







properties. All of the Company's programs are currently on hold due to capital constraints. Risks and Uncertainties The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development and regulatory success, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to secure additional capital to fund clinical trials and operations. Worldwide supply chain constraints and economic and capital markets uncertainty arising out of conflicts between Russia and Ukraine and conflicts in the Middle East triggered by attacks on Israel in October of 2023 have disrupted commercial and capital markets and emerged as new barriers to long-term economic recovery. Capital markets uncertainty, with public stock price decreases and volatility, could make it more difficult for us to raise capital when needed. In addition, the Company is subject to other challenges and risks specific to its business, its ability to maintain compliance with the continued listing requirements of The Nasdaq Capital Market and its ability to execute on its strategy, as well as risks and uncertainties common to companies in the biotechnology and pharmaceutical industries with development and commercial operations, including, without limitation, risks and uncertainties associated with: obtaining regulatory approval of its drug candidates; delays or problems in the manufacture and supply of its drug candidates, loss of single source suppliers or failure to comply with manufacturing regulations; identifying, acquiring or in-licensing additional products or drug candidates; pharmaceutical product development and the inherent uncertainty of clinical success; and the challenges of protecting and enhancing our intellectual property rights; complying with applicable regulatory requirements. -7-Table of Contents Principles of Consolidation The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") and include the accounts of Entero and its wholly owned subsidiaries, FWB and IMGX. Intercompany transactions and balances have been eliminated upon consolidation. In our opinion, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations, and cash flows. The consolidated balance sheet at December 31, 2023, has been derived from audited financial statements of that date. The unaudited interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the SEC. The Company believes that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim condensed consolidated financial statements are read in conjunction with the audited financial statements and notes previously distributed in our Annual Report Form 10-K for the year ended December 31, 2023, filed with the SEC on March 29, 2024. Substantial Doubt about the Company's Ability to Continue as a Going Concern The accompanying unaudited interim condensed consolidated financial statements have been prepared as if the Company will continue as a going concern. The Company has incurred significant operating losses and negative cash flows from operations since inception. On September 30, 2024, the Company had cash and cash equivalents of approximately \$0.4 million and an accumulated deficit of approximately \$190.1 million. The Company has incurred recurring losses, has experienced recurring negative operating cash flows, and requires significant cash resources to execute its business plans. Based on its cash on hand at September 30, 2024, the Company anticipates having sufficient cash to fund planned operations into December 2024. Historically, the Company's major sources of cash have been comprised of proceeds from various public and private offerings of its capital stock. The Company is dependent on obtaining additional working capital funding from the sale of equity and/or debt securities in order to continue to execute its development plans and continue operations. The Company has been, and is expected to continue, exploring various potential strategic alternatives including but not limited to raising capital, restructuring its indebtedness and identifying and evaluating potential strategic alternatives but there can be no assurance that these efforts will be successful, that the Company will be able to raise necessary capital on acceptable terms, reach agreement with lenders, or that the strategic review process will result in the Company pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. The Company is evaluating all potential strategic options, including a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased shareholder value or that it will make any cash distributions to stockholders. Any failure in these efforts could force the Company to delay, limit or terminate operations, make reductions in its workforce, discontinue research and development programs, liquidate all or a portion of assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code. Without adequate working capital, the Company may not be able to meet its obligations and continue as a going concern. These conditions raise substantial doubt about the Company's ability to continue as a going concern one year from the date these financial statements are issued. If the Company is not able to obtain necessary capital, it may be required to terminate operations, liquidate all or a portion of assets and/or seek bankruptcy protection. As a result, the Company concluded that its plans at this stage do not alleviate substantial doubt about the ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. -Note A 2 - Significant Accounting Policies and Recent Accounting Pronouncements Use of Estimates The accompanying unaudited condensed consolidated financial statements are prepared in conformity with GAAP and include certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements (including goodwill), and the reported amounts of revenue and expense during the reporting period, including contingencies. Accordingly, actual results may differ from those estimates. -8-Table of Contents Reverse Stock Split On December 18, 2023, the Company effected a reverse stock split, whereby every twenty shares of the Company's issued and outstanding common stock was converted automatically into one issued and outstanding share of common stock, but without any change in the number of authorized shares of common stock and the par value per share. On January 18, 2023, the Company effected a reverse stock split, whereby every seven shares of the Company's issued and outstanding common stock was converted automatically into one issued and outstanding share of common stock, but without any change in the number of authorized shares of common stock and the par value per share. All share and per share amounts have been retroactively restated to reflect the reverse stock splits referenced above. Cash and Cash Equivalents and Restricted Cash The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents. All cash and cash equivalent balances were highly liquid at September 30, 2024 and December 31, 2023. As of September 30, 2024 and December 31, 2023, the Company has classified approximately \$0.02 million as restricted cash. Concentrations of Credit Risk Financial instruments that potentially expose the Company to concentrations of credit risk consist of cash. The Company primarily maintains its cash balances with financial institutions in federally insured accounts in the U.S. The Company may from time to time have cash in banks in excess of FDIC insurance limits. At September 30, 2024 the Company had approximately \$0.4 million in one account in the U.S. which was in excess of these limits. The Company has not experienced any losses to date resulting from this practice. The Company mitigates its risk by maintaining the majority of its cash and equivalents with high quality financial institutions. Fair Value Measurements The Company follows Accounting Standards Codification ("ASC") Topic 820-10, Fair Value Measurements and Disclosures ("ASC 820-10"), which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows: Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions, which reflect those that a market participant would use. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, an instrument's level within the fair value hierarchy is based on the lowest level of input that is significant to the overall fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the financial instrument. The Company recognizes transfers between levels as if the transfers occurred on the last day of the reporting period. Goodwill Goodwill represents the excess of the purchase price of the acquired business over the fair value of amounts assigned to assets acquired and liabilities assumed. Goodwill and other intangible assets with indefinite useful lives are reviewed for impairment annually or more frequently if events or circumstances indicate impairment may be present. Any excess in carrying value over the estimated fair value is charged to results of operations. The Company has not recognized any impairment charges through September 30, 2024 related to goodwill. -9-Table of Contents Impairment of Long-Lived Assets The Company periodically evaluates its long-lived assets for potential impairment in accordance with ASC Topic 360, Property, Plant and Equipment ("ASC 360-10"). Potential impairment is assessed when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. The recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends and product development cycles. If impairments are identified, assets are written down to their estimated fair value. The Company has not recognized any impairment charges through September 30, 2024. Income Taxes Income taxes are recorded in accordance with ASC 740, Accounting for Income Taxes ("ASC 740-10"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. The Company determines its deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. At September 30, 2024 and 2023, the Company does not have any significant uncertain tax positions. Leases Leases are recorded on the balance sheet as right of use assets and lease obligations. Lease liabilities are recognized based on the present value of the future minimum lease payments over the least term at the commencement date. Leases with a term of 12 months or less at inception are expensed monthly over the lease term. The lease term is determined by assuming the exercise of renewal options that are reasonably certain. The implicit interest rate or the incremental borrowing rate is used in determining the present value of future payments. Research and Development Research and development costs are charged to operations when incurred and are included in operating expenses, except for goodwill related to patents. Research and development costs consist principally of compensation of employees and consultants that perform the Company's research activities, payments to third parties for preclinical and non-clinical activities, expenses with clinical research organizations ("CROs"), investigative sites, consultants and contractors that conduct or provide other services relating to clinical trials, costs to acquire drug product, drug supply and clinical trial materials from contract development and manufacturing organization ("CDMOs") and third-party contractors relating to chemistry, manufacturing and controls ("CMC") efforts, the fees paid for and to maintain the Company's licenses and research and development costs related to Adrilipase, Capeserod and Niclosamide. Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly. Research and Development A " Intellectual Property Acquired The Company records intellectual property acquired in business acquisitions that has not reached technological feasibility and which has no alternative future use, as In-Process R&D ("IPR&D") at the acquisition date. On March 13, 2024, the Company entered into an acquisition agreement with IMGX which included the intellectual property and patents for Latiglutenease and CypCel, which was accounted for as a business acquisition (see Note 3 and Note 4). -10-Table of Contents Intangible assets related to IPR&D are considered indefinite-lived intangible assets and are assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets will be written-off, and the Company will record a noncash impairment loss on its Consolidated Statements of Operations. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives. The impairment test for indefinite-lived intangible assets is a one-step test that compares the fair value of the intangible asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess. The Company has not recognized any impairment charges through September 30, 2024 related to IPR&D. For tax purposes, intangible assets related to IPR&D are considered indefinite-lived intangible assets. Stock-Based Compensation The Company's board of directors (the "Board") and stockholders have adopted and approved the Amended and Restated 2014 Omnibus Equity Incentive Plan (the "2014 Plan") which took effect on May 12, 2014, and the 2020 Omnibus Equity Incentive Plan, which took effect on September 11, 2020 (the "2020 Plan"). From the effective date of the 2020 Plan, no new awards have been or will be made under the 2014 Plan. On March 13, 2024, in connection with the IMGX acquisition, the Company assumed IMGX's 2021 Stock Option Plan (the "IMGX Plan"), including all IMGX stock options immediately outstanding prior to the IMGX acquisition, with each becoming an option to purchase Common Stock, subject to adjustment. The IMGX Plan was adopted and approved by the board of directors and stockholders of IMGX in 2021. Following the assumption of the IMGX Plan by the Company, no new awards have been or will be made under the IMGX Plan. The Company accounts for its stock-based compensation awards to employees, consultants, and Board members in accordance with ASC Topic 718, Compensation-Stock Compensation ("ASC 718-10"). ASC 718 requires all stock-based payments to employees, consultants, and Board members, including grants of employee stock options, to be recognized in the statements of operations by measuring the fair value of the award on the date of grant and recognizing this fair value as stock-based compensation using a straight-line method over the requisite service period, generally the vesting period. For awards with performance conditions that affect their vesting, such as the occurrence of certain transactions or the achievement of certain operating or financial milestones, recognition of fair value of the award occurs when vesting becomes probable. The Company estimates the grant date fair value of stock option awards using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the Common Stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the Common Stock. Assets Held for Sale and Discontinued Operations Assets and liabilities are classified as held for sale when all of the following criteria for a plan of sale have been met: (1) management, having the authority to approve the action, commits to a plan to sell the assets; (2) the assets are available for immediate sale, in their present condition, subject only to terms that are usual and customary for sales of such assets; (3) an active program to locate a buyer and other actions required to complete the plan to sell the assets have been initiated; (4) the sale of the assets is probable and is expected to be completed within one year; (5) the assets are being actively marketed for a price that is reasonable in relation to their current fair value; and (6) actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or the plan will be withdrawn. When all of these criteria have been met, the assets and liabilities are classified as held for sale in the condensed consolidated balance sheet. A newly acquired business in a business combination that has met the held for sale criteria should be measured at fair value less costs to sell. This is because the business has been recently acquired and its carrying value has been adjusted to its fair value. Depreciation and amortization of assets cease upon designation as held for sale. Discontinued operations comprise activities that were disposed of, discontinued or held for sale at the end of the period, represent a separate major line of business that can be clearly distinguished for operational and financial reporting purposes, and represent a strategic business shift having a major effect on the Company's operations and financial results according to ASC Topic 205, Presentation of Financial Statements. Additional details surrounding the Company's assets and liabilities held for sale and discontinued operations are included in Note 4. -11-Table of Contents Recent Accounting Pronouncements The Company has evaluated recently issued accounting pronouncements and has concluded that the impact of recently issued standards that are not yet effective, will not have a material impact on the Company's financial position or results of operations upon adoption. Note 3 " Business Acquisition On March 13, 2024, the Company acquired ImmunogenX, Inc., a Delaware corporation, in accordance with the terms of an Agreement and Plan of Merger, dated March 13, 2024 (the "Merger Agreement"), by and among the Company, IMMUNO Merger Sub I, Inc., a Delaware corporation ("First Merger Sub"), IMMUNO Merger Sub II, LLC, a Delaware limited liability company ("Second Merger Sub"), and ImmunogenX. Pursuant to the Merger Agreement, First Merger Sub merged with and into ImmunogenX, pursuant to which ImmunogenX was the surviving corporation (the "First Merger"). Immediately following the



ended December 31, 2023.July 2024 Inducement OfferingOn July 10, 2024, the Company entered into a warrant exercise inducement offer letter (the "Inducement Letter") with a holder (the "Holder") of warrants to purchase shares of the Company's common stock (the "Existing Warrants") pursuant to which the Holder agreed to exercise for cash their Existing Warrants to purchase 1,762,674 shares of the Company's common stock (the "Existing Warrant Shares"), in the aggregate, at a reduced exercised price of \$1.09 per share, in exchange for the Company's agreement to issue new warrants (the "Inducement Warrants") on substantially the same terms as the Existing Warrants as described below, to purchase up to 3,525,348 shares of the Company's common stock (the "Inducement Warrant Shares"). The Inducement Warrants will be exercisable upon the receipt of stockholder approval and may be exercised until the fifth anniversary of the date on which such stockholder approval is obtained. The Company received aggregate gross proceeds of approximately \$1.9 million from the exercise of the Existing Warrants by the Holder and the sale of the Inducement Warrants. The Company engaged Roth Capital Partners, LLC ("Roth") to act as its financial advisor in connection with the transactions summarized above and paid Roth approximately \$0.1 million for its services, in addition to reimbursement for certain expenses.-18-Table of ContentsMay 2024 Registered Direct OfferingOn May 14, 2024, the Company completed a Registered Direct Offering (the "May 2024 Offering") priced at market under Nasdaq rules, for an aggregate of (i) 275,000 shares of Common Stock, (ii) pre-funded warrants (the "May 2024 Pre-Funded Warrants") to purchase up to an aggregate of 91,000 shares of Common Stock and (iii) common warrants (the "May 2024 Warrants") to purchase up to an aggregate of 732,000 shares of Common Stock. The public offering price for each share of Common Stock and accompanying May 2024 Warrant to purchase one share of Common Stock was \$2.95 per share. The May 2024 Pre-Funded Warrants have an exercise price of \$0.0001 per share, are exercisable immediately and will expire when exercised in full. The May 2024 Warrants have an exercise price of \$2.70 per share, are exercisable immediately and will expire six years from the initial exercise date. The Company received gross proceeds of approximately \$1.1 million less placement agent's fees and other offering expenses of approximately \$0.2 million.March 2024 Registered Direct OfferingOn March 6, 2024, the Company completed a Registered Direct Offering (the "March 2024 Offering") priced at market under Nasdaq rules, for an aggregate of (i) 173,100 shares of Common Stock, (ii) pre-funded warrants (the "March 2024 Pre-Funded Warrants") to purchase up to an aggregate of 352,525 shares of Common Stock and (iii) common warrants (the "March 2024 Warrants") to purchase up to an aggregate of 525,625 shares of Common Stock. The public offering price for each share of Common Stock and accompanying March 2024 Warrant to purchase one share of Common Stock was \$7.61 per share. The March 2024 Pre-Funded Warrants have an exercise price of \$0.0001 per share, are exercisable immediately and will expire when exercised in full. The March 2024 Warrants have an exercise price of \$7.48 per share, are exercisable immediately and will expire five years from the initial exercise date. The Company received gross proceeds of approximately \$4.0 million less placement agent's fees and other offering expenses of approximately \$0.4 million.September 2023 Inducement OfferingOn September 14, 2023, the Company entered into warrant exercise inducement offer letters with certain holders (the "September 2023 Holders") of warrants to purchase shares of the Company's Common Stock (the "September 2023 Existing Warrants") pursuant to which the September 2023 Holders agreed to exercise for cash their September 2023 Existing Warrants to purchase 294,101 shares of the Company's Common Stock, in the aggregate, at a reduced exercised price of \$8.60 per share, in exchange for the Company's agreement to issue new warrants (the "September 2023 Inducement Warrants") on substantially the same terms as the September 2023 Existing Warrants as described below, to purchase up to 588,204 shares of the Company's Common Stock (the "September 2023 Inducement Warrant Shares") and a cash payment of \$2.50 per September 2023 Inducement Warrant Share which was paid in full upon the exercise of the September 2023 Existing Warrants (the "September 2023 Inducement Offering"). The Company received aggregate gross proceeds of approximately \$4.0 million from the exercise of the September 2023 Existing Warrants by the Holders and the sale of the September 2023 Inducement Warrants. The Company engaged Roth Capital Partners, LLC ("Roth") to act as its financial advisor in connection with the transactions summarized above and paid Roth approximately \$0.2 million for its services.July 2023 OfferingOn July 21, 2023, the Company completed an offering (the "July 2023 Offering") for an aggregate of (i) 30,500 shares of Common Stock, (ii) pre-funded warrants (the "July 2023 Pre-Funded Warrants") to purchase up to an aggregate of 133,750 shares of Common Stock, and (iii) common warrants (the "July 2023 Warrants") to purchase up to an aggregate of 328,500 shares of Common Stock. The public offering price for each share of Common Stock and accompanying July 2023 Warrant to purchase one share of Common Stock was \$12.80 per share. The July 2023 Pre-Funded Warrants have an exercise price of \$0.002 per share, are exercisable immediately and will expire when exercised in full. To date, pre-funded warrants have been exercised to purchase 133,750 shares of Common Stock. The July 2023 Warrants have an exercise price of \$12.80 per share, are exercisable immediately and will expire five years from the initial exercise date. The Company received gross proceeds of approximately \$2.1 million less placement agent's fees and other offering expenses of approximately \$0.3 million.-19-Table of ContentsJune 2023 Inducement OfferingOn June 13, 2023, the Company entered into warrant exercise inducement offer letters with certain holders (the "June 2023 Holders") of warrants to purchase shares of the Company's Common Stock (the "June 2023 Existing Warrants") pursuant to which the Holders agreed to exercise for cash their Existing Warrants to purchase 86,216 shares of the Company's Common Stock, in the aggregate, at a reduced exercised price of \$23.00 per share, in exchange for the Company's agreement to issue new warrants (the "June 2023 Inducement Warrants") on substantially the same terms as the Existing Warrants as described below, to purchase up to 172,433 shares of the Company's Common Stock (the "June 2023 Inducement Warrant Shares") and a cash payment of \$2.50 per Inducement Warrant Share which was paid in full upon the exercise of the Existing Warrants (the "June 2023 Inducement Offering"). The Company received aggregate gross proceeds of approximately \$2.4 million from the exercise of the Existing Warrants by the Holders and the sale of the Inducement Warrants. The Company engaged Roth Capital Partners, LLC ("Roth") to act as its financial advisor in connection with the transactions summarized above and paid Roth approximately \$0.2 million for its services.March 2023 Private PlacementOn March 15, 2023, the Company completed a private placement offering (the "March 2023 Offering") priced at market under Nasdaq rules, for an aggregate of (i) 6,400 shares of Common Stock, (ii) pre-funded warrants (the "March 2023 Pre-Funded Warrants") to purchase up to an aggregate of 44,751 shares of Common Stock and (iii) common warrants (the "March 2023 Warrants") to purchase up to an aggregate of 102,302 shares of Common Stock. The public offering price for each share of Common Stock and accompanying March 2023 Warrant to purchase one share of Common Stock was \$78.20 per share. The March 2023 Pre-Funded Warrants have an exercise price of \$73.20 per share, are exercisable immediately and will expire five years from the initial exercise date. The Company received gross proceeds of approximately \$4.0 million less placement agent's fees and other offering expenses of approximately \$0.3 million. Common Stock Issuances for the Three Months Ended September 30, 2024During the three months ended September 30, 2024, the Company issued 1,762,674 shares of Common Stock under the July 2024 Inducement Offering for which the Company received net proceeds of approximately \$1.7 million.During the three months ended September 30, 2024, the Company issued an aggregate of 38,182 shares of Common Stock upon the vesting of RSUs (See Note 12).Issuances for the Nine Months Ended September 30, 2024During the nine months ended September 30, 2024, the Company issued 173,100 and 275,000 shares of Common Stock under the March 2024 Offering and May 2024 Offering, respectively, for which the Company received net proceeds of approximately \$4.5 million.During the nine months ended September 30, 2024, the Company issued 1,762,674 shares of Common Stock under the July 2024 Inducement Offering for which the Company received net proceeds of approximately \$1.7 million.During the nine months ended September 30, 2024, the Company issued an aggregate of 36,830 shares of Common Stock with a value of \$2.3 million in connection with the IMGX acquisition.During the nine months ended September 30, 2024, the Company issued an aggregate of 18,475 shares of Common Stock with a value of \$0.1 million to its financial advisors in connection with the IMGX acquisition.During the nine months ended September 30, 2024, the Company issued an aggregate of 443,525 shares of Common Stock upon the exercise of pre-funded warrants issued at a par value of \$0.0001 (See Note 11).During the nine months ended September 30, 2024, the Company issued an aggregate of 27 shares of Common Stock upon the exchange of an aggregate of 30 shares of Series B Preferred Stock with a stated value of approximately \$234,376 plus accrued dividends of approximately \$70,429.-20-Table of ContentsDuring the nine months ended September 30, 2024, the Company issued an aggregate of 350,000 shares of its Common Stock to consultants with a grant date fair value of approximately \$1,541,995 for investor relations services provided, which was recorded as stock-based compensation and included as part of general and administrative expense.During the nine months ended September 30, 2024, the Company issued an aggregate of 121,335 shares of Common Stock upon the vesting of RSUs (See Note 12).Issuances for the Three Months Ended September 30, 2023During the three months ended September 30, 2023, the Company issued 1,762,674 shares of Common Stock under the July 2024 Inducement Offering for which the Company received net proceeds of approximately \$1.7 million.During the three months ended September 30, 2024, the Company issued 294,101 shares of Common Stock upon the exercise of an aggregate of 294,101 investor warrants for which the Company received net proceeds of approximately \$3.7 million (See Note 11).During the three months ended September 30, 2023, the Company issued an aggregate of 133,750 shares of Common Stock upon the conversion of pre-funded warrants issued at a par value of \$0.0001.During the three months ended September 30, 2023, the Company issued an aggregate of 22 shares of Common Stock upon the exchange of an aggregate of 24.22 shares of Series B Preferred Stock with a stated value of approximately \$186,500 plus accrued dividends of approximately \$43,300.During the three months ended September 30, 2023, the Company issued an aggregate of 2,500 shares of its Common Stock to consultants with a grant date fair value of approximately \$76,000 for investor relations services provided, which was recorded as stock-based compensation and included as part of general and administrative expense.During the three months ended September 30, 2023, the Company issued an aggregate of 1,851 shares of Common Stock upon the vesting RSUs (See Note 12).Issuances for the Nine Months Ended September 30, 2023During the nine months ended September 30, 2023, the Company issued 6,400 shares of Common Stock under the March 2023 Offering for which the Company received net proceeds of approximately \$3.7 million.During the nine months ended September 30, 2023, the Company issued 86,216 shares of Common Stock upon the exercise of an aggregate of 86,216 investor warrants for which the Company received net proceeds of approximately \$2.2 million.During the nine months ended September 30, 2023, the Company issued 30,500 shares of Common Stock under the July 2023 Offering for which the Company received net proceeds of approximately \$1.8 million.During the nine months ended September 30, 2023, the Company issued 294,101 shares of Common Stock upon the exercise of an aggregate of 294,101 investor warrants for which the Company received net proceeds of approximately \$3.7 million.During the nine months ended September 30, 2023, the Company issued an aggregate of 199,974 shares of Common Stock upon the exercise of pre-funded warrants issued at a par value of \$0.0001.During the nine months ended September 30, 2023, the Company issued an aggregate of 26 shares of Common Stock upon the exchange of an aggregate of 28.45 shares of Series B Preferred Stock with a stated value of approximately \$219,000 plus accrued dividends of approximately \$49,500.During the nine months ended September 30, 2023, the Company issued an aggregate of 2,500 shares of its Common Stock to consultants with a grant date fair value of approximately \$76,000 for investor relations services provided, which was recorded as stock-based compensation and included as part of general and administrative expense.-21-Table of ContentsDuring the nine months ended September 30, 2023, the Company issued an aggregate of 3,854 shares of Common Stock upon the vesting of RSUs.During the nine months ended September 30, 2023, the Company cancelled an aggregate of 148 shares of Common Stock in connection with the 1-for-7 reverse stock split on January 18, 2023.Notes 11A and 12A of the Warrants Warrant activity for the nine months ended September 30, 2024 and 2023 was as follows:Weighted-average Number of Exercise Price Remaining at the Per Share Price at the Term in Years Outstanding and exercisable on January 1, 2024 is \$779,780 at \$19.29 and 4,991 issued 5,226,498 at \$18.45 Assumed from IMGX at \$127,680 and \$3.48 at \$8.47 Expired at (3) at \$2,500.00 at \$18.45 Exercised at (2,206,199) at \$18.39 at 8,58 Warrants outstanding and exercisable on September 30, 2024 at \$4,927,756 at \$7.21 at \$4,964 at \$18.45 at \$18.45 at \$18.45 Warrants outstanding and exercisable on January 1, 2023 at \$108,797 at \$383.20 at \$5,501 issued 1,369,940 at \$14.60 at \$4,59 Expired at (4) at \$15,475,804 at \$18.45 Exercised at (580,293) at \$18.19 at 20.20 at \$4,72 Warrants outstanding and exercisable on September 30, 2023 at \$898,440 at \$47.60 at \$4,894 As of September 30, 2024, the outstanding warrants expire from 2024 through 2033.During the nine months ended September 30, 2024, the Company issued warrants to purchase 525,625 shares of the Company's Common Stock and pre-funded warrants to purchase 91,000 shares of the Company's Common Stock in connection with the May 2024 Offering, and warrants to purchase 3,525,348 shares of the Company's Common Stock in connection with the July Inducement Offering (See Note 10). Additionally, the Company assumed warrants to purchase 127,680 shares of the Company's Common Stock in connection with the IMGX acquisition.During the nine months ended September 30, 2024, an investor exercised pre-funded warrants to purchase 443,525 shares of the Company's Common Stock and common stock warrants to purchase 1,762,674 shares of the Company's Common Stock in connection with previous offerings.During the nine months ended September 30, 2023, the Company issued warrants to purchase 102,302 shares of the Company's Common Stock and pre-funded warrants to purchase 44,751 shares of the Company's Common Stock in connection with the March 2023 Offering, warrants to purchase 172,433 shares of the Company's Common Stock in connection with the June 2023 Inducement Offering, warrants and pre-funded warrants to purchase 462,250 shares of the Company's Common Stock in connection with the July 2023 Offering, and warrants to purchase 588,204 shares of the Company's Common Stock in connection with the September 2023 Inducement Offering (See Note 10).During the nine months ended September 30, 2023, an investor exercised pre-funded warrants to purchase 199,974 shares of the Company's Common Stock and common stock warrants to purchase 380,319 shares of the Company's Common Stock in connection with previous offerings.-22-Table of ContentsNotes 12A and 12B of the Equity Incentive Plan The Company's Board and stockholders adopted and approved the Amended and Restated 2014 Omnibus Equity Incentive Plan (the "2014 Plan"), which took effect on May 12, 2014. The Company's Board and stockholders adopted and approved the 2020 Omnibus Equity Incentive Plan (the "2020 Plan"), which took effect on September 11, 2020. From the adoption and approval of the 2020 Plan, no new awards have been or will be made under the 2014 Plan. The 2020 Plan allows for the issuance of securities, including stock options to employees, Board members and consultants. The initial number of shares of Common Stock available for issuance under the 2020 Plan was 238 shares, which will, on January 1 of each calendar year, unless the Board decides otherwise, automatically increase to equal ten percent (10%) of the total number of shares of Common Stock outstanding on December 31 of the immediately preceding calendar year, calculated on an As Converted Basis. As Converted Shares include all outstanding shares of Common Stock and all shares of Common Stock issuable upon the conversion of outstanding preferred stock, warrants and other convertible securities, but will not include any shares of Common Stock issuable upon the exercise of options and other convertible securities issued pursuant to either the 2014 Plan, the 2020 Plan, or the IMGX Plan. The number of shares permitted to be issued as incentive stock options (the "ISOs") is 357 under the 2020 Plan. On March 13, 2024, in connection with the IMGX acquisition, the Company assumed the IMGX Plan, including all 200,652 IMGX stock options immediately outstanding prior to the IMGX acquisition, with each becoming an option to purchase Common Stock, subject to adjustment. Such stock options were the only awards that had been made under the IMGX Plan as of the closing of the IMGX acquisition. The IMGX Plan was adopted and approved by the board of directors and stockholders of IMGX in 2021. Following the assumption of the IMGX Plan by the Company, no new awards have been or will be made under the IMGX Plan. As of January 1, 2024, the number of shares of Common Stock available for issuance under the 2020 Plan automatically increased to 334,078 under the 2020 Plan's evergreen provision. As of September 30, 2024, there were an aggregate of 73 total shares available (but un-issuable) under the 2014 Plan, of which 27 are issued and outstanding, and 9 shares are reserved subject to issuance of restricted stock and RSUs. As of September 30, 2024, there were an aggregate of 350,000 total shares available (but un-issuable) under the IMGX 2021 Plan, of which 200,652 are issued and outstanding. As of September 30, 2024, 334,078 total shares were authorized under the 2020 Plan, of which 208,763 were issued and outstanding and 125,315 shares were available for potential issuances. During the nine months ended September 30, 2024 and 2023, stock option activity under the 2014 Plan, 2020 Plan, and IMGX 2021 Plan was as follows:Weighted-average Number of Exercise Price Remaining at the Per Share Price at the Term in Years Outstanding and exercisable on January 1, 2024 is \$103,81 at \$8.53 and \$1 Assumed from Immunogen at \$200,652 at \$0.81 at \$7.05 and \$7.05 Expired at (15) at \$18,720,804 at \$8.45 Outstanding at September 30, 2024 at \$101,063 at \$12.01 at \$7.05 and \$7.05 Exercised at September 30, 2024 at \$201,052 at \$11.74 at \$7.05 As of September 30, 2024, the outstanding warrants expire from 2024 through 2033. Outstanding at January 1, 2023 at \$176 at \$15,956.72 at \$8.22 and \$8.22 Granted at \$250 at \$74.60 at \$9.40 and \$9.40 Outstanding at September 30, 2023 at \$426 at \$7,946.60 at \$8.68 and \$8.68 Exercisable at September 30, 2023 at \$331 at \$9,284.40 at \$8.62 and \$8.62 During the nine months ended September 30, 2024, the Company assumed fully vested options to purchase 200,652 shares of the Company's Common Stock issued under the IMGX 2021 Plan. During the nine months ended September 30, 2023, the Board approved the grant of options to purchase 250 shares of the Company's Common Stock pursuant to the 2020 Plan. In general, options granted under the 2020 Plan vest monthly over a 36-month



included in this Report and in our Annual Report filed on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 29, 2024. Readers are cautioned not to place undue reliance on these forward-looking statements. Overview We are engaged in the research and development of targeted, non-systemic therapies for the treatment of patients with gastrointestinal (âœGlâ€) diseases. Non-systemic therapies are non-absorbable drugs that act locally, i.e., in the intestinal lumen, skin or mucosa, without reaching an individualâ€™s systemic circulation. Our therapeutic pipeline primarily consists of multiple late-stage clinical programs built around three proprietary technologies â€” the biologic Adrulipase, a recombinant lipase enzyme designed to enable the digestion of fats and other nutrients in cystic fibrosis and chronic pancreatitis patients with exocrine pancreatic insufficiency; Capeserod, a selective 5-HT4 receptor partial agonist which we are developing for the treatment of gastroparesis; and Niclosamide, an oral small molecule with anti-inflammatory properties for patients with inflammatory bowel diseases such as ulcerative colitis and Crohnâ€™s disease. We are currently focusing on our Adrulipase and Capeserod programs and are exploring strategic alternatives for our Niclosamide program. In May 2024, we changed our name from First Wave Biopharma, Inc. to Entero Therapeutics, Inc. In March 2024, we announced the closing of a merger with ImmunogenX, Inc. (âœIMGXâ€) (the Companyâ€™s acquisition of IMGX, the âœMergerâ€), a private, clinical-stage biopharmaceutical company founded in 2013, which is developing the biologic Latiglutenaase for the treatment of celiac disease. IMGX is also developing CypCel, a metabolic marker compound that can measure the state of small-intestinal recovery of celiac patients undergoing gluten-free diets (âœGFDsâ€). We have initiated a plan to dispose of certain assets and liabilities of IMGX, including Latiglutenaase and CypCel, within 12 months of the date of the Merger. As of September 30, 2024, these were classified as assets and liabilities held for sale and due to the short period of time since the close of the Merger, are reported at their fair value less cost to sell. We determined that the discontinued operations of IMGX represents a strategic shift that will have a major effect on our operations and financial statements. In December 2023, we announced that we have entered into a non-binding term sheet to sell our Niclosamide program. The non-binding term sheet includes a low seven-figure upfront payment to us for rights to Niclosamide, as well as economics related to future milestones and royalties. This transaction is not expected to move forward at this time. -30-Table of ContentsRecent DevelopmentsMarch 2024 Registered Direct OfferingOn March 6, 2024, we completed the March 2024 Offering priced at market under Nasdaq rules, for an aggregate of (i) 173,100 shares of Common Stock, (ii) pre-funded warrants to purchase up to an aggregate of 352,525 shares of Common Stock and (iii) common warrants to purchase up to an aggregate of 525,625 shares of Common Stock. The public offering price for each share of Common Stock and accompanying March 2024 Warrant to purchase one share of Common Stock was \$7.61 per share. The March 2024 Pre-Funded Warrants have an exercise price of \$0.0001 per share, are exercisable immediately and will expire when exercised in full. The March 2024 Warrants have an exercise price of \$7.48 per share, are exercisable immediately and will expire five years from the initial exercise date. We received gross proceeds of approximately \$4.0 million less placement agentâ€™s fees and other offering expenses of approximately \$0.4 million. The March 2024 Offering included customary registration rights, for registration under the Securities Act, of the shares underlying the warrants in the March 2024 Offering. May 2024 Registered Direct OfferingOn May 10, 2024, we announced that we entered into a Registered Direct Offering (the âœMay 2024 Offeringâ€) likewise priced at market under Nasdaq rules. The May 2024 Offering was for an aggregate of (i) 275,000 shares of Common Stock, (ii) pre-funded warrants (the âœMay 2024 Pre-Funded Warrantsâ€) to purchase up to an aggregate of 91,000 shares of Common Stock and (iii) common warrants (the âœMay 2024 Warrantsâ€) to purchase up to an aggregate of 732,000 shares of Common Stock. The May 2024 Pre-Funded Warrants had the same exercise price and exercise terms as the March 2024 Pre-Funded Warrants. The public offering price for each share of Common Stock in the May 2024 Offering was \$2.95, and the public offering price for each May 2024 Pre-Funded Warrant, was \$2.9499. The May 2024 Warrants have an exercise price of \$2.70 per share, are exercisable immediately and will expire six years from the initial exercise date. In this offering, we received gross proceeds of approximately \$1.1 million less placement agentâ€™s fees and other offering expenses. In connection with the May 2024 Offering, we were obligated to file a registration statement with the SEC to register the shares underlying the warrants sold in the offering under the Securities Act, within 30 days of the closing of the May 2024 Offering and have such registration statement declared effective by the SEC within 60 days of such closing, or in the case of full review of the applicable registration statement by the SEC, within 120 days of such closing. If such registration statement is not so filed or declared effective, on each applicable monthly anniversary for which such registration even is not achieved or cured, we are required to pay to the holder an amount in cash, as partial liquidated damages and not as a penalty, equal to the product of 1.0% multiplied by the product of the most recent closing price of our Common Stock on the applicable event date, and the number of shares underlying such warrants, until the shares underlying such warrants are freely tradeable under Rule 144 of the Securities Act or we regain compliance with the registration rights. If we fail to pay partial liquidated damages required thereby within seven (7) days after the date payable, we are required to pay interest thereon at a rate of 12% per annum (or such lesser maximum amount that is permitted to be paid by applicable law) to the holder, accruing daily from the date such partial liquidated damages are due until such amounts, plus all such interest thereon, are paid in full. The partial liquidated damages provisions apply on a daily pro rata basis for any applicable portion of a month. July 2024 Inducement OfferingOn July 10, 2024, we entered into a warrant exercise inducement offer letter (the âœInducement Letterâ€) with a holder (the âœHolderâ€) of warrants to purchase shares of our Common Stock (the âœExisting Warrantsâ€) pursuant to which the Holder agreed to exercise for cash their Existing Warrants to purchase 1,762,674 shares of our Common Stock (the âœExisting Warrant Sharesâ€), in the aggregate, at a reduced exercised price of \$1.09 per share, in exchange for our agreement to issue new warrants (the âœInducement Warrantsâ€) on substantially the same terms as the Existing Warrants as described below, to purchase up to 3,525,348 shares of our Common Stock (the âœInducement Warrant Sharesâ€). The Inducement Warrants will be exercisable upon the receipt of stockholder approval and may be exercised until the fifth anniversary of the date on which such stockholder approval is obtained. We received aggregate gross proceeds of approximately \$1.9 million from the exercise of the Existing Warrants by the Holder and the sale of the Inducement Warrants. We engaged Roth Capital Partners, LLC (âœRothâ€) to act as our financial advisor in connection with the transactions summarized above and paid Roth approximately \$96,000 for its services, in addition to reimbursement for certain expenses. -31-Table of ContentsNasdaq Continued Listing RequirementsOn August 17, 2023, we received a letter from the Listing Qualifications Staff (the âœStaffâ€) of the Nasdaq Stock Market LLC (âœNasdaqâ€) indicating that we were not in compliance with the \$2.5 million minimum stockholdersâ€™ equity requirement for continued listing of our common stock on Nasdaq as set forth in Nasdaq Listing Rule 5550(b)(1) (the âœMinimum Stockholderâ€™s Equity Ruleâ€). In that regard, we reported stockholdersâ€™ equity of \$881,960 in our Quarterly Report on Form 10-Q for the period ended June 30, 2023 (we did not then, and do not now, meet the alternative compliance standards relating to the market value of listed securities of \$35.0 million or net income from continuing operations of \$0.5 million in the most recently completed fiscal year or in two of the last three most recently completed fiscal years). On April 1, 2024, we received a determination from the Staff that we are back in compliance with the Minimum Stockholderâ€™s Equity Rule and that the matter is closed. On October 26, 2023, we received a notice from the Staff of Nasdaq indicating that in connection with an offering completed in July 2023 (the âœJuly 2023 Offeringâ€), we were not in compliance with Nasdaqâ€™s shareholder approval requirements set forth in listing rule 5635(d), which requires prior shareholder approval for transactions, other than public offerings, involving the issuance of 20% or more of the pre-transaction shares outstanding at less than the Minimum Price, defined as a price that is the lower of: (i) the Nasdaq official closing Price (as reflected on Nasdaq.com) immediately preceding the signing of the binding agreement; or (ii) the average Nasdaq official Closing Price of the common stock (as reflected on Nasdaq.com) for the five trading days immediately preceding the signing of the binding agreement. On December 12, 2023, during the Special Meeting, our stockholders ratified our entry into the July 2023 Offering as we received the affirmative vote of the majority of the votes cast by shares of our common stock present or represented by proxy and entitled to vote at the Special Meeting. On March 19, 2024, we received a Letter of Reprimand from the Nasdaq Listing Qualifications Staff (the âœLetter of Reprimandâ€) stating that, while we failed to comply with Nasdaqâ€™s continued listing requirements, our violation of listing rule 5635(d) does not appear to have been the result of a deliberate intent to avoid compliance, and as such, the Staff does not believe that delisting our securities is an appropriate sanction and that it is appropriate to close these matters by issuing the Letter of Reprimand. On August 7, 2024, we notified the Staff of Nasdaq that, as the result of the resignations of two of our directors, we were no longer in compliance with Nasdaq Rule 5605(c)(2) (the âœAudit Committee Ruleâ€), which requires a Nasdaq-listed company to have an audit committee of the Board comprised of at least three independent directors meeting the eligibility requirements of the Audit Committee Rule. On August 8, 2024, our Board, having determined that both individuals meet the eligibility requirements of the Audit Committee Rule, appointed Chaitan Khosla and Alastair Riddell to the audit committee of the Board (the âœAudit Committeeâ€) to fill the vacancies on the Audit Committee created by the aforementioned resignations. Additionally, the Board appointed the existing Audit Committee member, Edward J. Borkowski, as chair of the Audit Committee. As a result of the appointments, the Audit Committee once again had three members, as required by the Audit Committee Rule. On September 6, 2024, we received a letter from the Staff of Nasdaq indicating that, based upon the closing bid price of our Common Stock for the last 30 consecutive business days, we are not currently in compliance with the requirement to maintain a minimum bid price of \$1.00 per share for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the âœNoticeâ€). The Notice has no immediate effect on the continued listing status of our common stock on The Nasdaq Capital Market, and, therefore, our listing remains fully effective. We are provided a compliance period of 180 calendar days from the date of the Notice, or until March 5, 2025, to regain compliance with the minimum closing bid requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). If at any time before March 5, 2025, the closing bid price of our common stock closes at or above \$1.00 per share for a minimum of 10 consecutive business days, subject to Nasdaqâ€™s discretion to extend this period pursuant to Nasdaq Listing Rule 5810(c)(3)(H), Nasdaq will provide written notification that we have achieved compliance with the minimum bid price requirement, and the matter would be resolved. If we do not regain compliance during the compliance period ending March 5, 2025, then Nasdaq may grant us a second 180 calendar day period to regain compliance, provided we meet the continued listing requirement for market value of publicly-held shares and all other initial listing standards for The Nasdaq Capital Market, other than the minimum closing bid price requirement, and notify Nasdaq of our intent to cure the deficiency. -32-Table of ContentsRationalization Activities and DevelopmentsAs of December 31, 2023, we had 9 employees, which increased to 15 employees in March 2024 following the IMGX Merger. In connection with certain cost reduction measures we have taken, on July 16, 2024, we reduced our headcount to 11 employees, and Dr. Syage agreed to reduce his annual base salary to \$66,560, effective July 1, 2024. On August 1, 2024, in order to further reduce costs and conserve resources, we approved the termination of all non-essential employees and are considering vacating the Boca Raton office. On August 2, 2024, in connection with the reduction in workforce, the Board approved the termination of (i) the employment agreement with our Chief Executive Officer, James Sapirstein (the âœSapirstein Employment Agreementâ€), and (ii) the offer letter between us and our President, Jack Syage. In connection with the termination of the Sapirstein Employment Agreement, on August 2, 2024, we entered into a consulting agreement with Mr. Sapirstein (the âœSapirstein Consulting Agreementâ€), whereby he will continue to serve as our Chief Executive Officer, and pursuant to which Mr. Sapirstein will be paid \$400 an hour monthly for services rendered to us. The Sapirstein Consulting Agreement has an initial term of six months, subject to early termination by either party for any reason at any time, and may be extended on a month-to-month basis upon mutual agreement after the expiration of the initial six-month term. Additionally, on August 2, 2024, as part of the reduction in workforce described above, the Board approved the payout of unused vacation time for all employees accrued through August 1, 2024, including Mr. Sapirstein, Dr. Syage, and our Chief Financial Officer, Sarah Romano. We paid Mr. Sapirstein, Dr. Syage, and Ms. Romano \$69,230, \$1,920, and \$45,590, respectively, to compensate for their unused vacation time accrued through August 1, 2024. As a result of the rationalization, we have paused development of Latiglutenaase, Adrulipase, Niclosamide, Capeserod, and any other non-essential research and development activities. We are exploring strategic alternatives, including a sale or wind-down of the IMGX entity, as well as other potential strategic options, including a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction, however our board of directors has not yet approved any strategic transactions. We are dependent on obtaining, and are continuing to pursue, the necessary funding from outside sources, including obtaining additional funding from the sale of securities in order to continue our operations. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be forced to delay, reduce or terminate our business activities. Notice of Default and AccelerationAs previously disclosed in our Current Report on Form 8-K filed with the SEC on March 14, 2024, we acquired ImmunogenX in a merger transaction, the terms of which included, among other things, our wholly owned subsidiary, IMGX, assuming the debt of ImmunogenX. On August 2, 2024, IMGX received a Notice of Default and Acceleration (the âœNoticeâ€) relating to that certain Credit Agreement, dated as of October 3, 2022 (as amended, modified, supplemented or restated from time to time, the âœCredit Agreementâ€) by and among Mattress Liquidators, Inc. (the âœLenderâ€) and ImmunogenX. The Notice informed IMGX that one or more events of default under the Credit Agreement (âœEvents of Defaultâ€) were existing and continuing. Such outstanding Events of Default include, among others, IMGX suffering an adverse change in its financial condition which would reasonably be expected to have a Material Adverse Effect (as defined in the Credit Agreement). The Notice indicated that, as a result of the outstanding Events of Default, pursuant to the terms of Section 8.3 of the Credit Agreement, (a) the outstanding principal balance of the loan made under the Credit Agreement, all interest and fees related thereto, and all other outstanding obligations are accelerated and declared immediately due and payable, and that the Lender demands immediate payment of all obligations, and (b) the Lender is increasing the effective interest rate to the Default Rate (as defined in the Credit Agreement). The Credit Agreement affords IMGX thirty (30) days to cure Events of Default (the âœCure Periodâ€), with a possible extension of an additional thirty (30) days, provided that in no event shall the Cure Period be greater than sixty (60) days in the aggregate. If IMGX is not able to cure the Events of Default within the Cure Period, IMGX may also be deemed to be in default of the stockholder notes ImmunogenX entered into with Jack Syage and Peter Felker as part of the acquisition of ImmunogenX by us (the âœStockholder Notesâ€), the entry into such notes having been previously disclosed by us on our Current Report on Form 8-K filed with the SEC on March 14, 2024. If IMGX is deemed to have defaulted under the Stockholder Notes, the holders of the Stockholder Notes may, at their option and upon notice to IMGX, declare the outstanding principal of, and all accrued interest on, the Stockholder Notes immediately due and payable. -33-Table of ContentsAs of the date of the Notice, the aggregate outstanding obligations under the Credit Agreement were \$6,997,583 (comprised of (i) \$5,360,000 in respect of outstanding principal, (ii) \$1,637,583 of accrued and unpaid interest, and (iii) other, presently unliquidated, amounts for fees and expenses (including legal fees) payable in accordance with the Credit Agreement and related documents). This outstanding amount does not include any additional obligations incurred following the date of the Notice (including additional interest, which shall continue to accrue on the outstanding obligations following the date of the Notice). As previously disclosed in our Current Report on Form 8-K filed with the SEC on September 3, 2024, on August 29, 2024, after discussions with the Lender, ImmunogenX received a letter (the âœLetterâ€) from the Lender informing ImmunogenX that at this time, the Lender is suspending the MAE Default. The Letter additionally provided that the Lenderâ€™s suspension of the MAE Default is not, and shall not be construed as, a waiver of the MAE Default and the Lender expressly reserves all rights with respect to its enforcement of the MAE Default. Letter of Intent with Data Vault Holdings, Inc. On September 9, 2024, we entered into the Letter of Intent with Data Vault Holdings, Inc. (âœDVHâ€) for the licensing of certain clinical trial software owned by DVH and associated intellectual property (the âœAssetsâ€). The Letter of Intent contemplates a worldwide exclusive license to the Assets with the right to grant sublicenses, and a right of first refusal for the Company to fully acquire the Assets in exchange for the issuance of \$250,000 of shares of the Companyâ€™s junior convertible preferred stock (the âœPreferred Sharesâ€) priced at a price per preferred share equal to 180% of the five (5) trading day Volume-Weighted Average Price (âœVWAPâ€) of the Companyâ€™s common stock (the âœCommon Share Priceâ€), immediately preceding the closing of the Proposed Transaction multiplied by 1,000, (the âœPreferred Share Priceâ€), and single digit royalties on net sales (the âœProposed Transactionâ€). Entry into definitive documentation for the Proposed Transaction will be conditioned upon the Company receiving no less than \$500,000 of strategic investment (the âœStrategic Investmentâ€), with a target of ultimately securing up to \$3.0 million of strategic investment with the assistance of DVH. There can be no assurance that the Proposed Transaction will be completed on the terms contemplated in the Letter of Intent or otherwise. Binding Term SheetOn November 8, 2024, we entered into a binding term sheet (the âœBinding Term Sheetâ€) with Journey Therapeutics, Inc. (âœJourneyâ€), a life sciences company. Pursuant to the Binding Term Sheet, we will acquire 100% of the outstanding equity interests of Journey in return for 99% of our fully-diluted equity (the âœAcquisitionâ€). Following the close of the Acquisition, it is anticipated that Henry Ji, M.D., Ph.D., the Chief Executive Officer of Journey, will assume the roles of Chief Executive Officer and Chairman of the Board of Entero. Further, following the close of the Acquisition, the Board will be of a size to be determined jointly by Entero and Journey, with one to two members of the post-closing Board to be designated by Entero. We anticipate adopting an equity incentive plan (the âœEquity Planâ€) for up to 15% of the outstanding shares of Common Stock of Entero at the time of the close of the Acquisition. We will also create an employee stock purchase plan for up to 1% of the outstanding shares of Common Stock of Entero at the time of the close of the Acquisition (the âœESPPâ€). The creation and adoption of the Equity Plan and the ESPP are subject to obtaining

requisite Company stockholder, Board and committee approvals. The Acquisition is subject to a number of conditions, including the completion of customary due diligence, negotiation of the definitive agreement, as well as approvals by our Board and our stockholders. Such definitive agreement will include a number of customary provisions, including without limitation, representations and warranties of Journey and Entero, restrictive covenants applicable to Journey and Entero and indemnification provisions. The Acquisition is also conditioned upon the completion of an equity financing providing net proceeds of at least \$5.0 million, the effectiveness of a Form S-4 Registration Statement with regard to the Acquisition, to be filed with the SEC, and the shares of Common Stock of the combined company being approved for initial listing on Nasdaq. Under the Binding Term Sheet, Journey and Entero are subject to an exclusivity period that is a minimum of 30 days, and such exclusivity shall continue after the 30-day period until a party delivers a notice of termination of exclusivity (the "Exclusivity Period"). During the Exclusivity Period, both parties are restricted from soliciting, negotiating or entering into any agreements with third parties for the sale of their respective businesses or material assets.<sup>34</sup> Table of ContentsLiquidity and Capital ResourcesTo date, we have not generated any revenues and have experienced net losses and negative cash flows from our activities. As of September 30, 2024, we had cash and cash equivalents of approximately \$0.4 million and had sustained cumulative losses attributable to common stockholders of approximately \$190.1 million. Based on our cash on hand at September 30, 2024, we anticipate having sufficient cash to fund planned operations into December 2024. We believe that we will need to raise substantial additional capital in the near term to fund our continuing operations, satisfy existing and future obligations and liabilities, and otherwise support our working capital needs and business activities. The acceleration or reduction of cash outflows by management can significantly impact the timing for the need to raise additional capital to complete development of our products. In order to manage our operating costs, we have reduced headcount and paused development activities, and we are exploring strategic alternatives for the purpose of maximizing value of all of our stakeholders of the Company. We have been, and expect to continue to, explore various potential strategies available to us, including but not limited to raising capital, restructuring our indebtedness and identifying and evaluating potential strategic alternatives but there can be no assurance that these efforts will be successful, that we will be able to raise necessary capital on acceptable terms, reach agreement with our lenders, or that the strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We are evaluating all potential strategic options, including a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transactions. As discussed above, in November 2024, we entered into a binding term sheet with Journey Therapeutics, Inc. pursuant to which we will acquire 100% of the outstanding equity interests of Journey in return for 99% of our fully-diluted equity, subject to a number of conditions. See Management's Discussion and Analysis of Financial Condition and Results of Operations "Recent Developments. However, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stakeholder value or that we will make any cash distributions to our stockholders. Any failure in these efforts could force us to delay, limit or terminate our operations, make reductions in our workforce, discontinue our research and development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code. We evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. As described herein, if we are not able to obtain necessary capital, we may be required to terminate our operations, liquidate all or a portion of our assets and/or seek bankruptcy protection. As a result, management has concluded that its plans at this stage do not alleviate substantial doubt about our ability to continue as a going concern. Under current Securities and Exchange Commission regulations, because our public float was less than \$75.0 million at the relevant measurement period pursuant to General Instruction I.B.6, to Form S-3, the amount we can raise through primary public offerings of securities in any subsequent twelve-month period under our shelf registration statement is limited to an aggregate of one-third of our public float until such time, if any, as our public float is \$75.0 million or more. Due to the late filing of our Form 10-Q for the quarter ended June 30, 2024, we are prohibited from registering shares under a Form S-3 for 12 months from the original filing due date, or August 14, 2025. Our ability to issue securities is subject to market conditions. Each issuance under the shelf registration statements will require the filing of a prospectus supplement identifying the amount and terms of the securities to be issued. Debt ObligationsRevolving line of credit in connection with the IMGX acquisition, we assumed a revolving line of credit. In October 2022, IMGX entered into a credit agreement, which allowed for a revolving line of credit (the "Revolver") for borrowings up to \$6.0 million, maturing on October 1, 2024, and bearing interest per annum of the prime rate plus 4.5%. The credit agreement was amended in September 2023 (the "First Amendment") to increase the maximum borrowings of the Revolver to \$7.5 million. The credit agreement was amended and restated on March 13, 2024 (the "Second Amendment"). Terms under the Second Amendment include a maturity date of September 13, 2025, interest per annum of the prime rate plus 6.0%, and no further draws on the line of credit after March 13, 2024. As of September 30, 2024, the Revolver and accrued interest has been reclassified to liabilities of the disposal group held for sale.<sup>35</sup> Table of ContentsPromissory notesIn connection with the IMGX acquisition, we assumed two promissory notes, one of which is with a related party. The notes are each in the amount of \$0.5 million, accrue interest at a rate of the prime rate plus 4.5% per annum, and have a maturity date of September 30, 2025. As of September 30, 2024, the promissory notes and all accrued interest has been reclassified to liabilities of the disposal group held for sale. EIDL loanIn connection with the IMGX acquisition, we assumed an EIDL loan with a principal balance of \$0.5 million bearing interest of 3.75% per annum, with interest payable monthly in arrears. All unpaid principal and interest are due at maturity on June 30, 2050. As of September 30, 2024, the EIDL loan and all accrued interest has been reclassified to liabilities of the disposal group held for sale. Consolidated Results of Operations for the Three Months Ended September 30, 2024 and 2023The following table summarizes our consolidated results of operations for the periods indicated:<sup>36</sup> Table of ContentsPromissory notesThe Research and development expenses for the three months ended September 30, 2024, decreased by \$1.8 million, or 30% over the approximately \$1.0 million recorded for the three months ended September 30, 2023. The approximately \$0.8 million decrease in total research and development expenses was primarily attributable to a decrease of \$0.5 million related to the September 2023 up-front payment to Sanofi per the executed license agreement for Capeserod, as well as a \$0.2 million decrease in clinical trial related expenses and a \$0.1 million decrease in personnel costs. We expect research and development expenses to decrease during the remainder of this fiscal year as we conserve cash. General and Administrative ExpensesGeneral and administrative expenses include expenses primarily relating to our overall operations and being a public company, including personnel, legal and financial professional services, insurance, corporate communications and investor relations, listing and compliance related costs, rent, and expenses associated with obtaining and maintaining intellectual property and patents, among others. General and administrative expenses for the three months ended September 30, 2024 totaled approximately \$1.7 million, a decrease of approximately \$0.7 million, or 30% over the approximately \$2.4 million recorded for the three months ended September 30, 2023. The approximately \$0.7 million decrease in total general and administrative expenses was primarily attributable to a decrease of \$0.5 million in public company costs and investor relations and \$0.1 million in share-based compensation.<sup>37</sup> Table of ContentsWe expect general and administrative expenses to decrease during the remainder of this fiscal year as we conserve cash. Other ExpensesOther expenses for the three months ended September 30, 2024 and 2023 were insignificant. Loss from discontinued operationsLoss from discontinued operations for the three months ended September 30, 2024 of \$0.7 million represents expenses related to the disposal group that was classified as held for sale as of September 30, 2024. Net LossAs a result of the factors above, our net loss for the three months ended September 30, 2024 totaled approximately \$2.6 million, a decrease of approximately \$0.9 million, or 25%, over the net loss of approximately \$3.4 million recorded for the three months ended September 30, 2023. Consolidated Results of Operations for the Nine Months Ended September 30, 2024 and 2023The following table summarizes our consolidated results of operations for the periods indicated:<sup>38</sup> Table of ContentsPromissory notesThe Research and development expenses for the nine months ended September 30, 2024, decreased by \$3.7 million, or 76%, over the approximately \$3.7 million recorded for the nine months ended September 30, 2023. The decrease in research and development expenses of \$2.8 million was primarily attributable to decreases of approximately \$2.0 million in clinical related expenses primarily related to our Phase 2b Adrulipase SPAN clinical trial which occurred during the nine months ended September 30, 2023 and a decrease of \$0.5 million related to the September 2023 up-front payment due to Sanofi per the executed license agreement for Capeserod. We expect research and development expenses to decrease during the remainder of this fiscal year as we conserve cash. General and Administrative ExpensesGeneral and administrative expenses include expenses primarily relating to our overall operations and being a public company, including personnel, legal and financial professional services, insurance, corporate communication and investor relations, listing and compliance related costs, rent, and expenses associated with obtaining and maintaining intellectual property and patents, among others.<sup>37</sup> Table of ContentsGeneral and administrative expenses for the nine months ended September 30, 2024 totaled approximately \$13.5 million, an increase of approximately \$5.6 million, or 70% over the approximately \$7.9 million recorded for the nine months ended September 30, 2023. The increase in general and administrative expenses of \$5.6 million was primarily due to \$4.0 million of non-cash expense recorded for financial advisor fees related to the IMGX acquisition, \$1.5 million in share-based compensation for consultants, and an increase of \$0.9 million in legal fees and professional fees related to the IMGX acquisition. The increase was partially offset by a decrease of \$0.5 million in public company costs and investor relations. We expect general and administrative expenses to decrease during the remainder of this fiscal year as we conserve cash. Other ExpensesOther expenses for the nine months ended September 30, 2024 and 2023 were insignificant. Income Tax BenefitA tax benefit of approximately \$10.6 million was recorded in the nine months ended September 30, 2024 due to the release of a portion of our valuation allowance in connection with the IMGX Merger of \$14.9 million, partially offset by an increase in our valuation allowance of \$4.3 million related to the reclassification of the IMGX IP&R to held for sale. Loss from discontinued operationsLoss from discontinued operations for the nine months ended September 30, 2024 of \$2.0 million represents expenses related to the disposal group that was classified as held for sale as of September 30, 2024. Net LossAs a result of the factors above, our net loss for the nine months ended September 30, 2023. Cash Flows for the Nine Months Ended September 30, 2024 and 2023The following table summarizes our cash flows for the periods indicated:<sup>39</sup> Table of ContentsPromissory notesThe Operating activities for the nine months ended September 30, 2024, decreased by \$10.867,899, which is a decrease in cash, cash equivalents and restricted cash of \$3,344,984, or 24.25% of operating activities. The investing activities for the nine months ended September 30, 2024, decreased by \$5,613,152, or 47.41% of investing activities. The financing activities for the nine months ended September 30, 2024, decreased by \$1,929,425, or 44.93% of financing activities. The net cash used in operating activities during the nine months ended September 30, 2024 of approximately \$9.0 million was primarily attributable to our non-cash change in deferred tax valuation allowance of \$10.6 million and our net loss of \$5.8 million, partially offset by other non-cash expenses totaling approximately \$7.4 million, mainly related to stock issued to our financial advisors in connection with the IMGX acquisition of \$4.0 million, common stock granted to consultants of \$1.5 million, and stock-based compensation of \$0.6 million, as well as a decrease in prepaid expenses of \$0.9 million. Net cash used in operating activities during the nine months ended September 30, 2023 of approximately \$8.9 million was primarily attributable to our net loss of approximately \$11.7 million; partially offset by a decrease in prepaid expenses of approximately \$1.3 million, non-cash expenses of approximately \$1.0 million, mainly related to stock-based compensation and common stock issued to consultants; and a net increase in accrued expenses and accounts payable of approximately \$0.4 million.<sup>40</sup> Table of ContentsInvesting ActivitiesNet cash provided by investing activities during the nine months ended September 30, 2024 of approximately \$0.1 million was due to the net cash acquired in the acquisition of IMGX. Financing ActivitiesNet cash provided by financing activities of approximately \$5.6 million for the nine months ended September 30, 2024 was primarily due to net proceeds of approximately \$4.5 million from the March 2024 and May 2024 registered direct offerings and \$1.7 million from the July Inducement offering, partially offset by approximately \$0.6 million of cash repayments of the note payable financing for corporate insurances. Net cash provided by financing activities of approximately \$10.9 million for the nine months ended September 30, 2023 was due to the net proceeds of approximately \$5.9 million from the exercise of warrants, the net proceeds of approximately \$5.5 million from the March 2023 and July 2023 offerings of our common stock, partially offset by repayments of approximately \$0.6 million related to the note payable. Critical Accounting Policies and EstimatesOur accounting policies are essential to understanding and interpreting the financial results reported on the consolidated financial statements. The significant accounting policies used in the preparation of our consolidated financial statements are summarized in Note 2 to the consolidated financial statements and notes thereto found in our Annual Report on Form 10-K for the year ended December 31, 2023. Certain of those policies are considered to be particularly important to the presentation of our financial results because they require us to make difficult, complex or subjective judgments, often as a result of matters that are inherently uncertain. During the nine months ended September 30, 2024, there were no material changes to matters discussed under the heading "Critical Accounting Policies and Significant Judgments and Estimates" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the year ended December 31, 2023.<sup>41</sup> ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKSNot applicable.<sup>42</sup> ITEM 4. CONTROLS AND PROCEDURESControl and ProceduresAs required by Rule 13a - 15(b) under the Securities Exchange Act of 1934, as amended, (the "Exchange Act") our Chief Executive Officer ("CEO") and our Chief Financial Officer ("CFO") conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10 - Q, of the effectiveness of our disclosure controls and procedures as defined in Rules 13a - 15(e) and 15d - 15(e) under the Exchange Act. Based on that evaluation, our CEO and our CFO each concluded that our disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act, (i) is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (ii) is accumulated and communicated to our management, including our CEO and our CFO, as appropriate to allow timely decisions regarding required disclosure. Changes in Internal Control Over Financial ReportingThere were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a - 15(d) or 15d - 15(d) of the Exchange Act during the period covered by this Quarterly Report on Form 10 - Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.<sup>43</sup> Table of ContentsPART II OTHER INFORMATIONITEM 1. LEGAL PROCEEDINGSNone.<sup>44</sup> ITEM 1A. RISK FACTORSExcept as described below, there have been no material changes in or additions to the risk factors included in our Quarterly Report on Form 10-Q for the period ended September 30, 2024 or our Annual Report on Form 10-K for the year ended December 31, 2023. There is substantial doubt about our ability to continue as a going concern, and we will require substantial additional funding to finance our near- and long-term operations. If we are unable to raise additional capital, we have delayed, and could be forced to further delay, reduce or terminate certain of our products or other operations. We have incurred substantial operating losses since inception and expect to continue to incur significant operating losses for the foreseeable future. As of September 30, 2024, we had cash and cash equivalents of approximately \$0.4 million and have sustained cumulative losses attributable to common stockholders of approximately \$190.1 million. Based on our cash on hand at November 13, 2024, we anticipate having sufficient cash to fund planned operations into December 2024. The acceleration or reduction of cash outflows by management can significantly impact the timing for the need to raise additional capital to complete development of our products. We believe that we will need to raise substantial additional capital in the near term to fund our continuing operations, satisfy existing and future obligations and liabilities, and otherwise support our working capital needs and business activities. In order to manage our operating costs, we have paused development activities for Latiglutene, Capeserod and Adrulipase, and we are exploring

strategic alternatives for Latiglutase and Niclosamide. We have not yet achieved profitability and anticipate that we will continue to incur net losses for the foreseeable future. We expect that our expenses will continue to grow and, as a result, we will need to generate significant product revenues to achieve profitability. We may never achieve profitability. Therefore, we are dependent on obtaining, and are continuing to pursue, the necessary funding from outside sources, including obtaining additional funding from the sale of securities in order to continue our operations. We are actively working to obtain additional funding. However, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to us on favorable terms, if at all. We believe these conditions may raise substantial doubt about our ability to continue as a going concern. If we are unable to secure additional capital, we may be required to delay or curtail any future development of products, and we may take additional measures to reduce expenses in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. This would negatively impact our business and operations, which would likely cause the price of our Common Stock to decline or ultimately force us to cease our operations. We have recently rationalized our operations and may further rationalize or terminate our operations if we cannot obtain sufficient capital. We are dependent on obtaining, and are continuing to pursue, the necessary funding from outside sources, including obtaining additional funding from the sale of securities in order to continue our operations. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be forced to delay, reduce or terminate our business activities. As of December 31, 2023, we had 9 employees, which increased to 15 employees in March 2024 following the IMGX Merger. In connection with certain cost reduction measures we have taken, on July 16, 2024, we reduced our headcount to 11 employees, and Dr. Syage agreed to reduce his annual base salary to \$66,560, effective July 1, 2024. On August 1, 2024, in order to further reduce costs and conserve resources, we approved the termination of all non-essential employees.40-Table of ContentsOn August 2, 2024, in connection with the reduction in workforce, the Board approved the termination of (i) the employment agreement with our Chief Executive Officer, James Sapirstein (the "Sapirstein Employment Agreement"), and (ii) the offer letter between us and our President, Jack Syage. In connection with the termination of the Sapirstein Employment Agreement, on August 2, 2024, we entered into a consulting agreement with Mr. Sapirstein (the "Sapirstein Consulting Agreement"), whereby he will continue to serve as our Chief Executive Officer, and pursuant to which Mr. Sapirstein will be paid \$400 an hour monthly for services rendered to us. The Sapirstein Consulting Agreement has an initial term of six months, is subject to early termination by either party for any reason at any time, and may be extended on a month-to-month basis upon mutual agreement after the expiration of the initial six-month term. Additionally, on August 2, 2024, as part of the reduction in workforce described above, the Board approved the payout of unused vacation time for all employees accrued through August 1, 2024, including Mr. Sapirstein, Dr. Syage, and our Chief Financial Officer, Sarah Romano. We paid Mr. Sapirstein, Dr. Syage, and Ms. Romano \$69,230, \$1,920, and \$45,590, respectively, to compensate for their unused vacation time accrued through August 1, 2024. As a result of the rationalization, we have paused research and development activities for our Latiglutase, Adrulipase and Capeserod product candidates and any other non-essential research and development activities and have paused or terminated third party service arrangements related thereto. We are exploring strategic alternatives for Niclosamide and are evaluating all potential strategic options, including a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction, including a potential sale or wind-down of the IMGX assets and liabilities. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stakeholder value or that we will make any cash distributions to our stockholders. Any failure in these efforts could force us to delay, limit or terminate our operations, make reductions in our workforce, discontinue our research and development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code. Due to the significant resources required for the development of our product candidates, we must prioritize development of certain product candidates and/or certain disease indications, and de-prioritize others. We may expend our limited resources, as they become available, on candidates or indications that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Our goal is to develop a pipeline of product candidates to treat GI and other diseases. Due to the significant resources required for the development of product candidates, we must focus our attention and resources on specific diseases and/or indications and decide which product candidates to pursue and the amount of resources to allocate to each. We intend to focus our resources, as they become available, on the development of our product candidates Adrulipase and Capeserod. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, any decision to delay, terminate or collaborate with third parties in respect of certain programs or product candidates may subsequently prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the GI, CF, CP, COVID-19, ICI-AC or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and indications that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.41-Table of ContentsITEM 3. DEFAULTS UPON SENIOR SECURITIESNone.41-Table of ContentsITEM 4. MINE SAFETY DISCLOSURESNot applicable.41-Table of ContentsITEM 5. OTHER INFORMATIONNone.41-Table of ContentsITEM 6. EXHIBITS41-Table of Contents(b)Exhibits41-Table of Contents(a)Exhibit No. A41-Table of Contents3.141-Table of ContentsAmended and Restated Certificate of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on October 21, 2024).3.241-Table of ContentsAmended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 of the Company's Quarterly Report on Form 10-Q filed with the SEC on August 15, 2022).4.141-Table of ContentsForm of Inducement Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on July 11, 2024).4.10.141-Table of ContentsForm of Inducement Letter (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 11, 2024).10.241-Table of ContentsConsulting Agreement, dated August 2, 2024, by and between the Company and James Sapirstein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 7, 2024).31.141-Table of ContentsCertification of the Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.31.241-Table of ContentsCertification of the Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.32.141-Table of ContentsCertification of the Principal Executive Officer and Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.101.INS41-Table of ContentsInline XBRL Instance DocumentA - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document101.SCH41-Table of ContentsInline XBRL Taxonomy Extension Schema Document101.CAL41-Table of ContentsInline XBRL Taxonomy Extension Calculation Linkbase Document101.DEF41-Table of ContentsInline XBRL Taxonomy Extension Definition Linkbase Document101.LAB41-Table of ContentsLinkbase Document101.PRE41-Table of ContentsInline XBRL Taxonomy Extension Presentation Linkbase Document104.Cover Page41-Table of ContentsInteractive Data File (embedded within the Inline XBRL Document and included in Exhibit 101)\*filed herewith\*furnished, not filed, herewith\*41-Table of ContentsSIGNATURES41-Table of ContentsPursuant 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.41-Table of ContentsENTERO THERAPEUTICS, INC.41-Table of ContentsBy/S/ James Sapirstein41-Table of ContentsChief Executive Officer and Chairman41-Table of ContentsBy/S/ Sarah Romano41-Table of ContentsSarah Romano41-Table of ContentsChief Financial Officer41-Table of ContentsDate: November 13, 202441-Table of Contents43-EXHIBIT 31.1CERTIFICATION PURSUANT TO RULE 13A-14 OF THE SECURITIES EXCHANGE ACT OF 1934ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 20021, James Sapirstein, Chief Executive Officer of Entero Therapeutics, Inc. (the "Company"), certify that:1.I have reviewed this Quarterly Report on Form 10-Q of the Company;2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;4.The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:a.Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;b.Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;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; andd.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; and5.The registrant's other certifying officer(s) 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; andb.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.41-Table of Contents43-EXHIBIT 31.2CERTIFICATION PURSUANT TO RULE 13A-14 OF THE SECURITIES EXCHANGE ACT OF 1934ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 20021, Sarah Romano, Chief Financial Officer of Entero Therapeutics, Inc. (the "Company"), certify that:1.I have reviewed this Quarterly Report on Form 10-Q of the Company;2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;4.The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:a.Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;b.Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;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; andd.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; and5.The registrant's other certifying officer(s) 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; andb.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.41-Table of Contents43-EXHIBIT 32.1CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 20021In connection with the Quarterly Report of Entero Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Sapirstein, Chief Executive Officer of the Company, and Sarah Romano, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:(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.41-Table of Contents43-EXHIBIT 32.2CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 20021In connection with the Quarterly Report of Entero Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Sapirstein, Chief Executive Officer of the Company, and Sarah Romano, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:(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.41-Table of Contents43-EXHIBIT 32.3CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 20021In connection with the Quarterly Report of Entero Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Sapirstein, Chief Executive Officer of the Company, and Sarah Romano, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:(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.41-Table of Contents43-EXHIBIT 32.4CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 20021In connection with the Quarterly Report of Entero Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Sapirstein, Chief Executive Officer of the Company, and Sarah Romano, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:(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.41-Table of Contents43-EXHIBIT 32.5CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 20021In connection with the Quarterly Report of Entero Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Sapirstein, Chief Executive Officer of the Company, and Sarah Romano, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:(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.41-Table of Contents43-EXHIBIT 32.6CERTIFICATION PURSUANT TO 18 U.S.C. 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SECTION 1350,AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 20021In connection with the Quarterly Report of Entero Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Sapirstein, Chief Executive Officer of the Company, and Sarah Romano, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:(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.41-Table of Contents43-EXHIBIT 32.13CERTIFICATION PURSUANT TO 18 U.S.C. 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SECTION 1350,AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 20021In connection with the Quarterly Report of Entero Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Sapirstein, Chief Executive Officer of the Company, and Sarah Romano, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:(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.41-Table of Contents43-EXHIBIT 32.16CERTIFICATION PURSUANT TO 18 U.S.C. 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