UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

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: 001-38244

GENPREX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**90-0772347**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3300 Bee Cave Road, #650-227 , Austin, TX	**78746**
(Address of principal executive offices)	(Zip Code)

(512) 537-7997

(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	GNPX	The Nasdaq Capital Market

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

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

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

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

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

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

As of November 5, 2024, the registrant had 8,508,068 shares of common stock, par value $0.001 per share, outstanding.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

Genprex, Inc.

Condensed Balance Sheets

	September 30, 2024 (unaudited)	December 31, 2023 (see Note 2)
Assets		
Current assets:		
Cash and cash equivalents	$ 1,488,281	$ 6,737,629
Prepaid expenses and other	429,222	794,138
Total current assets	1,917,503	7,531,767
Property and equipment, net	463	7,859
Other non-current assets:		
Security deposits	—	10,000
Research and development supplies	1,989,299	2,347,488
Intellectual property, net	—	773,478
Total other assets	1,989,299	3,130,966
Total assets	$ 3,907,265	$ 10,670,592
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,304,121	$ 1,397,610
Other current liabilities	938,173	1,856,598
Total current liabilities	2,242,294	3,254,208
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock $0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Common stock $0.001 par value: 200,000,000 shares authorized; 5,489,152 and 1,485,902 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	5,489	1,486
Additional paid-in capital	152,128,463	141,103,178
Accumulated deficit	(150,468,981)	(133,688,280)
Total stockholders' equity	1,664,971	7,416,384
Total liabilities and stockholders' equity	$ 3,907,265	$ 10,670,592

See accompanying notes to the unaudited condensed financial statements.

Genprex, Inc.

Condensed Statements of Operations (unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Depreciation	$ 1,272	$ 3,724	$ 6,230	$ 11,578
Research and development	2,756,081	4,616,546	7,696,982	13,903,611
General and administrative	1,566,085	3,166,057	9,135,225	11,173,643
Total operating expenses	4,323,438	7,786,327	16,838,437	25,088,832
Operating loss	(4,323,438)	(7,786,327)	(16,838,437)	(25,088,832)
Interest income	8,080	51,391	58,851	175,413
Realized loss	(629)	(13,307)	(1,115)	(17,790)
Net loss	$ (4,315,987)	$ (7,748,243)	$ (16,780,701)	$ (24,931,209)
Net loss per share—basic and diluted	$ (1.23)	$ (5.36)	$ (6.90)	$ (18.77)
Weighted average number of common shares—basic and diluted	3,499,802	1,445,172	2,431,695	1,327,930

See accompanying notes to the unaudited condensed financial statements.

Genprex, Inc.

Condensed Statements of Changes in Stockholders' Equity (unaudited)

	Common Stock Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2023	1,485,902	$ 1,486	$ 141,103,178	$ (133,688,280)	$ 7,416,384
Issuance of common stock, pre-funded warrants, and warrants for cash, net of issuance costs	323,474	323	6,792,876	—	6,793,199
Issuance of common stock for services	36,375	36	180,684	—	180,720
Company issued rounding of street name accounts for reverse stock split	64,690	65	(65)	—	—
RSUs conversion to common stock	12,145	13	(13)	—	—
Share-based compensation	—	—	335,246	—	335,246
Net loss	—	—	—	(5,968,869)	(5,968,869)
Balance at March 31, 2024	1,922,586	$ 1,923	$ 148,411,906	$ (139,657,149)	$ 8,756,680
Issuance of common stock, pre-funded warrants, and warrants for cash, net of issuance costs	608,671	609	20,153	—	20,762
Issuance of common stock for services	5,000	5	14,845	—	14,850
RSUs conversion to common stock	19,478	19	(19)	—	—
Share-based compensation	—	—	2,049,103	—	2,049,103
Net loss	—	—	—	(6,495,845)	(6,495,845)
Balance at June 30, 2024	2,555,735	$ 2,556	$ 150,495,988	$ (146,152,994)	$ 4,345,550
Issuance of common stock, pre-funded warrants, and warrants for cash, net of issuance costs	2,928,417	2,928	1,212,254	—	1,215,182
Issuance of common stock for services	5,000	5	9,645	—	9,650
Share-based compensation	—	—	410,576	—	410,576
Net loss	—	—	—	(4,315,987)	(4,315,987)
Balance at September 30, 2024	5,489,152	$ 5,489	$ 152,128,463	$ (150,468,981)	$ 1,664,971
Balance at December 31, 2022	1,202,677	$ 1,203	$ 125,101,356	$ (102,827,819)	$ 22,274,740
Issuance of common stock, pre-funded warrants, and warrants for cash, net of issuance costs	96,581	96	4,080,684	—	4,080,780
Issuance of common stock for services	125	—	21,885	—	21,885
Share-based compensation	—	—	1,310,230	—	1,310,230
Net loss	—	—	—	(9,202,774)	(9,202,774)
Balance at March 31, 2023	1,299,383	$ 1,299	$ 130,514,155	$ (112,030,593)	$ 18,484,861
Issuance of common stock, pre-funded warrants, and warrants for cash, net of issuance costs	—	—	—	—	—
Issuance of common stock for services	125	1	4,399	—	4,400
Share-based compensation	—	—	1,541,805	—	1,541,805
Net loss	—	—	—	(7,980,192)	(7,980,192)
Balance at June 30, 2023	1,299,508	$ 1,300	$ 132,060,359	$ (120,010,785)	$ 12,050,874
Issuance of common stock, pre-funded warrants, and warrants for cash, net of issuance costs	186,144	186	6,512,407	—	6,512,593
Issuance of common stock for services	125	—	4,795	—	4,795
Share-based compensation	—	—	1,485,474	—	1,485,474
Net loss	—	—	—	(7,748,243)	(7,748,243)
Balance at September 30, 2023	1,485,777	$ 1,486	$ 140,063,035	$ (127,759,028)	$ 12,305,493

See accompanying notes to the unaudited condensed financial statements.

Genprex, Inc.

Condensed Statements of Cash Flows (unaudited)

	Nine Months Ended September 30, 2024	2023
Cash flows from operating activities:		
Net loss	$ (16,780,701)	$ (24,931,209)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6,230	11,578
Share-based compensation and issuance of stock for services	3,000,145	4,368,589
Intellectual property	773,478	—
Changes in operating assets and liabilities:		
Accounts receivable	—	34,852
Prepaid expenses and other	374,916	(656,871)
Research and development supplies	358,189	(129,523)
Accounts payable	(93,488)	736,266
Other current liabilities	(918,427)	791,578
Net cash used in operating activities	(13,279,658)	(19,774,740)
Cash flows from investing activities:		
Disposals of property and equipment	1,167	—
Additions to intellectual property	—	(61,383)
Net cash provided by (used in) investing activities	1,167	(61,383)
Cash flows from financing activities:		
Net proceeds from issuances of common stock, pre-funded warrants, and warrants	8,029,143	10,593,373
Net cash provided by financing activities	8,029,143	10,593,373
Net decrease in cash and cash equivalents	(5,249,348)	(9,242,750)
Cash and cash equivalents, beginning of period	6,737,629	20,954,069
Cash and cash equivalents, end of period	$ 1,488,281	$ 11,711,319

See accompanying notes to the unaudited condensed financial statements.

GENPREX, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2024

Note 1 - Description of Business and Basis of Presentation

Unless the context requires otherwise, references to "Genprex," the "Company," "we," "us" or "our" in this Quarterly Report on Form 10-Q refer to Genprex, Inc. Genprex, incorporated in Delaware in April 2009, is a clinical stage gene therapy company pioneering the development of gene-based therapies for large patient populations with unmet medical needs. The Company's oncology platform utilizes its systemic, non-viral Oncoprex® Delivery System which uses lipid-based nanoparticles in a lipoplex form to deliver tumor suppressor gene-expressing plasmids to cancer cells. The product is administered intravenously, where it is taken up by tumor cells that then express tumor suppressor proteins that were deficient in the tumor. The Company's diabetes technology is designed to work in Type 1 diabetes by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but may be distinct enough from beta cells to evade the body's immune system. In Type 2 diabetes, the Company's technology is believed to work by replenishing and rejuvenating exhausted beta cells that make insulin.

Oncology Platform

Genprex's lead oncology drug candidate, Reqorsa® (*quaratusugene ozeplasmid*), previously referred to as GPX-001, is a gene therapy initially being developed in combination with prominent, approved cancer drugs to treat Non-Small Cell Lung Cancer ("NSCLC") and Small Cell Lung Cancer ("SCLC"). REQORSA has multimodal effects on cancer cells. It harms the metabolism of cancer cells, which leads to reduced cancer cell growth. It also interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for apoptosis, or programmed cell death, in cancer cells, and increases the immune response against cancer cells. In preclinical studies, REQORSA has been shown to be complementary with targeted drugs and immunotherapies. The Company's strategy is to develop REQORSA in combination with current approved therapies and the Company believes REQORSA's unique attributes position it to provide treatments that improve on these current therapies for patients with NSCLC, SCLC, and possibly other cancers.

The TUSC2 gene, which is the key component of REQORSA and plays a vital role in cancer suppression and normal cell metabolism, is one of a series of genes on the short arm of Chromosome 3 whose therapeutic use is covered by the Company's exclusive worldwide licenses from The University of Texas MD Anderson Cancer Center ("MD Anderson"). Genprex believes that its ONCOPREX Delivery System allows for the delivery of a number of cancer-fighting tumor suppressor genes, alone or in combination with other cancer therapies, to combat multiple types of cancer and the Company is in early stages of discovery programs to identify other cancer candidates. In August 2022, Genprex entered into a three-year sponsored research agreement with MD Anderson to support further preclinical studies of TUSC2 and other tumor suppressor genes. Additionally, the Company is collaborating with MD Anderson to discover, develop and utilize biomarkers to select the patient population most likely to respond to REQORSA and enable decisions on progression of the Company's drug candidates to the next phase of development. MD Anderson is currently analyzing biomarkers that would indicate lack of response in lung cancer that could enrich the Company's population of responders in its clinical trials and enhance patient screening and enrollment in order to increase the likelihood of potential success of the Acclaim studies for the Company.

Acclaim-3: The Company is currently enrolling and treating patients in the Phase 1 dose escalation portion of its Phase 1/2 Acclaim-3 clinical trial. The Acclaim-3 clinical trial uses a combination of REQORSA and Genentech, Inc.'s Tecentriq® (*atezolizumab*) as maintenance therapy in patients with extensive stage small cell lung cancer ("ES-SCLC") who did not develop tumor progression after receiving Tecentriq and chemotherapy as initial standard treatment. Patients are treated with REQORSA and Tecentriq until disease progression or unacceptable toxicity is experienced. In January 2024, the Company opened the Phase 1 portion of the Acclaim-3 study for enrollment and enrolled and dosed the first patient in May 2024. In October 2024, the Company announced the completion of the 0.09 mg/kg dose group of the Phase 1 portion and that there were no dose limiting toxicities in this dose group. The Acclaim-3 Safety Review Committee therefore approved escalation to the highest dose group of 0.12 mg/kg, which will now be enrolled. The Company continues to anticipate completion of enrollment in the Phase 1 dose escalation portion of the study and to start the Phase 2 expansion portion of the study in the second half of 2024, dependent on the number of patients needed to be enrolled in the 0.12 mg/kg dose group. The first patient treated in the Phase 1 dose escalation portion of the Acclaim-3 trial experienced an initial positive response after enrollment and dosing commenced in May. The patient had a partial remission ("PR"), which is defined as at least a thirty percent (30%) decrease in tumor size, from the time the patient had a baseline CT scan after induction therapy and prior to the start of maintenance therapy to the time of the CT scan performed after two cycles of maintenance therapy. As the maintenance therapy consists of REQORSA and Tecentriq, and the patient had already received four cycles of Tecentriq during induction therapy and thus responses to Tecentriq would likely have occurred earlier, the Company believes this suggests that REQORSA may be providing clinical benefit. A follow-up CT scan, performed after four cycles of maintenance therapy (three months), confirmed that the patient still had a 30% decrease in tumor size in measurable lesions; however, one lesion not previously measurable had grown in size, thus leading to a conclusion of disease progression at three months. In June 2023, the United States Food and Drug Administration ("FDA") granted Fast Track Designation for the Acclaim-3 treatment combination of REQORSA and Tecentriq as maintenance therapy in patients with ES-SCLC who did not develop tumor progression after receiving Tecentriq and chemotherapy as initial standard treatment. In August 2023, the FDA granted Orphan Drug Designation to REQORSA for the treatment of SCLC.

Acclaim-2: The Acclaim-2 trial involved a combination of REQORSA and Merck & Co.'s Keytruda® (*pembrolizumab*) in patients with late-stage NSCLC whose disease has progressed after treatment with Keytruda. As previously announced in August 2024, based on a number of factors, including enrollment challenges and delays due to competition for investigators and eligible patients with numerous other trials involving the same patient population, the Company decided to cease enrollment of new patients in the Acclaim-2 trial to prioritize its resources and focus on the other two Acclaim trials in SCLC and NSCLC, respectively. The one patient continuing to receive REQORSA treatment in the Phase 1 dose escalation portion of the study will continue to be treated until disease progression.

Acclaim-1:The Company is currently enrolling and treating patients in the Phase 2a expansion portion of its Phase 1/2 Acclaim-1 clinical trial. The Acclaim-1 trial uses a combination of REQORSA and AstraZeneca's Tagrisso® (*osimertinib*) in patients with late-stage NSCLC that has activating epidermal growth factor receptor ("EGFR") mutations and progression after treatment with Tagrisso. Following the May 2023 completion of the Phase 1 dose escalation portion of the study, the Acclaim-1 Safety Review Committee ("Acclaim-1 SRC") approved advancement from the Phase 1 dose escalation portion to the Phase 2a expansion portion of the study. Based on a review of safety data which showed no dose limiting toxicities, the Acclaim-1 SRC determined the recommended Phase 2 dose of REQORSA to be 0.12 mg/kg. This was the highest dose level delivered in the Phase 1 portion of the study and is twice the highest dose level delivered in the Company's prior clinical trial combining REQORSA with Tarceva® (*erlotinib*) for the treatment of late-stage lung cancer. There are still two patients originally enrolled in the Phase 1 dose escalation portion of the study who have had prolonged progression-free survival and continue to receive treatment with REQORSA and Tagrisso, one who attained a PR after the second course of REQORSA and Tagrisso and has maintained this response through 41 courses of treatment (approximately 30 months), and one with stable disease without disease progression through 26 courses of treatment (approximately 19 months) who is also continuing to receive REQORSA and Tagrisso treatment. Genprex opened the Phase 2a expansion portion of the study and enrolled and dosed the first patient in January 2024. The initial trial design of the Phase 2a expansion portion of the study included two cohorts with half being patients who received only prior Tagrisso treatment and the other half being patients who received prior Tagrisso treatment and chemotherapy. However, as previously announced in August 2024, based on resource prioritization and to focus on the patients for whom REQORSA is most likely to show a benefit, the Company decided to limit its enrollment efforts moving forward to patients who received only prior Tagrisso treatment and cease enrollment of the second cohort (patients who received prior Tagrisso treatment and chemotherapy). The Phase 2a expansion portion of the trial with one cohort is now expected to enroll approximately 33 patients. The Phase 2b randomized portion of the study, in which patients progressing on prior Tagrisso treatment will be randomized 1:1 to either REQORSA and Tagrisso combination therapy or to platinum-based chemotherapy, will remain unchanged. There will be an interim analysis following the treatment of 19 patients

in the Phase 2a portion of the Acclaim- 1 study. The Company expects to complete the enrollment of the first 19 patients in the Phase 2a expansion portion of the study and conduct an interim analysis in the first half of 2025. The FDA has granted Fast Track Designation for the Acclaim- 1 treatment combination of REQORSA and Tagrisso in NSCLC patients who have progressed after Tagrisso treatment.

Diabetes Gene Therapy

In diabetes, the Company has exclusively licensed from the University of Pittsburgh of the Commonwealth System of Higher Education ("University of Pittsburgh") multiple technologies relating to the development of a gene therapy product for each of Type 1 and Type 2 diabetes. The same general novel approach is used in each of Type 1 and Type 2 diabetes whereby an adeno-associated virus ("AAV") vector containing the Pdx1 and MafA genes is administered directly into the pancreatic duct. In humans, this can be done with a routine endoscopy procedure. The Company's diabetes product candidates are currently being evaluated and optimized in preclinical studies at the University of Pittsburgh. GPX-002 is being developed using the same construct for the treatment of both Type 1 diabetes and Type 2 diabetes. GPX-002 for Type 1 diabetes is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but may be distinct enough from beta cells to evade the body's immune system. In a similar approach, GPX-002 for Type 2 diabetes (formerly known as GPX-003), where autoimmunity is not at play, is believed to work by replenishing and rejuvenating exhausted beta cells that make insulin. Genprex finalized the components of the diabetes construct to take forward for nonclinical studies and in December 2023, the Company submitted a request to meet with the FDA to obtain their guidance on the nonclinical studies needed to file an Investigational New Drug ("IND") application and initiate first-in-human studies. As a result of the FDA's response, the Company will continue with its planned additional nonclinical studies before requesting regulatory guidance for the IND-enabling studies. The Company is currently working with the University of Pittsburgh on species analyses for the animal models as well as on other regulatory and clinical strategic planning and anticipates requesting further regulatory guidance from the FDA in the first half of 2025. In October 2023, Genprex entered into a one-year extension to its August 2022 sponsored research agreement with the University of Pittsburgh for the use of GPX-002 in a non-human primate ("NHP") model in Type 2 diabetes. The extension includes a revised research plan to encompass the Company's most recent technologies to which it acquired exclusive rights from the University of Pittsburgh in July 2023. These include using a MafB promoter to drive expression of the Pdx1 and MafA transcription factors that can potentially be used for both Type 1 and Type 2 diabetes. Additionally, in September 2024, Genprex announced that it is considering various strategic alternatives and opportunities to enhance stockholder value, including evaluating ways to optimize its clinical and research programs and operational strategies, such as its intention to potentially transfer the Company's diabetes clinical development program and its diabetes gene therapy assets into a new, initially wholly-owned subsidiary ("NewCo"). NewCo would focus on developing and commercializing GPX-002. The spin-out, if completed as presently contemplated, would result in NewCo focusing on developing GPX-002, while Genprex would retain its oncology clinical development programs and other oncology pipeline assets. The potential formation and transfer of the clinical development program into the wholly-owned subsidiary is currently anticipated to occur by the end of 2024, subject to adequate financing, the satisfaction of customary conditions and final approval from the Genprex management and board of directors.

Capital Requirements, Liquidity and Going Concern Considerations

The Company's unaudited condensed financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP") applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, the Company has sustained substantial losses from operations since inception and has no current source of revenue. In addition, the Company has used, rather than provided, cash in its operations. Genprex expects to continue to incur significant expenditures to further clinical trials for the commercial development of its patents.

The Company recognizes that it must obtain additional capital resources to successfully commercialize its product candidates. To date, Genprex has received funding in the form of equity and debt, and the Company plans to seek additional funding in the future. However, no assurances can be given that it will be successful in raising additional capital. If the Company is not able to timely and successfully raise additional capital, the timing of its clinical trials, financial condition and results of operations may be materially and adversely affected. These unaudited condensed financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities.

Genprex believes that its current cash and cash equivalents will be sufficient to fund expenditure requirements for its necessary operations and expected clinical trial activities into December 2024. The Company has based these estimates, however, on assumptions that may prove to be wrong, and could spend available financial resources much faster than it currently expects. The Company will need to raise additional funds to continue funding its development and operations. The Company plans to secure such additional funding, although there are no guarantees or commitments for additional funding.

As a result of its recurring losses from operations and the need for additional financing to fund its operating and capital requirements, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt as to the Company's ability to continue as a going concern. The unaudited condensed financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

GENPREX, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2024

Note 2 - Summary of Significant Accounting Policies

Genprex's unaudited condensed financial statements have been prepared in accordance with US GAAP and the requirements of the United States Securities and Exchange Commission (the "SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that is normally required by US GAAP can be condensed or omitted. Accordingly, they do not include all of the information and footnotes normally included in financial statements prepared in conformity with US GAAP. The December 31, 2023 condensed balance sheet was derived from the December 31, 2023 audited financial statements. Genprex's unaudited condensed financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's 2023 Annual Report on Form 10-K, filed with the SEC on April 1, 2024 (the "Form 10-K").

The accompanying condensed financial statements are unaudited and include all adjustments (consisting of normal recurring adjustments) that management considers necessary for a fair presentation of Genprex's condensed financial position and results of operations for the interim periods presented. The results of operations for the interim periods are not necessarily indicative of the results that may be expected for any other interim period or for the entire year.

A summary of Genprex's significant accounting policies consistently applied in the preparation of the accompanying unaudited condensed financial statements follows.

Change in Accounting Principle

During the nine months ended September 30, 2024, the Company changed an accounting principle related to accounting treatment of intellectual property expenditures. Previously, the Company capitalized certain intellectual property costs associated with the filing or maintenance of specific patents, including application costs, filing fees, and patent prosecution, in accordance with ASC 350-30. The Company voluntarily changed this accounting principle to expense, rather than capitalize, these intellectual property costs on the basis that the new treatment is favorable.

Reverse Stock Split

On February 2, 2024, Genprex completed a 1-for-40 reverse stock split ("Reverse Split") of its issued and outstanding shares of common stock. The Reverse Split did not change the number of authorized shares of common stock or par value. All references in these unaudited condensed financial statements to shares, share prices, exercise prices, and other per share information in all periods have been adjusted, on a retroactive basis, to reflect the Reverse Split (see Note 4 – Equity – Reverse Stock Split).

Use of Estimates

The preparation of Genprex's unaudited condensed financial statements in conformity with US GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Genprex considers all highly liquid short-term investments with an initial maturity of three months or less to be cash equivalents. Any amounts of cash in financial institutions which exceed Federal Deposit Insurance Corporation ("FDIC") insured limits expose the Company to cash concentration risk. The Company has cash in a money market account and had $1,238,246 and $6,490,117 in excess of FDIC insured limits of $250,000 at September 30, 2024 and December 31, 2023, respectively. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flows.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock, which includes common stock equivalents consisting of (i) 2,264,871 unexercised options granted by the Company's board of directors and unexercised warrants to purchase shares of common stock, and (ii) 10,143 unvested restricted stock units granted by the Company's board of directors representing the right upon vesting to receive shares of common stock as of September 30, 2024.

Fair Value of Financial Instruments

The carrying amounts reported in the condensed balance sheets for cash, money-market savings account, accounts receivable, and accounts payable approximate fair value because of the immediate or short-term maturity of these condensed financial instruments.

GENPREX, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2024

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Routine maintenance and repairs are charged to expense as incurred and major renovations or improvements are capitalized.

Research and Development Costs

Research and development expenditures consist of costs incurred to conduct research, develop engineering materials for further study, and develop clinical strategies for current and future programs associated with the Company's preclinical and Phase 1/2 clinical trials. These expenditures are expensed in the period incurred and include payments to collaborative research partners, manufacturing partners and consultants, and clinical strategy partners, wages and associated employee benefits, facilities, and overhead costs.

Materials acquired to be used in clinical research, that have an alternative future use, are capitalized when the materials are acquired, and included in research and development supplies. These supplies are recognized as expense as they are consumed through use for testing or clinical activities, or have spoiled. The costs of materials that were acquired for a particular research and development activity and have no alternative future use are expensed in the period acquired.

Research and development supplies purchased, valued at cost, and capitalized for future use were $ 1,989,299 and $2,347,488 at September 30, 2024 and December 31, 2023, respectively.

Intellectual Property

Intellectual property consists of legal and related costs associated with patents, trademarks, and other proprietary technology and rights developed, acquired, or licensed by Genprex. Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. These patent-related legal costs are reported as a component of general and administrative expenses.

Accounting for Stock-Based Compensation

Genprex uses the fair value-based method of accounting for stock-based compensation for options granted to employees, independent consultants and contractors. The Company measures options granted at fair value determined as of the grant date and recognizes the expense over the periods in which the options vest or are expected to vest and related services are rendered based on the terms and conditions of the award. Generally, where the award only has a service condition, the requisite service period is the same as the vesting period.

Long-Lived Assets

Genprex reviews long-lived assets and certain identifiable intangibles held and used for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In evaluating the fair value and future benefits of its intangible assets, the Company performs an analysis of the anticipated undiscounted future net cash flow of the individual assets over the remaining amortization period. The Company recognizes an impairment loss if the carrying value of the asset exceeds the discounted expected future cash flows. During the three and nine months ended September 30, 2024 and 2023, there were no deemed impairments of the Company's long-lived assets.

Recent Accounting Developments

Accounting pronouncements issued but not effective until after September 30, 2024, are not expected to have a significant effect on the Company's financial condition, results of operations, or cash flows.

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures," which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The purpose of the amendment is to enable investors to better understand an entity's overall performance and assess potential future cash flows. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the effect the amendments in ASU 2023-07 will have on its segment disclosures.

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," which modifies the rules on income tax disclosures to require disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the effect the amendments in ASU 2023-09 will have on its tax disclosures.

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Note 3 - Intellectual Property

As of September 30, 2024, Genprex owned or had exclusive license agreements on 22 granted patents and 26 pending patent applications worldwide for technologies developed in-house or by researchers at the National Cancer Institute, MD Anderson, the University of Texas Southwestern Medical Center, and the University of Pittsburgh. These patents comprise various therapeutic, diagnostic, technical and processing claims and costs are expensed as incurred.

University of Pittsburgh

On February 11, 2020, Genprex entered into an exclusive license agreement with the University of Pittsburgh for patented gene therapy technologies relating to the potential treatment of Type 1 and Type 2 diabetes. This license was first amended on August 17, 2022, to extend the milestone related to the filing of a new investigational drug ("IND") application. This license was amended again on November 3, 2022, to include a new licensed glucagon promoter technology related to Type 1 diabetes and set FDA and clinical milestones related to the glucagon technology (see Note 7 – Commitments and Contingences – Commitments – University of Pittsburgh).

On November 22, 2022, Genprex entered into an exclusive license agreement with the University of Pittsburgh relating to the transformation of macrophages enabling them to reduce autoimmunity activity in Type 1 diabetes.

On December 29, 2022, Genprex entered into an exclusive license agreement with the University of Pittsburgh relating to the use of an insulin promoter in combination with the Company's existing gene therapy, including the Pdx1 and MafA transcription factors, as a potential treatment for Type 2 diabetes.

On July 14, 2023, Genprex entered into an exclusive license agreement with the University of Pittsburgh related to a gene therapy for both Type 1 and Type 2 diabetes using a MafB promoter to drive expression of the Pdx1 and MafA transcription factors.

The University of Texas MD Anderson Cancer Center

On May 4, 2020, Genprex entered into an exclusive worldwide license agreement with The Board of Regents of the University of Texas System on behalf of MD Anderson relating to a portfolio of patent applications and related technology for the treatment of cancer using the Company's lead drug candidate and immunotherapies.

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Note 4 - Equity

Reverse Stock Split

At Genprex's special meeting of stockholders held on December 14, 2023, the Company's stockholders granted the Company's board of directors the discretion to effect a reverse stock split of the Company's issued and outstanding common stock through an amendment (the "Certificate of Amendment") to the Company's Amended and Restated Certificate of Incorporation, as amended and restated to date, at a ratio of not less than 1-for-10 and not more than 1-for-50, such ratio to be determined by the Company's board of directors. On January 19, 2024, the Company's board of directors approved a 1-for-40 reverse stock split and authorized the filing of the Certificate of Amendment for the Reverse Split with the Secretary of State of the State of Delaware. The Reverse Split became effective in accordance with the terms of the Certificate of Amendment on February 2, 2024. The Certificate of Amendment did not change the number of authorized shares of common stock or the par value. All references in these unaudited condensed financial statements to shares, share prices, exercise prices, and other per share information in all periods have been adjusted, on a retroactive basis, to reflect the Reverse Split.

Registered Direct Offerings

On March 1, 2023, Genprex completed a registered direct offering, in which the Company sold to an accredited healthcare-focused institutional investor an aggregate of 95,239 shares of its common stock and warrants to purchase up to 95,239 shares of its common stock, at a combined offering price of $42.00 per share of common stock and accompanying warrant. The warrants are exercisable immediately upon issuance, expire five years from the date of issuance and have an exercise price of $44.00 per share. The Company received net proceeds of approximately $ 3.6 million after $400,000 of commissions and expenses, excluding any proceeds that may be received in the future from any exercise of the warrants.

On July 21, 2023, Genprex completed a registered direct offering priced at the market under Nasdaq rules, in which the Company sold to accredited healthcare-focused institutional investors an aggregate of (i) 185,644 shares of its common stock, and (ii) warrants to purchase up to 185,644 shares of its common stock, at a combined offering price of $40.40 per share of common stock and accompanying warrant. The warrants are exercisable immediately upon issuance, expire 5 years from the date of issuance and have an exercise price of $ 35.40 per share. Also, the Company agreed to issue to H.C. Wainwright & Co., LLC or its designees (the "Placement Agent") warrants to purchase up to an aggregate of 11,140 shares of the Company's common stock. The warrants issued to the Placement Agent have substantially the same terms as the warrants issued to the investors except that the Placement Agent warrants have an exercise price of $50.50 per share and expire on July 18, 2028. Genprex received net proceeds of approximately $6.7 million after approximately $800,000 of commissions and expenses, excluding any proceeds that may be received in the future from any exercise of the warrants.

On March 21, 2024, the Company completed a registered direct offering priced at the market under Nasdaq rules, in which the Company sold to an institutional investor an aggregate of (i) 165,000 shares of common stock, (ii) pre-funded warrants (the "March 2024 Pre-Funded Warrants") exercisable for up to an aggregate of 1,377,112 shares of common stock, and (iii) warrants (the "March 2024 Common Warrants") exercisable for up to an aggregate of 1,542,112 shares of common stock. The offering price for each share of common stock and accompanying March 2024 Common Warrant was $4.215, and the offering price for each March 2024 Pre-Funded Warrant and accompanying March 2024 Common Warrant was $4.2149. The March 2024 Pre-Funded Warrants were exercisable immediately upon issuance at an exercise price of $ 0.0001 per share and expired when exercised in full. The March 2024 Common Warrants are exercisable immediately upon issuance at an exercise price of $ 4.09 per share and will expire in five years from the date of issuance. The Company received net proceeds of approximately $5.8 million after commissions and expenses, excluding any proceeds received from any exercise of the March 2024 Common Warrants. In connection with the offering, the Company also amended certain existing warrants to purchase up to an aggregate of 194,248 shares of common stock that were previously issued to investors in March 2023 and July 2023, with exercise prices of $44.00 and $35.40 per share and expiration dates of March 1, 2028 and July 21, 2028 for $0.125 per amended warrant, such that the amended warrants have a reduced exercise price of $4.09 per share and an expiration date of five years from the closing of the March 2024 offering. As of September 30, 2024, all of the 1,377,112 March 2024 Pre-Funded Warrants had been exercised for shares of common stock.

At-The-Market Offering

On December 13, 2023, Genprex entered into an At The Market ("ATM") Offering Agreement (the "Agreement") with H.C. Wainwright & Co., LLC, serving as agent (the "Agent") with respect to an at-the-market offering program (the "2023 ATM Facility") under which the Company may offer and sell through the Agent, from time to time at its sole discretion, up to such number or dollar amount of shares of its common stock (the "Shares") as registered on the prospectus supplement covering the 2023 ATM Facility offering, as may be amended or supplemented from time to time. Any Shares offered and sold pursuant to this Agreement will be issued pursuant to the Company's currently effective shelf Registration Statement on Form S-3 (File No. 333-271386) filed with the SEC on April 21, 2023, which was declared effective on June 9, 2023. The Company has agreed to pay the Agent a commission equal to three percent (3%) of the gross sales proceeds of any Shares sold through the Agent under the Agreement, and also have provided the Agent with customary indemnification and contribution rights. During the three months ended September 30, 2024, the Company sold 2,149,417 shares of common stock for aggregate net proceeds of $1,215,105 under the 2023 ATM Facility. During the nine months ended September 30, 2024, the Company sold 2,318,450 shares of common stock for aggregate net proceeds of $ 2,117,752 under the 2023 ATM Facility (inclusive of the shares issued during the three months ended September 30, 2024, as described in the immediately preceding sentence).

On November 18, 2022, Genprex entered into an Equity Distribution Agreement with JMP Securities LLC ("JMP Securities") pursuant to which the Company could sell from time to time, at its option, shares of its common stock through JMP Securities, as sales agent (the "2022 ATM Facility"), up to an aggregate offering price of $50 million. Sales of the shares were made under the Company's previously filed Registration Statement on Form S- 3 (Reg. No. 333-239134), by means of ordinary brokers' transactions on the NASDAQ Global Market or otherwise. Additionally, under the terms of the Equity Distribution Agreement, the shares could be sold at market prices, at negotiated prices or at prices related to the prevailing market price. Genprex agreed to pay JMP Securities a commission of 3.0% of the gross proceeds from the sale of the shares. The Company did not use the 2022 ATM Facility during the three months ended September 30, 2023. During the nine months ended September 30, 2023, the Company sold 1,342 shares of common stock for aggregate net proceeds of $78,355 under the 2022 ATM Facility. On December 12, 2023, the Company provided notice to JMP Securities of its termination of the 2022 ATM Facility. The termination of the Equity Distribution Agreement with JMP Securities was effective as of December 13, 2023.

Stock Issuances

During the three months ended September 30, 2024, Genprex issued (i) 5,000 shares of common stock for services provided to the Company valued at $9,650 to the Chairman of its Scientific Advisory Board, (ii) 779,000 shares of common stock upon the exercise of pre-funded warrants at a nominal price associated with the Company's March 2024 offering, and (iii) 2,149,417 shares of common stock sold for aggregate net proceeds of $ 1,215,105 under the Company's 2023 ATM Facility.

During the nine months ended September 30, 2024, Genprex issued (i) 10,125 shares of common stock for services provided to the Company valued at $25,670 to the Chairman of its Scientific Advisory Board, (ii) 36,250 shares of common stock to service providers of the Company valued at $179,550, (iii) 31,623 shares of common stock upon the vesting of restricted stock units ("RSUs") valued at $ 96,460 to Company executives and employees, non-employee directors, and former Company executives (Mr. Varner and Ms. Vaczy) pursuant to the terms of employment and/or separation agreements, (iv) 64,690 shares of common stock due to adjustments related to the Company's Reverse Split, (v) 165,000 shares of common stock sold for aggregate net proceeds of approximately $5.8 million associated with the Company's March 2024 offering, as described above, (vi) 2,318,450 shares of common stock sold for aggregate net proceeds of $2,117,752 under the Company's 2023 ATM Facility, as described above, and (vii) 1,377,112 shares of common stock upon the exercise of pre-funded warrants at a nominal price associated with the Company's March 2024 offering (inclusive of the shares issued during the three months ended September 30, 2024, as described in the immediately preceding sentence).

During the three months ended September 30, 2023, the Company issued (i) 125 shares of common stock for services provided to the Company valued at $4,800 to the Chairman of our Scientific Advisory Board, (ii) 185,644 shares of common stock sold for aggregate net proceeds of approximately $ 6.7 million associated with the Company's July 2023 offering, as described above and (iii) 500 shares of common stock upon the exercise of options by a former board member. During the nine months ended September 30, 2023, the Company issued (i) 375 shares of common stock for services provided to the Company valued at $17,150 to the Chairman of the Company's Scientific Advisory Board (inclusive of the 125 shares issued during the three months ended September 30, 2023, as described in the immediately preceding sentence), (ii) 1,342 shares of common stock for aggregate net proceeds of $78,355 under the 2022 ATM Facility, (iii) 280,883 shares of common stock sold for aggregate net proceeds of approximately $ 10.5 million associated with the Company's March 2023 and July 2023 offerings, as described above, and (iv) 500 shares of common stock upon the exercise of options by a former board member (inclusive of the shares issued during the three months ended September 30, 2023, as described in the immediately preceding sentence).

Preferred Stock

Genprex is authorized to issue 10,000,000 shares of preferred stock with a par value of $ 0.001 per share, none of which are outstanding as of September 30, 2024 and December 31, 2023.

Common Stock

Genprex is authorized to issue 200,000,000 shares of common stock with a par value of $ 0.001 per share, all of which are voting common stock. There were 5,489,152 and 1,485,902 shares of its common stock outstanding as of September 30, 2024 and December 31, 2023, respectively.

Common Stock Purchase Warrants

Common stock purchase warrant activity for the three and nine months ended September 30, 2024 and 2023, respectively, is as follows:

	2024		2023	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Outstanding at January 1,	346,440	$ 57.79	53,695	$ 172.81
Warrants issued	3,011,751	2.26	95,989	44.17
Warrants cancelled or expired	—	—	960	250.00
Outstanding at March 31,	3,358,191	$ 5.93	148,724	$ 64.01
Warrants exercised	598,112	0.00	—	—
Outstanding at June 30,	2,760,079	$ 7.22	148,724	$ 64.01
Warrants issued	—	—	200,284	20.68
Warrants exercised	779,000	0.00	—	—
Outstanding at September 30,	1,981,079	$ 10.05	349,008	$ 39.14

The Company (i) did not issue any warrants, and (ii) issued 779,000 shares of common stock associated with the partial exercise of March 2024 Pre-Funded Warrants, during the three months ended September 30, 2024. During the nine months ended September 30, 2024, and in connection with the registered direct offering, with an institutional investor, completed on March 21, 2024, Genprex (i) issued pre-funded warrants to purchase up to an aggregate of 1,377,112 shares of common stock at a nominal exercise price of $ 0.0001 per share, the remaining balance of the purchase price of each share of common stock associated with each pre-funded warrant net of the portion of the subscription price therefor paid at closing, (ii) issued warrants to purchase up to 1,542,112 shares of common stock, at an exercise price of $ 4.09 per share, (iii) issued warrants to purchase up to 92,527 shares of common stock to H.C. Wainwright & Co., LLC or its designees ("Placement Agent"), at an exercise price of $5.2688 per share, (iv) amended existing warrants to purchase up to an aggregate of 194,248 shares of common stock that were previously issued to the same institutional investor in March 2023 and July 2023, such that the amended warrants have a reduced exercise price of $ 4.09 per share and an expiration date of five years from the closing of the March 2024 offering, and (v) issued 598,112 shares of common stock associated with the partial exercise of March 2024 Pre-Funded Warrants (inclusive of the shares issued during the three months ended September 30, 2024, as described in the immediately preceding sentence). During the three and nine months ended September 30, 2024, Genprex recorded share-based compensation of $ 2,281 and $18,039, respectively, associated with the vesting and issuance of warrants. The Company does not expect to record any additional share-based compensation for time-based vesting through the end of the fiscal year 2024 and $300,000 of share-based compensation based on performance-based vesting in the future with respect to its warrants outstanding as of September 30, 2024.

The Company issued (i) warrants to purchase up to an aggregate of 3,500 shares of common stock to service providers at exercise prices ranging from $26.00 to $37.94 per share, the fair market value of a share of common stock on the date of issuance, (ii) warrants to purchase up to 185,644 shares of common stock to accredited healthcare-focused institutional investors in connection with the registered direct offering completed on July 21, 2023, at an exercise price of $35.40 per share, and (iii) warrants to purchase up to 11,140 shares of common stock to H.C. Wainwright & Co., LLC or its designees ("Placement Agent") in connection with the registered direct offering completed on July 21, 2023, at an exercise price of $50.50 per share, during the three months ended September 30, 2023. During the nine months ended September 30, 2023, the Company (i) issued warrants to purchase up to an aggregate of 4,250 shares of common stock to service providers at exercise prices ranging from $ 26.00 to $66.00 per share, the fair market value of a share of common stock on the date of issuance, (ii) issued warrants to purchase up to an aggregate of 292,023 shares of common stock at exercise prices ranging from $29.20 to $66.00 per share to service providers, institutional investors, and the Placement Agent, and (iii) was deemed to cancel warrants to purchase 960 shares of common stock upon termination of warrants previously issued to placement agents associated with our Initial Public Offering in March 2018 (inclusive of the warrants issued during the three-month period ended September 30, 2023, as described in the immediately preceding sentence). During the three and nine months ended September 30, 2023, the Company recorded share-based compensation of $ 50,853 and $128,164, respectively, associated with the vesting and issuance of warrants.

As of September 30, 2024, the Company had outstanding warrants to purchase 1,981,079 shares of common stock at a weighted average exercise price of $10.05 that have been issued to various consultants, investors, and placement agents. The warrants are fully vested, are exercisable for a period of up to five years, enable the holders to purchase shares of the Company's common stock at exercise prices ranging from $ 4.09 to $288.80 per share and have per-share fair values ranging from $1.21 to $185.00, based on Black-Scholes-Merton pricing models. The following assumptions were used in calculation of fair market value of options via Black-Scholes-Merton pricing models for the three and nine months ended September 30, 2024 and 2023:

	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Expected term (in years):	—	2.5	2.5 - 3.0	2.5 - 3.0
Risk-free rate:	—	4.52%	5.33% - 5.52%	4.99% - 5.52%
Volatility:	—	87.49%	83.42%	83.14% - 83.42%
Dividend yield:	—	0%	0%	0%

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2018 Equity Incentive Plan

The Company's board of directors and stockholders have approved and adopted the Genprex 2018 Equity Incentive Plan ("2018 Plan"), which became effective on the completion of the Company's IPO on April 3, 2018. The 2018 Plan provides for the grant of incentive stock options that are intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended ("ISOs"), nonstatutory stock options, stock appreciation rights, restricted stock awards, RSU awards, performance-based stock awards and performance-based cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to the Company's non-employee directors and consultants.

A total of 104,000 shares of common stock were initially available under the 2018 Plan, plus a number of shares of common stock (not to exceed 65,719 shares) subject to outstanding awards under the Company's 2009 Equity Incentive Plan (the "2009 Plan") as of the IPO that expire, are forfeited or otherwise terminate or that are used to cover the exercise price or applicable tax withholdings. No further grants will be made under the 2009 Plan.

In addition, the number of shares of common stock reserved for issuance under the 2018 Plan automatically increases on January 1 of each year, since January 1, 2019, by 5% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors or a committee of the board of directors appointed to administer the 2018 Plan.

On January 1, 2023 and 2024, the number of shares of common stock reserved for issuance under the 2018 Plan was increased by an aggregate of 60,132 and 74,294 shares, respectively. As of September 30, 2024, a total of 96,617 shares of common stock remain available for issuance under the 2018 Plan.

2018 Employee Stock Purchase Plan

The Company's board of directors and stockholders approved and adopted the Genprex 2018 Employee Stock Purchase Plan ("ESPP"), which became effective on April 3, 2018. The ESPP has not yet been utilized as a benefit available to the Company's employees. The ESPP authorizes the issuance of 5,202 shares of common stock pursuant to purchase rights that may be granted to eligible employees. The number of shares of common stock reserved for issuance under the ESPP is automatically increased on January 1 of each calendar year, beginning on January 1, 2019, by 2% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the administrator of the ESPP. The administrator of the ESPP determined not to increase the number of shares reserved for issuance under the ESPP on January 1, 2024.

Stock Options

As of September 30, 2024, Genprex had outstanding stock options to purchase 283,792 shares of common stock that have been granted to various executives, employees, non-employee directors, and independent contractors of the Company, including outstanding stock options to purchase 25,417 shares of common stock issued as inducement grants, outside of the 2018 Plan, associated with the hiring of new executives in 2021 and 2023. These options vest immediately or over periods ranging from 12 to 48 months, are exercisable for a period of up to ten years, and enable the holders to purchase shares of the Company's common stock at exercise prices ranging from $18.00 to $392.00 per share. The per-share fair values of these options range from $12.62 to $317.20. There were no options issued for the three and nine months ended September 30, 2024. Assumptions of the Black-Scholes-Merton pricing model for options issued for the three and nine months ended September 30, 2024, and 2023, respectively, is as follows:

	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Expected term (in years):	—	—	6.0	6.0
Risk-free rate:	—	—	5.37%	4.60% - 5.37%
Volatility:	—	—	83.42%	83.14% - 83.42%
Dividend yield:	—	—	0%	0%

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The Company did not issue stock options for the three or nine months ended September 30, 2024. During the three months ended September 30, 2024, the Company cancelled stock options to purchase 460 shares of common stock with exercise prices ranging from $ 54.80 to $59.60 per share in connection with the termination of employees. During the nine months ended September 30, 2024, the Company cancelled stock options to purchase 2,091 shares of common stock with exercise prices ranging from $ 32.40 to $80.00 per share in connection with the termination of employees (inclusive of the options cancelled during the three months ended September 30, 2024 described in the immediately preceding sentence).

During the three months ended September 30, 2023, the Company (i) granted stock options to purchase an aggregate of 5,000 shares of common stock with an exercise price of $18.00 per share to an employee, (ii) cancelled options to purchase 308 shares of common stock at exercise prices ranging from $88.00 to $142.00 per share in connection with the termination of certain employees, and (iii) issued 500 shares of the Company's common stock upon the exercise of options held by a former board member with an exercise price of $12.00 per share. During the nine months ended September 30, 2023, the Company (i) granted stock options to purchase an aggregate of 8,251 shares of common stock with exercise prices ranging from $ 18.00 to $60.40 per share to employees, (ii) cancelled options to purchase 308 shares of common stock at exercise prices ranging from $ 88.00 to $142.00 per share in connection with the termination of certain employees, and (iii) issued 500 shares of the Company's common stock upon the exercise of options held by a former board member with an exercise price of $12.00 per share (inclusive of the options granted or cancelled, and shares issued, during the three months ended September 30, 2023, as described in the immediately preceding sentence).

The weighted average remaining contractual term for the outstanding options at September 30, 2024 and December 31, 2023 is 5.36 and 6.13 years, respectively.

Stock option activity for the three and nine months ended September 30, 2024 and 2023, respectively, is as follows:

	2024		2023	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding at January 1,	285,883	$ 121.11	284,377	$ 123.19
Options granted	—	—	2,063	57.23
Options expired or cancelled	438	32.40	—	—
Outstanding at March 31,	285,445	$ 121.25	286,440	$ 122.72
Options granted	—	—	1,188	34.17
Options expired or cancelled	1,193	14.75	—	—
Outstanding at June 30,	284,252	$ 121.52	287,628	$ 122.35
Options granted	—	—	5,000	18.00
Options exercised	—	—	500	11.92
Options expired or cancelled	460	55.25	308	124.64
Outstanding at September 30,	283,792	$ 121.63	291,820	$ 120.75

Restricted Stock Units

During the three months ended September 30, 2024, the Company (i) did not issue RSUs, and (ii) cancelled nine RSUs associated with the termination of employees. During the nine months ended September 30, 2024, the Company (i) withheld 9,830 RSUs to cover taxes associated with the vesting of employee issued RSUs, (ii) cancelled 275 RSUs associated with the termination of employees, and (iii) issued 31,623 shares of common stock associated with the vesting of RSUs to executives, employees, and non-employee directors (inclusive of the RSUs described in the immediately preceding sentence during the three months ended September 30, 2024).

During the three months ended September 30, 2023, the Company (i) did not issue RSUs, and (ii) cancelled 257 RSUs associated with the termination of employees. During the nine months ended September 30, 2023, the Company issued 57,119 RSUs to executives, employees, and non-employee directors.

A summary of the RSU activity under the 2018 Plan during the three and nine months ended September 30, 2024 and 2023, respectively, is presented below. These amounts include RSUs granted to executives, other employees, and board members.

	2024		2023	
	Number of Units	Weighted Average Grant Date Fair Value	Number of Units	Weighted Average Grant Date Fair Value
Outstanding at January 1,	51,862	$ 59.48	—	—
Restricted stock units granted	—	—	47,834	66.00
Restricted stock units vested	12,145	66.00	—	—
Restricted stock units forfeited or cancelled	6,086	66.00	—	—
Outstanding at March 31,	33,631	$ 55.95	47,834	$ 66.00
Restricted stock units granted	—	—	9,285	29.60
Restricted stock units vested	19,478	48.65	—	—
Restricted stock units forfeited or cancelled	4,010	66.00	—	—
Outstanding at June 30,	10,143	$ 66.00	57,119	$ 60.08
Restricted stock units forfeited or cancelled	9	66.00	257	66.00
Outstanding at September 30,	10,134	$ 66.00	56,862	$ 60.06

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Share-Based Compensation

For the three and nine months ended September 30, 2024, the Company's total share-based compensation was approximately $ 0.4 million, including $0.2 million of R&D expense and $0.2 million of G&A expense, and $2.7 million, including $0.5 million of R&D expense and $2.2 million of G&A expense, respectively, which represents the expected vesting of options or RSUs issued to executives, other employees, board members, and service providers, as well as the issuance of shares to service providers. As of September 30, 2024, the Company's total compensation cost related to non-vested time-based stock option awards and warrants granted to executives, other employees, board members, and service providers and not yet recognized was approximately $0.6 million. The Company expects to record this stock-based compensation expense over the next three years using a graded vesting method. As of September 30, 2024, the weighted average term over which these expenses are expected to be recognized is 0.58 years.

For the three and nine months ended September 30, 2023, the Company's total share-based compensation was approximately $ 1.5 million, including $0.3 million of R&D expense and $1.2 million of G&A expense, and $4.4 million, including $1.0 million of R&D expense and $3.4 million of G&A expense, respectively, nearly all of which represents the expected vesting of options issued to executives, other employees, and service providers and RSUs issued to executives, other employees, and board members. As of September 30, 2023, the Company's total compensation cost related to non-vested time-based stock option awards and warrants granted to executives, other employees, board members, and service providers and not yet recognized was approximately $5.9 million. The Company expects to record this stock-based compensation expense over the next three years using a graded vesting method. As of September 30, 2023, the weighted average term over which these expenses are expected to be recognized is 1.37 years.

As of September 30, 2024, there are no performance-based stock option awards outstanding and one performance-based warrant outstanding issued to a service provider. The Company's total compensation cost related to the non-vested performance-based warrant not yet recognized was approximately $0.3 million. The entirety of this warrant may be recognized and recorded upon the achievement of certain clinical milestones.

Note 5 - 401(k) Savings Plan

In 2022, Genprex established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code ("401(k) Plan") and established an employer matching program for participants in the 401(k) Plan. The 401(k) Plan covers all employees who meet defined minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company incurred $31,930 and $105,848 of expense for matching contributions to the 401(k) Plan during the three and nine months ended September 30, 2024, respectively. We incurred $29,817 and $120,623 of expense for matching contributions to the 401(k) Plan during the three and nine months ended September 30, 2023, respectively.

Note 6 - Related Party Transactions

Introgen Research Institute

Introgen Research Institute ("IRI") is a Texas-based technology company formed by Rodney Varner, the Company's former President, Chief Executive Officer and Chairman of the Board, who served in such capacity until his death on May 7, 2024, and who was IRI's sole officer. IRI is owned by trusts of which Mr. Varner's descendants are the sole beneficiaries. In April 2009, prior to Mr. Varner becoming an officer and director of Genprex in August 2012, the Company entered into an Assignment and Collaboration Agreement with IRI, providing Genprex with the exclusive right to commercialize a portfolio of intellectual property. This agreement was amended in 2011 to include additional sublicensing of additional intellectual property made available to IRI from MD Anderson (see Note 7 – Commitments and Contingences – Commitments – MD Anderson Cancer Center). There were no amounts incurred or due under this agreement at September 30, 2024 and December 31, 2023.

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Note 7 - Commitments and Contingencies

Commitments

MD Anderson Cancer Center

In July 2018, Genprex entered into a two-year sponsored research agreement with MD Anderson to sponsor preclinical studies focused on the combination of REQORSA with an immunotherapy with a projected total cost of approximately $2 million. This agreement was extended beyond the original expiration date, expiring in May 2022 after giving effect to such extension. In August 2022, the Company entered into a three-year sponsored research agreement with MD Anderson ("August 2022 SRA") to sponsor preclinical studies focused on REQORSA and NPRL2 in oncology to resensitize NSCLC and SCLC to targeted therapies and immunotherapies with an initial projected total cost of approximately $2.9 million. On June 7, 2024, the Company amended the August 2022 SRA with MD Anderson to (i) extend the sponsored research program an additional six months, (ii) amend the quarterly budget from approximately $240,000 to $165,000 per quarter, and (iii) amend the total commitment from $ 2.9 million to approximately $2.75 million. The Company incurred approximately $165,701 of expense from this agreement during the three months ended September 30, 2024. The Company incurred approximately $645,839 of expense from this agreement during the nine months ended September 30, 2024 inclusive of the amount stated in the preceding sentence. As of September 30, 2024, the Company has paid approximately $1.2 million toward this $2.76 million commitment.

In 2011, the Company agreed to assume certain contractual and other obligations of IRI in consideration for the sublicense rights, expertise, and assistance associated with certain technologies and intellectual property originally licensed to another party under the 1994 License Agreement with MD Anderson ("Original MD Anderson License Agreement"). These technologies and intellectual property were later sublicensed to IRI (the "IRI Sublicense"). The Company also agreed to pay royalties of 1% on sales of certain licensed products for a period of 21 years following the termination of the later of the Original MD Anderson License Agreement and the IRI Sublicense. The Company assumed patent prosecution costs and an annual minimum royalty of $20,000 payable to the National Institutes of Health ("NIH").

On March 3, 2021, the Company entered into an amendment (the "MD License Amendment") to the Patent and Technology License Agreement dated May 4, 2020, with MD Anderson. The MD License Amendment grants Genprex a worldwide, exclusive, sublicensable license to an additional portfolio of six patents and one patent application and related technology for methods for treating cancer by administration of a TUSC2 therapy in conjunction with EGFR inhibitors or other anti-cancer therapies in patients predicted to be responsive to TUSC2 therapy. Pursuant to the MD License Amendment, the Company agreed to (i) pay annual maintenance fees ranging from the mid five figures to the low six figures, (ii) total milestone payments of $ 6,150,000, (iii) a one-time fee in the mid five figures and (iv) certain patent related expenses. The Company incurred no expense for the three months ended September 30, 2024 and 2023, respectively. The Company incurred $50,000 and $45,000 of expense from this agreement during the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, the Company has paid approximately $370,000 toward the above-described commitment under this agreement.

National Institutes of Health

Genprex has a royalty obligation to the National Institutes of Health to be paid upon the Company's receipt of FDA approval using NIH technology. The $240,000 contingent obligation, which increases annually by $20,000, and is $380,000 and $360,000 as of September 30, 2024 and December 31, 2023, respectively, will be recognized if and when it is probable the Company will obtain regulatory approval (the event that triggers the payment obligation).

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University of Pittsburgh

Pursuant to an exclusive license agreement dated February 11, 2020, by and between Genprex and the University of Pittsburgh, amended on August 17, 2022, and amended again on November 3, 2022, the Company agreed to pay (i) an initial licensing fee of $ 25,000, (ii) annual maintenance fees of $25,000 for the first three years and $40,000 for each subsequent year following the first anniversary of the agreement, (iii) royalties ranging from 1.5% to 3% of net sales of licensed technologies, (iv) an annual minimum royalty payment of $ 250,000 per year beginning in the year of the first commercial sale of licensed technology, (v) a share of non-royalty sublicense income of 20%, and (vi) an aggregate of $3,975,000 in milestone payments related to the usage of a glucagon promoter and gene therapy technologies to potentially treat Type 1 diabetes. Unless earlier terminated pursuant to its terms, the agreement expires upon the later of (i) 20 years after the first commercial sale of the licensed technology thereunder and (ii) expiration of the last valid claim under the patent rights. The Company incurred no expense from this agreement for the three months ended September 30, 2024, and 2023, respectively. The Company incurred $40,000 and $25,000 of expense from this agreement during the nine months ended September 30, 2024, and 2023, respectively. As of September 30, 2024, the Company has incurred and paid approximately $ 150,000 toward this commitment.

Pursuant to an exclusive license agreement dated November 22, 2022, by and between Genprex and the University of Pittsburgh, the Company agreed to pay (i) an initial licensing fee of $25,000, (ii) annual maintenance fees of $25,000 for the first three years and $40,000 for each subsequent year following the first anniversary of the agreement, (iii) royalties ranging from 1.5% to 3% of net sales of licensed technologies, (iv) an annual minimum royalty payment of $250,000 per year beginning in the year of the first commercial sale of licensed technology, (v) a share of non-royalty sublicense income of 20%, and (vi) an aggregate of $3,975,000 in milestone payments related to the usage of a macrophage technology and gene therapy technologies to potentially treat Type 1 diabetes. Unless earlier terminated pursuant to its terms, the agreement expires upon the later of (i) 20 years after the first commercial sale of the licensed technology thereunder and (ii) expiration of the last valid claim under the patent rights. The Company incurred no expense from this agreement during the three and nine months ended September 30, 2024. The Company incurred $0 and $25,000 of expense from this agreement during the three and nine months ended September 30, 2023. As of September 30, 2024, the Company has incurred and paid approximately $50,000 toward this commitment.

Pursuant to an exclusive license agreement dated December 29, 2022, by and between Genprex and the University of Pittsburgh, the Company agreed to pay (i) an initial licensing fee of $25,000, (ii) annual maintenance fees of $25,000 for the first three years and $40,000 for each subsequent year following the first anniversary of the agreement, (iii) royalties ranging from 1.5% to 3% of net sales of licensed technologies, (iv) an annual minimum royalty payment of $250,000 per year beginning in the year of the first commercial sale of licensed technology, (v) a share of non-royalty sublicense income of 20%, and (vi) an aggregate of $3,975,000 in milestone payments related to the usage of an insulin promoter and gene therapy technologies to potentially treat Type 2 diabetes. Unless earlier terminated pursuant to its terms, the agreement expires upon the later of (i) 20 years after the first commercial sale of the licensed technology thereunder and (ii) expiration of the last valid claim under the patent rights. The Company incurred no expense from this agreement during the three and nine months ended September 30, 2024. The Company incurred $0 and $25,000 of expense from this agreement during the three and nine months ended September 30, 2023. As of September 30, 2024, the Company has incurred and paid approximately $50,000 toward this commitment.

Pursuant to an exclusive license agreement dated July 14, 2023, by and between Genprex and the University of Pittsburgh, the Company agreed to pay (i) an initial licensing fee of $25,000, (ii) annual maintenance fees of $25,000 for the first year, $50,000 for the second and third years, and $100,000 for the fourth year and each subsequent year following the fourth anniversary of the agreement thereafter until the anniversary prior to the year of the first commercial sale, (iii) royalties ranging from 1.5% to 3% of net sales of licensed technologies, (iv) an annual minimum royalty payment of $ 250,000 per year beginning in the year of the first commercial sale of licensed technology, (v) a share of non-royalty sublicense income of 20%, and (vi) an aggregate of $4,225,000 in milestone payments related to the usage of an MafB promoter and gene therapy technologies to potentially treat Type 1 and Type 2 diabetes. Unless earlier terminated pursuant to its terms, the agreement expires upon the later of (i) 20 years after the first commercial sale of the licensed technology thereunder and (ii) expiration of the last valid claim under the patent rights. The Company incurred no expense from this agreement during the three months ended September 30, 2024 and 2023, respectively. The Company incurred $25,000 of expense from this agreement during each of the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, the Company has incurred and paid approximately $50,000 toward this commitment.

Contract Development and Manufacturing Organization

Genprex entered into a three-year development services agreement in July 2022, amended in each of January 2023 and March 2023, with a contract development and manufacturing organization (“CDMO”) to manufacture good manufacturing practices (“GMP”) grade materials for use in the Company’s clinical trials with a projected total cost at inception of approximately $4.5 million. On April 2, 2024, the Company was informed by the CDMO that the CDMO was ceasing certain manufacturing operations subject to the development services agreement. On June 30, 2024, the development services agreement was terminated by mutual agreement and the CDMO agreed to return $1.3 million to the Company and no additional commitments are obligated or owed by the Company. The Company incurred $0 and $2.2 million of expense from this agreement during the nine months ended September 30, 2024 and 2023, respectively.

Contingencies

From time to time, the Company may become subject to threatened and/or asserted claims arising in the ordinary course of its business. Management is not aware of any pending matters, either individually or in the aggregate, that are reasonably likely to have a material impact on the Company’s financial condition, results of operations or liquidity.

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Note 8 - Subsequent Events

The Company has evaluated subsequent events through the filing of this Quarterly Report on Form 10-Q and determined that there have been no recognized subsequent events that have occurred that would require adjustments to the Company's disclosures in the condensed financial statements. The following are nonrecognized subsequent events through the filing of this Quarterly Report on Form 10-Q.

Share Issuances

On October 1, 2024, Genprex issued 5,000 shares of its common stock to the Chairman of its Scientific Advisory Board in consideration for services. Subsequent to September 30, 2024, the Company has sold 3,013,916 shares of its common stock for aggregate net proceeds to the Company totaling $1,286,014 under the 2023 ATM Facility.

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

You should read the following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") together with our interim condensed financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, in this filing, and in our other SEC filings, as may be amended, supplemented or superseded from time to time by other reports we file with the SEC. All amounts in this report are in United States ("U.S.") dollars, unless otherwise noted.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This Quarterly Report contains forward-looking statements that involve substantial risks and uncertainties. Unless the context requires otherwise, references to "Genprex," the "Company," "we," "us" or "our" in this Quarterly Report refer to Genprex, Inc. Any statements in this Quarterly Report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as "believe," "will," "expect," "anticipate," "estimate," "intend," "plan" and "would." For example, statements concerning financial condition, possible or assumed future results of operations, growth opportunities, industry ranking, plans and objectives of management, markets for our common stock and future management and organizational structure and statements about our current or future product candidates and their development, our beliefs regarding their preclinical or clinical profile or efficacy, and the regulatory approval process and pathway and the timing thereof, are all forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, levels of activity, performance or achievements expressed or implied by any forward-looking statement.

Any forward-looking statements are qualified in their entirety by reference to the risk factors discussed throughout this Quarterly Report. Some of the risks, uncertainties and assumptions that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include but are not limited to:

- Market conditions;
- Our capital position;
- Our ability to raise additional future financing and possible lack of financial and other resources, and our ability to continue to support and fund our pre-clinical and clinical development programs and growth of our business;
- Our ability to continue as a going concern;
- Our ability to maintain compliance with the continued listing requirements of The Nasdaq Capital Market and maintain the listing of our common stock;
- Our ability to compete effectively and with larger and/or better-financed biotechnology and pharmaceutical companies;
- Our uncertainty of developing marketable products;
- Our ability to develop and commercialize our products;
- Our ability to obtain regulatory approvals;
- Our ability and third-parties' ability to maintain and protect intellectual property rights;
- The effects and ultimate impact of public health crises such as the coronavirus pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole;

- The success of our clinical trials through all phases of clinical development, including the ability of our third-party suppliers or manufacturers to supply or manufacture our products on a timely, consistent basis in a manner sufficient and appropriate as is commensurate to meet our clinical trial timing, courses of treatment, and other requisite fulfillment considerations necessary to adequately advance our development programs;

- Our ability to conduct and complete our clinical trials in accordance with projected timelines;

- Any delays in regulatory review and approval of our current and future product candidates;

- The effects of any strategic research and development prioritization initiatives, and any other strategic alternatives or other efforts that we take or may take in the future that are aimed at optimizing and re-focusing our diabetes, oncology and/or other clinical development programs including prioritization of resources, and the extent to which we are able to implement such efforts and initiatives successfully to achieve the desired and intended results thereof;

- Our dependence on third-party suppliers or manufacturers to supply or manufacture our key ingredients and/or raw materials, products and/or product components and successfully carry out a sustainable, reproducible and scalable manufacturing process in accordance with specifications or applicable regulations;

- Our ability to control product development costs;

- Our ability to attract and retain key employees;

- Our ability to enter into new strategic collaborations, licensing or other arrangements;

- Changes in government regulation affecting product candidates that could increase our development costs;

- Our involvement in patent, trademark and other intellectual property litigation that could be expensive and divert management's attention;

- The possibility that there may be no market acceptance for our products; and

- Changes in third-party reimbursement policies which could adversely affect potential future sales of any of our products that are approved for marketing.

The foregoing list sets forth some, but not all, of the factors that could affect our ability to achieve results described in any forward-looking statements, which speak only as of the date of this Quarterly Report or the date of the document incorporated by reference into this Quarterly Report. Except as required by law, we assume no obligation and expressly disclaim any duty to update any forward-looking statement to reflect events or circumstances after the date of this Quarterly Report or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements contained in this Quarterly Report. All forward-looking statements are expressly qualified in their entirety by the cautionary statements contained in this section.

Overview

We are a clinical stage gene therapy company pioneering the development of gene-based therapies for large patient populations with unmet medical needs. Our oncology platform utilizes our systemic, non-viral Oncoprex® Delivery System which uses lipid-based nanoparticles in a lipoplex form to deliver tumor suppressor gene-expressing plasmids to cancer cells. The product is administered intravenously, where it is taken up by tumor cells that then express tumor suppressor proteins that were deficient in the tumor. Our diabetes technology is designed to work in Type 1 diabetes by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but may be distinct enough from beta cells to evade the body's immune system. In Type 2 diabetes, our technology is believed to work by replenishing and rejuvenating exhausted beta cells that make insulin.

Oncology Platform

Our lead oncology drug candidate, Reqorsa® (*quaratusugene ozeplasmid*), previously referred to as GPX-001, is a gene therapy initially being developed in combination with prominent, approved cancer drugs to treat Non-Small Cell Lung Cancer ("NSCLC") and Small Cell Lung Cancer ("SCLC"). REQORSA has multimodal effects on cancer cells. It harms the metabolism of cancer cells, which leads to reduced cancer cell growth. It also interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for apoptosis, or programmed cell death, in cancer cells, and increases the immune response against cancer cells. In preclinical studies, REQORSA has been shown to be complementary with targeted drugs and immunotherapies. Our strategy is to develop REQORSA in combination with current approved therapies and we believe REQORSA's unique attributes position it to provide treatments that improve on these current therapies for patients with NSCLC, SCLC, and possibly other cancers.

The TUSC2 gene, which is the key component of REQORSA and plays a vital role in cancer suppression and normal cell metabolism, is one of a series of genes on the short arm of Chromosome 3 whose therapeutic use is covered by our exclusive worldwide licenses from The University of Texas MD Anderson Cancer Center ("MD Anderson"). We believe that our ONCOPREX Delivery System allows for the delivery of a number of cancer-fighting tumor suppressor genes, alone or in combination with other cancer therapies, to combat multiple types of cancer and we are in early stages of discovery programs to identify other cancer candidates. In August 2022, we entered into a three-year sponsored research agreement with MD Anderson to support further preclinical studies of TUSC2 and other tumor suppressor genes. Additionally, we are collaborating with MD Anderson to discover, develop and utilize biomarkers to select the patient population most likely to respond to REQORSA and enable decisions on progression of our drug candidates to the next phase of development. MD Anderson is currently analyzing biomarkers that would indicate lack of response in lung cancer that could enrich our population of responders in our clinical trials and enhance patient screening and enrollment in order to increase the likelihood of potential success of the Acclaim studies for the Company.

Acclaim-3: We are currently enrolling and treating patients in the Phase 1 dose escalation portion of our Phase 1/2 Acclaim-3 clinical trial. The Acclaim-3 clinical trial uses a combination of REQORSA and Genentech, Inc.'s Tecentriq® (*atezolizumab*) as maintenance therapy in patients with extensive stage small cell lung cancer ("ES-SCLC") who did not develop tumor progression after receiving Tecentriq and chemotherapy as initial standard treatment. Patients are treated with REQORSA and Tecentriq until disease progression or unacceptable toxicity is experienced. In January 2024, we opened the Phase 1 portion of the Acclaim-3 study for enrollment and enrolled and dosed the first patient in May 2024. In October 2024, the Company announced the completion of the 0.09 mg/kg dose group of the Phase 1 portion and that there were no dose limiting toxicities in this dose group. The Acclaim-3 Safety Review Committee therefore approved escalation to the highest dose group of 0.12 mg/kg, which will now be enrolled. We continue to anticipate completion of enrollment in the Phase 1 dose escalation portion of the study and to start the Phase 2 expansion portion of the study in the second half of 2024, dependent on the number of patients needed to be enrolled in the 0.12 mg/kg dose group. The first patient treated in the Phase 1 dose escalation portion of the Acclaim-3 trial experienced an initial positive response after enrollment and dosing commenced in May. The patient had a partial remission ("PR"), which is defined as at least a thirty percent (30%) decrease in tumor size, from the time the patient had a baseline CT scan after induction therapy and prior to the start of maintenance therapy to the time of the CT scan performed after two cycles of maintenance therapy. As the maintenance therapy consists of REQORSA and Tecentriq, and the patient had already received four cycles of Tecentriq during induction therapy and thus responses to Tecentriq would likely have occurred earlier, we believe this suggests that REQORSA may be providing clinical benefit. A follow-up CT scan, performed after four cycles of maintenance therapy (three months), confirmed that the patient still had a 30% decrease in tumor size in measurable lesions; however, one lesion not previously measurable had grown in size, thus leading to a conclusion of disease progression at three months. In June 2023, the United States Food and Drug Administration ("FDA") granted Fast Track Designation for the Acclaim-3 treatment combination of REQORSA and Tecentriq as maintenance therapy in patients with ES-SCLC who did not develop tumor progression after receiving Tecentriq and chemotherapy as initial standard treatment. In August 2023, the FDA granted Orphan Drug Designation to REQORSA for the treatment of SCLC.

Acclaim-2: The Acclaim-2 trial involved a combination of REQORSA and Merck & Co.'s Keytruda® (*pembrolizumab*) in patients with late-stage NSCLC whose disease has progressed after treatment with Keytruda. As previously announced in August 2024, based on a number of factors, including enrollment challenges and delays due to competition for investigators and eligible patients with numerous other trials involving the same patient population, we decided to cease enrollment of new patients in the Acclaim-2 trial to prioritize our resources and focus on the other two Acclaim trials in SCLC and NSCLC, respectively. The one patient continuing to receive REQORSA treatment in the Phase 1 dose escalation portion of the study will continue to be treated until disease progression.

Acclaim-1:We are currently enrolling and treating patients in the Phase 2a expansion portion of our Phase 1/2 Acclaim-1 clinical trial. The Acclaim-1 trial uses a combination of REQORSA and AstraZeneca's Tagrisso® (*osimertinib*) in patients with late-stage NSCLC that has activating epidermal growth factor receptor ("EGFR") mutations and progression after treatment with Tagrisso. Following the May 2023 completion of the Phase 1 dose escalation portion of the study, the Acclaim-1 Safety Review Committee ("Acclaim-1 SRC") approved advancement from the Phase 1 dose escalation portion to the Phase 2a expansion portion of the study. Based on a review of safety data which showed no dose limiting toxicities, the Acclaim-1 SRC determined the recommended Phase 2 dose of REQORSA to be 0.12 mg/kg. This was the highest dose level delivered in the Phase 1 portion of the study and is twice the highest dose level delivered in our prior clinical trial combining REQORSA with Tarceva® (*erlotinib*) for the treatment of late-stage lung cancer. There are still two patients originally enrolled in the Phase 1 dose escalation portion of the study who have had prolonged progression-free survival and continue to receive treatment with REQORSA and Tagrisso, one who attained a PR after the second course of REQORSA and Tagrisso and has maintained this response through 41 courses of treatment (approximately 30 months), and one with stable disease without disease progression through 26 courses of treatment (approximately 19 months) who is also continuing to receive REQORSA and Tagrisso treatment. We opened the Phase 2a expansion portion of the study and enrolled and dosed the first patient in January 2024. The initial trial design of the Phase 2a expansion portion of the study included two cohorts with half being patients who received only prior Tagrisso treatment and the other half being patients who received prior Tagrisso treatment and chemotherapy. However, as previously announced in August 2024, based on resource prioritization and to focus on the patients for whom REQORSA is most likely to show a benefit, we decided to limit our enrollment efforts moving forward to patients who received only prior Tagrisso treatment and cease enrollment of the second cohort (patients who received prior Tagrisso treatment and chemotherapy). The Phase 2a expansion portion of the trial with one cohort is now expected to enroll approximately 33 patients. The Phase 2b randomized portion of the study, in which patients progressing on prior Tagrisso treatment will be randomized 1:1 to either REQORSA and Tagrisso combination therapy or to platinum-based chemotherapy, will remain unchanged. There will be an interim analysis following the treatment of 19 patients in the Phase 2a portion of the Acclaim-1 study. We expect to complete the enrollment of the first 19 patients in the Phase 2a expansion portion of the study and conduct an interim analysis in the first half of 2025. The FDA has granted Fast Track Designation for the Acclaim-1 treatment combination of REQORSA and Tagrisso in NSCLC patients who have progressed after Tagrisso treatment.

Diabetes Gene Therapy

In diabetes, we have exclusively licensed from the University of Pittsburgh of the Commonwealth System of Higher Education ("University of Pittsburgh") multiple technologies relating to the development of a gene therapy product for each of Type 1 and Type 2 diabetes. The same general novel approach is used in each of Type 1 and Type 2 diabetes whereby an adeno-associated virus ("AAV") vector containing the Pdx1 and MafA genes is administered directly into the pancreatic duct. In humans, this can be done with a routine endoscopy procedure. Our diabetes product candidates are currently being evaluated and optimized in preclinical studies at the University of Pittsburgh. GPX-002 is being developed using the same construct for the treatment of both Type 1 diabetes and Type 2 diabetes. GPX-002 for Type 1 diabetes is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but may be distinct enough from beta cells to evade the body's immune system. In a similar approach, GPX-002 for Type 2 diabetes (formerly known as GPX-003), where autoimmunity is not at play, is believed to work by replenishing and rejuvenating exhausted beta cells that make insulin. We finalized the components of the diabetes construct to take forward for nonclinical studies and in December 2023, we submitted a request to meet with the FDA to obtain their guidance on the nonclinical studies needed to file an Investigational New Drug ("IND") application and initiate first-in-human studies. As a result of the FDA's response, we will continue with our planned additional nonclinical studies before requesting regulatory guidance for the IND-enabling studies. We are currently working with the University of Pittsburgh on species analyses for the animal models as well as on other regulatory and clinical strategic planning and anticipate requesting further regulatory guidance from the FDA in the first half of 2025. In October 2023, we entered into a one-year extension to our August 2022 sponsored research agreement with the University of Pittsburgh for the use of GPX-002 in a non-human primate ("NHP") model in Type 2 diabetes. The extension includes a revised research plan to encompass our most recent technologies to which we acquired exclusive rights from the University of Pittsburgh in July 2023. These include using a MafB promoter to drive expression of the Pdx1 and MafA transcription factors that can potentially be used for both Type 1 and Type 2 diabetes. Additionally, in September 2024, we announced that we are considering various strategic alternatives and opportunities to enhance stockholder value, including evaluating ways to optimize our clinical and research programs and operational strategies, such as our intention to potentially transfer our diabetes clinical development program and our diabetes gene therapy assets into a new, initially wholly-owned subsidiary ("NewCo"). NewCo would focus on developing and commercializing GPX-002. The spin-out, if completed as presently contemplated, would result in NewCo focusing on developing GPX-002, while Genprex would retain its oncology clinical development programs and other oncology pipeline assets. The potential formation and transfer of the clinical development program into the wholly-owned subsidiary is currently anticipated to occur by the end of 2024, subject to adequate financing, the satisfaction of customary conditions and final approval from the Genprex management and board of directors.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed below and in Note 2 to our unaudited condensed financial statements appearing in this Quarterly Report on Form 10-Q. As of September 30, 2024, recently issued accounting pronouncements are not expected to have a significant effect on the Company's financial condition, results of operations, or cash flows.

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures," which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The purpose of the amendment is to enable investors to better understand an entity's overall performance and assess potential future cash flows. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the effect the amendments in ASU 2023-07 will have on its segment disclosures.

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," which modifies the rules on income tax disclosures to require disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the effect the amendments in ASU 2023-09 will have on its tax disclosures.

Critical Accounting Estimates

Our unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles in the U.S. ("US GAAP"). The preparation of these unaudited condensed financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the unaudited condensed financial statements, and the reported amounts of expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the following accounting policies and estimates are the most critical to aid in fully understanding and evaluating our reported financial results, and they require our most difficult, subjective or complex judgments, resulting from the need to make estimates about the effect of matters that are inherently uncertain**.**

Research and Development Costs

We record accrued expenses for costs invoiced from research and development activities conducted on our behalf by third-party service providers, which include the conduct of preclinical studies and clinical trials and contract research, manufacturing, and testing activities. We record the costs of research and development activities based upon the amount of services provided, and we include these costs in accrued liabilities in the unaudited condensed balance sheets and within research and development expense in the unaudited condensed statements of operations. These costs are a significant component of our research and development expenses. Purchased materials to be used in future research are valued at cost and capitalized and included in research and development supplies.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed, the number of patients enrolled and the rate of patient enrollment in any of our clinical trials may vary from our estimates and could result in our reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from contract research organizations ("CROs") and other third-party service providers.

Impairment of Long-Lived Assets

Management evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be realizable or at a minimum annually during the fourth quarter of the year. If an evaluation is required, the estimated future undiscounted cash flows associated with the asset are compared to the asset's carrying value to determine if an impairment of such asset is necessary. The effect of any impairment would be to expense the difference between the fair value of such asset and its carrying value based upon discounted cash flows.

Components of our Results of Operations and Financial Condition

Operating expenses

We classify our operating expenses into three categories: research and development, general and administrative, and depreciation.

Research and development. Research and development expenses consist primarily of:

- costs incurred to conduct research, such as the discovery and development of our current and potential product candidates;
- costs related to the production and storage of supplies for engineering purposes and storage and usage of clinical supplies, including waste created in the process of producing clinical materials, spoilage, and testing of clinical materials;
- costs related to the use of contract manufacturers, manufacturing consultants, testing organizations, cold-storage facilities, and logistics service providers;
- fees paid to clinical consultants, clinical trial sites and vendors, including CROs in conjunction with implementing and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related fees, such as patient screening fees, laboratory work, and statistical compilation and analysis;
- costs related to compliance with drug development regulatory requirements; and
- costs related to staffing and personnel associated with research and development activities, including wages, taxes, benefits, leases, overheads, supplies, and share-based compensation.

We recognize all research and development costs as they are incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third-parties are expensed as the contracted work is performed.

We expect our research and development expenses to increase in the future as we (i) advance our current and future product candidates into and through clinical trials, (ii) transition some of our manufacturing activities to new vendors for a variety of reasons, such as to incorporate more advanced processes and scale production, including any additional work that has been or may be required to successfully adapt our process to these new processes, (iii) pursue regulatory approval of our current and potential product candidates in the U.S. and Europe, and (iv) expand our research programs to include new therapies and new therapy combinations. The process of conducting the necessary pre-clinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our current and potential product candidates may be affected by a variety of factors including the quality of our current and potential product candidates, early clinical data, investment in our clinical program, competition, manufacturing capability and commercial viability, and limited contracted partners. We may never succeed in achieving regulatory approval for any of our current or future product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if at all. However, we continue to evaluate ways to optimize our clinical and research programs and operational strategies, as part of our ongoing prioritization initiative. Additionally, we are considering various strategic alternatives and opportunities to enhance stockholder value.

General and administrative. General and administrative expense consists of personnel related costs, which include administrative and executive salaries, as well as the costs of professional services, such as accounting and legal, travel, facilities, information technology and other administrative expenses. We expect our general and administrative expense to increase in future periods due to the anticipated growth of our business and related infrastructure as well as accounting, insurance, investor relations, and other costs associated with being a public company.

Depreciation. Depreciation expense consists of depreciation from our fixed assets consisting of our property, equipment, and furniture. We depreciate our assets over their estimated useful life. We estimate furniture and computer and office equipment to have a five-year life.

Results of Operations

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

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

Research and Development Expense

Research and Development ("R&D") expense for the three months ended September 30, 2024 was $2,756,081, compared to $4,616,546 for the three months ended September 30, 2023, a decrease of $1,860,465, or 40%. This decrease was primarily due to (i) changes in CDMOs that significantly reduced manufacturing and R&D materials expense, and (ii) implementation of expense reduction strategies by leadership in the three months ended September 30, 2024, which reduced travel expenses and reduced headcount and associated overhead of R&D staff from 18 employees at September 30, 2023 to 13 employees at September 30, 2024.

Research and Development ("R&D") expense for the nine months ended September 30, 2024 was $7,696,982, compared to $13,903,611 for the nine months ended September 30, 2023, a decrease of $6,206,629, or 45%. This decrease was primarily due to (i) changes in CDMOs that significantly reduced manufacturing expense, (ii) a significant reduction in share-based compensation for R&D personnel due to the timing of equity awards, and (iii) implementation of expense reduction strategies by leadership in the nine months ended September 30, 2024, which reduced travel expenses and reduced headcount and associated overhead of R&D staff from 18 employees at September 30, 2023 to 13 employees at September 30, 2024. Additionally, the Company had a higher than normal manufacturing expense in the nine months ended September 30, 2023 due to the Company switching CDMOs that required both comparability and scaling of programs accordingly compared to the nine months ended September 30, 2024.

General and Administrative Expense

General and administrative ("G&A") expense for the three months ended September 30, 2024 was $1,566,085, compared to $3,166,057 for the three months ended September 30, 2023, a decrease of $1,599,972, or 51%. This decrease was primarily due to the implementation of expense reduction strategies by leadership in the nine months ended September 30, 2024, which significantly reduced travel expenses, the number of professional service providers and associated expenses, and reduced headcount and associated overhead of G&A staff from 13 employees at September 30, 2023 to 7 employees at September 30, 2024.

General and administrative ("G&A") expense for the nine months ended September 30, 2024 was $9,135,225, compared to $11,173,643 for the nine months ended September 30, 2023, a decrease of $2,038,418, or 18%. Despite one-time charges associated with the separation with a former Company executive and changes in accounting policies that resulted in a non-cash expense of approximately $800,000 due to reclassifying capitalized intellectual property, this slight decrease was primarily due to the implementation of expense reduction strategies by leadership in the nine months ended September 30, 2024, which significantly reduced travel expenses, the number of professional service providers and associated expenses, and reduced headcount and associated overhead of G&A staff from 13 employees at September 30, 2023 to 7 employees at September 30, 2024.

Interest Income. Interest income was $8,080 and $51,391 for the three months ended September 30, 2024, and 2023, respectively, representing a decrease of $43,311. The decrease was primarily due to lower cash balances held in interest bearing accounts for the three months ended September 30, 2024 compared to the three months ended September 30, 2023.

Interest income was $58,851 and $175,413 for the nine months ended September 30, 2024, and 2023, respectively, representing a decrease of $116,562. The decrease was primarily due to lower cash balances held in interest bearing accounts for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023.

Depreciation Expense. Depreciation expense was $1,272 and $3,724 for the three months ended September 30, 2024, and 2023, respectively, representing a decrease of $2,452, or 66%. The change in depreciation expense for the three months ended September 30, 2024 was primarily due to the timing of purchases of computer equipment for new employees and changes to accounting policies related to depreciation.

Depreciation expense was $6,230 and $11,578 for the nine months ended September 30, 2024, and 2023, respectively, representing a decrease of $5,348, or 46%. The change in depreciation expense for the nine months ended September 30, 2024 was primarily due to the timing of purchases of computer equipment for new employees and changes to accounting policies related to depreciation.

Net Loss. We had a net loss of $4,315,987 and $7,748,243 for the three months ended September 30, 2024 and 2023, respectively, representing a decrease of $3,432,256, or 44%. The decrease in net loss between these periods was primarily due to the implementation of expense reduction strategies by leadership in the three months ended September 30, 2024, which reduced travel expenses, the number of professional service providers and associated expenses, and reduced headcount and associated overhead of overall Company staff from 31 employees at September 30, 2023 to 19 employees at September 30, 2024.

We had a net loss of $16,780,701 and $24,931,209 for the nine months ended September 30, 2024, and 2023, respectively, representing a decrease of $8,150,508, or 33%. The decrease in net loss between these periods was primarily due to the implementation of expense reduction strategies by leadership in the nine months ended September 30, 2024, which reduced travel expenses, the number of professional service providers and associated expenses, and reduced headcount and associated overhead of overall Company staff from 31 employees at September 30, 2023 to 19 employees at September 30, 2024.

Liquidity and Capital Resources

From inception through September 30, 2024, we have never generated revenue from product sales and have incurred net losses in each year. As of September 30, 2024, we had an accumulated deficit of $150,468,981. We have funded our operations primarily through the sale and issuance of capital stock.

For the year ended December 31, 2023, we (i) sold an aggregate of 1,342 shares of common stock for total net proceeds of $78,355 pursuant to our 2022 ATM Facility (defined below) as governed by the Equity Distribution Agreement (as further described below), (ii) issued 500 shares of common stock upon the exercise of options for gross proceeds of $5,960, and (iii) completed a registered direct offerings where we sold 280,883 shares of our common stock for net proceeds of approximately $10.5 million.

During the nine months ended September 30, 2024, we (i) sold 2,318,450 shares of common stock for aggregate net proceeds of $2,117,752 pursuant to our 2023 ATM Facility (defined below), and (ii) completed a registered direct offering in which we sold (x) 165,000 shares of our common stock, (y) pre-funded warrants exercisable for up to an aggregate of 1,377,112 shares of our common stock ("March 2024 Pre-Funded Warrants"), and (z) warrants exercisable for up to an aggregate of 1,542,112 shares of our common stock ("March 2024 Common Warrants"), for net proceeds of approximately $5.8 million. In connection with the March 2024 registered direct offering, we amended certain existing warrants to reduce the exercise price and extend the term thereof. See also "Note 4 - Equity - Registered Direct Offerings" to our unaudited condensed financial statements included in this Quarterly Report on Form 10-Q. As of September 30, 2024, all of the 1,377,112 March 2024 Pre-Funded Warrants had been exercised for shares of common stock.

On November 18, 2022, we entered into an Equity Distribution Agreement with JMP Securities, with respect to an at-the-market offering program (our "2022 ATM Facility") under which we could offer and sell, from time to time at our sole discretion, shares of our common stock, having an aggregate offering price of up to $50.0 million. We agreed to pay JMP Securities a commission equal to three percent (3%) of the gross sales proceeds of any shares sold under the Equity Distribution Agreement, and also provided JMP Securities with customary indemnification and contribution rights. For the year ended December 31, 2023, we sold 1,342 shares of our common stock for net proceeds to us totaling $78,355. On December 12, 2023, we provided notice to JMP Securities of our termination of the 2022 ATM Facility. The termination of the Equity Distribution Agreement with JMP Securities was effective as of December 13, 2023.

On December 13, 2023, we entered into an At The Market ("ATM") Offering Agreement (the "Agreement") with H.C. Wainwright & Co., LLC, serving as agent (the "Agent") with respect to an at-the-market offering program (our "2023 ATM Facility") under which we may offer and sell through the Agent, from time to time at our sole discretion, up to such number or dollar amount of shares of our common stock (the "Shares") as registered on the prospectus supplement covering the 2023 ATM Facility offering, as may be amended or supplemented from time to time. We have agreed to pay the Agent a commission equal to three percent (3%) of the gross sales proceeds of any Shares sold through the Agent under the Agreement, and also have provided the Agent with customary indemnification and contribution rights. See also "Note 4 - Equity - At-The-Market Offering" to our unaudited condensed financial statements included in this Quarterly Report on Form 10-Q.

As of September 30, 2024, we had $1,488,281 in cash and cash equivalents.

We do not expect to generate revenue from product sales unless and until we successfully complete development of, obtain regulatory approval for and begin to commercialize one or more of our current or potential product candidates, which we expect will take a number of years and which is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital to fund our future operations, which include conducting our Acclaim-1 and Acclaim-3 clinical trials (of which both are currently enrolling) and completing preclinical work for potential other oncology candidates and completing preclinical work and conducting clinical trials for our diabetes program. We expect to complete the enrollment of the first 19 patients in the Phase 2a expansion portion of the Acclaim-1 trial in the first half of 2025. We continue to anticipate completion of enrollment in the Phase 1 dose escalation portion of the Acclaim-3 clinical trial and to start the Phase 2 expansion portion of the trial in the second half of 2024, dependent on the number of patients needed to be enrolled in the 0.12 mg/kg dose group. Until such time as we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, drawdowns on our ATM pursuant to our Agreement with the Agent, and debt financings and we may seek to raise additional capital through strategic collaborations or transactions. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our research and development programs or commercialization efforts or grant rights to others to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to curtail or cease our operations. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations. As a result of the Company's recurring losses from operations and the need for additional financing to fund its operating and capital requirements, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively over the next 12 months, which raises substantial doubt as to the Company's ability to continue as a going concern.

Based on our current cash, we estimate that we will be able to fund our expenditure requirements for our current operations and planned clinical trial activities into December 2024. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently plan due to incorrect assumptions or due to a decision to expand our activities beyond those currently planned. We previously have experienced delays in engaging clinical sites as a result of disruptions at these clinical sites caused by the COVID-19 pandemic. We also have experienced delays in clinical trial enrollment as a result of competition for patients and additional time required in connection with transitions to new third party CDMOs and the manufacture of final drug product. Delays in the conduct of our trials could result in utilizing our capital resources sooner without advancing our clinical trials as anticipated.

The following table sets forth the primary sources and uses of cash during the nine months ended September 30, 2024, and 2023:

	Nine Months Ended September 30,	
	2024	**2023**
Net cash used in operating activities	$ (13,279,658)	$ (19,774,740)
Net cash provided by (used in) investing activities	1,167	(61,383)
Net cash provided by financing activities	8,029,143	10,593,373
Net decrease in cash and cash equivalents	$ (5,249,348)	$ (9,242,750)

Cash used in operating activities

Net cash used in operating activities was $13,279,658 and $19,774,740 for the nine months ended September 30, 2024, and 2023, respectively, a decrease of $6,495,082, or 33%. This decrease was primarily due to the implementation of expense reduction strategies by Company leadership in the nine months ended September 30, 2024, which reduced travel expenses, the number of professional service providers and associated expenses, and reduced headcount and associated overheads of overall Company staff from 30 employees at September 30, 2023 to 19 employees at September 30, 2024.

Cash provided by (used in) investing activities

Net cash provided by investing activities was $1,167 for the nine months ended September 30, 2024, compared to net cash used in investing activities of $61,383 for the nine months ended September 30, 2023, or a net change of $62,550. This difference in period-over-period net cash provided by (used in) investing activities was primarily due to timing associated with filing and patent prosecution costs of our intellectual property.

Cash provided by financing activities

Net cash provided by financing activities was $8,029,143 and $10,593,373 during the nine months ended September 30, 2024, and 2023, respectively. This decrease of $2,564,230 was primarily due to differences in amounts raised by sales of our securities in capital raising activities conducted during the nine months ended September 30, 2024, and 2023, respectively.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The Company is not required to provide the information called for by this Item as it is a “smaller reporting company,” as defined in Rule 12b-2 of the Exchange Act.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. The term “disclosure controls and procedures” as defined in Rules 13a-15(e) and 15d-15(e) under 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 officer (currently the same person following the passing of Mr. Varner, the Company’s former President, Chief Executive Officer and Chairman of the Board, on May 7, 2024), as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, because of certain material weaknesses in our internal controls over financial reporting, our disclosure controls and procedures were not effective as of September 30, 2024. The material weaknesses relate to a lack of segregation of duties between accounting and other functions and the absence of sufficient depth of in-house accounting personnel with the ability to properly account for complex transactions.

Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions are performed by separate individuals. Our size and nature also do not allow for our accounting staff to have depth of expertise in all areas that might be desirable, such as expertise in accounting for a variety of complex transactions. Management evaluated the impact of our failure to maintain effective segregation of duties and sufficient depth of personnel on our assessment of our internal control over financial reporting and has concluded that these control deficiencies represent material weaknesses.

In response to the material weaknesses described above, during the quarter ended September 30, 2024, we performed additional analysis and other post-closing procedures to ensure our financial statements were prepared in accordance with US GAAP. Accordingly, we believe that the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

Remediation Plans

Management is actively engaged in remediation efforts to address the material weaknesses identified in the management’s evaluation of internal controls and procedures. The remediation efforts, which have been or are in the process of being implemented, are intended to address the identified material weaknesses, and include:

- new accounting software, processes, and workflows to further segregate duties among limited accounting staff;
- specific review procedures, including the added involvement of our legal department to review certain accounting transactions following a given period in an effort to enhance accuracy of reporting;
- specific review procedures, including the added involvement of our manufacturing staff to enhance controls associated with the tracking and reporting of inventory values in our supply chain;
- a formal Disclosure Committee that has oversight responsibility for the accuracy and timeliness of disclosures made by us through controls and procedures and the monitoring of their integrity and effectiveness;
- additional hiring of staff and development of accounting processes and policies to further segregate accounting responsibilities and increase the depth of our expertise in accounting for a variety of complex transactions; and
- additional training, testing, and certification of key accounting, finance, IT, and legal team members.

During the quarter ended September 30, 2024, we took actions to remediate the material weaknesses relating to our internal controls over financial reporting including: (i) continued evaluation and documentation of policies, processes, and controls, both manual and automated; (ii) evaluation and updates to software workflows to further segregate duties, enhance accuracy of vendor billing, and ensure transparency and oversight from vendor or project managers, department leaders, legal team members, and finance team members; and (iii) training related to general controls for information technology and security for key staff.

As management continues to evaluate and work to improve its internal control over financial reporting, we may take additional measures to address control deficiencies, or we may modify certain of the remediation measures described above. While remediation efforts are active, management requires additional time to demonstrate the operating effectiveness of our remediation efforts. The material weaknesses cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control over Financial Reporting

Except as described above, there were no changes in our internal control over financial reporting during the quarter ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Disclosure Controls and Internal Control over Financial Reporting

Because of their inherent limitations, our disclosure controls and procedures and our internal control over financial reporting may not prevent material errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The effectiveness of our disclosure controls and procedures and our internal control over financial reporting is subject to risks, including that the controls may become inadequate because of changes in conditions or that the degree of compliance with our policies or procedures may deteriorate.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in legal proceedings that arise during the ordinary course of business. Although the results of legal proceedings cannot be predicted with certainty, we do not currently have any pending litigation to which we are a party or to which our property is subject that we believe to be material. Regardless of the outcome, litigation can be costly and time consuming, and it can divert management's attention from important business matters and initiatives, negatively impacting our overall operations.

Item 1A. Risk Factors

The Company is not required to provide the information called for by this Item as it is a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act.

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

During the three months ended September 30, 2024, we issued and sold the following unregistered securities:

On July 1, 2024, we issued 5,000 shares of our common stock to the Chairman of our Scientific Advisory Board in consideration for services during the three months ended September 30, 2024.

The foregoing issuances of securities were not registered under the Securities Act or the securities laws of any state, and the securities were offered and issued in reliance on the exemption from registration under the Securities Act afforded by Section 4(a)(2).

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Rule 10b5-1 Trading Arrangements and Non-Rule 10b5-1 Trading Arrangements

During the fiscal quarter ended September 30, 2024, none of our officers or directors, as those terms are defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

Item 6. Exhibits

INDEX TO EXHIBITS

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of the Registrant, dated April 3, 2018, as amended by the Certificate of Amendment of the Amended and Restated Certificate of Incorporation, filed with the Secretary of State of the State of Delaware on January 31, 2024, incorporated by reference to Exhibit 3.1 of the Registrant's Annual Report on Form 10-K filed on April 1, 2024.
3.2	Amended and Restated Bylaws of Genprex, Inc., as amended by Amendment No. 1 adopted and approved by Genprex, Inc.'s Board of Directors on October 18, 2023, incorporated by reference to Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q filed on November 14, 2023.
31.1*	Certification of Chief 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 Chief 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.
32.1**	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (Formatted as Inline XBRL and contained in Exhibit 101).

* 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.

GENPREX, INC.
(Registrant)

Date: November 13, 2024

By: /s/ Ryan M. Confer
Ryan M. Confer
Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER OF GENPREX, INC. 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, Ryan M. Confer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Genprex, Inc., a Delaware corporation (the "registrant");

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 13, 2024

By: /s/ Ryan M. Confer
Ryan M. Confer
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER OF GENPREX, INC. 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, Ryan M. Confer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Genprex, Inc., a Delaware corporation (the "registrant");

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 13, 2024

By: /s/ Ryan M. Confer
Ryan M. Confer
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF CEO AND CFO 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 Genprex, Inc. (the "Company") for the quarter ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Ryan M. Confer, Chief Executive Officer and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: November 13, 2024

By: /s/ Ryan M. Confer
Ryan M. Confer
Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

This certification accompanies the Report, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.