exclusive rights to pandemic pathogens. The CSL Collaboration Agreement became effective on December 8, 2022. The collaboration combines CSL Seqirus’ established global vaccine commercial and manufacturing infrastructure with Arcturus’ manufacturing expertise and innovative STARR self-amplifying mRNA vaccine and LUNAR delivery platform technologies. Under the framework of our collaboration with CSL Seqirus, we continue the development of the COVID-19 vaccine to establish a differentiated platform and address routine recommendations for periodic vaccine composition updates in a timely manner.

In November 2023, KOSTAIVE[®], a self-amplifying messenger RNA (sa-mRNA) vaccine, received marketing authorization approval from the Japanese Ministry of Health, Labour and Welfare for use as a primary immunization and booster in Japan for adults 18 years and older. The approval was based on positive clinical data from several ARCT-154 studies, including a 19,000-subject efficacy, safety, and immunogenicity study performed in Vietnam, as well as a Phase 3 booster study in Japan.

KOSTAIVE[®] is the brand name approved in Japan for ARCT-154, which is the version of the sa-mRNA COVID vaccine encoding the ancestral strain of SARS-CoV-2, and for updated variant-specific versions of this vaccine. We may use KOSTAIVE or the specific internally generated name, such as ARCT-154, ARCT-2302 and ARCT-2303, to identify the vaccine.

In September 2024, we announced that Japan's Ministry of Health, Labor and Welfare (MHLW) granted approval and authorization for an updated version of KOSTAIVE, targeted to protect against the JN.1 lineage of Omicron subvariants for adults 18 years of age and older. CSL's exclusive partner in Japan, Meiji Holdings Co., Ltd ("Meiji") began distributing the updated vaccine in Japan in October 2024, marking the world's first commercially available sa-mRNA COVID-19 vaccine for adults 18 and older. The approval was based on manufacturing data demonstrating the quality and consistency of the vaccine product, non-clinical immunogenicity data against JN.1 lineage of Omicron subvariants of KOSTAIVE (JN.1), and clinical evidence supporting the safety and immunogenicity of KOSTAIVE (bivalent, BA.4/5 and ancestral strain).

The European Medicines Agency (EMA) is currently reviewing a marketing authorization application for ARCT-154. The review procedure started on August 17, 2023.

Earlier this year, CSL Seqirus' partner Meiji Seika Pharma announced that it submitted a partial change application for an amendment to the manufacturing and marketing approval of KOSTAIVE® to include manufacturing sites in Japan, including ARCALIS, Inc., Arcturus' manufacturing joint venture in Japan. Meiji Seika Pharma will begin selling domestically produced KOSTAIVE® this season.

Clinical Studies of KOSTAIVE (COVID-19 vaccine)

In connection with our collaboration with CSL Seqirus, we continue to collect data from the various ongoing studies described below.

Pivotal Phase 3 Non-Inferiority Study of KOSTAIVE (ARCT-154) in Japan

Meiji sponsored a randomized, multicenter, Phase 3, observer-blind, active-controlled comparative study to evaluate the safety and immunogenicity of a booster dose of ARCT-154 and to evaluate the non-inferiority of ARCT-154 over COMIRNATY® (Monovalent, Original strain). The study targeted 780 adult participants, with half in the ARCT-154 group and half in a comparator group, and completed enrollment with 828 participants in February 2023. The study met all primary and secondary immunogenicity endpoints, including a secondary pre-defined superiority assessment over COMIRNATY® (Omicron BA.4/5 strain). Overall, the safety and immunogenicity results of the study support the favorable benefit/risk profile of the ARCT-154 vaccine when administered as a booster dose in adult individuals who previously received other mRNA COVID-19 vaccines.

On February 1, 2024, the journal Lancet Infectious Diseases published the article 'Persistence of immune responses of a self-amplifying RNA COVID-19 vaccine (ARCT154) versus BNT162b2' ([https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(24\)00060-4/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(24)00060-4/fulltext)), with six-month follow-up results from this study. These additional data demonstrate the extended persistence of neutralizing antibodies after administration with ARCT-154 compared with conventional mRNA vaccine in the clinical setting, indicating longer-lasting immunity and implying a longer duration of protection by ARCT-154.

On September 30, 2024, we announced results from this study demonstrating that ARCT-154 maintained superior immunogenicity compared to the conventional mRNA vaccine (COMIRNATY) for up to 12 months against Wuhan-Hu-1, Omicron BA.4-5 and certain other COVID-19 variants, and at one-sixth the dose of the comparator (5µg vs 30µg, respectively).

In October 2024, Lancet Infectious Diseases published the follow-up article '12-month persistence of immune responses to self-amplifying mRNA COVID-19 vaccines: ARCT-154 versus BNT162b2 vaccine' ([https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(24\)00615-7/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(24)00615-7/fulltext)), which confirmed a better neutralizing immune response against a panel of SARS-CoV-2 strains in pre-immunized Japanese adults boosted with ARCT-154 compared with the conventional mRNA vaccine, BNT162b2, which persisted up to 12 months post-vaccination, including in those age 50 years and older.

Phase 3 Study of Bivalent Version of COVID-19 KOSTAIVE in Japan

On September 29, 2023, Meiji initiated an additional Phase 3 clinical study with ARCT-2301, a bivalent version of KOSTAIVE (ancestral strain and Omicron BA.4/5) to further support immunogenicity and safety data for our self-amplifying mRNA platform, which may facilitate the timely release of future seasonal updates of our COVID-19 vaccine against evolving variants of concern. On March 19, 2024, Meiji announced that the bivalent vaccine met the primary study endpoint (non-inferiority). The study enrolled 930 healthy adults and individuals with comorbidities, who previously received three to five doses of mRNA COVID-19 vaccines, including the last booster at least three months prior to recruitment. The study compares the investigational vaccine (ARCT-2301) and COMIRNATY (ancestral strain and BA.4/5) to evaluate safety and immunogenicity between observer-blind groups. Both the geometric mean titer (GMT) ratio and seroresponse rate (SRR) difference of neutralizing antibodies against SARS-CoV-2 (Omicron BA.4/5 and Wuhan strains) met pre-specified non-inferiority and superiority criteria versus COMIRNATY. There were no causally-associated severe or serious adverse events with ARCT-2301.

In September 2024, we announced 6-month immunogenicity and safety results from this study. As with the monovalent vaccine, the bivalent sa-mRNA formulation demonstrates superior immunogenicity over the conventional bivalent mRNA vaccine

COMIRNATY, a higher immune response persisting up to six months after a booster dose, and improved breadth, supporting the robustness of the sa-mRNA vaccine platform for future vaccine strain updates. The study results were presented at OPTIONS XII for the Control of Influenza conference in Brisbane, Australia, in September 2024.

Phase 3 Study in Southern Hemisphere of KOSTAIVE (Monovalent XBB1.5)

In March 2024, Arcturus and CSL Seqirus initiated a Phase 3 pivotal study with the ARCT-2303 candidate vaccine containing the XBB1.5 Omicron variant. The study aims to generate additional immunogenicity and safety data in multiple ethnicities to support regulatory filings in the US and globally. In addition, the study will assess the co-administration of the ARCT-2303 vaccine with the age-appropriate seasonal influenza vaccines. Overall, 1,499 young and older adults were recruited in the study in Australia, Costa Rica, Honduras and the Philippines.

The study results show that all four primary study objectives and key secondary study objectives were met. ARCT-2303 demonstrated superior immune response compared to ARCT-154 as measured by neutralizing antibodies against Omicron XBB.1.5 in terms of GMT ratio and SCR difference. Co-administration of ARCT-2303 and quadrivalent influenza vaccine (QIV; Flucelvax, CSL) in adults 18-64 years old showed noninferior immune response compared to standalone QIV. Co-administration of ARCT-2303 and QIV also showed noninferior immune response compared to standalone ARCT-2303. Co-administration of ARCT-2303 and adjuvanted QIV (Fluad, CSL) in adults 65 years of age and above showed similar results for co-administered and separately administered groups. The safety and reactogenicity of co-administered vaccines were comparable with standalone administration. No safety concerns were raised based on the study results.

Seasonal Flu Collaboration Program Updates

Our LUNAR-qsFLU (qs; quadrivalent seasonal) program, now exclusively licensed to CSL Seqirus, has the objective of producing a safe and effective seasonal influenza vaccine candidate with significant advantages over the traditional egg-based inactivated quadrivalent vaccine. Inaccurate predictions of circulating influenza strains as well as mutations due to adaptation in egg-grown vaccines can substantially reduce efficacy on a year-to-year basis. We believe the ability of mRNA platforms to nimbly adapt to new viral strains should help improve efficacy. In addition, we do not expect mRNA vaccines to face the challenge from mutations common to egg-grown vaccines.

LUNAR-qsFLU has been designed to take advantage of our expertise in both LUNAR lipid delivery systems and our STARR self-amplifying mRNA technology. This platform has been shown to deliver effective protection against COVID-19 and has been optimized to elicit robust immunogenicity with acceptable reactogenicity at a lower dose than conventional mRNA vaccines with the objective of creating a highly effective influenza vaccine for use in general and high-risk populations. Working with CSL Seqirus, we generated a comprehensive non-clinical data package to support the initiation of the Phase 1 clinical trial with a novel influenza sa-mRNA vaccine candidate. A Phase 1 dose-finding safety and immunogenicity study was initiated in January 2024 in Australia.

Pandemic Influenza Program



Our LUNAR-pandFLU program continues to progress under the award from the Biomedical Advanced Research and Development Authority (“BARDA”) that we obtained in 2022. The program includes all non-clinical, manufacturing, and regulatory support to advance a vaccine to protect against disease caused by H5N1 highly pathogenic avian influenza. A pre-IND meeting was

granted, and a Written Response Only (“WRO”) was received for integration into future development plans. Nonclinical safety studies have been completed that will enable the Phase 1 clinical trial.

The IND application was submitted on October 9, 2024. Enrollment for a Phase 1 clinical trial designed to evaluate the safety and immunogenicity of ARCT-2304 (LUNAR-pandFLU candidate vaccine) is expected to begin before the end of 2024.

Key Updates on Arcturus-Owned mRNA Therapeutic Development Candidates

The following chart represents our current pipeline of Arcturus-owned mRNA therapeutic candidates:

Franchise	Candidate	Funded By	Indication	Global Prevalence	Clinical Trial Phase
Hepatic	LUNAR-OTC (ARCT-810)		Ornithine Transcarbamylase Deficiency (OTC)	> 10,000	Phase 2
Respiratory	LUNAR-CF (ARCT-032)		Cystic Fibrosis	85,000-100,000	Phase 2

- LUNAR-OTC/ARCT-810
 - o A Phase 1b study in stable OTC-deficient adults was completed in the United States in September 2023. The trial assessed safety, tolerability and pharmacokinetics of a single dose of ARCT-810, and exploratory biomarkers of drug activity. The Phase 1b study was a single ascending dose, placebo-controlled study that enrolled 16 adults with mild OTC-deficiency. ARCT-810 was generally safe and well tolerated at doses ranging from 0.1-0.5mg/kg and no serious or severe adverse events were observed. Sporadic infusion-related reactions (IRRs) were managed with symptomatic treatment and appeared to be less frequent with slower infusion rates. In plasma, ARCT-810 mRNA could be detected up to 4 weeks, while ionizable lipid was no longer measurable after 48 hours, indicating rapid degradation of the lipid nanoparticle that was utilized to deliver ARCT-810 mRNA. Study results were presented at the Society for Inherited Metabolic Disorders meeting in Charlotte, North Carolina in April 2024 and at the annual symposium for the Society for the Study of Inborn Errors of Metabolism in Porto, Portugal in August 2024.
 - o A Phase 2 double-blind study of ARCT-810 in OTC-deficient adolescents and adults in the European Union and United Kingdom completed dosing of eight subjects in August 2024 at the 0.3 mg/kg dose level. The participants in this group were randomized 3:1 to receive 6 doses of ARCT-810 or placebo administered every 14 days, and follow-up is ongoing.
 - o We are expanding the Phase 2 clinical program of ARCT-810 to the U.S. with an open-label, multiple-dose study to evaluate pharmacodynamics and safety in adult and adolescent patients requiring clinical management for OTC-deficiency. The study is currently recruiting patients.
 - o ARCT-810 was granted Orphan Drug Designation in June 2019, Fast Track Designation in May 2023, and Rare Pediatric Disease Designation in June 2023 by the FDA, and Orphan Medicinal Product Designation in August 2022 by the European Commission (EC) by the FDA.
- LUNAR-CF/ARCT-032 – Our program for cystic fibrosis is being supported in part by the Cystic Fibrosis Foundation (“CFF”). In 2023 we initiated and successfully completed a safety and tolerability Phase 1 single ascending dose study of ARCT-032 (LUNAR-CF), our mRNA therapeutic candidate for cystic fibrosis (CF). Thirty-two healthy participants (eight subjects in each of four dose cohorts) received a single inhaled dose of ARCT-032. A subsequent protocol amendment to transition to a safety and tolerability Phase 1b clinical study of ARCT-032 in adults with CF received regulatory approval in August 2023 and completed dosing and follow-up visits for 7 CF participants in August 2024, with each CF participant having received two administrations of ARCT-032 separated by two days.
 - o In the Phase 1/1b clinical study, ARCT-032 was generally safe and well tolerated in healthy volunteers and in the participants with CF. Of the seven total CF participants in the Phase 1b study, six were being treated with CFTR modulators while one subject had Class I mutations that do not benefit from modulator therapy. No serious or severe adverse events (SAEs) were observed, and the safety profile was similar between healthy volunteers and CF participants. Mild, transient events of elevated temperature or feeling hot accompanied by other nonspecific symptoms were observed at dose levels that are higher than those planned for the Phase 2 study. In the CF subjects, lung function measured over 8 days did not demonstrate a discernable pattern or safety concern after 2 doses of

ARCT-032. Preliminary findings from the study were presented at the European CF Society Conference in June 2024 in Glasgow, Scotland, and at the North American CF Conference in September 2024 in Boston, MA.

- o We submitted an IND application at the end of July 2024, and on August 29, 2024, the FDA issued a “Study May Proceed” notification for an ARCT-032 Phase 2 multiple ascending dose study designed to identify a safe and effective dose in Class I (null) and other CF participants who do not benefit from CFTR modulators. This study is supported by safety and tolerability data collected in healthy volunteers (N = 32) and the two-administration Phase 1b study.
- o In February 2024, the European Commission (EC), based on a positive opinion issued by the European Medicines Agency (EMA), granted Orphan Medicinal Product Designation for ARCT-032 to treat CF. ARCT-032 was granted Rare Pediatric Disease Designation in October 2023, and Orphan Drug Designation in November 2023 by the FDA.

Updates on Research and Platform Activities

We continue to invest and improve our LUNAR-lipid mediated delivery of mRNA with continuous improvements in our mRNA and sa-mRNA platforms in conjunction with improvements in our next generation proprietary lipids to improve targeting, efficacy and safety profiles for both our vaccine and therapeutic protein platforms. This investment has led to key innovations ensuring that our LUNAR formulated drug product candidates have optimal characteristics for therapeutic use, which we believe sets us apart from other nucleic acid therapeutics and lipid-mediated delivery platforms. As such, we consider ourselves a leader in the research and development of mRNA therapeutics for multiple indications.

We continue to conduct exploratory platform development activities, including the evaluation of genome editing, and new targeting approaches, where our LUNAR[®] and STARR[®] platforms could potentially be useful for identification and development of additional products for our portfolio.

Discovery Programs – Vaccine Programs (Lyme Disease and Gonorrhea)

Based on the clinical and regulatory validation of LUNAR and STARR technologies provided by the approval of KOSTAIVE, a self-amplifying messenger RNA (sa-mRNA) vaccine for COVID-19, we initiated new vaccine discovery programs earlier this year for Lyme disease and gonorrhea and continue to progress such programs. The discovery programs rely on the evidence of superior immunogenicity, durability, and breadth of immune response compared to conventional mRNA vaccines, as observed in the COVID-19 program.

Lyme disease is a bacterial infection and is the most common vector-borne disease in the United States. Infection can spread to joints, the heart and the nervous system. Gonorrhea is a sexually transmitted disease (STD) that can infect the mucous membranes of the reproductive tract. It is the second most commonly reported bacterial sexually transmitted infection in the United States. We selected these diseases based on high unmet medical needs, good understanding of the path forward in vaccine target selection, and demonstration of proof of concept, as well as platform advantages that may be translated in a favorable vaccine product.

Updates on Supply and Manufacturing

We have built a global manufacturing footprint with our partners, including Aldevron, Catalent, Recipharm, Polymun and ARCALIS. With such collaborations we have established an Integrated Global Supply Chain Network with our primary and secondary sourcing contract development & manufacturing organizations (CDMOs) based in the United States, EU and Asia for producing critical raw materials, drug substance, and packaged finished product. As the market for COVID vaccines shifts from multi-dose vial to lower and single-dose vial presentation, we continue, with our collaborator CSL Seqirus, to evaluate and pursue different forms of drug product presentations, advance manufacturing process and capabilities and technology transfers, and prepare for stockpiling and commercialization of COVID vaccines.

Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Report and our audited financial statements and related notes for the year ended December 31, 2023. Our historical results of operations and the year-to-year comparisons of our results of operations that follow are not necessarily indicative of future results.

Revenue

We enter into arrangements with pharmaceutical and biotechnology partners and government agencies that may contain upfront payments, license fees for research and development arrangements, research and development funding, milestone payments, option exercise and exclusivity fees, royalties on future sales, consulting fees and payments for technology transfers. We expect that sales of KOSTAIVE[®] by Meiji Holdings Co., Ltd, CSL's partner in Japan will commence in the fourth quarter of 2024 in Japan. However, revenues for us will be subject to a profit sharing mechanism whereby development costs are deducted from sales revenues prior to any distribution to the Company. The following table summarizes our total revenues for the periods indicated:

(in thousands)	Three Months Ended September 30,		2023 to 2024	
	2024	2023	\$ change	% change
Revenue	\$ 41,673	\$ 45,140	\$ (3,467)	-7.7%

Revenue decreased by \$3.5 million during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. The decline was mostly attributable to a lower milestone achievement from the CSL agreement during the third quarter of 2024. This decrease was offset by revenue recognized from a supply agreement related to the commercial production of KOSTAIVE[®] and an increase in revenue from the BARDA agreement during the three months ended September 30, 2024.

(in thousands)	Nine Months Ended September 30,		2023 to 2024	
	2024	2023	\$ change	% change
Revenue	\$ 129,544	\$ 135,944	\$ (6,400)	-4.7%

Revenue decreased by \$6.4 million during the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023. The decrease was due to the timing and value of milestone achievements and the achievement of a conditional payment during the nine months ended 2023, offset by revenue from supply agreements during the current year. Additionally, there was a decrease in revenue recognized under other agreements during the nine months ended September 30, 2024 due to lower activity or completion of collaboration agreements. The total decrease in revenue was offset by an increase in revenue recognized from the BARDA Contract.

Operating expenses

Our operating expenses consist of research and development and general and administrative expenses.

(in thousands)	Three Months Ended September 30,		2023 to 2024		Nine Months Ended September 30,		2023 to 2024	
	2024	2023	\$ change	% change	2024	2023	\$ change	% change
Operating expenses:								
Research and development, net	\$ 39,134	\$ 51,077	\$ (11,943)	-23.4%	\$ 151,376	\$ 155,513	\$ (4,137)	-2.7%
General and administrative	13,276	13,377	(101)	-0.8%	40,443	40,364	79	0.2%
Total	\$ 52,410	\$ 64,454	\$ (12,044)	-18.7%	\$ 191,819	\$ 195,877	\$ (4,058)	-2.1%

Research and Development Expenses, net

The following table presents our total research and development expenses by category:

(in thousands)	Three Months Ended September 30,		2023 to 2024		Nine Months Ended September 30,		2023 to 2024	
	2024	2023	\$ change	% change	2024	2023	\$ change	% change
External pipeline development expenses:								
LUNAR-COVID, net	\$ 12,035	\$ 24,892	\$ (12,857)	-51.7%	\$ 55,092	\$ 71,501	\$ (16,409)	-22.9%
LUNAR-OTC, net	890	2,001	(1,111)	-55.5%	7,200	7,520	(320)	-4.3%
BARDA	1,347	930	417	44.8%	6,949	1,576	5,373	*
Early-stage programs	7,602	2,326	5,276	*	26,543	10,018	16,525	*
Discovery technologies	2,071	4,662	(2,591)	-55.6%	4,453	16,266	(11,813)	-72.6%
External platform development expenses:								
Personnel related expenses	13,718	13,478	240	1.8%	43,234	40,206	3,028	7.5%
Facilities and equipment expenses	1,471	2,788	(1,317)	-47.2%	7,905	8,426	(521)	-6.2%
Total research and development expenses, net	<u>\$ 39,134</u>	<u>\$ 51,077</u>	<u>\$ (11,943)</u>	-23.4%	<u>\$ 151,376</u>	<u>\$ 155,513</u>	<u>\$ (4,137)</u>	-2.7%

* Greater than 100%

Our research and development expenses consist primarily of external manufacturing costs, in-vivo research studies and clinical trials performed by contract research organizations, clinical and regulatory consultants, personnel related expenses, facility related expenses and laboratory supplies related to conducting research and development activities. Research and development expenses were \$39.1 million for the three months ended September 30, 2024, compared with \$51.1 million for the three months ended September 30, 2023. The decrease was due to high manufacturing expenses in 2023 for Meiji supply batches and other clinical trial batches which were not incurred in 2024. The decrease was also due to lower facilities and equipment expenses in 2024. This was offset by an increase in clinical trial related expenses. Research and development expenses for the nine months ended September 30, 2024 were \$151.4 million compared with \$155.5 million for the nine months ended September 30, 2023. The decrease was due to lower manufacturing expenses in 2023 for Meiji supply batches and other clinical trial batches which were not incurred in 2024. Additionally, there was a decrease in consulting expenses as well as facilities and equipment expenses in 2024. This was offset by increased clinical related expenses for the COVID program and increased personnel related expenses in 2024. We expect that our research and development efforts and associated costs will continue to be substantial over the next several years as our pipeline progresses.

Early-stage programs represent programs that are in the pre-clinical or Phase 1 clinical stage and may be partnered or unpartnered, including the LUNAR-CF and LUNAR-FLU programs. Discovery technologies represent our efforts to expand our product pipeline and are primarily related to pre-partnered studies and new capabilities assessment. For some of our programs, the activities are part of our collaborative and other relationships, and the expenses may be partially offset with funds that have been awarded to the Company. The expenses for early-stage programs and discovery technologies primarily consist of external manufacturing costs, lab supplies, equipment, and consulting and professional fees. Early-stage programs and discovery technologies expenses are expected to steadily increase over the coming years.

Personnel related expenses primarily consist of employee salaries and benefits, share-based compensation and consultants. Although such expenses increased during 2024 as compared to 2023, we expect that they will not increase over the next twelve months.

Facilities and equipment expenses primarily consist of rent expenses, common area maintenance charges, shipping costs, various costs of our offices and laboratories and depreciation expenses. Facilities and equipment expenses are not expected to increase during the next twelve months.

General and Administrative Expenses

General and administrative expenses primarily consist of salaries and related benefits for our executive, administrative, legal and accounting functions and professional service fees for legal and accounting services as well as other general and administrative expenses.

General and administrative expenses were \$13.3 million for the three months ended September 30, 2024 compared with \$13.4 million for the three months ended September 30, 2023. The decrease in general and administrative expenses was attributable to decreased personnel expenses, partially offset by increased legal and other professional expenses, facilities expenses and other various general and administrative expenses. General and administrative expenses for the nine months ended September 30, 2024 remained consistent compared to the nine months ended September 30, 2023. The Company expects that general and administrative expenses will remain relatively consistent over the next fiscal year with the current pipeline.

Finance income (expense), net

(in thousands)	Three Months Ended September 30,		2023 to 2024		Nine Months Ended September 30,		2023 to 2024	
	2024	2023	\$ change	% change	2024	2023	\$ change	% change
Interest income	\$ 3,818	\$ 4,001	(183)	-4.6%	\$ 11,981	\$ 10,473	\$ 1,508	14.4%
Interest expense	—	(20)	20	-100.0%	—	(763)	763	-100.0%
Total	\$ 3,818	\$ 3,981	\$ (163)	-4.1%	\$ 11,981	\$ 9,710	\$ 2,271	23.4%

Interest income is generated on cash and cash equivalents. The decrease in interest income for the three months ended September 30, 2024 as compared to the three months ended September 30, 2023 was primarily the result of decreased interest earned on investment accounts. The increase in interest income for the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 was primarily the result of increased interest earned on investment accounts caused by higher interest rates. Interest expense during the nine months ended September 30, 2023 was incurred in connection with the Western Alliance Agreement and the Singapore Loan, both of which have since been terminated.

Other income and expense

(in thousands)	Three Months Ended September 30,		2023 to 2024		Nine Months Ended September 30,		2023 to 2024	
	2024	2023	\$ change	% change	2024	2023	\$ change	% change
(Loss) gain from foreign currency	\$ (201)	\$ 4	\$ (205)	*	\$ (642)	\$ (175)	\$ (467)	*
Gain on debt extinguishment	—	—	—	—	—	33,953	(33,953)	*
Total	\$ (201)	\$ 4	\$ (205)	*	\$ (642)	\$ 33,778	\$ (34,420)	*

* Greater than 100%

Other income and expense items primarily relate to gains and losses from foreign currency transactions. Additionally, we recorded a gain on debt extinguishment related to the Singapore Loan of \$34.0 million during the first quarter of 2023 as a result of the Singapore Loan being forgiven.

Off-balance sheet arrangements

Through September 30, 2024, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Liquidity and Capital Resources

From the Company's inception through the quarter ended September 30, 2024, the Company has funded its operations principally with the proceeds from the sale of capital stock, long-term debt and revenues earned through collaboration agreements and government contracts. Through the third quarter of 2024, we have achieved a total of approximately \$462.1 million in upfront payments and milestones from CSL Seqirus, including a milestone of \$25.0 million achieved in the current quarter with payment anticipated in the fourth quarter of 2024. At September 30, 2024, we had \$294.1 million in cash and cash equivalents and restricted cash.

CSL Seqirus, Inc. Collaboration and License Agreement

We entered into the CSL Collaboration Agreement with CSL Seqirus, a part of CSL Limited, one of the world's leading influenza vaccine providers, for the global exclusive rights to research, develop, manufacture and commercialize mRNA vaccines.

CSL Seqirus received exclusive global rights to our technology for vaccines against SARS-CoV-2 (COVID-19), influenza and three other respiratory infectious diseases and non-exclusive rights to pandemic pathogens. We received an up-front payment of \$200.0 million during the fourth quarter of 2022. We will be eligible to receive development milestones totaling more than \$1.3 billion if all products are registered in the licensed fields. We will also be entitled to receive up to \$3.0 billion in commercial milestones based on "net sales" of vaccines in the various fields.

In addition, we are entitled to receive a 40% share of net profits from COVID-19 vaccine sales and up to low double-digit royalties of annual net sales for vaccines against influenza and the other three specified infectious disease pathogens, as well as royalties on revenues from vaccines that may be developed for pandemic preparedness.

The CSL Collaboration Agreement sets forth how CSL Seqirus and we shall collaborate to research and develop vaccine candidates. In the COVID-19 field, we will lead activities for certain regulatory filings for ARCT-154 in the US and Europe and for research and development activities of a next-generation COVID vaccine candidate. CSL Seqirus will lead and be responsible for all other research and development in COVID-19, influenza and the other fields.

Wells Fargo Credit Agreement

On April 21, 2023, our wholly-owned subsidiary, Arcturus Therapeutics, Inc. entered into a credit agreement with Wells Fargo Bank, National Association (“Wells Fargo”) whereby Wells Fargo agreed to make a \$50.0 million revolving credit line available to the Company (the “Wells Fargo Loan”) and each Wells Fargo Loan evidenced by a revolving line of credit note (the “Note”).

Borrowings under the agreement will bear interest at a rate of 1.00% above either the Daily Simple SOFR or Term SOFR (as such terms are defined in the Wells Fargo Note), with “SOFR” being the rate per annum equal to the secured overnight financing rate as administered by the Federal Reserve Bank of New York. If an Event of Default (as defined in the credit agreement) occurs, then all Wells Fargo Loans shall bear interest at a rate equal to 2.00% above the interest rate applicable immediately prior to the occurrence of the Event of Default. As of September 30, 2024, no borrowings were made against the Wells Fargo Note.

The term of the agreement was originally two years, with an option for one-year renewals subject to Wells Fargo approval and the Company furnishing to Wells Fargo a non-refundable commitment fee equal to 0.25% of the Wells Fargo Loan amount for each such renewal. In June 2024, Arcturus Therapeutics and Wells Fargo entered into an amendment to the Note, whereby the term of the Note was extended by one year to April 2026. There is no penalty for terminating the agreement. There is no penalty for terminating the facility prior to the maturity date of the Wells Fargo Note. As collateral, we agreed to pledge \$55.0 million in cash to be held in our securities accounts with Wells Fargo Securities, LLC, an affiliate of Wells Fargo, pursuant to a security agreement.

Grant from the Biomedical Advanced Research and Development Authority

On August 31, 2022, we entered into a cost reimbursement contract (the “BARDA Contract”) with the Biomedical Advanced Research and Development Authority (“BARDA”), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS) to support the development of a low-dose pandemic influenza candidate based on our proprietary self-amplifying messenger RNA-based vaccine platform. The BARDA Contract is to support our non-clinical and pre-clinical development, early-stage clinical development through Phase 1, and associated drug product manufacturing, regulatory and quality-assurance activities over a period of three years. It provides for reimbursement by BARDA of our permitted costs up to \$63.2 million. As of September 30, 2024, the remaining available funding net of revenue earned was \$41.6 million.

Vinbiocare Agreement

During 2021, we entered into a technology license and technical support agreement and the framework drug substance supply agreement with Vinbiocare, a member of Vingroup Joint Stock Company (collectively, the “Vinbiocare License & Supply Agreements”), whereby we would provide technical expertise and support services to Vinbiocare to assist in the build out of an mRNA drug product manufacturing facility in Vietnam. We received an upfront payment in aggregate of \$40.0 million as part of the Vinbiocare License and Supply Agreements. In October 2022, in association with the termination of the Vinbiocare License and Supply Agreements, we signed the Vinbiocare Support Agreement with Vinbiocare which continues Vinbiocare’s clinical obligations and reserved a portion of the original \$40.0 million upfront payment received from the License and Supply Agreements to be paid over the future periods.

The Vinbiocare Support Agreement requires us to pay Vinbiocare certain limited payments, including upon the occurrence of specified events through the first quarter of 2025. Vinbiocare is also eligible to receive a single digit percentage of amounts received by Arcturus on net sales, if any, of ARCT-154 (or next-generation COVID vaccine) up to a capped amount.

General Financial Resources

A portion of our current cash balance is expected to be utilized during fiscal year 2024 to fund (i) advances to our LUNAR-CF program in clinical trials, (ii) the continued Phase 2 trial of ARCT-810, our LUNAR-OTC candidate, (iii) expenses incurred prior to customer payments under the CSL Collaboration Agreement and BARDA Contract and (iv) continued exploratory activities related to our platform and other general administrative activities.

Our future capital requirements are difficult to forecast and will depend on many factors that are out of our control. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected. There can be no assurance that we will be able to obtain additional needed financing on acceptable terms or at all. Additionally, equity or debt financings may have a dilutive effect on the holdings of our existing shareholders.

We expect to continue to incur additional losses in the long term, and we will need to execute on milestones within the CSL Collaboration Agreement, raise additional debt or equity financing or enter into additional partnerships to fund development. Our ability to transition to profitability is dependent on executing on milestones within the CSL Collaboration Agreement, successful clinical trials for OTC and CF and identifying and developing successful mRNA drug and vaccine candidates. If we are not able to

achieve planned milestones or incur costs in excess of our forecasts, we will need to reduce discretionary spending, discontinue the development of some or all of our programs, which will delay part of our development programs, all of which will have a material adverse effect on our ability to achieve our intended business objectives.

Funding Requirements

We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin commercialization of our products. As a result, we will require additional capital to fund our operations in order to support our long-term plans. We believe that our current cash position will be sufficient to meet our anticipated cash requirements through at least the next twelve months, assuming, among other things, no significant unforeseen expenses and continued funding from partners at anticipated levels. We intend to seek additional capital through equity and/or debt financings, collaborative or other funding arrangements with partners or through other sources of financing. Should we seek additional financing from outside sources, we may not be able to raise such financing on terms acceptable to us or at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to scale back or discontinue the advancement of product candidates, reduce headcount, liquidate our assets, file for bankruptcy, reorganize, merge with another entity, or cease operations.

Our future funding requirements are difficult to forecast and will depend on many factors, including the following:

- the development and commercialization of our LUNAR-COV19 and LUNAR-FLU vaccine candidates;
- the achievement of milestones under our strategic alliance agreements;
- maintaining and/or expanding our manufacturing network and capabilities;
- the terms and timing of any other strategic alliance, licensing and other arrangements that we may establish, including those with CSL Seqirus and CSL Seqirus' arrangement with Meiji, and any related payments thereunder;
- the initiation, progress, timing and successful completion of preclinical studies and clinical trials for our product candidates, including OTC and CF;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and cost of regulatory approvals;
- delays that may be caused by changing regulatory requirements;
- the cost and timing of hiring new employees to support our continued growth;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the costs and timing of procuring clinical and commercial supplies of our product candidates;
- the costs and timing of establishing sales, marketing and distribution capabilities;
- the costs associated with legal proceedings;
- the costs associated with potential litigation related to collaboration agreements; and
- the extent to which we acquire or invest in businesses, products or technologies.

Critical Accounting Policies and Estimates

We prepare our condensed consolidated financial statements in conformity with GAAP. As such, we make certain estimates, judgments and assumptions that we believe are reasonable, based upon information available to us. These judgments involve making estimates about the effect of matters that are inherently uncertain and may significantly impact our reported results of operations and financial condition. We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2023.

There have been no material changes to our critical accounting policies and estimates from the information provided in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, included in the 2023 Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates in the United States. Due to the nature of our cash and cash equivalents, we believe that we are not subject to any material market risk exposure. We do not have any foreign currency or other derivative financial instruments.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Exchange Act, our management, including our principal executive officer, our principal financial officer and our principal accounting officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, management has concluded that as of September 30, 2024, our disclosure controls and procedures were not effective due to the material weaknesses in internal control over financial reporting described below.

The Company's disclosure controls and procedures have been designed to ensure that: (i) information required to be disclosed by us in reports that we file or submit to the SEC under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms and (ii) material information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including the CEO and the CFO, as appropriate, to allow for accurate and timely decisions regarding required disclosure.

Management does not expect that our disclosure controls and procedures will prevent all error and all fraud. The effectiveness of our or any system of disclosure controls and procedures, however well designed and operated, can provide only reasonable assurance that the objectives of the system will be met and is subject to certain limitations, including the exercise of judgment in designing, implementing, and evaluating controls and procedures and the assumptions used in identifying the likelihood of future events.

Material Weaknesses in Internal Control over Financing Reporting Existing as of September 30, 2024

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Management concluded that the material weaknesses disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 continued to exist as of September 30, 2024. Specifically, management concluded that the following material weaknesses exist as of September 30, 2024:

- A material weakness related to information technology general controls ("ITGCs") that support our financial reporting processes; Management determined that we did not maintain effective controls over (i) user access to ensure appropriate segregation of duties and adequately restrict user and privileged access to financial applications, programs and data to the appropriate personnel; (ii) program change management for financial applications to ensure that information technology ("IT") program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately; and (iii) IT operations controls to ensure that critical interface jobs are monitored. As a result, our related IT dependent manual and application controls that rely upon the affected ITGCs, or information coming from IT systems with affected ITGCs, were also deemed ineffective.
- A material weakness related to revenue recognition. Management determined that certain control activities within the area of revenue did not operate effectively, specifically controls over the review of costs incurred in satisfaction of our performance obligations under collaboration arrangements.

Notwithstanding the identified material weaknesses, management does not believe that the deficiencies had an adverse effect on our reported operating results or financial condition, and management has determined that the financial statements and other information included in this report and other periodic filings present fairly in all material respects our financial condition and results of operations at and for the periods presented.

Plan for Remediation of Material Weaknesses

Our remediation efforts are ongoing, and we will continue our initiatives to implement measures designed to ensure that control deficiencies contributing to the material weaknesses are remediated, such that these controls are designed, implemented, and operating effectively. We are committed to making the necessary changes and improvements to our system of controls to address the material weaknesses in internal control over financial reporting described above.

Our renewed emphasis of designing and implementing improved processes and controls involves but is not limited to the following:

- Expand available resources with experience designing and implementing control activities, including ITGCs and automated controls, both by hiring internally and the use of third-party consultations and specialists.
- Adjust access profiles in IT systems and relevant software, and adjust access review controls accordingly.
- Refine the control to identify access profiles in IT systems and software that result in risks of segregation of duties.
- Perform ongoing training with control performers to improve documentation that supports effective control activities, including evidence over the completeness and accuracy of information produced by the Company.
- Add additional technical accounting resource to review our revenue accounting along with financial disclosures for collaboration arrangements on a quarterly basis.

We are in the process of implementing the remediation activities as of the date of this report and believe that upon completion, we will have strengthened our ITGCs, and controls related to accounting for collaboration arrangements to address and successfully remediate the identified material weaknesses. However, control weaknesses are not considered remediated until new internal controls have been operational for a period of time, are tested, and management concludes that these controls are operating effectively. We expect to complete the remediation activities in the fiscal year 2024. We will continue to monitor the effectiveness of these remediation measures, and we will make any changes to the design of this plan and take such other actions that we deem appropriate given the circumstances.

Changes in Internal Control over Financial Reporting

As required by Rule 13a-15(d) and Rule 15d-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial and accounting officer, conducted an evaluation of the internal control over financial reporting to determine whether any other changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and our principal financial and accounting officer concluded that there were no changes in our internal controls over financial reporting during the periods covered by this Quarterly Report on Form 10-Q that materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in various legal proceedings and subject to claims that arise in the ordinary course of business, including those related to governmental inquiries, intellectual property and commercial relationships. The subject matter of any such legal proceedings or claims are or will be highly complex and subject to substantial uncertainties. The outcome of any such proceedings or claims, regardless of the merits, are and will be inherently uncertain; therefore, assessing the likelihood of loss and any estimated damages is difficult and subject to considerable judgment.

Item 1A. Risk Factors.

Our business is subject to various risks, including those described in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which we strongly encourage you to review. There have been no material changes from the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Commission on March 14, 2024.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Arrangements

During the three months ended September 30, 2024, none of our directors or officers adopted or terminated a "Rule 10b5-1 trading arrangement" (as defined in Item 408 of Regulation S-K of the Exchange Act) intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

Item 6. Exhibits.**Exhibit Index**

Exhibit Number	Description
1.1	<u>Controlled Equity OfferingSM Sales Agreement, dated as of December 23, 2022 by and between Cantor Fitzgerald & Co, Wells Fargo Securities, LLC and Arcturus Therapeutics Holdings Inc. Incorporated by reference to Exhibit 1.2 to Registration Statement on Form S-3 filed on December 23, 2022 (File No. 333269003).</u>
1.2	<u>Amendment No. 1 to Controlled Equity OfferingSM Sales Agreement by and between Cantor Fitzgerald & Co, Wells Fargo Securities, LLC, William Blair & Company, L.L.C., and Arcturus Therapeutics Holdings Inc. Incorporated by reference to Exhibit 1.1 to Form 8-K filed on August 7, 2023.</u>
3.1	<u>Certificate of Incorporation. Incorporated by reference to Annex B to the proxy statement/prospectus which forms part of the Registration Statement on Form S-4 filed on March 18, 2019 (File No. 333-230353).</u>
3.2	<u>Certificate of Amendment, dated November 25, 2020. Incorporated by reference to Exhibit 3.1 to Form 8-K filed on November 25, 2020 (File No. 001-38942).</u>
3.3	<u>Bylaws of Arcturus Therapeutics Holdings Inc. Incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-3, filed with the SEC on May 8, 2020 (File No. 333-238139).</u>
4.1	<u>Description of Registrant's Securities. Incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed on February 28, 2022 (File No. 001-38942).</u>
10.1†	<u>Form of Indemnification Agreement. Incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 16, 2020 (File No. 001-38942).</u>
10.2†	<u>Amended and Restated 2019 Omnibus Equity Incentive Plan. Incorporated by reference Exhibit 4.3 to the Registration Statement on Form S-8 filed on August 5, 2020 (File No. 333-240397).</u>
10.3**	<u>Amended and Restated Amendment to Development and Option Agreement, dated as of September 28, 2018, by and between CureVac AG and Arcturus Therapeutics Inc. Incorporated by reference to Exhibit 99.2 to the Company's Report of Foreign Private Issuer on Form 6-K filed on October 1, 2018 (File No. 001-35932).</u>
10.4**	<u>Research and Exclusive License Agreement, by and between Arcturus Therapeutics, Inc. and Synthetic Genomics, Inc., effective October 24, 2017. Incorporated by reference to Exhibit 4.8 to Form 20-F filed on May 14, 2018 (File No. 001-35932).</u>
10.5**	<u>Research Collaboration and License Agreement, by and between Arcturus Therapeutics, Inc. and Ultragenyx Pharmaceutical Inc., entered into as of October 26, 2015, as amended October 17, 2017 and April 20, 2018. Incorporated by reference to Exhibit 4.10 to Form 20-F filed on May 14, 2018 (File No. 001-35932).</u>
10.6**	<u>Third Amendment to Research Collaboration and License Agreement, by and between Arcturus Therapeutics, Inc. and Ultragenyx Pharmaceutical Inc., effective June 18, 2019. Incorporated by reference to Exhibit 10.2 to Form 8-K filed on June 20, 2019 (File No. 001-38942).</u>
10.7**	<u>Letter Agreement, by and between Arcturus Therapeutics, Inc. and the Cystic Fibrosis Foundation, dated May 16, 2017. Incorporated by reference to Exhibit 4.11 to Form 20-F filed on May 14, 2018 (File No. 001-35932).</u>
10.8**	<u>Amendment No. 2 to Letter Agreement, by and between Arcturus Therapeutics, Inc. and the Cystic Fibrosis Foundation, dated August 1, 2019. Incorporated by reference to Exhibit 10.16 to Form 10-Q filed on August 14, 2019.</u>
10.9**	<u>Development and Option Agreement, by and between Arcturus Therapeutics, Inc. and CureVac AG, dated January 1, 2018, as amended May 3, 2018. Incorporated by reference to Exhibit 4.12 to Form 20-F filed on May 14, 2018 (File No. 001-35932).</u>
10.10**	<u>Third Amendment to Development and Option Agreement, by and between Arcturus Therapeutics, Inc. and CureVac AG, dated July 26, 2019. Incorporated by reference to Exhibit 10.20 to Form 10-Q filed on August 14, 2019 (File No. 001-38942).</u>
10.11**	<u>License Agreement, by and between Arcturus Therapeutics, Inc., as successor-in-interest to Marina Biotech, Inc., and Protiva Biotherapeutics Inc., dated as of November 28, 2012. Incorporated by reference to Exhibit 4.14 to Form 20-F/A filed on July 10, 2018 (File No. 001-35932).</u>

- 10.12** [Patent Assignment and License Agreement, by and between Arcturus Therapeutics, Inc. and Marina Biotech, Inc., dated as of August 9, 2013. Incorporated by reference to Exhibit 4.15 to Form 20-F filed on May 14, 2018 \(File No. 001-35932\).](#)
- 10.13 [Share Exchange Agreement, dated as of February 11, 2019, by and between Arcturus Therapeutics Ltd. and Arcturus Therapeutics Holdings Inc. Incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed on March 18, 2019 \(File No. 001-35932\).](#)
- 10.14 [Lease Agreement, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated October 4, 2017. Incorporated by reference to Exhibit 4.6 to Form 20-F filed on May 14, 2018 \(File No. 001-35932\).](#)
- 10.15 [First Amendment to Lease Agreement, by and between Arcturus Therapeutics Holdings Inc. and ARE-SD Region No. 44, LLC dated February 1, 2020. Incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 16, 2020 \(File No. 001-38942\).](#)
- 10.16** [Acceptance Letter, dated March 4, 2020, by and between Arcturus Therapeutics Holdings Inc. and the Economic Development Board of Singapore. Incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 16, 2020 \(File No. 001-38942\).](#)
- 10.17† [2020 Employee Stock Purchase Plan. Incorporated by reference to Exhibit 4.3 to Form S-8 filed on August 5, 2020 \(File No. 333-240392\).](#)
- 10.18 [Second Amendment to Lease, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated November 13, 2020. Incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed on March 1, 2020 \(File No. 001-38942\).](#)
- 10.19 [Third Amendment to Lease, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated February 25, 2021. Incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed on March 1, 2020 \(File No. 001-38942\).](#)
- 10.20 [Arcturus Therapeutics Holdings Inc. Severance Policy for Executives. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on April 26, 2021 \(File No. 001-38942\).](#)
- 10.21 [Lease, by and between Arcturus Therapeutics, Inc. and TPSC IX, LLC, dated September 29, 2021. Incorporated by reference to Exhibit 10.35 to Form 10-Q filed on November 9, 2021 \(File No. 001-38942\).](#)
- 10.22† [Arcturus Therapeutics Holdings Inc. 2021 Inducement Equity Incentive Plan. Incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-8 filed on October 20, 2021 \(File No. 333-260391\).](#)
- 10.23† [Amended and Restated 2019 Omnibus Equity Incentive Plan, as amended. Incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-8 filed on June 30, 2022.](#)
- 10.24** [Cost Reimbursement Contract dated August 31, 2022, by and between Arcturus Therapeutics Holdings Inc. and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services. Incorporated by reference to Exhibit 10.36 to Quarterly Report on Form 10-Q filed on November 9, 2022 \(File No. 001-38942\).](#)
- 10.25** [Study Support Agreement, dated October 31, 2022, by and between Arcturus Therapeutics, Inc. and Vinbiocare Research and Manufacture Joint Stock Company. Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on November 4, 2022 \(File No. 001-38942\).](#)
- 10.26** [Collaboration and License Agreement, dated November 1, 2022, by and between Arcturus Therapeutics Holdings Inc. and CSL Limited. Incorporated by reference to Exhibit 10.38 to Quarterly Report on Form 10-Q filed on November 9, 2022 \(File No. 001-38942\).](#)
- 10.27** [Manufacturing Support Agreement Termination Letter, dated March 23, 2023, by and between Arcturus Therapeutics, Inc. and the Economic Development of Singapore. Incorporated by reference to Exhibit 10.41 to Annual Report on Form 10-K filed on March 29, 2023 \(File No. 001-38942\).](#)
- 10.28** [Credit Agreement dated April 21, 2023, by and between Arcturus Therapeutics, Inc. and Wells Fargo Bank, National Association. Incorporated by reference to Exhibit 10.28 to Quarterly Report on Form 10-Q filed on May 9, 2023 \(File No. 001-38942\).](#)

- 10.29** [Security Agreement dated April 21, 2023, by and between Arcturus Therapeutics, Inc. and Wells Fargo Bank, National Association. Incorporated by reference to Exhibit 10.29 to Quarterly Report on Form 10-Q filed on May 9, 2023 \(File No. 001-38942\).](#)
- 10.30** [Revolving Line of Credit Note dated April 21, 2023, by and between Arcturus Therapeutics, Inc. and Wells Fargo Bank, National Association. Incorporated by reference to Exhibit 10.30 to Quarterly Report on Form 10-Q filed on May 9, 2023 \(File No. 001-38942\).](#)
- 10.31** [Amendment Number One to Collaboration and License Agreement, dated August 3, 2023, by and between Arcturus Therapeutics, Inc. and Seqirus Inc. Incorporated by reference to Exhibit 10.31 to Quarterly Report on Form 10-Q filed on November 14, 2023 \(File No. 001-38942\).](#)
- 10.32** [Amendment No. 4 to Letter Agreement, dated September 25, 2023, by and between Arcturus Therapeutics, Inc. and the Cystic Fibrosis Foundation. Incorporated by reference to Exhibit 10.32 to Quarterly Report on Form 10-Q filed on November 14, 2023 \(File No. 001-38942\).](#)
- 10.33** [Amendment Number Two to Collaboration and License Agreement, dated March 29, 2024, by and between Arcturus Therapeutics, Inc. and Seqirus Inc. Incorporated by reference to Exhibit 10.33 to Quarterly Report on Form 10-Q filed on May 8, 2024 \(File No. 001-38942\).](#)
- 10.34† [Amended and Restated 2019 Omnibus Equity Incentive Plan, as amended. Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on June 14, 2024 \(File No. 001-38942\).](#)
- 10.35** [First Amendment to Credit Agreement and First Amendment to Revolving Line of Credit, dated June 26, 2024, by and between Arcturus Therapeutics, Inc. and Wells Fargo Bank, National Association. Incorporated by reference to Exhibit 10.35 to Quarterly Report on Form 10-Q filed on August 5, 2024 \(File No. 001-38942\).](#)
- 10.36* [Fifth Amendment to Lease, by and between Arcturus Therapeutics, Inc. and ARE-SD Region No. 44, LLC, dated July 12, 2024.](#)
- 31.1* [Certification of Principal Executive Officer Pursuant to Rule 13a-14\(a\) or 15d-14\(a\) under the Securities Exchange Act of 1934, as amended.](#)
- 31.2* [Certification by Principal Financial Officer pursuant to Rule 13a-14\(a\) or 15d-14\(a\) under the Securities Exchange Act of 1934, as amended.](#)
- 32.1* [Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 32.2* [Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 101* The following financial statements and footnotes from the Registrant’s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2024 formatted in Inline Extensible Business Reporting Language (Inline XBRL):
101.INS Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH Inline XBRL Taxonomy Extension Schema
101.CAL Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB Inline XBRL Taxonomy Extension Label Linkbase
101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase
- 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Certain confidential portions of this exhibit have been redacted from the publicly filed document because such portions are (i) not material and (ii) would be competitively harmful if publicly disclosed.

† Management compensatory plan, contract or arrangement.

SIGNATURE

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.

ARCTURUS THERAPEUTICS HOLDINGS INC.

Date: November 7, 2024

By: /s/ Andy Sassine

Andy Sassine

Chief Financial Officer

Principal Financial and Accounting Officer

FIFTH AMENDMENT TO LEASE

THIS FIFTH AMENDMENT TO LEASE (this "Fifth Amendment") is made as of July ____, 2024, by

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and between **ARE-SD REGION NO. 44, LLC**, a Delaware limited liability company ("Landlord"), and **ARCTURUS THERAPEUTICS, INC.**, a Delaware corporation ("Tenant").

RECITALS

A.Landlord and Tenant are parties to that certain Lease Agreement dated as of October 4, 2017, as amended by that certain First Amendment to Lease dated as of January 31, 2020, as further amended by that certain Second Amendment to Lease dated as of November 13, 2020, as further amended by that certain Third Amendment to Lease dated as of February 25, 2021, and as further amended by that certain Fourth Amendment to Lease dated as of March 25, 2024 (as amended, the "Lease"), wherein Landlord leases to Tenant certain premises containing approximately 24,705 rentable square feet, commonly known as Suite 250, located at 10628 Science Center Drive, San Diego, California (the "Premises"), and certain temporary premises containing approximately 11,749 rentable square feet, commonly known as Suite 150, located at 10578 Science Center Drive, San Diego, California (the "Temporary Premises"), as more particularly described in the Lease. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.

B.The Term of the Lease, with respect to the Temporary Premises only, is scheduled to expire on March 31, 2025.

C.Landlord and Tenant desire, subject to the terms and conditions set forth below, to amend the Lease to, among other things, reflect the early termination of the Lease with respect to the Temporary Premises only as of the date this Fifth Amendment is executed (the "Temporary Premises Termination Date").

NOW, THEREFORE, in consideration of the foregoing Recitals, which are incorporated herein by this reference, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

- 1. Temporary Premises Termination.** The Term of the Lease with respect to the Temporary Premises shall terminate on the Temporary Premises Termination Date. Tenant shall voluntarily surrender the Temporary Premises on the Temporary Premises Termination Date in accordance with the surrender requirements contained in the Lease and in the condition in which Tenant is required to surrender the Temporary Premises pursuant to the Lease. From and after the Temporary Premises Termination Date, Tenant shall have no further rights of any kind with respect to the Temporary Premises. Notwithstanding the foregoing, those provisions of the Lease which, by their terms, survive the termination of the Lease shall survive the surrender of the Temporary Premises and termination of the Lease with respect to the Temporary Premises as provided for herein. Nothing herein shall excuse Tenant from its obligations under the Lease with respect to the Temporary Premises prior to the Temporary Premises Termination Date. If Tenant fails to surrender the Temporary Premises by the Temporary Premises Termination Date pursuant to this Section 1, such failure shall constitute a hold over without Landlord's consent under Section 8 of the original Lease. For the avoidance of doubt, the Term of the Lease shall otherwise continue in full force and effect with respect to the Premises.
- 2. Rent.** Tenant shall continue paying Base Rent, Operating Expenses, the Amenities Fee and all other amounts due under the Lease with respect to the Temporary Premises through the Temporary Premises Termination Date.
- 3. Brokers.** Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "Broker") in connection with the transaction reflected in this

Fifth Amendment and that no Broker brought about this transaction, other than Savills, Cushman & Wakefield and CBRE. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, other than Savills, Cushman & Wakefield and CBRE, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this Fifth Amendment.

4. California Accessibility Disclosure. The provisions of Section 44(r) of the original Lease are hereby incorporated into this Fifth Amendment by reference.

5. OFAC. Tenant and all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of the Lease remain in compliance with the regulations of the Office of Foreign Assets Control (“**OFAC**”) of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the “**OFAC Rules**”), (b) not listed on, and shall not during the term of the Lease be listed on, the Specially Designated Nationals and Blocked Persons List maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

6. Miscellaneous.

a. This Fifth Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. Reference to the Lease in this Fifth Amendment shall mean the Lease as amended by this Fifth Amendment. This Fifth Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. Once executed by both parties, this Fifth Amendment is binding upon and shall inure to the benefit of the parties hereto and their respective successors and assigns.

c. This Fifth Amendment may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Fifth Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Except as amended and/or modified by this Fifth Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Fifth Amendment. In the event of any conflict between the provisions of this Fifth Amendment and the provisions of the Lease, the provisions of this Fifth Amendment shall prevail. Whether or not specifically amended by this Fifth Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Fifth Amendment.

[Signatures are on the next page]

IN WITNESS WHEREOF, the parties hereto have executed this Fifth Amendment as of the day and year first above written.

TENANT:

ARCTURUS THERAPEUTICS, INC.,

a Delaware corporation

By:
Name: Joe Payne
Its: .President & CEO

I hereby certify that the signature, name, and title above are my signature, name and title

LANDLORD:

ARE-SD REGION NO. 44, LLC,
a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,

general partner

By:
Name: Gary Dean

Its: Executive Vice President – Real Estate Leg



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

The undersigned, the President and Chief Executive Officer of Arcturus Therapeutics Holdings Inc. (the "Company"), hereby certifies on the date hereof, pursuant to 18 U.S.C. 1350(a), as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q for the period ended September 30, 2024 (the "Form 10-Q"), filed concurrently herewith by the Company, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2024

By: _____ /s/ Joseph E. Payne

Joseph E. Payne
President and Chief Executive Officer

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

The undersigned, the Chief Financial Officer of Arcturus Therapeutics Holdings Inc. (the "Company"), hereby certifies on the date hereof, pursuant to 18 U.S.C. 1350(a), as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q for the period ended September 30, 2024 (the "Form 10-Q"), filed concurrently herewith by the Company, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2024

By: _____ /s/ Andy Sassine
Andy Sassine
Chief Financial Officer
