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, 2022

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: 001-39615

CODIAK BIOSCIENCES, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-4926530**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
35 CambridgePark Drive, Suite 500 Cambridge, MA	**02140**
(Address of principal executive offices)	**(Zip Code)**

(617) 949-4100
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

As of October 27, 2022, the registrant had 36,829,626 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains express or implied forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our ability to obtain sufficient funding for our operations, including funding necessary to complete the further development and commercialization of our product candidates and to continue our operations;
- the success, cost and timing of our product development activities, preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the effects on our business of our program reprioritization and restructuring of our operations;
- the design and conduct of our clinical trials of exoASO-STAT6;
- our ability to successfully advance any of our engEx product candidates into and through clinical trials, or obtain marketing approval;
- the potential and capabilities of our engEx Platform, engEx product candidates and engEx discovery programs;
- the potential and capability of our engEx Platform to generate additional engEx product candidates;
- our ability to secure from Lonza Rockland, Inc. ("Lonza"), under our manufacturing arrangement with them, sufficient supply of our product candidates for, clinical trials or commercial use, if approved;
- our ability to successfully procure from third parties sufficient supply of our product candidates for preclinical studies, clinical trials or commercial use, if approved;
- our ability to utilize our engEx Platform to engineer exosomes to carry various biologically active drug molecules, target specific cell types or cellular pathways or enhance the value of existing drug modalities;
- the potential indications that we may be able to target with engineered exosomes generated from our engEx Platform;
- the size, composition and growth potential of the patient populations and markets we intend to target with our engEx product candidates and our ability to develop and commercialize engEx product candidates to address those patient populations and markets;
- the ability and willingness of our current and future collaborators to continue research and development activities relating to our engEx exosomes;
- our ability to maintain regulatory approval, if obtained, of any of our current or future engEx product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to license intellectual property relating to our product candidates and to comply with our existing license and collaboration agreements;
- our ability to commercialize our products, if approved, in light of the intellectual property rights of others;
- developments relating to the use of exosomes to develop therapeutics;

- the success of competing therapies that are or become available;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our engEx product candidates and enhance the capabilities of our engEx Platform;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the rate and degree of market acceptance of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to attract and retain key scientific or management personnel;
- our shares of common stock could be delisted from the Nasdaq Global Market which could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act (the "JOBS Act");
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the impact of laws and regulations; and
- the direct or indirect impact of the COVID-19 pandemic on our business, operations, development timelines and the markets and communities in which we and our partners, collaborators, vendors and customers operate.

In some cases, you can identify forward-looking statements by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under “Summary of the Material Risks Associated with Our Business” and under the section titled “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 ("2021 Annual Report"), and elsewhere in this Quarterly Report on Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the Securities and Exchange Commission as exhibits hereto completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances that may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this Quarterly Report on Form 10-Q, their estimates, in particular as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors, including those discussed under the section titled “Risk Factors” and elsewhere in our 2021 Annual Report, and this Quarterly Report on Form 10-Q.

NOTE REGARDING COMPANY REFERENCES

Unless the context otherwise requires, the terms “Codiak,” “the Company,” “we,” “us,” and “our” in this Form 10-Q refer to Codiak BioSciences, Inc. and its consolidated subsidiaries.

Item 1. Financial Statements

CODIAK BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in thousands, except share and per share data)

	SEPTEMBER 30, 2022	DECEMBER 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 51,762	$ 76,938
Prepaid manufacturing services	6,727	7,315
Prepaid expenses and other current assets	2,744	5,918
Total current assets	61,233	90,171
Property and equipment, net of accumulated depreciation of $14,990 and $11,809	20,538	23,479
Restricted cash	4,170	4,170
Operating right-of-use assets	20,955	21,957
Prepaid manufacturing services, net of current portion	27,500	31,893
Total assets	$ 134,396	$ 171,670
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,956	$ 1,838
Accrued expenses	8,126	9,703
Deferred revenue	1,363	12,963
Operating lease liabilities	3,011	2,661
Total current liabilities	14,456	27,165
Long-term liabilities:		
Deferred revenue, net of current portion	17,317	30,686
Note payable, net of discount	25,693	25,430
Derivative liability - warrants	5,428	—
Operating lease liabilities, net of current portion	32,573	34,884
Total liabilities	95,467	118,165
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock, $0.0001 par value; 150,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 36,829,626 and 22,383,830 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	4	2
Additional paid-in capital	398,253	378,750
Accumulated deficit	(359,328)	(325,247)
Total stockholders' equity	38,929	53,505
Total liabilities and stockholders' equity	$ 134,396	$ 171,670

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

CODIAK BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, in thousands, except share and per share data)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Revenue:				
Collaboration revenue	$ 28	$ 1,157	$ 25,877	$ 15,238
Grant revenue	494	—	494	—
Total revenue	522	1,157	26,371	15,238
Operating expenses:				
Research and development	10,847	15,467	37,893	47,436
General and administrative	6,563	7,186	20,634	20,711
Impairment of prepaid manufacturing services	4,508	—	4,508	—
Total operating expenses	21,918	22,653	63,035	68,147
Loss from operations	(21,396)	(21,496)	(36,664)	(52,909)
Other income (expense):				
Interest expense	(758)	(689)	(2,007)	(2,091)
Interest income	119	4	157	18
Other income	35	479	1,711	1,163
Change in fair value of derivative liability - warrants	2,722	—	2,722	—
Total other income (expense), net	2,118	(206)	2,583	(910)
Net loss	$ (19,278)	$ (21,702)	$ (34,081)	$ (53,819)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.77)	$ (0.97)	$ (1.46)	$ (2.49)
Weighted average common shares outstanding, basic and diluted	25,159,757	22,325,334	23,373,684	21,599,405

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

CODIAK BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2022 AND 2021

(Unaudited, in thousands, except share data)

	COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED	TOTAL STOCKHOLDERS
	SHARES	AMOUNT	CAPITAL	DEFICIT	EQUITY
Balance at December 31, 2021	22,383,830	$ 2	$ 378,750	$ (325,247)	$ 53,505
Stock-based compensation	—	—	2,349	—	2,349
Issuance of common stock in at-the-market offering, net of issuance costs of $17	110,037	—	553	—	553
Net loss	—	—	—	(8,028)	(8,028)
Balance at March 31, 2022	22,493,867	2	381,652	(333,275)	48,379
Common stock issued under Employee Stock Purchase Plan (ESPP)	51,664	—	126	—	126
Stock-based compensation	—	—	2,668	—	2,668
Net loss	—	—	—	(6,775)	(6,775)
Balance at June 30, 2022	22,545,531	2	384,446	(340,050)	44,398
Stock-based compensation	—	—	2,287	—	2,287
Issuance of common stock in at-the-market offering, net of issuance costs of $12	126,266	—	384	—	384
Issuance of common stock, net of issuance costs of $491 and warrant $8,150	14,027,665	2	11,136	—	11,138
Issuance of common stock from restricted stock units	130,164	—	—	—	—
Net loss	—	—	—	(19,278)	(19,278)
Balance at September 30, 2022	36,829,626	$ 4	$ 398,253	$ (359,328)	$ 38,929

	COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED	TOTAL STOCKHOLDERS
	SHARES	AMOUNT	CAPITAL	DEFICIT	EQUITY
Balance at December 31, 2020	18,787,579	$ 2	$ 302,655	$ (288,090)	$ 14,567
Exercise of options to purchase common stock	46,807	—	316	—	316
Stock-based compensation	—	—	2,273	—	2,273
Issuance of common stock upon public offering, net of issuance costs of $560	3,162,500	—	61,868	—	61,868
Net loss	—	—	—	(10,308)	(10,308)
Balance at March 31, 2021	21,996,886	2	367,112	(298,398)	68,716
Exercise of options to purchase common stock	276,089	—	2,454	—	2,454
Stock-based compensation	—	—	2,690	—	2,690
Issuance costs related to common stock	—	—	(187)	—	(187)
Net loss	—	—	—	(21,809)	(21,809)
Balance at June 30, 2021	22,272,975	2	372,069	(320,207)	51,864
Exercise of options to purchase common stock	88,330	—	752	—	752
Stock-based compensation	—	—	3,092	—	3,092
Net loss	—	—	—	(21,702)	(21,702)
Balance at September 30, 2021	22,361,305	$ 2	$ 375,913	$ (341,909)	$ 34,006

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

CODIAK BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (34,081)	$ (53,819)
Adjustments to reconcile net loss to net cash from operating activities:		
Stock-based compensation expense	7,304	8,055
Change in fair value of derivative liability - warrants	(2,722)	—
Impairment of prepaid manufacturing services	4,508	—
Non-cash interest expense	308	392
Depreciation and amortization expense	3,181	4,205
Non-cash manufacturing expense	462	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,949	(651)
Prepaid manufacturing services	12	—
Operating right-of-use assets	1,003	745
Accounts payable	175	206
Accrued expenses	(1,725)	1,118
Deferred revenue	(24,970)	(11,953)
Operating lease liabilities	(1,962)	(920)
Net cash used in operating activities	(45,558)	(52,622)
Cash flows from investing activities:		
Purchases of property and equipment	(362)	(2,913)
Net cash used in investing activities	(362)	(2,913)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	—	3,523
Net cash received from Employee Stock Purchase Program (ESPP)	126	—
Proceeds from issuance of common stock, net of issuance costs	20,618	61,681
Net cash provided by financing activities	20,744	65,204
Net (decrease) increase in cash, cash equivalents and restricted cash	(25,176)	9,669
Cash, cash equivalents and restricted cash, beginning of period	81,108	93,085
Cash, cash equivalents and restricted cash, end of period	$ 55,932	$ 102,754
Supplemental disclosures:		
Cash paid for interest	$ 1,696	$ 1,713
Non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 28	$ 388
Offering costs included in accrued expenses	$ 267	$ —
Issuance of derivative liability - warrants	$ 8,150	$ —

	AS OF SEPTEMBER 30,	
Reconciliation to amounts within the consolidated balance sheets	**2022**	**2021**
Cash and cash equivalents	$ 51,762	$ 98,584
Restricted cash	4,170	4,170
Cash, cash equivalents and restricted cash at end of period	$ 55,932	$ 102,754

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

1. Nature of the Business

Codiak BioSciences, Inc. (collectively, with its consolidated subsidiaries, any of "Codiak", "we", "us", or the "Company") was incorporated in Delaware on June 12, 2015 and is headquartered in Cambridge, Massachusetts. Codiak is a clinical-stage biopharmaceutical company focused on pioneering the development of exosome-based therapeutics, a new class of medicines with the potential to transform the treatment of a wide spectrum of diseases with high unmet medical need. Exosomes have evolved as intercellular transfer mechanisms for complex, biologically active macromolecules and have emerged in recent years as a compelling potential drug delivery vehicle. By leveraging its deep understanding of exosome biology, the Company has developed its engineering and manufacturing platform (the "engEx Platform"), to expand upon the innate properties of exosomes to design, engineer and manufacture novel exosome therapeutics. Codiak has utilized its engEx Platform to generate a deep pipeline of engineered exosomes ("engEx exosomes") aimed at treating a broad range of diseases, including oncology, and infectious disease and rare disease. In September 2020, Codiak initiated clinical trials for two of its lead product candidates, exoSTING and exoIL-12, which were being developed to address oncology indications. In June 2022, the Company initiated a Phase 1 clinical trial of exoASO-STAT6, Codiak's first systemically delivered exosome therapeutic candidate. In August 2022, the Company paused clinical trials for exoSTING and exoIL-12 to prioritize focus on its Phase 1 clinical trial for exoASO-STAT6 (see Note 13).To the Company's knowledge, exoSTING and exoIL-12 are the first engineered exosomes to enter clinical development.

Since its inception, the Company has devoted substantially all of its resources to its research and development efforts, including activities to develop its engEx Platform, advance engEx product candidates into clinical trials, perform preclinical research to identify potential engEx product candidates, perform process development to refine Codiak's exosome engineering and manufacturing processes, and provide general and administrative support for these operations.

The Company has primarily funded its operations with proceeds from the sales of common stock, redeemable convertible preferred stock, collaborative and research arrangements with Jazz Pharmaceuticals Ireland Limited ("Jazz") and Sarepta Therapeutics, Inc. ("Sarepta") and its loan and security agreement with Hercules Capital, Inc. ("Hercules"). As of September 30, 2022, the Company has raised an aggregate of $168.2 million through the issuance of its redeemable convertible preferred stock and convertible debt, net of issuance costs, $24.6 million from its term loan facility with Hercules, net of issuance costs, and received $66.0 million in payments from its collaborations with Jazz and Sarepta. On October 16, 2020, the Company completed its initial public offering ("IPO"), pursuant to which it issued and sold 5,500,000 shares of its common stock at a public offering price of $15.00 per share, resulting in net proceeds of $74.4 million, after deducting underwriting discounts and commissions and other offering expenses. On February 17, 2021, the Company completed a follow-on public offering, pursuant to which it issued 3,162,500 shares of its common stock (inclusive of the exercise of the underwriter's option to purchase 412,500 additional shares of common stock) at a public offering price of $21.00 per share, resulting in aggregate net proceeds of $61.7 million, after deducting underwriting discounts and commissions and other offering expenses. On September 15, 2022, the Company completed a follow-on public offering, pursuant to which it issued 14,027,665 shares of its common stock and accompanying warrants to purchase 14,027,665 shares of its common stock (inclusive of the partial exercise of the underwriter's option to purchase 694,332 additional shares of common stock and accompanying warrants to purchase 694,332 additional shares of common stock) at a combined public offering price of $1.50 per share, resulting in aggregate net proceeds of $19.8 million, after deducting underwriting discounts and commissions and other offering expenses. During the nine-month period ended September 30, 2022, the Company raised $0.9 million utilizing an "at-the-market" offering facility, pursuant to which it sold 236,303 shares of its common stock.

The Company has incurred significant operating losses and negative cash flows from operations since inception and expects to continue to incur operating losses for the foreseeable future. In addition, the Company anticipates that its expenses will increase significantly in connection with ongoing activities to support its engEx Platform development, drug discovery and preclinical and clinical development, in addition to creating a portfolio of intellectual property and providing administrative support.

The Company does not expect to generate significant revenue from sales of its engEx product candidates unless and until clinical development has been successfully completed and regulatory approval is obtained. If the Company obtains regulatory approval for any of its investigational products, it expects to incur significant commercialization expenses.

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. The Company expects that its cash and cash equivalents of $51.8 million as of September 30, 2022 will be insufficient to allow the Company to fund its current operating plan through at least the next 12 months from the issuance of these financial statements. Maintaining the Company's ongoing operations is dependent upon its ability to obtain additional financing, as to which it can make no assurance. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of at least one year from the date these financial statements are issued. Accordingly, the Company will be required to raise additional funds through an additional public equity financing, establish collaborations with or license its technology to other companies, or seek alternative means of financial support in order to continue to fund its operations in the future. There can be no assurance, however, that additional fundraising will be successful and available on terms acceptable to the Company, or at all. If the Company is unable to raise capital when needed or on attractive terms, it may be forced to delay, reduce, or eliminate certain costs related to its operations and research and development programs.

The Company is subject to those risks associated with any biopharmaceutical company that has substantial expenditures for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees and consultants. If the Company fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and be forced to reduce its operations.

2. Summary of Basis of Presentation and Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The unaudited condensed consolidated financial statements that accompany these notes have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and applicable rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial reporting, consistent in all material respects with those applied in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 ("2021 Annual Report") as filed with the SEC on March 10, 2022. Any reference in these notes to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the U.S. as found in the Accounting Standard Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). This report should be read in conjunction with the consolidated financial statements in the Company's 2021 Annual Report.

The consolidated financial statements include the Company and its subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

We have made estimates and judgments affecting the amounts reported in our consolidated financial statements and the accompanying notes. On an ongoing basis, we evaluate our estimates, including critical accounting policies or estimates related to revenue recognition, stock-based compensation, accrued expenses, leases, gain upon derecognition, contingent consideration, prepaid manufacturing services, warrants and impairment assessments. We base our estimates on historical experience and various relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. The actual results that we experience may differ materially from our estimates.

Accounting Pronouncements and Significant Accounting Policies

The Company reviews new accounting standards as they are issued by the FASB or other standard-setting bodies. As of September 30, 2022, the Company has not identified any new standards that it believes will have a material impact on the Company's financial statements.

Restructuring

The Company records costs and liabilities associated with exit and disposal activities based on estimates of fair value in the period in which the liabilities are incurred. The Company evaluates and adjusts these costs as appropriate for changes in circumstances as additional information becomes available. Restructuring costs comprise severance costs related to workforce reductions. When employees are not required to provide service beyond the minimum retention period, employee termination benefits are accrued at the date management has committed to a plan of termination and employees have been notified of their termination dates and expected severance payments.

Grant Revenue

The Company received a grant award from the Coalition for Epidemic Preparedness Innovations ("CEPI") for research and development related activities that provide for payments for qualifying costs, which may include overhead and general and administrative costs. We recognize revenue from this agreement as we perform services under the arrangement when the funding is committed and the costs are deemed to qualify pursuant to the grant. Associated expenses are recognized when incurred as research and development expenses. The services being rendered under this agreement are part of the Company's primary operations. Revenues and related expenses are presented gross in the consolidated statements of operations as we have determined we are the primary obligor under the arrangements relative to the research and development services we perform.

Derivative Liability - Warrants

In September 2022, the Company completed a follow-on offering of common stock. In connection with the follow-on offering, each share of common stock issued was accompanied by a warrant to purchase a single share of common stock. These warrants are derivative financial instruments under ASC Topic 815, *Derivatives and Hedging* ("ASC 815") and do not qualify for the scope exceptions from derivative accounting. These derivatives are recorded as liabilities at fair value each reporting date and the fair value is determined using the Black-Scholes option-pricing model. The warrants are initially recorded as a reduction to proceeds from the common stock issuance in additional paid-in-capital. The changes in fair value are recorded as a component of other (expense) income in the consolidated statements of operations. Significant inputs used to determine the fair value at execution and as of September 30, 2022, included the price per share of the Company's common stock, expected terms of the derivative instruments, strike price of the derivative instrument, risk-free interest rate, and expected volatility of peer company common stock. Changes to these inputs could materially affect the valuation of the warrants.

There were no other changes to the Company's significant accounting policies during the nine months ended September 30, 2022.

3. Derecognition of Business

Arrangement Summary

On November 1, 2021, the Company entered into an Asset Purchase Agreement (the "APA") with Lonza Rockland, Inc. ("Lonza"). Under the terms of the APA, Lonza acquired all of the assets, properties and rights related to the Company's business of manufacturing exosomes for use in clinical and non-clinical studies and the associated laboratory facility, with the exception of any activities associated with exosome modification and formulation. The closing of the transactions contemplated by the APA (the "Lonza Closing") occurred on November 15, 2021. In connection with the Lonza Closing, certain specialized manufacturing and quality personnel of the Company became employees of Lonza.

In connection with the Lonza Closing, the Company entered into a Manufacturing Services Agreement (the "MSA") with Lonza, which became effective on November 15, 2021. Pursuant to the terms of the MSA, Lonza became the exclusive manufacturing partner for the production of the Company's exosome products, subject to limited exceptions. As consideration for the transactions contemplated by the APA and the associated ancillary agreements, the Company is entitled to approximately $65.0 million worth of exosome manufacturing services for its clinical programs during the next four years. To the extent the Company elects to use any free and/or discounted manufacturing services available under the MSA, it would be responsible for bearing any accompanying materials costs, external costs and a handling fee. Lonza is permitted to terminate the MSA with 12 months advance notice provided at any time after November 15, 2023. Accordingly, the Company's ability to utilize the free and discounted manufacturing services available under the MSA in periods beyond November 15, 2024 is subject to Lonza's right to terminate. The MSA may also be terminated upon the occurrence of certain other events, including customary termination provisions.

Concurrently with the Lonza Closing, the Company and Lonza executed a license and collaboration agreement (the "License Agreement") on November 15, 2021. Pursuant to the terms of the License Agreement, the Company granted to Lonza an exclusive, worldwide, perpetual and sublicensable license to its high-throughput exosome manufacturing intellectual property in the contract development and manufacturing field. The Company is eligible to receive from Lonza a double-digit percentage of future sublicensing revenues per the terms of the License Agreement. No sublicensing revenue had been received by the Company or earned by Lonza as of September 30, 2022.

Also contemporaneous with the Lonza Closing, the Company and Lonza entered into a sublease agreement (the "Sublease Agreement"), pursuant to which Lonza subleased the premises at which the Company's exosome manufacturing operations were located. The initial lease term commenced on November 15, 2021 and continues through November 30, 2024. Under the terms of the Sublease Agreement, Lonza is obligated to pay the Company approximately $1.0 million of fixed rent charges per year, subject to a 2.8% annual increase, plus certain operating expenses and other costs. The Company retained the primary obligation under the original lease upon execution of the Sublease Agreement.

Upon termination of the MSA on or prior to December 31, 2025, some aspects of the transactions contemplated by the APA and related ancillary agreements are required to be reverted, including with respect to certain assets, properties and rights that were transferred to Lonza. Upon termination or expiration of the Sublease Agreement at any time after December 31, 2025, some aspects of the transactions contemplated by the APA and related ancillary agreements are subject to potential reversion at Lonza's option, including with respect to certain assets, properties and rights that were transferred to Lonza.

Accounting Analysis

The APA and pertinent elements of the MSA, the License Agreement and the Sublease Agreement comprise a single transaction because they were entered into in contemplation of one another and designed to achieve an overall commercial effect. Together, the related transactions consummated amongst the multiple contracts culminate in the transfer of the Company's exosome manufacturing operations to Lonza (the "Lonza Transfer Transaction").

The Lonza Transfer Transaction represents the disposition of a business. Accordingly, the Company applied the derecognition guidance in ASC 810 in accounting for the transaction since Lonza is not a customer for any aspect of the arrangement. The Company's control over the exosome manufacturing business transferred to Lonza was lost upon the closing of the APA and related ancillary agreements on November 15, 2021. Therefore, the Company recognized a gain upon derecognition on November 15, 2021.

The gain was calculated as the difference between: (i) the fair value of the non-cash consideration and (ii) the carrying amount of the underlying group of assets. Because Lonza is entitled to terminate the MSA for any or no reason with 12 months' notice after November 15, 2023, the Company determined that any non-cash consideration scheduled beyond November 15, 2024 is contingent consideration since its ability to utilize the associated free and discounted manufacturing services is subject to Lonza's right to terminate. The Company also treated the sublicensing revenue that may become payable under the License Agreement as contingent consideration as the receipt of any such amounts is dependent on Lonza engaging in sublicensing transactions, which is not expected to be material. Neither of the elements of contingent consideration is required to be accounted for as a derivative instrument because either the payments do not meet the definition of a derivative or qualify for a scope exception from derivative accounting.

Consequently, the consideration attributable to the Lonza Transfer Transaction is limited to the non-cash consideration due to the Company under the MSA and the sublicensing fees to which the Company is entitled under the License Agreement. The Company recorded the aggregate consideration, including the contingent consideration, at its fair value as of November 15, 2021. The aggregate fair value of the non-cash consideration represents the total discounted cash flows associated with the manufacturing expenditures expected to be avoided over the period the free and discounted services are available. The value of the costs that would otherwise be incurred was determined in reference to comparable costs charged by unrelated third parties. The Company also incorporated a breakage factor in deriving the estimated fair value of the non-cash consideration to reflect expectations around utilization by the Company and termination by Lonza. The Company classified the MSA as a Level 3 fair value measurement at the date of the closing of the transaction. The discounted cash flow approach relies primarily on Level 3 unobservable inputs, whereby expected future cash flows are discounted using a rate that includes assumptions regarding an entity's average cost of debt and equity, incorporates expected future cash flows based on internal business plans, and applies certain assumptions about risk and uncertainties. As of November 15, 2021, the Company estimated the aggregate fair value of such non-cash consideration, including the associated contingent consideration, to be approximately $39.2 million. The Company does not expect to earn any significant sublicensing fees or other consideration from the transaction.

Amounts payable under the Sublease Agreement based on the contractually stated rates approximate the fair value of the associated rights conveyed as of November 15, 2021. Therefore, the Company has accounted for the Sublease Agreement separately from the disposition of the business. No amount has been allocated from the other consideration in the arrangement to this element.

The Company has recorded the aggregate fair value of the non-cash consideration as a prepaid manufacturing services asset as of November 15, 2021. The Company will amortize the prepaid manufacturing services asset as requested services are rendered by Lonza under the MSA, subject to impairment assessments. Such amount is classified as current or noncurrent based on the timing of when the associated services are expected to be utilized by the Company. Amounts expected to be consumed within the 12 months following September 30, 2022 are classified within current assets as prepaid manufacturing services as of September 30, 2022, while the remainder was classified as a noncurrent asset as of September 30, 2022. The Company periodically assesses whether its prepaid manufacturing services asset is impaired based on its forecasted manufacturing needs. The use of the prepaid manufacturing services asset is heavily dependent on the continued progress of the Company's current product candidates. Should there be changes to the Company's forecasted manufacturing needs, the Company may be required to record an impairment charge. The Company has utilized $0.5 million of the prepaid manufacturing services for preliminary work as of September 30, 2022, which is recorded as research and development expenses. During the three and nine months ended September 30, 2022, the Company mutually agreed with Lonza to not utilize a portion of prepaid manufacturing services under the MSA in 2022. As the services were not being utilized, the Company recognized an impairment charge to the prepaid manufacturing services asset of $4.5 million, which is reflected in the consolidated statements of operations.

4. Fair Value Measurements

The following tables present information about the Company's assets measured at fair value on a recurring basis, and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	SEPTEMBER 30, 2022				
	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3	NOT SUBJECT TO LEVELING(1)
Liabilities:					
Derivative liability – warrants	$ 5,428	$ —	$ —	$ 5,428	$ —
	$ 5,428	$ —	$ —	$ 5,428	$ —

	DECEMBER 31, 2021				
	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3	NOT SUBJECT TO LEVELING(1)
Assets:					
Cash equivalents:					
Money market funds	$ 67,603	$ —	$ —	$ —	$ 67,603
	$ 67,603	$ —	$ —	$ —	$ 67,603

(1) Certain cash equivalents that are valued using the net asset value per share (or its equivalent) practical expedient have not been classified in the fair value hierarchy.

As of September 30, 2022 the Company held no cash equivalents. As of December 31, 2021, the Company's cash equivalents consisted of money market funds invested in U.S. Treasury securities with original maturities of less than 90 days from the date of purchase.

Warrants

The Company's warrants are recorded as derivative liabilities, and are classified as Level 3 measurements under the fair value hierarchy. These derivatives are not actively traded and are valued using the Black-Scholes option-pricing model, which requires the use of subjective assumptions.

The following inputs were used in the fair market valuation of warrants as of September 30, 2022:

	September 30, 2022
Risk-free rate(1)	4.06%
Expected term	4.96
Stock price(2)	$ 0.78
Strike price(3)	$ 1.88
Common stock volatility(4)	79.93%
Dividend yield(5)	—%

(1) Based on the U.S. Treasury yield curve, with terms commensurate with the expected term of the warrants.
(2) The closing price of the Company's common stock on the last trading day of the quarter ended September 30, 2022.
(3) As per the agreement for the warrant.
(4) Expected volatility based on historical volatility of the Company's peer companies that are commensurate with the expected term of the warrants.
(5) The Company has not paid and does not anticipate paying cash dividends on its shares of common stock in the foreseeable future; therefore, the expected dividend yield is assumed to be zero.

The warrants are recorded at fair value at each reporting date and changes in fair value are recorded in other (expense) income, net within the Company's consolidated statements of operations.

The following table reflects the change in the Company's Level 3 warrants from December 31, 2021 through September 30, 2022 (in thousands):

	Warrants (in thousands)
Balance at December 31, 2021	$ —
Issuance fair value at September 15, 2022	8,150
Change in fair value, recorded as a gain on derivative liability - warrants	(2,722)
Balance at September 30, 2022	$ 5,428

5. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	SEPTEMBER 30, 2022	DECEMBER 31, 2021
Employee compensation	$ 4,266	$ 5,142
External research and development costs	2,045	2,420
Professional services and consulting	1,201	1,523
Facilities costs	263	190
Other expenditures	351	428
	$ 8,126	$ 9,703

6. Leases

The Company has several long-term non-cancelable lease arrangements for its facilities, expiring at various times through 2029. Certain arrangements have free rent periods or escalating rent payment provisions; costs under such arrangements are recognized on a straight-line basis over the life of the leases. The Company has two locations in Massachusetts, its office and laboratory, located in Cambridge and manufacturing space, located in Lexington, which is currently being leased and operated by Lonza (see Note 3).

Operating Leases

4 Hartwell Place

On March 5, 2019, the Company entered into a lease for manufacturing space at 4 Hartwell Place in Lexington, Massachusetts. Under the terms of the lease, the Company leases 18,707 square feet for $0.9 million per year in base rent, which is subject to a 2.6% annual rent increase during the initial lease term, plus certain operating expenses and taxes. The lease term commenced in July 2019 and will end in December 2029. The Company has the option to extend the lease twice, each for a five-year period, on the same terms and conditions as the current lease, subject to a change in base rent based on market rates. The Company had fully occupied the space as of December 31, 2020. Upon execution of the lease agreement, the Company provided a security deposit of $0.4 million, which is held in the form of a letter of credit and was classified as non-current restricted cash as of September 30, 2022 and December 31, 2021. The lease provided the Company with a tenant improvement allowance of $1.3 million, which is being amortized as a reduction to rent expense over the remaining lease term. As of September 30, 2021, the Company had received all $1.3 million of the tenant improvement allowance. Costs incurred related to the allowance are capitalized as leasehold improvements.

On November 15, 2021, the Company entered into an amendment to the lease (the "Master Lease Amendment") for the property located at 4 Hartwell Place in Lexington, Massachusetts. The only change to the terms of the lease was to increase the base rent by $0.1 million per year. There were no initial direct costs incurred, incremental incentives received or any other payments made to or by the Company with respect to the Master Lease Amendment. The Company accounted for the changes made to the lease agreement as a lease modification. The Company determined that the associated lease should continue to be accounted for as an operating lease with a lease term commensurate with the initial lease term, which ends in December 2029. The Company remeasured the lease liability as of November 15, 2021, based on the then-current applicable incremental borrowing rate resulting in an increase of $1.0 million, which was offset by an equal adjustment made to the corresponding right-of-use asset.

35 CambridgePark Drive

On March 22, 2019, the Company entered into a non-cancelable property lease for its corporate headquarters, which included office and laboratory space at 35 CambridgePark Drive in Cambridge, Massachusetts. Under the terms of the lease, the Company leases 68,258 square feet for $4.9 million per year in base rent, which is subject to a 3.0% annual rent increase during the initial lease term, plus certain operating expenses and taxes. The Company accounts for this lease as an operating lease. The lease term commenced on March 26, 2019 and is expected to end in November 2029. The Company has the option to extend the lease for a 10-year period on the same terms and conditions as the current lease, subject to a change in base rent based on market rates. The Company occupied the space in February 2020 as its new corporate headquarters. Upon execution of the lease agreement, the Company provided a security deposit of $3.7 million, which is held in the form of a letter of credit and was classified as non-current restricted cash as of September 30, 2022 and December 31, 2021. The lease provides the Company with a tenant improvement allowance of $12.3 million, subject to reduction for a 2.0% construction oversight fee due to the landlord, which is being amortized as a reduction to rent expense over the remaining lease term. The Company has received all $12.3 million of the tenant improvement allowance. Costs incurred related to the allowance are capitalized as leasehold improvements.

Subleases

4 Hartwell Place

On November 15, 2021, the Company entered into a sublease agreement with Lonza for the entirety of its leased space at 4 Hartwell Place in Lexington, Massachusetts. Under the terms of the Sublease Agreement, Lonza is obligated to pay the Company base rent of $1.0 million per year, subject to a 2.8% annual increase, plus certain operating expenses and other costs. The initial lease term commenced on November 15, 2021 and continues through November 30, 2024. Lonza has the option to extend the sublease term for five 12-month periods on the same terms and conditions as the current sublease, subject to an increase of 2.8% in the annual fixed rent charges. Additionally, Lonza has the right to have the associated master lease assigned to it beginning on January 1, 2026, subject to the landlord's consent. As of September 30, 2022, the Company has not been legally released from its primary obligations under the original lease. Therefore, the Company continues to account for the original lease as it did before commencement of the sublease, inclusive of the effects of the Master Lease Amendment. The Company determined that the sublease term is commensurate with the initial sublease term because it is not reasonably certain that any of the extension options will be exercised.

35 CambridgePark Drive

On April 27, 2020, the Company entered into a sublease for 23,280 square feet of its leased space at 35 CambridgePark Drive. Under the terms of the sublease, the sublessee was to pay the Company $1.3 million per year, which was subject to a 3.0% annual rent increase, plus certain operating expenses. The lease term commenced on May 18, 2020 and was expected to end in May 2022. Effective July 1, 2021, the sublessee exercised its option to extend the sublease for a one-year period through May 2023, on the same terms and conditions as the original sublease, subject to a change in base rent based on the greater of (i) an increase of 3.0% of the annual rent owed by the sublessee in year two, and (ii) market rent for the subleased premises. Upon execution of the sublease agreement, the sublessee provided the Company a security deposit of $0.3 million, which is held in the form of a letter of credit. In July 2022, the sublessee defaulted on its lease payments. The Company and the sublessee mutually agreed to terminate the sublease effective September 16, 2022. The Company claimed the $0.3 million security deposit and wrote off lease assets of $0.4 million, which was recorded in other income. The Company is currently marketing the sublease to new tenants.

During the three and nine months ended September 30, 2022, the Company recognized sublease income of $0.4 million and $2.1 million, respectively, which was recorded in other income. During the three and nine months ended September 30, 2021, the Company recognized sublease income of $0.5 million and $1.2 million, respectively, which was recorded in other income.

The components of operating lease costs were as follows (in thousands):

	FOR THE THREE MONTHS ENDED SEPTEMBER 30,		FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Operating lease costs	$ 1,240	$ 1,208	$ 3,720	$ 3,626
Short-term lease costs	5	8	12	21
Variable lease costs	712	638	2,026	1,897
Sublease income	(430)	(484)	(2,102)	(1,188)
	$ 1,527	$ 1,370	$ 3,656	$ 4,356

Variable lease costs were primarily related to operating expenses, taxes and utilities associated with the operating leases, which were assessed based on the Company's proportionate share of such costs for the leased premises.

Additional lease information is summarized in the following table (in thousands, except lease term and discount rate):

	FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021
Cash paid for amounts included in the measurement of operating lease liabilities	$ 4,700	$ 4,500
Weighted-average remaining lease term - operating leases (years)	7.2	8.2
Weighted-average discount rate - operating leases	10.1%	10.3%

Undiscounted cash flows used in calculating the Company's operating lease liabilities and amounts to be received under the sublease at 4 Hartwell Place as of September 30, 2022 are as follows (in thousands):

Fiscal Year	OPERATING LEASE PAYMENTS	SUBLEASE RECEIPTS	NET OPERATING LEASE PAYMENTS
2022 (remainder of the year)	$ 1,573	$ 250	$ 1,323
2023	6,436	1,024	5,412
2024	6,625	965	5,660
2025	6,820	—	6,820
2026	7,020	—	7,020
Thereafter	21,779	—	21,779
Total undiscounted cash flows	$ 50,253	$ 2,239	$ 48,014
Less: Amounts representing interest	(14,669)		
Present value of lease liabilities	$ 35,584		

7. Commitments and contingencies

Manufacturing Services Agreement

The Company and Lonza entered into a MSA, which became effective on November 15, 2021. The MSA outlines the terms and conditions under which Lonza will develop, manufacture and supply exosome products for development and clinical purposes. The parties will negotiate and execute an amendment to the MSA to address the commercial manufacture of the Company's exosome products. Each individual project to be completed under the MSA is governed by an associated statement of work which sets forth the activities to be performed, timeline, charges and payment schedule applicable to such project. Pricing is established on a project-by-project basis. Statements of work are executed between the parties on an as-requested basis. Activities had commenced with respect to outstanding statements of work as of September 30, 2022. The Company is subject to certain cancellation fees and/or other charges upon its termination of statements of work and in the event of a suspension or delay in the conduct of statements of work, including with respect to the reimbursement of non-cancelable costs incurred by Lonza. As of September 30, 2022, the Company has not incurred any cancellation fees or other charges relating to a termination, suspension or delay of outstanding statements of work.

Under the terms of the MSA, the Company is obligated to purchase the entirety of its aggregate production needs from Lonza, subject to limited exceptions. Starting on July 1, 2022, the Company was initially scheduled to provide to Lonza rolling forecasts of its anticipated manufacturing time requirements for the next 24 months from the date of the forecast, which will be updated no less frequently than quarterly. The delivery of rolling forecasts was postponed to September 2022, as agreed to by Lonza and the Company and the initial forecast has been provided to Lonza as of September 30, 2022. The first 12 months of each forecast will be a binding commitment, while the remaining 12 months will be non-binding. Commencing on January 1, 2026, the Company is bound by a commitment to purchase from Lonza a minimum of a specified number of weeks of manufacturing time each year at a predetermined price throughout the term of the arrangement. The Company's minimum purchase commitments under the MSA may be relieved at its option upon the occurrence and during the pendency of certain liquidation events or clinical discontinuations. As of September 30, 2022, the Company did not have any minimum non-cancelable purchase obligations under the MSA.

Pursuant to the terms of the MSA, the Company is entitled to a specified number of weeks of manufacturing time and a defined number of technology transfers from Lonza at no cost, with the exception of any accompanying materials costs, external costs and a handling fee. Additionally, the terms of the MSA provide the Company with a specified number of weeks of manufacturing time from Lonza at a discounted rate, subject to annual adjustment. The Company bears the expense associated with any materials costs, external costs and a handling fee related to the discounted manufacturing time. Manufacturing services in excess of the free and discounted time are priced at a fixed weekly rate, plus materials costs, external costs and a handling fee. The Company's consumption of the free and discounted manufacturing time, including the associated technology transfer services, is subject to a contractually-specified apportionment by year, which commenced in 2022 and continues through 2025. The Company's failure to use the free and discounted manufacturing time within the assigned period results in its forfeiture unless such inability is not due to the Company or Lonza permits carryover to a subsequent period. The Company has utilized $0.5 million of the manufacturing services for preliminary work as of September 30, 2022, which is recorded as research and development expenses. During the three and nine months ended September 30, 2022, the Company mutually agreed with Lonza to not utilize a portion of prepaid manufacturing services under the MSA in 2022. As the services were not being utilized, the Company recognized an impairment charge to the prepaid manufacturing services asset of $4.5 million, which is recorded within operating expenses.

Unless earlier terminated or extended by the parties, the MSA remains in effect until the earlier of the: (i) fifth anniversary of the first approval of a biologics license application by the FDA for any of the Company's exosome products or (ii) tenth anniversary of Lonza's completion of the services associated with the free manufacturing time. The MSA is subject to customary termination provisions. Additionally, Lonza may terminate the MSA with 12 months' advance notice for any or no reason at any time after November 15, 2023. To the extent the MSA is terminated on or prior to December 31, 2025, certain aspects of the transactions consummated in connection with the Lonza Transfer Transaction will be reverted, including with respect to assets, properties and rights that were transferred to Lonza effective on November 15, 2021.

Lonza has the right to cease manufacturing under the MSA upon either: (i) the Company unreasonably withholding, conditioning or delaying its approval of certain price changes or (ii) the Company enduring certain liquidation events or clinical discontinuations. Any termination of the MSA for any reason will be without prejudice to any rights that will have accrued to the benefit of a party prior to such termination.

Purchase orders

The Company has agreements with third parties for various services, including services related to clinical and preclinical operations and support, for which the Company is not contractually able to terminate for convenience to avoid future obligations to the vendors. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, the Company is contractually obligated to make certain payments to vendors, primarily to reimburse them for their unrecoverable outlays incurred prior to cancelation. The actual amounts the Company could pay in the future to the vendors under such agreements may differ from the purchase order amounts due to cancellation provisions.

Indemnification agreements

The Company enters into standard indemnification agreements and/or indemnification sections in other agreements in the ordinary course of business. Pursuant to the agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company does not believe that the outcome of any existing claims under indemnification arrangements will have a material impact on its financial statements, and it had not accrued any liabilities related to such obligations as of September 30, 2022 or December 31, 2021.

Legal proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of FASB ASC Topic 450, *Contingencies*. The Company expenses costs related to its legal proceedings as incurred.

8. Indebtedness

On September 30, 2019 (the "Hercules Closing Date"), the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules pursuant to which a term loan in an aggregate principal amount of up to $75.0 million (the "Term Loan Facility") was available to the Company in four tranches, subject to certain terms and conditions. On the Hercules Closing Date, $10.0 million of the first tranche was advanced to the Company and an additional $15.0 million under the first tranche was drawn down on July 24, 2020. Under the Loan Agreement, there were three additional tranches available to the Company of $10.0 million ("tranche two"), $10.0 million ("tranche three"), and $30.0 million ("tranche four"). As of September 30, 2022, tranches two, three and four had expired.

Upon issuance, the initial advance under the first tranche was recorded as a liability with an initial carrying value of $9.5 million, net of debt issuance costs. The July 24, 2020 advance under the first tranche was recorded as a liability with an initial carrying value of $15.0 million. The initial carrying value of all outstanding advances is accreted to the repayment amount, which includes the outstanding principal plus the end of term charge, through interest expense using the effective interest rate method over the term of the loan.

Effective September 17, 2021 (the "Amended Closing Date"), the Company amended the Loan Agreement with Hercules (the "Amended Loan Agreement"), increasing aggregate principal amount available from $75.0 million under the Term Loan Facility to $85.0 million (the "Amended Term Loan Facility").

Under the Amended Term Loan Facility, a new tranche three of $10.0 million was established and was available through December 15, 2021. Tranche four was amended such that $30.0 million is now available through the interest only period, subject to future lender investment committee approval. Tranche five of up to $20.0 million was established under the Amended Loan Agreement and is available through September 30, 2023, upon satisfaction of certain clinical milestones. Tranche five is only available in minimum draws of $5.0 million.

Advances under the Amended Term Loan Facility bear interest at a rate equal to the greater of (i) 8.25% plus the Prime Rate (as reported in *The Wall Street Journal*) less 3.25%, and (ii) 8.25%. The interest only period under the Term Loan Facility was extended from November 1, 2022 to October 1, 2023 under the Amended Term Loan Facility and is further extendable to October 1, 2024 upon the achievement of certain clinical milestones. Under the Amended Term Loan Facility, following the interest only period, the Company will repay the principal balance and interest on the advances in equal monthly installments through October 1, 2025, compared to October 1, 2024 under the Term Loan Facility.

Prepayments on the Amended Loan Agreement, in whole or in part, at any time are subject to a prepayment charge (Prepayment Premium) equal to: (i) 2.0% of amounts so prepaid, if such prepayment occurs during the first year following the Amended Closing Date, (ii) 1.5% of the amount so prepaid, if such prepayment occurs during the second year following the Amended Closing Date, or (iii) 1.0% of the amount so prepaid, if such prepayment occurs after the second year following the Amended Closing Date.

Additionally, upon prepayment or repayment of all or any of the term loans under the Amended Term Loan Facility, the Company will pay an end of term charge of 5.5% of the aggregate funded amount under the Term Loan Facility. The end of term charge of $1.4 million, or 5.6% of the $25.0 million of principal advanced under the Term Loan Facility, remains payable at the maturity date under the original Term Loan Facility of October 1, 2024.

The terms under the Amended Loan Agreement were not substantially different from those under the original Loan Agreement, and the Amended Loan Agreement will be accounted for prospectively.

The Amended Term Loan Facility remains secured by a lien on substantially all of the Company's assets, other than the Company's intellectual property. The Company has agreed not to pledge or grant a security interest on the Company's intellectual property to any third party. The Amended Term Loan Facility also contains customary covenants and representations, including a liquidity covenant, whereby the Company is obligated to maintain, in an account covered by Hercules' account control agreement, an amount equal to the lesser of: (i) 110% of the amount of the Company's obligations under the Amended Term Loan Facility, and (ii) the Company's then-existing cash and cash equivalents, financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries.

The events of default under the Amended Loan Agreement include, without limitation, and subject to customary grace periods, the following: (i) any failure by the Company to make any payments of principal or interest under the Amended Loan Agreement, (ii) any breach or default in the performance of any covenant under the Amended Loan Agreement, (iii) the occurrence of a material adverse effect, (iv) any making of false or misleading representations or warranties in any material respect, (v) the Company's insolvency or bankruptcy, (vi) certain attachments or judgments on the assets of the Company, or (vii) the occurrence of any material default under certain agreements or obligations of the Company's involving indebtedness. If an event of default occurs, Hercules is entitled to take enforcement action, including acceleration of amounts due under the Amended Loan Agreement.

As of September 30, 2022 and December 31, 2021, the carrying value of the Term Loan Facility was $25.7 million and $25.4 million, respectively, which was classified as a long-term liability. The fair value of debt was classified as Level 2 for the periods presented and approximates its carrying value due to the variable interest rate.

The future principal payments under the Amended Loan Agreement are as follows as of September 30, 2022 (in thousands):

Fiscal Year	PRINCIPAL
2022	$ —
2023	2,694
2024	11,559
2025	10,747
	$ 25,000

During the three months ended September 30, 2022 and 2021, the Company recognized $0.8 million and $0.7 million of interest expense related to the Amended Loan Agreement, respectively. During the nine months ended September 30, 2022 and 2021, the Company recognized $2.0 million and $2.1 million of interest expense related to the Amended Loan Agreement, respectively.

9. Stock-Based Compensation

2020 Stock Option and Incentive Plan

The 2020 Stock Option and Incentive Plan (the "2020 Plan") became effective in October 2020. The 2020 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, and other stock-based awards. The number of shares of the Company's common stock initially reserved for issuance under the 2020 Plan was 1,043,402 shares. The number of shares reserved annually increase on the first day of each calendar year, beginning on January 1, 2021 and ending on and including January 1, 2030, equal to the lesser of 5% of the number of shares of common stock outstanding on the final day of the immediately preceding calendar year or such lesser number of shares determined by the compensation committee. As of January 1, 2022, 1,119,192 additional shares of common stock were reserved for issuance under the 2020 Plan.

The shares of the Company's common stock subject to outstanding awards under the 2015 Stock Option and Grant Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right will be added back to the shares of common stock available for issuance under the 2020 Plan. As of September 30, 2022, there were 501,018 shares available for future issuance under the 2020 Plan.

The Company's stock options expire after approximately ten years from the date of grant. As of September 30, 2022, the Company does not hold any treasury shares. Upon stock option exercise, the Company issues new shares and delivers them to the participant.

2020 Employee Stock Purchase Plan

The Company's 2020 Employee Stock Purchase Plan, (the "ESPP") was adopted by the Company's board of directors, approved by the Company's stockholders and became effective in October 2020. The ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 208,680 shares of the Company's common stock. The number of shares of common stock reserved for issuance under the ESPP may be increased on the first day of each calendar year, beginning on January 1, 2021 and ending on January 1, 2030, by the lesser of (i) 834,720 shares of common stock, (ii) 0.5% of the outstanding shares of common stock on the immediately preceding December 31 and (iii) such lesser number of shares as determined by the administrator of the ESPP. There had been no increase in the number of shares of common stock reserved for issuance under the ESPP as of September 30, 2022.

Stock Options

The following table summarizes the Company's option activity during the nine months ended September 30, 2022:

	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE PER SHARE	WEIGHTED AVERAGE REMAINING CONTRACTUAL TERM	AGGREGATE INTRINSIC VALUE (1)
			(In years)	(In thousands)
Outstanding as of December 31, 2021	4,763,489	$ 12.56	6.44	$ 10,370
Granted	1,253,675	5.74		
Exercised	—	—		
Forfeited/Cancelled	(796,424)	13.44		
Outstanding as of September 30, 2022	5,220,740	$ 10.79	5.98	$ —
Exercisable as of September 30, 2022	3,166,270	$ 10.08	4.53	$ —
Vested and expected to vest as of September 30, 2022	5,220,740	$ 10.79	5.98	$ —

(1) Aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock as of September 30, 2022 and December 31, 2021.

The aggregate intrinsic value of stock options exercised during the three months ended September 30, 2022 and 2021 was $0.0 million and $0.8 million, respectively. The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2022 and 2021 was $0.0 million and $5.1 million, respectively.

Restricted Stock Units

The following table summarizes the Company's restricted stock unit activity during the nine months ended September 30, 2022:

	NUMBER OF SHARES	WEIGHTED AVERAGE GRANT DATE FAIR VALUE
Outstanding as of December 31, 2021	—	$ —
Granted	1,896,683	3.21
Vested	(130,164)	5.18
Forfeited/Cancelled	(162,408)	5.86
Outstanding as of September 30, 2022	1,604,111	$ 0.74
Vested and expected to vest as of September 30, 2022	1,604,111	$ 0.74

Stock-Based Compensation Expense

The following table presents the components and classification of stock-based compensation expense (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Research and development	$ 1,121	$ 1,646	$ 3,262	$ 3,925
General and administrative	1,166	1,446	4,042	4,130
	$ 2,287	$ 3,092	$ 7,304	$ 8,055
Employee	$ 2,143	$ 3,049	$ 6,599	$ 7,908
Non-employee	144	43	705	147
	$ 2,287	$ 3,092	$ 7,304	$ 8,055

As of September 30, 2022, the total unrecognized compensation expense related to the Company's stock compensation awards was $16.4 million, which the Company expects to recognize over a weighted-average period of approximately 2.3 years.

10. Collaboration agreements

Detailed description of contractual terms and the Company's accounting for agreements described below were included in the Company's audited financial statements and notes in the 2021 Annual Report.

The following table summarizes our total consolidated revenue from our current and former strategic collaborators for the periods presented (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
Collaboration Revenue by Strategic Collaborator:	2022	2021	2022	2021
Jazz	$ 28	$ 118	$ 26,044	$ 11,225
Sarepta	—	1,039	(167)	4,013
Total collaboration revenue	$ 28	$ 1,157	$ 25,877	$ 15,238

The following tables present changes in the Company's contract assets and liabilities for the period presented (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30, 2022			
	BALANCE BEGINNING OF PERIOD	ADDITIONS	DEDUCTIONS	BALANCE END OF PERIOD
Contract assets:				
Account receivable (1)	$ 628	—	(628)	$ —
Contract liabilities:				
Deferred revenue	$ 43,649	—	(26,044)	$ 17,605

(1) Included in prepaid expenses and other current assets as shown within the condensed consolidated balance sheets.

During the three and nine months ended September 30, 2022 and 2021, the Company recognized the following revenue (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Revenue recognized in the period from:				
Amounts included in deferred revenue at the beginning of the period	$ 28	$ 1,157	$ 26,044	$ 15,238

Jazz collaboration and license agreement

During the three and nine months ended September 30, 2022, the Company continued to perform under its Collaboration and License Agreement (the "Jazz Collaboration Agreement"), pursuant to which the Company recognizes revenues utilizing the cost-based input method. As a result, the Company recognizes over time as revenue the transaction price allocated to each performance obligation as research and development services are performed. The following table summarizes research and development costs incurred and revenue recognized in connection with Company's performance under the Jazz Collaboration Agreement (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Revenue recognized	$ 28	$ 118	$ 26,044	$ 11,225
Costs incurred	$ 226	$ 606	$ 1,178	$ 1,947

Four of the targets were identified at the inception of the collaboration (the "Initial Collaboration Targets"). In April 2021, the Company and Jazz mutually agreed to discontinue their work on exoASO-STAT3 ("STAT3"), one of the five oncogene targets subject to the Jazz Collaboration Agreement. The Company recognized the remaining $10.9 million in deferred revenue allocated to this target during the nine months ended September 30, 2021. On June 30, 2021, Jazz formally nominated the fifth collaboration target. The Company will recognize the $2.8 million of revenue allocated to this performance obligation consistent with all active Jazz targets, recording revenue based on actual costs incurred relative to the budgeted costs to complete each of the respective programs.

In January 2022, the Company and Jazz mutually agreed to discontinue their work on NRAS. The Company recognized the remaining $12.6 million in deferred revenue allocated to this target during the three months ended March 31, 2022. In July 2022, the Company and Jazz mutually agreed to discontinue their work on an undisclosed third target, and the Company recognized the remaining $13.3 million in deferred revenue allocated to this target during the three months ended June 30, 2022, as the preclinical activities that informed this decision were completed prior to the end of the period. For the nine months ended September 30, 2022, the Company recognized a combined $26.0 million in deferred revenue primarily allocated to NRAS and an undisclosed third target, two of the five oncogene targets subject to the Jazz Collaboration Agreement. As of September 30, 2022, except for the decision relating to NRAS and the undisclosed third target, there were no significant changes in the Company's assumptions or estimates related to the costs to complete development. Jazz also has the option to nominate an additional target (a "Replacement Target") if two of the Initial Collaboration Targets fail prior to acceptance of an Investigational New Drug application ("IND"). As of September 30, 2022, there are three remaining material rights outstanding under the Jazz Collaboration Agreement

Codiak and Jazz continue to jointly advance their research and development efforts on other exosome-based therapeutic programs to treat cancer pursuant to the Jazz Collaboration Agreement. Jazz has the contractual right to revive terminated targets as active targets in the future.

There have been no changes to the Company’s estimate of variable consideration on active performance obligations since inception of the arrangement through September 30, 2022. As of September 30, 2022, the Company has not achieved any preclinical development, IND acceptance, clinical, regulatory or sales milestones or earned any royalties or profit share under the Jazz Collaboration Agreement.

As of September 30, 2022 and December 31, 2021, the Company had $17.6 million and $43.6 million, respectively, of deferred revenue related to the Company’s collaboration with Jazz, which is classified as current or long-term in the accompanying consolidated balance sheet based on the expected timing of recognizing such amounts as revenue.

Sarepta license and option agreement

On October 1, 2021, Sarepta notified the Company that it was terminating early the research license and option agreement (the "Sarepta Research Agreement"). The termination was effective as of December 3, 2021. As a result of the termination, each of the license and options granted to Sarepta were terminated in their entirety, and the Company regained all rights previously granted to Sarepta. During the nine months ended September 30, 2022, the Company was no longer obligated to perform under its Sarepta Research Agreement, pursuant to which the Company recognized revenue utilizing the cost-based input method. The Company recognized contract to date revenue of $13.9 million as research and development services that were performed through December 3, 2021. During the nine months ended September 30, 2022, the Company collected on a receivable for services performed under the Sarepta Research Agreement, which was held at $0.6 million at January 1, 2022. The transaction price related to such services was subsequently revised during the period, which resulted in a reduction to revenue. The following table summarizes research and development costs incurred and revenue recognized in connection with Company's performance under the Sarepta Research Agreement (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Revenue recognized	$ —	$ 1,039	$ (167)	$ 4,013
Costs incurred	$ —	$ 1,039	$ —	$ 4,013

11. Other significant agreements

MDACC in-license agreement

In November 2015, the Company entered into a patent and technology license agreement with MDACC, as amended in April 2018 (the "MDACC License Agreement"). Pursuant to the MDACC License Agreement, the Company holds exclusive worldwide license rights to certain intellectual property relating to the use of exosomes for diagnostic and therapeutic applications and a non-exclusive worldwide license under certain related technologies, with the right to grant sublicenses. The Company also obtained the exclusive right of first negotiation, for a specified time period, for a license to certain of MDACC’s rights in future exosome technology.

Under the terms of the MDACC License Agreement, the Company is responsible for all patent costs incurred by MDACC for the underlying licensed technology in excess of $1.5 million from the effective date of the agreement through February 1, 2021, and for all patent costs incurred or invoiced after this date. As of September 30, 2022, there was no remaining funding provided by MDACC for patent-related costs under the MDACC License Agreement.

Pursuant to the MDACC License Agreement, the Company is also required to make future payments to MDACC upon the occurrence of events related to the development of products and upon the achievement of certain development and regulatory approval milestones up to an aggregate of $11.9 million, comprising up to $2.4 million for diagnostic products and up to $9.5 million for therapeutic products. The Company may at its discretion pay up to $4.4 million in such contingent payments in cash or through the issuance of equity in the form of redeemable convertible preferred stock or common stock, as applicable. Such payments will be expensed or capitalized based on the nature of the associated asset at the date the related contingency is resolved. In addition, the Company is obligated to pay certain payments upon the execution of sublicenses for qualifying products, as well as single digit percentage royalty payments on net sales from a licensed product.

The MDACC License Agreement will continue until the last to occur of: (i) the expiration of all patents issued underlying the licenses conveyed, (ii) the cancellation, withdrawal or express abandonment of all patent rights underlying the licenses conveyed, and (iii) the fifteenth anniversary of the effective date of the agreement. Upon expiration of the MDACC License Agreement, the licenses granted will automatically convert to a fully-paid irrevocable and perpetual license. The Company may terminate the license for convenience upon 180 days' prior written notice to MDACC. The license automatically terminates upon the Company’s bankruptcy, if the Company challenges the validity or enforceability of any of the licensed patent rights, or if the Company fails to make a number of payments in a timely manner over a specified period of time. Additionally, MDACC may terminate the license for the Company’s breach subject to certain specified cure periods.

As of September 30, 2022, no milestones had been achieved, nor had any royalties, sublicensing fees or other contingent payments been incurred under the MDACC License Agreement. The Company did not make any payments to MDACC for the three and nine months ended September 30, 2022 and 2021 with respect to the MDACC License Agreement.

Kayla Therapeutics S.A.S license agreement

On November 6, 2018, the Company entered into a license agreement with Kayla, pursuant to which it obtained a co-exclusive worldwide, sublicensable license under certain patent rights and to related know-how and methods to research, develop, manufacture and commercialize compounds and products covered by such patent rights in all diagnostic, prophylactic and therapeutic uses (the "Kayla License Agreement"). The foregoing license is co-exclusive with Kayla, but Kayla’s retained rights are subject to certain restrictions.

During the first six years following the effective date of the Kayla License Agreement, Kayla and its affiliates may not research, develop, manufacture or commercialize anywhere in the world any product containing a small molecule STING agonist and an exosome. In addition, during the term of the Kayla License Agreement, Kayla and its affiliates may not grant a license to any third party under the licensed patent rights to, develop, manufacture or commercialize anywhere in the world a product containing certain STING compounds for therapeutic or veterinary purpose. The Kayla License Agreement also restricts the Company from developing any competing product containing a small molecule STING agonist and an exosome until the expiration of a non-compete period determined by the achievement of clinical milestones.

The Company has certain diligence obligations under the Kayla License Agreement, which include using commercially reasonable efforts to develop, commercialize and market the products developed under the licensed patent rights, including using commercially reasonable efforts to initiate a cohort extension of a Phase 1/2 trial after obtaining IND approval. The Company is also obligated to pay up to $100.0 million in cash payments and up to $13.0 million payable in shares of the Company’s common stock upon the achievement of specified clinical and regulatory milestones, including approvals in the U.S., the EU and Japan. Such payments will be expensed or capitalized based on the nature of the associated asset at the date the related contingency is resolved. Additionally, the Company is obligated to pay to Kayla a percentage of the payments that the Company receives from sublicensees of the rights licensed to it by Kayla, excluding any royalties. This percentage varies from single digits to low double digits. The first milestone was achieved upon the dosing of the first subject in the Company’s exoSTING Phase 1/2 clinical trial in September 2020. Upon achievement of the milestone, the Company was obligated to make a nonrefundable payment of $15.0 million in cash and issue 177,318 shares of common stock to Kayla. The common stock was issued as of the date of dosing, and the cash payment of $15.0 million was paid as of December 31, 2020. As of September 30, 2022, no other milestones had been achieved.

The Company is obligated to pay to Kayla tiered royalties ranging from low single-digits to mid-single-digits based on annual net sales by the Company, its affiliates and its sublicensees of licensed products. The royalty term is determined on a product-by-product and country-by-country basis and continues until the later of (i) the expiration of the last valid claim of the licensed patent rights that covers such product in such country, (ii) the loss or expiration of any period of marketing exclusivity for such product in such country, and (iii) ten years after the first commercial sale of such product in such country; provided that if the royalty is payable when no valid claim covers a given product in a given country, the royalty rate for sales of such product in such country is decreased. The Company may terminate the Kayla License Agreement on a licensed compound-by-licensed compound basis and on a region-by region basis for any reason upon 30 days' prior written notice to Kayla. The Company or Kayla may terminate the Kayla License Agreement for the other's material breach that remains uncured for 60 days after receiving notice thereof. As of September 30, 2022, no royalties, or other contingent payments had been incurred under the Kayla License Agreement.

12. Grant revenue

In July 2022, the Company entered into a new partnership with CEPI to advance our exoVACC pan betacoronavirus program. As part of the partnership, CEPI is providing seed funding of up to $2.5 million, which the Company anticipates will fund the completion of preclinical development and identification of a clinical candidate by early 2023. All funding received from CEPI must be used for preclinical studies, assessing the immune response against known *Betacoronaviruses* that already pose a significant epidemic or pandemic risk, such as SARS-CoV-1, SARS-CoV-2, and MERS-CoV, and the potential of the immune response to protect against infection and disease caused by these viruses. As of September 30, 2022, the Company has received $1.6 million in grants.

During both the three and nine months ended September 30, 2022, the Company recognized $0.5 million in grant revenue under its partnership with CEPI. As of September 30, 2022, the Company had $1.1 million in deferred revenue with respect to its partnership with CEPI.

13. Restructuring

In August 2022, the board of directors of the Company approved a reduction of the Company's workforce by approximately 37% across all areas of the Company. This workforce reduction was completed as of September 30, 2022. These actions reflect the reprioritization of its clinical and research initiatives. The Company has paused plans to initiate Phase 2 trials of exoSTING and exoIL-12 while prioritizing its Phase 1 clinical trial of exoASO-STAT6.

During each of the three and nine months ended September 30, 2022, the Company recognized $0.7 million of restructuring charges in the condensed consolidated statement of operations. These charges included $0.5 million of one-time termination benefits and contractual termination benefits for severance, healthcare, and related benefits and $0.2 million of non-cash stock-based compensation expense. The Company recorded $0.5 million and $0.2 million in research and development expenses and general and administrative expenses, respectively.

Details of the restructuring liability activity for the Company's workforce reduction for the period ended September 30, 2022 are as follows:

	September 30, 2022 (in thousands)
Balance at December 31, 2021	$ —
Restructuring charges	651
Severance payments	(329)
Stock-based compensation expense	(151)
Balance at September 30, 2022	$ 171

14. Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Numerator:				
Net loss	$ (19,278)	$ (21,702)	$ (34,081)	$ (53,819)
Net loss attributable to common stockholders	$ (19,278)	$ (21,702)	$ (34,081)	$ (53,819)
Denominator:				
Weighted average common shares outstanding, basic and diluted	25,159,757	22,325,334	23,373,684	21,599,405
Net loss per share attributable to common stockholders, basic and diluted	$ (0.77)	$ (0.97)	$ (1.46)	$ (2.49)

The following common stock equivalents, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have been anti-dilutive:

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Restricted stock units	1,604,111	—	1,604,111	—
Warrants	14,027,665	—	14,027,665	—
Outstanding stock options	5,220,740	4,953,272	5,220,740	4,953,272
Outstanding awards	20,852,516	4,953,272	20,852,516	4,953,272

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 (the "Quarterly Report"), and our consolidated financial statements and related notes and other financial information in our Annual Report on Form 10-K for the year ended December 31, 2021. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, such as statements regarding our plans, objectives, expectations, intentions, and projections, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, our actual results could differ materially from the results described in, or implied by, these forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company focused on pioneering the development of exosome-based therapeutics, a new class of medicines with the potential to transform the treatment of a wide spectrum of diseases with high unmet medical need. Exosomes have evolved as intercellular transfer mechanisms for complex, biologically active macromolecules and have emerged in recent years as a compelling potential drug delivery vehicle. By leveraging our deep understanding of exosome biology, we have developed our engineering and manufacturing platform ("engEx Platform") to expand upon the innate properties of exosomes to design, engineer and manufacture novel exosome therapeutics. We have utilized our engEx Platform to generate a deep pipeline of engineered exosomes ("engEx exosomes"), aimed at treating a broad range of diseases, including oncology, and infectious disease and rare disease.

In September 2020, we initiated clinical trials of our lead engEx product candidates, exoSTING and exoIL-12, which were being developed to address oncology indications. In June 2022, we initiated a Phase 1 clinical trial of exoASO-STAT6. This is our first systemically delivered exosome therapeutic candidate. In August 2022, we paused clinical trials of exoSTING and exoIL-12 and prioritized our focus on our Phase 1 clinical trial of exoASO-STAT6. To our knowledge, exoSTING and exoIL-12 are the first engineered exosomes to enter clinical development.

In December 2020 and February 2021, we reported positive results from Part A of our Phase 1 clinical trial of exoIL-12 in healthy human volunteers. In this randomized, placebo controlled, double-blind study, exoIL-12 demonstrated a favorable safety and tolerability profile, with no local or systemic treatment-related adverse events and no detectable systemic exposure of IL-12. Results also confirmed retention of active IL-12 at the injection site and prolonged pharmacodynamic effects. These results in healthy volunteers, which are consistent with our preclinical observations, provide validation of our engEx Platform and one of the founding principles of Codiak—that engineered exosomes can offer the opportunity to tailor therapeutic payloads to provide an active biological response while at the same time limiting unwanted side effects.

In November 2021, we reported initial data from the first three dose escalating cohorts (0.3 mcg, 1.0 mcg, and 3.0 mcg) enrolled in the Phase 1/2 study of exoSTING. Trial participants (n=11) were administered exoSTING intratumorally and all subjects had received at least two prior therapies prior to study entry, with most (73%) having progressed on checkpoint inhibitors. Plasma pharmacokinetic ("PK") measurements of subjects that received exoSTING showed no systemic exposure to the agonist. Further, analyses of available plasma biomarkers indicated a lack of systemic inflammatory cytokines detectable in blood after exoSTING administration. exoSTING appeared to be generally well-tolerated. Blood biomarker assessments conducted post-dosing showed evidence of dose-dependent activation of the STING pathway and Type I INF induction along with CXCL10, indicating activation of the innate immune response. Paired tumor biopsies available from two subjects showed evidence of an adaptive immune response and CD8 effector T cell infiltration into the tumor, as well as an increase in PD-L1 expression. Finally, in subjects evaluable for early signs of antitumor activity (n=8), tumor shrinkage was observed in injected as well as distal, non-injected tumors, in a subset of subjects.

In June 2022, we reported initial data from cohorts 4 (6 mcg) and 5 (12 mcg) for trial participants enrolled in the Phase 1 study of exoSTING and exoIL-12. In the CTCL portion of the study, two patients with early stage CTCL whose disease progressed on prior therapy have been treated as of the June 10, 2022 data cut-off. Each patient has received more than 20 injections of exoIL-12 (6.0 µg) across multiple lesions. Duration of treatment has been greater than six months, and no treatment-related adverse events Grade 3 or higher or SAEs were observed, and no dose modifications were required. exoIL-12 demonstrated improvement in overall tumor burden, as measured by mSWAT, and lesion severity, as measured by CAILS, in both patients treated. PK measurements of both healthy volunteers and patients that received exoIL-12 showed no systemic exposure with levels of IL-12 below the limit of quantification. In contrast, previous rIL-12 clinical studies showed dose-dependent systemic exposure with dosages of 5 and 12 mcg resulting in Cmax plasma levels of approximately 15 to 45 pg/ml within six to 12 hours after dosing.

Data as of June 10, 2022 have been reported from all five escalation dose cohorts (0.3 mcg, 1.0 mcg, 3.0 mcg, 6.0 mcg and 12.0 mcg) enrolled in the Phase 1/2 study. Trial participants (n=23) were administered exoSTING intratumorally, and nearly all had received at least two prior therapies prior to study entry with most (65%) having progressed on checkpoint inhibitors. PK measurements of patients that received exoSTING showed no systemic exposure to the agonist. Further, analyses of available plasma biomarkers indicated a lack of systemic inflammatory cytokines detectable in blood after exoSTING administration. Blood biomarker assessments conducted post dosing demonstrated dose-dependent activation of the STING pathway at doses 100-fold lower in comparison to other free STING agonists. Paired tumor biopsies available from Cohorts 1-4 show evidence of an adaptive immune response, including consistent increases in CD-8 effector T-cells and PD-L1 in the tumor micro-environment. Signs of antitumor activity were observed with tumor shrinkage in injected as well as distal, non-injected tumors.

Furthermore, we have multiple preclinical and discovery programs of our engEx exosomes that we are or have previously been advancing either independently or through our strategic collaborations with Jazz Pharmaceuticals Ireland Limited ("Jazz"), and Lonza Rockland, Inc. ("Lonza").

On August 30, 2022, we announced a reprioritization of our clinical and research initiatives, an acceleration of discussions related to potential strategic corporate and program-based partnerships, and a restructuring of operations to support a streamlined set of priorities. We aligned our organization to reflect our smaller, refocused pipeline and our workforce has been reduced by 37%, to 53 full-time employees, to support the priority programs mentioned below.

- exoASO-STAT6 is our first systemically administered exosome-based drug candidate, and our third candidate to enter clinical trials. exoASO-STAT6 is engineered to selectively deliver antisense oligonucleotides to disrupt STAT6 signaling in tumor associated macrophages (“TAMs”) and induce an anti-tumor immune response. Preclinical studies of exoASO-STAT6 showed single agent anti-tumor activity in models of aggressive hepatocellular carcinoma (“HCC”). Enrollment continues in the Phase 1 clinical trial of exoASO-STAT6 in patients with advanced HCC, liver metastases from primary gastric cancer and colorectal cancer where high STAT6 transcript levels correlate with poor prognosis for patients. Data is expected during the first half of 2023.
- In July 2022, we announced a new partnership with the Coalition for Epidemic Preparedness Innovations (“CEPI”) to advance our exoVACC pan betacoronavirus program. As part of the partnership, CEPI is providing seed funding of up to $2.5 million, which we anticipate will fund the completion of preclinical development and identification of a clinical candidate by early 2023.
- Preclinical data presented at the annual meeting of the American Society of Gene & Cell Therapy held on May 16-20, 2022 on our discovery program demonstrated incorporation of AAV capsids inside exosomes where they were not subject to neutralization by antibodies against AAV. These engineered constructs transduce target cells and support the idea for repeat dosing of gene delivery constructs. Our team will continue to advance this program toward generation of in vivo proof-of-concept data later this year.
- We have paused plans to initiate Phase 2 trials of exoSTING and exoIL-12. Platform-supporting data from Phase 1 trials for both programs were reported in June 2022, which we believe demonstrates potential for best-in-class profiles, and we identified a recommended Phase 2 dose for each candidate.
- We are prioritizing discussions related to establishing potential new strategic and collaborative initiatives for us, including program-based partnerships. Our existing research and business partnerships with Lonza and Jazz are continuing, with resources committed to attain key goals.

We were incorporated and commenced operations in 2015. Since inception, we have devoted substantially all of our resources to developing our engEx Platform, our engEx product candidates and engEx exosomes, clinical and preclinical candidates; building our intellectual property portfolio, process development and manufacturing function; business planning; and raising capital and providing general and administrative support for these operations. To date, we have financed our operations primarily with proceeds from sales of our common stock and redeemable convertible preferred stock, our term loan facility with Hercules Capital, Inc. ("Hercules"), and our collaborations with Jazz and Sarepta. As of September 30, 2022, we had raised an aggregate of $168.2 million through the issuance of our redeemable convertible preferred stock, net of issuance costs, $24.6 million from our term loan facility with Hercules, net of issuance costs, and received $66.0 million in payments from our collaboration with Jazz and our prior collaboration with Sarepta. On October 16, 2020, we completed our initial public offering ("IPO"), pursuant to which we issued and sold 5,500,000 shares of our common stock at a public offering price of $15.00 per share, resulting in net proceeds of $74.4 million, after deducting underwriting discounts and commissions and other offering expenses. On February 17, 2021, we completed a follow-on public offering, pursuant to which we issued and sold 3,162,500 shares of our common stock (inclusive of the exercise of the underwriter’s option to purchase 412,500 additional shares of common stock) at a public offering price of $21.00 per share, resulting in aggregate net proceeds of $61.7 million, after deducting underwriting discounts and commissions and other offering expenses. On September 15, 2022, we completed a follow-on public offering, pursuant to which we issued and sold 14,027,665 shares of our common stock and accompanying warrants to purchase 14,027,665 shares of our common stock (inclusive of the partial exercise of the underwriter’s option to purchase 694,332 additional shares of common stock and accompanying warrants to purchase 694,332 additional shares of common stock) at a combined public offering price of $1.50 per share, resulting in net proceeds of $19.8 million, after deducting underwriting discounts and commissions and other offering expenses. During the nine-month period ended September 30, 2022, we raised $0.9 million, utilizing an “at-the-market” offering facility, pursuant to which we sold 236,303 shares of our common stock.

On November 1, 2021, we and Lonza entered into an asset purchase agreement (the "APA"), pursuant to which Lonza acquired our exosome manufacturing facility and related assets, and subleased the premises, located at 4 Hartwell Place, Lexington, Massachusetts. On November 15, 2021, we and Lonza closed the transactions contemplated by the APA (the "Lonza Closing"). In connection with the Lonza Closing, and as consideration for the APA, we and Lonza entered into a Manufacturing Services Agreement (the "MSA"). Pursuant to the MSA, Lonza will become the exclusive manufacturing partner for future clinical and commercial manufacturing of our exosome products pipeline, subject to limited exceptions. As consideration for the transactions contemplated by the APA and the associated ancillary agreements, we are entitled to approximately $65.0 million worth of exosome manufacturing services for our clinical programs during the next four years. Commencing in 2026, we shall purchase from Lonza a contractually agreed minimum amount of exosome manufacturing services per year for ten years, or if earlier, until the fifth (5th) anniversary of the first commercial sale of a Codiak exosome product, subject to limited exceptions.

Also in connection with the Lonza Closing, we and Lonza entered into a licensing and collaboration agreement (the "License Agreement"). Pursuant to the License Agreement, we granted Lonza a worldwide, exclusive and sub-licensable license to our high throughput exosome manufacturing intellectual property in the contract development and manufacturing field, and a worldwide, non-exclusive and sub-licensable license to such intellectual property for non-therapeutical uses outside the contract development and manufacturing field. Pursuant to the License Agreement, we are eligible to receive from Lonza a double-digit percentage of future sublicensing revenues. We shall retain our pipeline of therapeutic candidates and core exosome engineering, drug-loading expertise and related intellectual property. The companies will collaborate to establish a joint Center of Excellence for further development of exosome manufacturing technology, with a shared oversight committee. The Center of Excellence will leverage the strengths of both companies to pursue developments in exosome production, purification and analytics.

In July 2022, we entered into a new partnership with CEPI to advance our exoVACC pan betacoronavirus program. As part of the partnership, CEPI is providing seed funding of up to $2.5 million, which we anticipate will fund the completion of preclinical development and identification of a clinical candidate by early next year. All funding received from CEPI must be used for preclinical studies, assessing the immune response against known *Betacoronaviruses* that already pose a significant epidemic or pandemic risk, such as SARS-CoV-1, SARS-CoV-2, and MERS-CoV, and the potential of the immune response to protect against infection and disease caused by these viruses.

We have not generated any revenue from product sales and do not expect to do so for several years, and may never do so. We advanced our first two engEx product candidates, exoSTING and exoIL-12, into clinical trials in September 2020, and in June 2022, we initiated a Phase 1 clinical trial of exoASO-STAT6. In August 2022, we paused clinical trials of exoSTING and exoIL-12 to prioritize the clinical trials of exoASO-STAT6. All of our other engEx exosomes are still in preclinical development. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our engEx product candidates. Since our inception, we have incurred significant losses, including net losses of $37.2 million and $91.7 million for the years ended December 31, 2021 and 2020, respectively. During the nine months ended September 30, 2022, we incurred a net loss of $34.1 million. As of September 30, 2022, we had an accumulated deficit of $359.3 million. We expect to incur substantial additional losses in the future as we expand our research and development activities. We anticipate that our expenses will increase in connection with our ongoing research and development activities, as we:

- initiate and conduct clinical trials for exoASO-STAT6 and any other engEx product candidates we identify and choose to develop;
- continue our current research programs and preclinical development of our potential engEx product candidates;
- seek to identify additional research programs and additional engEx product candidates;
- further develop and expand the capabilities of our engEx Platform;
- secure supply chain capacity sufficient to support our planned preclinical studies and early-stage clinical trials;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other biologically active molecules, potential engEx product candidates or technologies;
- seek regulatory approvals for any engEx product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any engEx products for which we may obtain regulatory approval;
- add operational, financial and management information systems and personnel, including personnel to support our product development and any future commercialization efforts, as well as to support our continued operations as a public company; and
- take temporary precautionary measures to minimize the risk of COVID-19 to our employees, contractors and those who may participate in our studies.

We do not anticipate generating revenue from product sales for the foreseeable future, if ever, unless and until we successfully complete clinical development and obtain marketing approvals for our engEx product candidates. In addition, if we obtain marketing approval for any of our engEx product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our engEx product candidates or delay our pursuit of potential in-licenses or acquisitions.

Further, business interruptions resulting from the COVID-19 pandemic or similar public health crises could cause a significant disruption in the development of our engEx product candidates and our business operations. Securing the necessary approvals for new drugs requires the expenditure of substantial time and resources and any delay or failure to obtain such approvals could materially adversely affect our development efforts. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2022, we had cash and cash equivalents of $51.8 million. We expect that our existing cash and cash equivalents as of September 30, 2022 will not enable us to fund our current operating plan and capital expenditure requirements for 12 months following the date of this filing. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. These factors raise substantial doubt about our ability to continue as a going concern. See ‘‘Liquidity and capital resources’’ for further information.

Financial operations overview

Collaboration Revenue

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products for several years, if at all. If our development efforts for our current or future engEx product candidates are successful and result in marketing approval or additional collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from current or additional collaboration or license agreements.

In January 2019, we entered into a collaboration and license agreement with Jazz (the "Collaboration and License Agreement"), pursuant to which we granted Jazz an exclusive, worldwide, royalty-bearing license to use our engEx Platform for the purposes of developing, manufacturing and commercializing exosome therapeutic candidates directed at up to five targets. In April 2021, we and Jazz mutually agreed to discontinue our work on STAT3, one of five oncogene targets subject to the Collaboration and License Agreement. On June 30, 2021, Jazz formally nominated the fifth collaboration target. In January 2022, we and Jazz mutually agreed to discontinue work on the NRAS program. As a result of this discontinuation, Jazz may nominate a replacement target, subject to nomination requirements as outlined in the collaboration agreement. In July 2022, we and Jazz mutually agreed to discontinue work on an undisclosed third target. We recognized the remaining deferred revenue allocated to NRAS and the undisclosed third target during the nine months ended September 30, 2022.

In June 2020, we entered into a research license and option agreement with Sarepta (the "Sarepta Research Agreement"), pursuant to which we received funding to conduct collaborative research, and provided Sarepta with options to obtain exclusive licenses for exosome therapeutic candidates directed at up to five targets. Sarepta notified us that it was terminating early the two-year Sarepta Research Agreement, effective as of December 3, 2021. In the future, we expect substantially all of our revenue to be generated from our collaboration with Jazz and any other collaboration and license agreements we may enter into going forward.

During the three and nine months ended September 30, 2022, we recognized less than $0.1 million and $26.0 million of revenue under our Collaboration and License Agreement with Jazz, respectively. We recognized a reduction to revenue of $0.2 million related to the Sarepta Research Agreement during the nine months ended September 30, 2022. No additional revenue will be recognized related to the Sarepta Research Agreement, as it was terminated effective December 3, 2021. During the three and nine months ended September 30, 2021, we recognized $1.0 and $4.0 million of revenue under the Sarepta Research Agreement, respectively. During the three and nine months ended September 30, 2021, we recognized revenue of $0.1 million and revenue of $11.2 million under the Collaboration and License Agreement with Jazz, respectively. As of September 30, 2022 and December 31, 2021, we had $17.6 million and $43.6 million, respectively, of deferred revenue with respect to the Collaboration and License Agreement.

Grant Revenue

In July 2022, we entered into a new partnership with CEPI to advance its exoVACC pan betacoronavirus program. As part of the partnership, CEPI is providing seed funding of up to $2.5 million, which we anticipate will fund the completion of preclinical development and identification of a clinical candidate by early 2023. All funding received from CEPI must be used for preclinical studies, assessing the immune response against known *Betacoronaviruses* that already pose a significant epidemic or pandemic risk, such as SARS-CoV-1, SARS-CoV-2, and MERS-CoV, and the potential of the immune response to protect against infection and disease caused by these viruses. As of September 30, 2022, we have received $1.6 million in funding.

During both the three and nine months ended September 30, 2022 we recognized $0.5 million in grant revenue under our partnership with CEPI. As of September 30, 2022 we had $1.1 million in deferred revenue with respect to our partnership with CEPI.

Operating expenses

In August 2022, as part of a restructuring plan, the board of directors of the Company approved a reduction of the Company's workforce by approximately 37%. This workforce reduction was completed by September 30, 2022. The total restructuring costs are $0.7 million and consist of $0.5 million in severance expense and $0.2 million in stock compensation expense. We also made a reprioritization of our clinical and research initiatives. We have paused plans to initiate Phase 2 trials of exoSTING and exoIL-12 while prioritizing our Phase I clinical trial of exoASO-STAT6. All restructuring expenses were recorded in the condensed consolidated statement of operations as research and development or general and administrative expenses based upon the department of the personnel to whom the expenses applied. The charges were recorded pursuant to ASC 420, Exit or Disposal Cost Obligations, depending on the employee and have been fully recognized. We recognized expenses of $0.5 million and $0.2 million in research and development expenses and general and administrative expenses, respectively.

Research and development expense

The nature of our business and primary focus of our activities generate a significant amount of research and development costs. Research and development expenses represent costs incurred by us for the following:

- conduct of the clinical development of exoSTING in a Phase 1/2 clinical trial;
- conduct of the clinical development of exoIL-12 in a Phase 1 clinical trial;
- conduct of the clinical development of exoASO-STAT6 in a Phase 1 clinical trial;
- costs to develop our engEx Platform;
- discovery efforts leading to the selection and advancement of engEx product candidates for clinical development;
- preclinical development costs for our programs;
- costs to develop our manufacturing technology and infrastructure; and
- costs of acquiring, developing and manufacturing materials for preclinical studies, including both internal manufacturing and third-party contract manufacturing organizations ("CMOs").

The costs above comprise the following categories:

- personnel-related expenses, including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with third parties, such as contract research organizations ("CROs"), that conduct our preclinical and clinical studies;
- licensing costs;
- costs of outside consultants and advisors, including their fees, stock-based compensation and related travel expenses;
- expenses incurred for the procurement of materials, laboratory supplies and non-capital equipment used in the research and development process; and
- facilities, depreciation, amortization and other direct and allocated expenses incurred as a result of research and development activities.

Our primary focus of research and development since inception has been the development of our engEx Platform and our pipeline of engEx product candidates, including our initial product candidates, exoSTING, exoIL-12, exoASO-STAT6 and discovery programs. In August 2022, we paused our clinical trials of exoSTING and exoIL-12 to prioritize our focus on clinical trials of exoASO-STAT6. Our research and development costs consist of personnel costs, external costs, such as fees paid to CMOs, CROs, and consultants in connection with our clinical and preclinical studies and experiments, and other internal costs, including rent, depreciation, and other miscellaneous costs. We do not allocate employee-related costs and other internal costs to specific research and development programs because these costs are used across all programs under development. We present external research and development costs for any individual engEx product candidate when we obtain Investigational New Drug ("IND") approval. As IND approval was received for exoSTING and exoIL-12 in 2020 and exoASO-STAT6 in 2021, we have presented our research and development costs separately for these programs below.

The following table reflects our research and development expenses for each period presented (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Personnel-related (including stock-based compensation)	$ 4,827	$ 6,874	$ 16,086	$ 20,091
Other research and development expenses	2,982	3,220	8,763	9,706
engEx Platform	1,035	2,856	4,440	9,364
exoSTING	805	1,370	3,551	3,534
exoIL-12	467	599	2,452	1,978
exoASO-STAT6	731	548	2,601	2,763
Total research and development expenses	$ 10,847	$ 15,467	$ 37,893	$ 47,436

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses related to our exoSTING and exoIL-12 product candidates will decrease in the foreseeable future as we have paused work on these programs. We expect to continue to incur research and development costs as we conduct clinical trials for our lead engEx product candidate exoASO-STAT6, continue to discover and develop additional engEx product candidates, continue to invest in manufacturing technologies, enhance our engEx Platform, expand into additional therapeutic areas and incur expenses associated with hiring additional personnel to support our research and development efforts.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our engEx product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of our engEx product candidates. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, our engEx product candidates;
- whether and when we are able to resume clinical development of exoSTING and exoIL-12;
- our successful enrollment in and completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- the costs associated with the development of any additional development programs we identify in-house or acquire through collaborations;
- our ability to retain key research and development personnel;
- our ability to establish an appropriate safety profile with IND-enabling toxicology and other preclinical studies;
- our ability to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression, as applicable, of our engEx product candidates;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our engEx product candidates are approved;
- our ability to secure from Lonza, under our manufacturing arrangement with them, sufficient supply of our product candidates for clinical trials or commercial use, if approved;
- our ability to maintain our collaborative arrangement with Jazz and earn milestone payments thereunder;
- the terms and timing of any additional collaborations, license or other arrangements, including the terms and timing of any milestone payments thereunder;
- our ability to obtain and maintain patent, trade secret and other intellectual property protection and regulatory exclusivity for our engEx product candidates if and when approved;
- our receipt of marketing approvals from applicable regulatory authorities; and
- the continued acceptable safety profiles of any engEx product following approval.

A change in any of these variables with respect to the development of any of our engEx product candidates would significantly change the costs, timing and viability associated with the development of that engEx product candidate.

General and administrative expense

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs. These costs relate to the operation of the business unrelated to the research and development function or any individual program.

We expect to continue to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Impairment of prepaid manufacturing services

Impairment of prepaid manufacturing services consists of non-utilized portions of prepaid manufacturing services under the MSA. As certain 2022 services were not being utilized, the Company recognized an impairment charge to the prepaid manufacturing services asset from the third-party provider.

Interest income

Interest income consists of interest income earned from our cash, cash equivalents and investments.

Interest expense

Interest expense consists of interest expense incurred from our term loan facility with Hercules.

Other income

Other income primarily consists of sublease income under the sublease portion of our 35 CambridgePark Drive office and laboratory space and 4 Hartwell Place manufacturing facility.

Change in fair value of derivative liability - warrants

Change in fair value of derivative liability - warrants consists of changes in the fair value of outstanding warrants to purchase shares of our common stock. Significant inputs used to determine the fair value at execution and as of September 30, 2022 included the price per share of our common stock, expected terms of the derivative instruments, strike price of the derivative instrument, risk-free interest rate, and expected volatility of peer company common stock.

Income taxes

Since our inception in 2015, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2021, we had federal and state net operating loss carryforwards of $189.4 million and $188.7 million, respectively, which may be available to offset future taxable income. During the year ended December 31, 2021, we generated a federal net operating loss of $152.9 million, which has an indefinite carryforward period. The remaining $36.4 million of federal net operating loss carryforwards and our state net operating loss carryforwards would begin to expire in 2035. As of December 31, 2021, we had federal and state research and development credit carryforwards of $10.5 million and $5.0 million, respectively, which may be available to offset future income tax liabilities and which would begin to expire in 2035 and 2031, respectively. During the three and nine months ended September 30, 2022, we recorded no income tax benefits for the net operating losses incurred or research and development tax credits earned in each interim period due to our uncertainty of realizing a benefit from those items.

Results of operations

The following table summarizes our condensed consolidated statements of operations for each period presented (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Revenue:				
Collaboration revenue	$ 28	$ 1,157	$ 25,877	$ 15,238
Grant revenue	494	—	494	—
Total revenue	522	1,157	26,371	15,238
Operating expenses:				
Research and development	10,847	15,467	37,893	47,436
General and administrative	6,563	7,186	20,634	20,711
Impairment of prepaid manufacturing services	4,508	—	4,508	—
Total operating expenses	21,918	22,653	63,035	68,147
Loss from operations	(21,396)	(21,496)	(36,664)	(52,909)
Other income (expense):				
Interest expense	(758)	(689)	(2,007)	(2,091)
Interest income	119	4	157	18
Other income	35	479	1,711	1,163
Change in fair value of derivative liabilities - warrants	2,722	—	2,722	—
Total other income (expense), net	2,118	(206)	2,583	(910)
Net loss	$ (19,278)	$ (21,702)	$ (34,081)	$ (53,819)

Comparison of the three months ended September 30, 2022 and 2021

Collaboration revenue

Collaboration revenue decreased by $1.2 million from $1.2 million for the three months ended September 30, 2021 to less than $0.1 million for the three months ended September 30, 2022. The decrease for the three month period ended September 30, 2022 was driven by the fact that the Company recognized revenue in connection with the now-terminated collaboration agreement with Sarepta during the three months ended September 30, 2021.

Grant revenue

Grant revenue increased by $0.5 million from no activity for the three months ended September 30, 2021 to $0.5 million for the three months ended September 30, 2022 after recognizing revenue from our agreement with CEPI.

Research and development expense

The following table summarizes our research and development expenses for the three months ended September 30, 2022 and 2021, along with the changes in those items (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		ABSOLUTE INCREASE (DECREASE)	PERCENTAGE INCREASE (DECREASE)
	2022	2021		
Personnel-related (including stock-based compensation)	$ 4,827	$ 6,874	$ (2,047)	(30)%
Other research and development expenses	2,982	3,220	(238)	(7)%
engEx Platform	1,035	2,856	(1,821)	(64)%
exoSTING	805	1,370	(565)	(41)%
exoASO-STAT6	731	548	183	33%
exoIL-12	467	599	(132)	(22)%
Total research and development expenses	$ 10,847	$ 15,467	$ (4,620)	

Research and development expenses decreased $4.6 million from $15.4 million for the three months ended September 30, 2021 to $10.8 million for the three months ended September 30, 2022.

The decrease in research and development expenses was primarily due to a

- $2.0 million decrease in personnel-related costs primarily due to a lower number of employees related to the disposition of the CMF facility to Lonza;
- $1.8 million decrease in engEx Platform expenses driven mainly by decreases in lab expenses and a decrease in the number of contractors and consultants, which were both primarily related to the disposition of the CMF facility to Lonza; and
- $0.6 million decrease in exoSTING driven by a reduction in clinical trial costs as the Phase 1 trial winds down.

General and administrative expense

The following table summarizes our general and administrative expenses for the three months ended September 30, 2022 and 2021, along with the changes in those items (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		ABSOLUTE INCREASE (DECREASE)	PERCENTAGE INCREASE (DECREASE)
	2022	2021		
Personnel-related (including stock-based compensation)	$ 3,245	$ 3,751	$ (506)	(13)%
Facility-related and other general and administrative	1,624	1,959	(335)	(17)%
Professional fees	1,694	1,476	218	15%
Total general and administrative expenses	$ 6,563	$ 7,186	$ (623)	

General and administrative expenses decreased $0.6 million from $7.2 million for the three months ended September 30, 2021 to $6.6 million for the three months ended September 30, 2022.

The decrease in general and administrative expenses was due to natural attrition of our labor workforce, offset by increased professional services related to legal fees for intellectual property rights.

Impairment expense

Impairment expense increased $4.5 million from no activity in the three months ended September 30, 2021 to $4.5 million for the three months ended September 30, 2022. The increase was due to the Company's mutual agreement with Lonza to not utilize a portion of prepaid manufacturing services under the MSA in 2022.

Interest income

There was an immaterial change of less than $0.1 million in interest income between the three months ended September 30, 2021 and the three months ended September 30, 2022. All of our investments matured prior to the three months ended September 30, 2022. As of September 30, 2022, we did not hold any investments.

Interest expense

Interest expense increased $0.1 million from $0.7 million for the three months ended September 30, 2021 to $0.8 million for three months ended September 30, 2022. The increase was driven by a continued rise in the Prime Rate (as reported in The Wall Street Journal).

Other income

Other income decreased by $0.5 million from $0.5 million for the three months ended September 30, 2021 to less than $0.1 million for the three months ended September 30, 2022. The decrease in other income was driven by the 35 CambridgePark Drive sublease termination.

Change in fair value of derivative liability - warrants

The change in the fair value of derivative liabilities increased by $2.7 million from no activity for the three months ended September 30, 2021 to $2.7 million for the three months ended September 30, 2022. The increase was due to the issuance of warrants and a subsequent decrease in fair value of our common stock.

Comparison of the nine months ended September 30, 2022 and 2021

Collaboration revenue

Collaboration revenue increased by $10.7 million from $15.2 million for the nine months ended September 30, 2021 to $25.9 million for the nine months ended September 30, 2022. The increase for the nine-month period ended September 30, 2022 was driven by $26.0 million recognized as a result of our agreement with Jazz to discontinue work on NRAS and an undisclosed third target, two of the five oncogene targets subject to the Jazz Collaboration Agreement. In the nine months ended September 30, 2021, we recognized $10.9 million of revenue under the Jazz Collaboration Agreement as a result of our agreement with Jazz to discontinue work on STAT3, one of the five oncogene targets subject to the Jazz Collaboration Agreement, and an additional $3.0 million of revenue was recognized related to our Sarepta Research License and Option Agreement, which was terminated, effective December 3, 2021.

Grant revenue

Grant revenue increased by $0.5 million from no activity for the nine months ended September 30, 2021 to $0.5 million for the nine months ended September 30, 2022 after recognition of revenue from our agreement with CEPI.

Research and development expense

The following table summarizes our research and development expenses for the nine months ended September 30, 2022 and 2021, along with the changes in those items (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,		ABSOLUTE INCREASE (DECREASE)	PERCENTAGE INCREASE (DECREASE)
	2022	2021		
Personnel-related (including stock-based compensation)	$ 16,086	$ 20,091	$ (4,005)	(20)%
Other research and development expenses	8,763	9,706	(943)	(10)%
engEx Platform	4,440	9,364	(4,924)	(53)%
exoSTING	3,551	3,534	17	0%
exoIL-12	2,452	1,978	474	24%
exoASO-STAT6	2,601	2,763	(162)	(6)%
Total research and development expenses	$ 37,893	$ 47,436	$ (9,543)	

Research and development expenses decreased by $9.5 million from $47.4 million for nine months ended September 30, 2021 to $37.9 million for the nine months ended September 30, 2022.

The decrease in research and development expenses was primarily due to

- $4.9 million decrease in engEx Platform expenses, driven mainly by decreases in lab expenses and a decrease of contractors and consultants, which were both primarily related to the disposition of the CMF facility to Lonza;
- $4.0 million decrease in personnel-related costs due to a lower number of employees related to both the disposition of the CMF facility to Lonza and the natural attrition of our labor workforce; and
- $0.9 million decrease in depreciation expense in other research and development costs, primarily related to the disposition of the CMF facility to Lonza.

General and administrative expense

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2022 and 2021, along with the changes in those items (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,		ABSOLUTE INCREASE (DECREASE)	PERCENTAGE INCREASE (DECREASE)
	2022	2021		
Personnel-related (including stock-based compensation)	$ 10,588	$ 10,987	$ (399)	(4)%
Facility-related and other general and administrative	5,317	5,833	(516)	(9)%
Professional fees	4,729	3,891	838	22%
Total general and administrative expenses	$ 20,634	$ 20,711	$ (77)	

General and administrative expenses increased by $0.1 million from $20.7 million for the nine months ended September 30, 2021 to $20.6 million for the nine months ended September 30, 2022.

The increase in general and administrative expenses was due to professional services, driven by legal fees for intellectual property rights and offset by lower personnel, facility-related and other general and administrative costs, due to a lower number of employees.

Impairment expense

Impairment expense increased $4.5 million from no activity in the nine months ended September 30, 2021 to $4.5 million for the nine months ended September 30, 2022. The increase was due to our mutual agreement with Lonza to not utilize a portion of prepaid manufacturing services under the MSA in 2022.

Interest income

There was an immaterial change of less than $0.1 million in interest income between the nine months ended September 30, 2021 and the nine months ended September 30, 2022. All of our investments matured prior to the nine months ended September 30, 2022. As of September 30, 2022, we did not hold any investments.

Interest expense

Interest expense decreased by $0.1 million from $2.1 million for the nine months ended September 30, 2021 to $2.0 million for nine months ended September 30, 2022. The decrease was driven by slightly lower interest rates in the Amended Term Loan Facility, which became effective in September 2021.

Other income

Other income increased by $0.5 million from $1.2 million for the nine months ended September 30, 2021 to $1.7 million for the nine months ended September 30, 2022. The increase was due to the rental income received from our sublease at 4 Hartwell Place, which commenced in November 2021 and offset by the termination of our sublease at 35 CambridgePark Drive in September 2022.

Change in fair value of derivative liability - warrants

The change in the fair value of derivative liabilities increased by $2.7 million from no activity for the nine months ended September 30, 2021 to $2.7 million for the nine months ended September 30, 2022. The increase was due to the issuance of warrants and a subsequent decrease in fair value of our common stock.

Liquidity and capital resources

Sources of liquidity

Since our inception, we have incurred significant losses in each period and on an aggregate basis. We have not yet commercialized any of our engEx product candidates, which are in various phases of early-stage and clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. We have funded our operations through September 30, 2022 with aggregate net proceeds of $168.2 million from sales of our redeemable convertible preferred stock, $24.6 million from our term loan facility with Hercules, net of issuance costs, and $66.0 million received from our current collaboration with Jazz and our former collaboration with Sarepta. On October 16, 2020, we completed our IPO for net proceeds of $74.4 million, after deducting underwriting discounts and commissions and other offering expenses. On February 17, 2021, we completed a follow-on public offering for net proceeds of $61.7 million, after deducting underwriting discounts and commissions and other offering expenses. On September 15, 2022, we completed a follow-on public offering, pursuant to which we issued 14,027,665 shares of our common stock and accompanying warrants to purchase 14,027,665 shares of our common stock (inclusive of the partial exercise of the underwriter's option to purchase 694,332 additional shares of common stock and accompanying warrants to purchase 694,332 additional shares of our common stock) at a combined public offering price of $1.50 per share, resulting in aggregate net proceeds of $19.8 million, after deducting underwriting discounts and commissions and other offering expenses. During the nine-month period ended September 30, 2022, we raised $0.9 million, utilizing an "at-the-market" offering facility, pursuant to which we sold 236,303 shares of our common stock. As of September 30, 2022, we had cash and cash equivalents of $51.8 million. This amount will not be sufficient to fund our operations at the levels described in this Quarterly Report for the next 12 months. Maintaining our ongoing operations is dependent on our ability to obtain additional financing, as to which we can make no assurance.

Hercules Loan Agreement

On September 30, 2019 (the "Closing Date"), we entered into a loan and security agreement (the "Loan Agreement") with Hercules pursuant to which a term loan in an aggregate principal amount of up to $75.0 million (the "Term Loan Facility") was made available to us in four tranches, subject to certain terms and conditions. On the Closing Date, $10.0 million of the first tranche was advanced to us and an additional $15.0 million under the first tranche was drawn down on July 24, 2020. Under the Loan Agreement, there were three additional tranches available to us of $10.0 million ("tranche two"), $10.0 million ("tranche three"), and $30.0 million ("tranche four"). As of September 30, 2022, tranches two, three and four had expired.

Upon issuance, the initial advance under the first tranche was recorded as a liability with an initial carrying value of $9.5 million, net of debt issuance costs. The July 24, 2020 advance under the first tranche was recorded as a liability with an initial carrying value of $15.0 million. The initial carrying value of all outstanding advances is accreted to the repayment amount, which includes the outstanding principal plus the end of term charge, through interest expense using the effective interest rate method over the term of the loan.

Effective September 17, 2021 (the "Amended Closing Date"), we amended the Loan Agreement with Hercules (the "Amended Loan Agreement"), increasing the aggregate principal amount available under the Term Loan Facility to $85.0 million (the "Amended Term Loan Facility").

Under the Amended Term Loan Facility, a new tranche three of $10.0 million was established and was available through December 15, 2021. Tranche Four was amended such that $30.0 million was available through the interest only period, subject to future lender investment committee approval. A fifth tranche ("tranche five") of up to $20.0 million was established under the Amended Loan Agreement and is available through September 30, 2023, upon satisfaction of certain clinical milestones. Tranche five is only available in minimum draws of $5.0 million.

Advances under the Amended Term Loan Facility bear interest at a rate equal to the greater of (i) 8.25% plus the Prime Rate (as reported in *The Wall Street Journal*) less 3.25%, and (ii) 8.25%. The interest only period under the Term Loan Facility was extended from November 1, 2022 to October 1, 2023 under the Amended Term Loan Facility and is further extendable to October 1, 2024 upon achievement of certain clinical milestones. Under the Amended Term Loan Facility, following the interest only period, we will repay the principal balance and interest on the advances in equal monthly installments through October 1, 2025, compared to October 1, 2024 under the Term Loan Facility.

Prepayments on the Amended Loan Agreement, in whole or in part, at any time are subject to a prepayment charge (Prepayment Premium) equal to: (i) 2.0% of amounts so prepaid, if such prepayment occurs during the first year following the Amended Closing Date, (ii) 1.5% of the amount so prepaid, if such prepayment occurs during the second year following the Amended Closing Date, or (iii) 1.0% of the amount so prepaid, if such prepayment occurs after the second year following the Amended Closing Date.

Additionally, upon prepayment or repayment of all or any of the term loans under the Amended Term Loan Facility, the Company will pay an end of term charge of 5.5% of the aggregate funded amount under the Term Loan Facility. The end of term charge of $1.4 million, or 5.5% of the $25.0 million of principal advanced under the Term Loan Facility, remains payable at the maturity date under the original term Loan Facility of October 1, 2024.

The terms under the Amended Loan Agreement were not substantially different from those under the original Loan Agreement and the Amended Loan Agreement will be accounted for prospectively.

The Amended Term Loan Facility remains secured by a lien on substantially all of our assets, other than our intellectual property. We have agreed not to pledge or grant a security interest on our intellectual property to any third party. The Term Loan Facility also contains customary covenants and representations, including a liquidity covenant, whereby we are obligated to maintain, in an account covered by Hercules' account control agreement, an amount equal to the lesser of: (i) 110% of the amount of our obligations under the Term Loan Facility, or (ii) our then-existing cash and cash equivalents; financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries.

The events of default under the Amended Loan Agreement include, without limitation, and subject to customary grace periods, the following: (i) any failure by us to make any payments of principal or interest under the Amended Loan Agreement, (ii) any breach or default in the performance of any covenant under the Amended Loan Agreement, (iii) the occurrence of a material adverse effect, (iv) any making of false or misleading representations or warranties in any material respect, (v) our insolvency or bankruptcy, (vi) certain attachments or judgments on our assets, or (vii) the occurrence of any material default under certain of our agreements or obligations involving indebtedness. If an event of default occurs, Hercules is entitled to take enforcement action, including acceleration of amounts due under the Amended Loan Agreement.

Historical cash flows

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

	NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021
Net cash provided by (used in):		
Operating activities	$ (45,558)	$ (52,622)
Investing activities	(362)	(2,913)
Financing activities	20,744	65,204
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (25,176)	$ 9,669

Operating activities

The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in components of operating assets and liabilities, which are generally attributable to timing of payments, and the related effect on certain account balances, operational and strategic decisions and contracts to which we may be a party.

During the nine months ended September 30, 2022, operating activities used $45.6 million of cash, primarily due to a net loss of $34.1 million, coupled with a $25.0 million decrease in deferred revenue and a $4.5 million decrease in prepaid manufacturing services, which were partially offset by non-cash charges of $7.3 million for stock-based compensation, $2.7 million in change in fair value of the warrants and $3.2 million for depreciation and amortization. The change in our deferred revenue was due to activity under our Collaboration and License Agreement with Jazz.

During the nine months ended September 30, 2021, operating activities used $52.6 million of cash, primarily due to a net loss of $53.8 million, which was partially offset by non-cash charges of $8.1 million for stock-based compensation and $4.2 million for depreciation and amortization. The change in our deferred revenue was due to activity under our Collaboration and License Agreement with Jazz.

Investing activities

During the nine months ended September 30, 2022 and September 30, 2021, net cash used in investing activities was $0.4 million and $2.9 million, respectively, for purchases of property.

Financing activities

During the nine months ended September 30, 2022, net cash provided by financing activities was $20.7 million, driven by our follow-on offering completed on September 15, 2022 and our "at-the-market" offering facility. During the nine months ended September 30, 2021, net cash provided by financing activities was $65.2 million, driven by our follow-on public offering, completed on February 17, 2021 and additional proceeds from the exercise of stock options.

Plan of operation and future funding requirements

In August 2022, the board of directors of the Company approved a reduction of the Company's workforce by approximately 37% across all areas of the Company. This workforce reduction was completed as of September 30, 2022. These actions reflect the reprioritization of our clinical and research initiatives. We have paused plans to initiate Phase 2 trials of exoSTING and exoIL-12 while prioritizing our Phase 1 clinical trial of exoASO-STAT6.

We expect our expenses to increase in connection with our ongoing research and development activities, particularly as we advance our clinical trials of exoASO-STAT6 and our preclinical activities for our engEx development programs. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Based on our current operating plan, we expect that our cash and cash equivalents as of September 30, 2022 will be insufficient to allow us to fund our operating expenses and capital expenditure requirements for 12 months following the date of this Quarterly Report on Form 10-Q. We have based this estimate on assumptions that may prove to be wrong and we could exhaust our capital resources sooner than we expect.

On November 1, 2021, we and Lonza entered into an asset purchase agreement (the "APA") pursuant to which to Lonza acquired our exosome manufacturing facility and related assets, and subleased the premises, located at 4 Hartwell Place, Lexington, MA. As consideration for the asset purchase, we shall receive approximately $65.0 million worth of exosome manufacturing services for our clinical programs for four years. At the Lonza Closing, certain specialized manufacturing and quality personnel of ours became employees of Lonza.

In connection with, and as consideration for the APA, at the Lonza Closing, we and Lonza entered into a manufacturing services agreement (the "MSA"). Pursuant to the MSA, Lonza became the exclusive manufacturing partner for future clinical and commercial manufacturing of our exosome products pipeline.

In connection with, and at the Closing, we and Lonza entered into a licensing and collaboration agreement (the "License Agreement"). Pursuant to the License Agreement, we granted Lonza a worldwide, exclusive and sub-licensable license to our high-throughput exosome manufacturing intellectual property in the contract development and manufacturing field. Pursuant to the License, we are eligible to receive from Lonza a double-digit percentage of future sublicensing revenues. We shall retain our pipeline of therapeutic candidates and core exosome engineering, drug-loading expertise and related intellectual property. The companies will collaborate to establish a joint Center of Excellence for further development of exosome manufacturing technology, with a shared oversight committee. The Center of Excellence will leverage the strengths of both companies to pursue developments in exosome production, purification and analytics.

Because of the numerous risks and uncertainties associated with the development of our product candidates, and because the extent to which we may receive payments under our existing collaboration agreements or enter into collaborations with third parties for development of our product candidates is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including, but not limited to:

- the rate of progress in the development of our engEx Platform, engEx product candidates and development programs;
- whether and when we are able to resume clinical development of exoSTING and exoIL-12;
- the scope, progress, results and costs of preclinical studies and clinical trials for any engEx product candidates and development programs;
- the number and characteristics of programs and technologies that we develop or may in-license;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs necessary to obtain regulatory approvals, if any, for any approved products in the U.S. and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where any such approval is obtained;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the continuation of our existing strategic collaborations and licensing arrangements and entry into new collaborations and licensing arrangements;
- the costs we incur in maintaining business operations;
- the costs associated with being a public company;
- the revenue, if any, received from commercial sales of our engEx product candidates for which we receive marketing approval;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our engEx product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of our common stock. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially result in dilution to the holders of our common stock.

If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

The following table summarizes our contractual obligations as of September 30, 2022 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

	Payments due by period				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Operating lease commitments(1)(2)	$ 50,253	$ 6,389	$ 13,348	$ 14,145	$ 16,371
Long-term debt obligations(3)	25,000	—	23,830	1,170	—
Total	$ 75,253	$ 6,389	$ 37,178	$ 15,315	$ 16,371

(1) On March 5, 2019, we entered into a non-cancelable property lease for 18,707 square feet of manufacturing space in Lexington, Massachusetts. The lease term commenced in July 2019 and is expected to end in December 2029. We have the option to extend the lease twice, each for a five-year period, at market-based rent. We fully occupied the space in late 2020. Included in the table above are the future lease payments, which exclude operating expenses and real estate taxes. Lease payments began in January 2020 and are expected to be approximately $1.1 million in each of 2022, 2023, 2024, and 2025, $1.2 million in 2026, and $3.7 million thereafter. The landlord contributed a total of up to $1.3 million toward the cost of tenant improvements. We were required to provide a $0.4 million security deposit, which we provided in the form of a letter of credit in favor of the landlord. These amounts are excluded from the table above. In November 2021, we executed an amendment to the lease (the "Master Lease Amendment"). The only substantive change made to the terms and conditions of the master lease as instituted by the Master Lease Amendment relates to the fact that base rent charges increased by $7 per square foot per year for the remainder of the lease term.

(2) On March 22, 2019, we entered into a non-cancelable property lease for 68,258 square feet of office and laboratory space in Cambridge, Massachusetts. The lease term commenced upon execution of the lease on March 26, 2019 and is expected to end in November 2029. We have the option to extend the lease once for a ten-year period at market-based rent. We occupied the space in February 2020 as our new corporate headquarters. Included in the table above are the future lease payments, which exclude operating expenses and real estate taxes. Lease payments began in November 2019 and are expected to be approximately $5.2 million in 2022, $5.3 million in 2023, $5.5 million in 2024, $5.7 million in 2025, $5.8 million in 2026, and $18.1 million thereafter. The landlord has contributed a total of $12.3 million toward the cost of tenant improvements. We were required to provide a $3.7 million security deposit, which we provided in the form of a letter of credit in favor of the landlord. These amounts are excluded from the table above.

(3) On September 30, 2019 and amended on September 17, 2021, we entered into the Hercules Loan Agreement pursuant to which we may receive advances in separate tranches based on specified terms and provisions, of up to an aggregate principal amount of $85.0 million. As of December 31, 2021, we received advances at closing of $10.0 million and under the first tranche totaling $15.0 million, respectively, and paid issuance costs of $0.6 million. Advances under the Amended Term Loan Facility bear interest at a rate equal to the greater of (i) 8.25% plus the Prime Rate (as reported in The Wall Street Journal) less 3.25%, and (ii) 8.25%. The interest only period under the Term Loan Facility was extended from November 1, 2022 to October 1, 2023 under the Amended Term Loan Facility. We will now make interest only payments through October 1, 2023, which is further extendable to October 1, 2024 upon achievement of certain clinical milestones. Under the Amended Term Loan Facility, following the interest only period, we will repay the principal balance and interest on the advances in equal monthly installments through October 1, 2025.

Commencing on May 18, 2020, we entered into a sublease for 23,280 square feet of our leased space in Cambridge, Massachusetts. The term of the sublease was extended to three years following the sublessee's decision to exercise its option to extend the term for one additional year, effective July 1, 2021. We increased the base rent during the option period to reflect a market-based fixed annual rate beginning June 2022. We remained jointly and severally liable under the terms of the head lease and therefore present the cash payments, inclusive of our obligation under the head lease for the subleased premises. As such, operating lease commitments do not include the expected cash receipts under the sublease. Upon execution of the sublease agreement, the sublessee provided the Company with a security deposit of $0.3 million, which is held in the form of a letter of credit. In July 2022, the sublessee defaulted on its lease payments. The Company and the sublessee mutually agreed to terminate the sublease effective September 16, 2022. The Company claimed the $0.3 million security deposit and wrote off outstanding receivables of $0.3 million, which was recorded in other income. The Company is currently marketing the sublease to new tenants.

On November 15, 2021, we entered into a sublease agreement with Lonza (the "Sublease Agreement") for the entirety of the Company's leased space at 4 Hartwell Place in Lexington, Massachusetts. Under the terms of the Sublease Agreement, Lonza is obligated to pay the Company base rent of approximately $1.0 million per year, subject to a 2.8% annual increase, plus certain operating expenses and other costs. The initial lease term commenced on November 15, 2021 and continues through November 30, 2024. Lonza has the option to extend the sublease term for five 12-month periods on the same terms and conditions as the current sublease, subject to an increase of 2.8% in the annual fixed rent charges. Additionally, Lonza has the right to have the associated master lease assigned to it beginning on January 1, 2026, subject to the landlord’s consent. As of September 30, 2022, the Company has not been legally released from its primary obligations under the original lease. Therefore, the Company continues to account for the original lease as it did before commencement of the sublease, inclusive of the effects of the Master Lease Amendment. The Company determined that the sublease term is commensurate with the initial sublease term because it is not reasonably certain that any of the extension options will be exercised.

We have a license agreement with MDACC under which, pursuant to exclusive license rights granted to us under certain patents owned or co-owned by MDACC, we are obligated to pay milestone payments upon the achievement of development and regulatory milestones and the execution of sublicenses for qualifying products covered by rights granted under the agreement. MDACC is eligible to receive, on a product-by-product basis, milestone payments upon the achievement of development and regulatory milestones totaling up to $2.4 million for diagnostic products and up to $9.5 million for therapeutic products. Under this agreement, we may also be obligated to pay royalty payments on commercial products, on a product-by-product basis. Due to the variable and contingent nature of these payments, they are excluded from our contractual obligations as they are not fixed and estimable. We may terminate the license for convenience upon 180 days' prior written notice to MDACC. The license automatically terminates upon our bankruptcy, if we challenge the validity or enforceability of any of the licensed patent rights, or we fail to make a number of payments in a timely manner over a specified period of time. Additionally, MDACC may terminate the license for our breach subject to certain specified cure periods.

We have a license agreement with Kayla Therapeutics, pursuant to which we obtained a co-exclusive worldwide, sublicensable license, under certain patent rights and to related know-how and methods to research, develop, manufacture and commercialize compounds and products covered by such patent rights in all diagnostic, prophylactic and therapeutic uses. Such license rights include certain exclusive rights to the STING agonist compound in our exoSTING product candidate. Under the terms of the agreement, we are obligated to use commercially reasonable efforts to develop and commercialize products under the licensed patent rights, and are obligated to pay up to $100.0 million in cash payments and up to $13.0 million payable in shares of our common stock upon the achievement of specified clinical and regulatory milestones. The first milestone was achieved upon the dosing of exoSTING to the first subject in a Phase 1/2 clinical trial in September 2020. Upon the achievement of the milestone, the Company was obligated to make a nonrefundable payment of $15.0 million in cash and issue 177,318 shares of common stock to Kayla. The common stock was issued as of the date of dosing, and the cash payment of $15.0 million and was paid in October 2020. In addition, we are required to pay Kayla a percentage of the payments that we receive from sublicensees of the rights licensed to us by Kayla, excluding any royalties. The royalty term is determined on a product-by-product and country-by-country basis and continues until the later of (i) the expiration of the last valid claim of the licensed patent rights that covers such product in such country, (ii) the loss or expiration of any period of marketing exclusivity for such product in such country, and (iii) ten years after the first commercial sale of such product in such country; provided that if the royalty is payable when no valid claim covers a given product in a given country, the royalty rate for sales of such product in such country is decreased. We do not include these variable and contingent payments in the consideration of our contractual obligations as they are not fixed and estimable. We may terminate the license agreement on a licensed compound-by-licensed compound basis and on a region-by region basis for any reason upon 30 days' prior written notice to Kayla. We or Kayla may terminate the license agreement for the other’s material breach that remains uncured for 60 days after receiving notice thereof.

We have agreements with certain vendors for various services, including services related to preclinical operations and support, for which we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly, to reimburse them for their unrecoverable outlays incurred prior to cancellation. The exact amounts of such obligations are dependent on the timing of termination, and the exact terms of the relevant agreement and cannot be reasonably estimated. We do not include these payments in the consideration of our contractual obligations as they are not fixed and estimable.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical accounting policies and significant judgments and estimates

Our condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these condensed consolidated financial statements requires the application of appropriate technical accounting rules and guidance, as well as the use of estimates. The application of these policies necessarily involves judgments regarding future events. These estimates and judgments, in and of themselves, could materially impact the condensed consolidated financial statements and disclosures based on varying assumptions. The accounting policies discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 10, 2022 (the "2021 Annual Report"), are considered by management to be the most important to an understanding of the consolidated financial statements because of their significance to the portrayal of our financial condition and results of operations. There have been no material changes to that information disclosed in our 2021 Annual Report during the nine months ended September 30, 2022, except as noted in the footnotes.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including expenses, clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets. We have made estimates of the impact of COVID-19 within our financial statements and there may be changes to those estimates in future periods. Actual results could differ from our estimates.

Emerging growth company and smaller reporting company status

In April 2012, the Jumpstart Our Business Startups Act (the "JOBS Act") was enacted. As an emerging growth company ("EGC"), under the JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include an exemption from the requirement to provide an auditor’s report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. We have elected to avail ourselves of the exemption regarding the timing of the adoption of accounting standards and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not EGCs.

We will remain classified as an EGC until the earlier of: (i) the last day of our first fiscal year in which we have total annual gross revenues of $1.07 billion or more, (ii) the last day of the fiscal year following the fifth anniversary of our IPO, (iii) the date on which we have issued more than $1.0 billion of non-convertible debt instruments during the previous three fiscal years, or (iv) the date on which we are deemed a “large accelerated filer” under the rules of the SEC with at least $700.0 million of outstanding equity securities held by non-affiliates.

We are also a “smaller reporting company” and may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently issued accounting pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, such standards will not have a material impact on our financial statements or do not otherwise apply to our operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest rate fluctuation risk

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents are primarily invested in short-term U.S. Treasury obligations, and our Term Loan Facility bears interest at a variable rate.

Given the short-term nature of the instruments in our portfolio, an immediate change in market interest rates of 100 basis points would not have a material impact on the fair market value of our portfolio or on our financial position or results of operations.

Our Amended Term Loan Facility bears interest at a rate equal to the greater of (i) 8.25% plus the prime rate as reported in The Wall Street Journal less 3.25%, and (ii) 8.25%. Accordingly, increases in such prime rate could increase our interest payments under the Term Loan Facility. An increase of 100 basis points in the interest rate of the Term Loan Facility would not have a material impact on our financial position or results of operations.

Foreign currency fluctuation risk

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation fluctuation risk

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three months ended September 30, 2022 or 2021.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Principal Executive Officer (our Chief Executive Officer) and Principal Financial Officer (our Chief Financial Officer, Treasurer), has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2022, our Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Information regarding risks and uncertainties related to our business appears below and in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the Securities and Exchange Commission (the "SEC") on March 10, 2022 ("2021 Annual Report"). There have been no material changes from the risk factors previously disclosed in the 2021 Annual Report, except as discussed below. You should carefully consider the risks and uncertainties described in our 2021 Annual Report, together with all of the other information contained in this Quarterly Report on Form 10-Q. If any of the risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report.

Pursuant to our recently announced restructuring, we have paused clinical trials for exoSTING and exoIL-12 to prioritize focus on clinical trials for exoASO-STAT6. If we fail to execute successfully on this re-prioritized strategic focus, our business and prospects may be adversely affected.

On August 30, 2022, we announced that we have paused clinical trials for exoSTING and exoIL-12 to prioritize focus on Phase 1 clinical trials for exoASO-STAT6. We believe this re-prioritized strategic focus is the best way to optimize our financial and other resources to advance exoASO-STAT6. However, there is no assurance that we will be successful at executing on this strategy, and we cannot currently specify when, if ever, we will be able to resume clinical development of exoSTING and exoIL-12. If we are unable to execute successfully on this re-prioritized strategic focus, our business and prospects may be adversely affected.

Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the business development expertise of Douglas E. Williams, Ph.D., our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time.

On May 3, 2022, we implemented a restructuring that reduced our workforce by approximately 37%, to 53 full-time employees. The uncertainty inherent in this ongoing restructuring may be difficult to manage, may cause concerns from third parties with whom we do business, and may increase the likelihood of turnover of other key officers and employees.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully.

Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

We are undertaking internal restructuring activities that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition.

There can be no assurance that our restructuring will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. Restructuring activities may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. In addition, internal restructurings can require a significant amount of time and focus from management and other employees, which may divert attention from operations. Further, our restructuring may result in unexpected expenses or liabilities and/or write-offs. If our restructuring fails to achieve some or all of the anticipated benefits, our cash resources may not last as long as estimated and our business, results of operations and financial condition could be materially and adversely affected.

We may become involved in securities litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities litigation has often followed certain significant business transactions, such as the announcement of a strategic restructuring. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential partnership or other opportunities, or the ultimate value our stockholders receive in any such partnership or other opportunity.

Our shares of common stock could be delisted from the Nasdaq Global Market which could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock.

Our common stock is listed on the Nasdaq Global Market ("Nasdaq GM"), which imposes, among other requirements, a minimum $1.00 per share bid price requirement for continued inclusion on the Nasdaq GM pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Requirement"). The closing bid price for our common stock must remain at or above $1.00 per share to comply with the Bid Price Requirement for continued listing. On October 31, 2022 we received a deficiency letter (the "Notice") from the Listing Qualifications Department of the Nasdaq Stock Market, LLC ("Nasdaq") notifying us that, for the preceding 30 consecutive trading days, the closing bid price of our common stock was below the Bid Price Requirement.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have until May 1, 2023 (the "Compliance Date"), to regain compliance with the Bid Price Requirement. According to the Notice, if at any time before May 1, 2023, the closing bid price of our common stock is at least $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that we have achieved compliance with the Bid Price Requirement and our common stock will continue to be eligible for listing on the Nasdaq GM. If we do not regain compliance with the Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180 day compliance period under the following circumstances. To qualify, we would need to transfer the listing of the common stock to the Nasdaq Capital Market, provided that we meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards, with the exception of the Bid Price Requirement. To effect such a transfer, we would also need to pay an application fee to Nasdaq and will need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional compliance period by effecting a reverse stock split, if necessary. As part of its review process, Nasdaq would make a determination of whether it believes we will be able to cure this deficiency.

If Nasdaq concludes that we will not be able to cure the deficiency, or if we do not cure the deficiency within such additional 180 day compliance period, Nasdaq will provide written notification to us that our common stock will be subject to delisting. At that time, we may appeal Nasdaq's delisting determination to a Nasdaq Listing Qualifications Panel (the "Panel"). However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by Nasdaq to the Panel, such appeal would be successful.

There can be no assurance that we will be able to keep the Closing Bid Price above $1.00 per share for the required 10 consecutive trading days by May 1, 2023. Further, if we are unable to maintain the closing bid price at $1.00 for the required period, there is no guarantee that we will regain compliance with the Bid Price Requirement. There is no guarantee that a reverse stock split would be approved by the stockholders or that a reverse stock split would allow us to regain compliance with the Bid Price Requirement.

Additionally, delisting from the Nasdaq GM could make trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. If our common stock is delisted by the Nasdaq GM, our common stock may be eligible to trade on the Nasdaq Capital Market or an over-the-counter quotation system, where an investor may find it more difficult to sell our stock or obtain accurate quotations as to the market value of our common stock. We cannot assure you that our common stock, if delisted from the Nasdaq GM, will be listed on another national securities exchange or quoted on an over-the counter quotation system.

We intend to actively monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the minimum bid price requirement under the Nasdaq Listing Rules.

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

Recent Sales of Unregistered Securities

None.

Issuer Repurchases of Equity Securities

Not applicable.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Nasdaq Deficiency Notice

On October 31, 2022, we received a deficiency letter (the "Notice") from the Listing Qualifications Department of Nasdaq notifying us that, for the preceding 30 consecutive trading days, the closing bid price of our common stock was below the $1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Requirement"). At this current time, this Notice has no effect on the listing of our common stock, which continues to trade on the Nasdaq Global Market ("Nasdaq GM") under the symbol "CDAK".

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have until May 1, 2023 (the "Compliance Date") to regain compliance with the Bid Price Requirement. According to the Notice, if at any time before May 1, 2023, the closing bid price of our common stock is at least $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that we have achieved compliance with the Bid Price Requirement and our common stock will continue to be eligible for listing on the Nasdaq GM.

If we do not regain compliance with the Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180 day compliance period under the following circumstances. To qualify, we would need to transfer the listing of the common stock to the Nasdaq Capital Market, provided that we meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards, with the exception of the Bid Price Requirement. To effect such a transfer, we would also need to pay an application fee to Nasdaq and will need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional compliance period by effecting a reverse stock split, if necessary. As part of its review process, Nasdaq would make a determination of whether it believes we will be able to cure this deficiency.

If Nasdaq concludes that we will not be able to cure the deficiency, or if we do not cure the deficiency within such additional 180 day compliance period, Nasdaq will provide written notification to us that our common stock will be subject to delisting. At that time, we may appeal Nasdaq's delisting determination to a Nasdaq Listing Qualifications Panel (the "Panel"). However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by Nasdaq to the Panel, such appeal would be successful.

We intend to actively monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the minimum bid price requirement under the Nasdaq Listing Rules.

Item 6. Exhibits.

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document: the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set.

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

Codiak BioSciences, Inc.

Date: November 3, 2022

By: /s/ Douglas E. Williams

Douglas E. Williams, Ph.D.
Chief Executive Officer, Director
(Principal Executive Officer)

Date: November 3, 2022

By: /s/ Linda C. Bain

Linda C. Bain
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Douglas E. Williams, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Codiak BioSciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2022

By: /s/ DOUGLAS E. WILLIAMS
Douglas E. Williams, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Linda C. Bain, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Codiak BioSciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2022

By: /s/ LINDA C. BAIN
Linda C. Bain
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of Codiak BioSciences, Inc. (the "Company") for the period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers herby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to such officer's knowledge:

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

2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated in the Report.

Date: November 3, 2022

By: /s/ DOUGLAS E. WILLIAMS
Douglas E. Williams, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 3, 2022

By: /s/ LINDA C. BAIN
Linda C. Bain
Chief Financial Officer
(Principal Financial and Accounting Officer)