UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2025

OR

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

For the transition period from to

Commission File Number: 001-38022

MATINAS BIOPHARMA HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**No. 46-3011414**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1545 Route 206 South, Suite 302
Bedminster, New Jersey 07921
(Address of principal executive offices) (Zip Code)

908-484-8805
(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001	MTNB	NYSE American

Securities registered pursuant to Section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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

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

Emerging growth company ☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold on June 30, 2025 was approximately $4.5 million.

As of March 26, 2026, there were 6,406,191 shares of the registrant's common stock, $0.0001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

MATINAS BIOPHARMA HOLDINGS, INC.

Annual Report on Form 10-K

Fiscal Year Ended December 31, 2025

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our ability to complete one or more strategic transactions that will maximize our asset or otherwise provide value to stockholders;
- our ability to raise capital when needed;
- our history of operating losses in each year since inception and the expectation that we will continue to incur operating losses for the foreseeable future;
- our ability to maintain compliance with the continued listing requirements of the NYSE American LLC (the "NYSE American");
- our ability to maintain or protect the validity of our patents and other intellectual property; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report on Form 10-K and are subject to risks and uncertainties. We discuss many of these risks in greater detail under "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should read this Annual Report on Form 10-K and the documents that we reference and have filed as exhibits to the Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Annual Report on Form 10-K by these cautionary statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

Item 1. Business

Background

Matinas BioPharma Holdings, Inc. ("Matinas" or the "Company") is a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using our lipid nanocrystal ("LNC") platform delivery technology (the "LNC Platform").

Our lead product candidate is MAT2203 (oral amphotericin B), a highly potent antifungal drug which, by virtue of LNC delivery, has been made oral, safe, and well-tolerated for prolonged administration in patients with life-threatening invasive fungal infections. Following the successful EnACT Phase 2 trial in the treatment of cryptococcal meningitis, MAT2203 is now positioned for a single, Phase 3 registration trial (the "ORALTO trial") in support of a New Drug Application ("NDA") for the treatment of invasive aspergillosis in patients with limited treatment options.

We had also been seeking to develop an internal pipeline of products utilizing the LNC Platform to successfully encapsulate small molecules and small oligonucleotides and facilitate targeted and extrahepatic delivery to desired cells and tissues without toxicity, with a focus on small molecule oncology applications as well as the formulation and delivery of small oligonucleotides with a primary therapeutic focus on inflammation.

Following an 80% reduction in workforce implemented in late October 2024, we implemented a cost-cutting strategy and paused further clinical development of MAT2203 while continuing to engage in dialogue with prospective partners for the product with the goal of consummating a licensing, sale or other similar transaction as soon as possible to advance the development of MAT2203 into Phase 3. In addition, we continue to engage with the United States Food and Drug Administration ("FDA") to keep the MAT2203 Investigational New Drug Application ("IND") active and are actively maintaining and prosecuting intellectual property relating to MAT2203 and to the LNC Platform generally as well as maintaining all of our obligations under our license agreement with Rutgers University. We also continue to support the patients in our Expanded/Compassionate Use Access Program with the assistance of outside medical clinician consultants. As a result of the reduction in force, we have paused the internal development of a pipeline of products utilizing the LNC Platform as we evaluate strategic alternatives for those early-stage programs in oncology and inflammatory diseases.

We remain engaged in an ongoing partnership process for MAT2203, seeking one or more development and/or commercialization partners. We will require either (i) the consummation of a partnership transaction, or (ii) raising additional capital, prior to commencing the ORALTO trial. In the event a partnership is consummated, the partner may seek to revise the ORALTO trial or could determine a completely new development program and pathway for MAT2203. There can be no assurance that we will be successful in consummating a transaction involving MAT2203.

Corporate Events

- In February 2024, we announced agreement with the FDA on the design of a single Phase 3 registration trial of MAT2203 in patients with invasive aspergillosis who have limited treatment options, including consensus on all critical elements of the ORALTO trial.

- In March 2024, we announced that we would require either (i) the consummation of a partnership transaction, or (ii) raising significant additional capital, prior to commencing the ORALTO trial. We continued to support (a) the ongoing MAT2203 Compassionate/Expanded Use Access Program, (b) all MAT2203 regulatory requirements, (c) the prosecution and maintenance of all intellectual property relevant to MAT2203 and the LNC Platform and (d) the early stage research and development of other applications of the LNC Platform in the oncology and inflammation spaces.

- On April 2, 2024, we announced entry into a securities purchase agreement (the "April 2024 Purchase Agreement"), with certain institutional investors. The April 2024 Purchase Agreement provided for the sale and issuance by the Company of (i) 666,667 shares of common stock and warrants (the "April 2024 Warrants") to purchase up to 666,667 shares of common stock. The offering price per share and accompanying warrant was $15.00. The April 2024 Warrants have an exercise price of $17.50, were exercisable beginning October 2, 2024 and expire on the five-and-a-half year anniversary of the date of issuance, or October 5, 2029. The offering resulted in gross proceeds to the Company of approximately $10 million before deducting placement agent's fees and related offering expenses.

- On August 20, 2024, pursuant to the NYSE American's Compliance Guidance Memo which requires ten calendar days public notice for certain corporate actions, we announced that our Board of Directors (the "Board") approved a reduction in the total number of authorized shares of our common stock from 500,000,000 to 250,000,000 (the "Authorized Share Reduction") and a reverse stock split of the common stock at a ratio of one-for-fifty (1:50) (the "Reverse Stock Split"), which would become effective at 5:00PM (EST) on August 30, 2024.

- On August 27, 2024, we received notice that trading of our shares of common stock had been halted by the NYSE American due to its low trading price. The trading halt remained in effect until after we consummated the communicated reverse stock split of the common stock and the market opened on September 3, 2024.

- On August 30, 2024, the Authorized Share Reduction and the Reverse Stock Split became effective at 5:00 P.M. (EST) and the shares of our common stock began trading on the split-adjusted basis under the Company's existing trading symbol, "MTNB," when the market opened on September 3, 2024.

- On October 31, 2024, we announced that negotiations under a non-binding term sheet with a single partner for global licensing rights to develop, manufacture and commercialize MAT2203 for all future treatment indications (the "MAT2203 Term Sheet"), including the intended initial indication of treatment for patients with invasive aspergillosis with limited or no other treatment options, were terminated following notification from the perspective partner for reasons unrelated to MAT2203. As a result, we implemented an immediate 80% workforce reduction, eliminating 15 positions, including three members of senior management, and ceased certain product development activities to preserve cash while we evaluated a potential sale of MAT2203 and/or other strategic alternatives, including a potential winddown or dissolution of the Company.

- On January 10, 2025, we announced that we received a deficiency letter (the "January 2025 NYSE Notice") from the NYSE American stating that the Company failed to hold an annual meeting of stockholders during the fiscal year ended December 31, 2024, as required by Section 704 of the NYSE American Company Guide. The January 2025 NYSE Notice had no immediate impact on the listing of our common stock, which continued to be listed and traded on the NYSE American during the applicable cure period but was assigned a ".BC" indicator by the NYSE American to indicate that the Company was below compliance. We received a letter from the NYSE American on June 23, 2025 that we had resolved the deficiency set forth in the January 2025 NYSE Notice by virtue of holding our Annual Meeting for the fiscal year ended December 31, 2023 on June 23, 2025. As a result, the BC indicator was removed from our stock symbol.

- On February 13, 2025, we entered into a securities purchase agreement (the "February 2025 Agreement") with a certain group of investors (the "February 2025 Investors"), pursuant to which they agreed to purchase from the Company 3,300 shares of our Series C Convertible Preferred Stock, par value $0.0001 per share (the "Preferred Stock"), and warrants to purchase up to 11,262,808 shares of common stock (the "2025 Warrants") at a purchase price of $1,000 per share of Preferred Stock and accompanying 2025 Warrants, for aggregate gross proceeds of $3.3 million before deducting offering expenses payable by the Company. The February 2025 Investors purchased 1,650 shares of Preferred Stock and accompanying 2025 Warrants to purchase up to 5,631,404 shares of common stock for gross proceeds to the Company of $1.65 million at an initial closing on February 13, 2025. Subject to the satisfaction of certain closing conditions, the February 2025 Investors purchased an additional 1,650 shares of Preferred Stock and accompanying 2025 Warrants to purchase up to 5,631,404 shares of common stock for gross proceeds to the Company of $1.65 million at a second closing on April 8, 2025. The shares of Preferred Stock are convertible into common stock at a conversion price of $0.586, and each share of Preferred Stock is initially convertible into 1,706 shares of common stock. The 2025 Warrants have an exercise price of $0.6446 per share. The 2025 Warrants purchased in the initial closing became exercisable on April 4, 2025, the effective date of the approval by our stockholders of the Stock Issuance Proposal (as defined below) (the "Shareholder Approval") and will expire five years from the effective date of the Shareholder Approval, or April 4, 2030. The 2025 Warrants purchased in the second closing were immediately exercisable and will expire on April 8, 2030. In connection with the February 2025 Agreement, Dr. Robin L. Smith, MD, MBA was appointed to the Board.

- On March 3, 2025, we filed a Notice of Special Meeting of Stockholders to be held on April 4, 2025 (the "Special Meeting). At the Special Meeting, stockholders approved: (1) for purposes of complying with the applicable provisions of Section 713 of the NYSE American Company Guide (a) the issuance of up to an aggregate of 16,894,212 shares of common stock upon the conversion of the Preferred Stock and the exercise of the 2025 Warrants (the "Stock Issuance Proposal"), and (b) the terms thereof, which may constitute a "Change of Control" as defined in the NYSE American Company Guide; and (2) ratified the appointment of EisnerAmper LLP as our independent registered public accounting firm for the year ended December 31, 2025.

- On April 30, 2025, we amended our bylaws to reduce the quorum requirement for stockholders meetings from a majority to one-third of the voting power of the outstanding shares of capital stock entitled to vote at such meeting.

- On June 23, 2025, at our annual meeting of stockholders, our stockholders approved (i) an amendment to our Certificate of Incorporation, as amended (the "Certificate of Incorporation"), to effect up to two reverse stock splits of our common stock having an aggregate ratio in the range of 1-for-2 to 1-for-199 over a period of two years, with such reverse stock splits to be effected at such ratios, times and dates, if at all, as determined by the Board in its sole discretion, (ii) an amendment to our Certificate of Incorporation to increase the number of our authorized shares of common stock from 250,000,000 shares to 500,000,000 and to make a corresponding change to the number of authorized shares of capital stock and (iii) our 2025 Equity Incentive Plan.

- On August 6, 2025, we filed a Certificate of Amendment to our Certificate of Incorporation with the Secretary of State of the State of Delaware to increase the number of authorized shares of common stock from 250,000,000 shares to 500,000,000 shares. The Certificate of Amendment was approved by the Company's stockholders at the annual meeting on June 23, 2025 and became effective upon filing.

- On August 15, 2025, we entered into Warrant Exchange Agreements (the "Exchange Agreements") with certain holders (the "Exchanging Holders") of April 2024 Warrants to purchase an aggregate of 466,666 shares of common stock. Pursuant to the Exchange Agreements, on August 15, 2025, the Company issued to the Exchanging Holders one share of common stock for each April 2024 Warrant, for an aggregate of 466,666 shares of common stock.

MAT2203

Our lead drug candidate based on the LNC Platform is MAT2203, an oral formulation of amphotericin B, a well-known and highly effective antifungal drug. Amphotericin B is currently only available in IV formulations which are associated with significant renal toxicity and have labeled restrictions on their use for up to 2 weeks in the United States and only 1 week in most parts of the world due to toxicities, the most prevalent of which is severe nephrotoxicity. Despite these limitations, amphotericin B is currently used and approved to treat a variety of invasive, and potentially deadly, fungal infections due to its potency. MAT2203, which is formulated using our LNC Platform, has the potential to preserve or even increase the efficacy of amphotericin B, while eliminating the risk of nephrotoxicity and providing more convenient and cost-effective oral administration. MAT2203's product profile has allowed physicians and patients to use MAT2203 for longer periods of time and more broadly than amphotericin B has ever have been used previously and in an outpatient setting.

MAT2203 has been developed to date with the assistance and financial support of the National Institutes of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). MAT2203 has been designated as a Qualified Infectious Disease Product (QIDP) with Fast Track Status for the treatment of invasive candidiasis, the treatment of aspergillosis, the prevention of invasive fungal infections, or IFIs, in patients who are on immunosuppressive therapy, and, most recently with an Orphan Designation for the treatment of cryptococcosis. We believe that it is possible to pursue additional orphan designations for the treatment of aspergillosis, the treatment of invasive candidiasis and the treatment of certain endemic mycoses. Upon approval, MAT2203 could be eligible for up to 12 years of regulatory or marketing exclusivity in the United States.

The initial planned indication for MAT2203 is early step-down therapy from IV amphotericin B for the treatment of invasive aspergillosis in patients with limited treatment options. Invasive aspergillosis is a serious and life-threatening invasive fungal infection that occurs primarily in severely immunocompromised patients with hematological malignancies and in transplant recipients. This initial step-down indication is a gateway indication, as we believe that a partner could expand the utilization of MAT2203 into the treatment of other IFIs and potentially even for prophylaxis against IFIs in immunocompromised patients, such as transplant patients.

The EnACT (*Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial*) Phase 2 study was a Phase 2 prospective, randomized, open-label, sequential cohort study, financially supported by the NIH, evaluating the safety, tolerability, and efficacy of MAT2203 in 100 HIV-positive persons with cryptococcal meningitis. The EnACT trial included a total of four cohorts of patients, with the first two cohorts testing MAT2203 as early step-down therapy following initial treatment with IV amphotericin B during the induction period, and the second two cohorts testing MAT2203 as potentially all oral therapy. The induction period for all patients in each cohort (active or control) is 14 days, followed by an additional four weeks of treatment (active or control) during a consolidation/maintenance period. Cohorts 1 and 3 were safety lead-ins to Cohorts 2 and 4, respectively, which were the key efficacy cohorts for EnACT.

The primary endpoint in EnACT was Early Fungicidal Activity (EFA), a measurement of cerebrospinal fluid fungal clearance. EFA is a well-validated quantitative measure of the efficacy of antifungal agents and is a key surrogate marker for survival. EFAs of less than 0.20 $\log_{10}$ Cryptococcus colony forming units (CFUs) per mL CSF per day are associated with significantly higher mortality and worse clinical outcomes[1]. EFA measured above this threshold is clinically meaningful and represents robust fungal clearance. In the second cohort of EnACT, the mean EFA achieved with patients treated with MAT2203 was 0.38 $\log_{10}$ CFU/mL/day, with 95% confidence intervals (0.30 to 0.46) significantly higher than the prespecified primary endpoint threshold of >0.20. All patients treated with MAT2203 who completed the induction phase achieved sterile CSF cultures during treatment (either during induction or early consolidation phases). There was no evidence of breakthrough or relapsed cryptococcal infections observed in any of the patients during treatment with MAT2203 through 10 weeks. In Cohort 2, the secondary endpoint of overall survival was 90% after 18 weeks in 40 patients randomized to receive MAT2203.

Interim data from Cohort 4 of the Phase 2 EnACT study of MAT2203 (oral amphotericin B) for the treatment of cryptococcal meningitis (CM) were presented at IDWeek in October 2022. As part of IDWeek, the EnACT abstract was the recipient of the Outstanding Abstract and IDSA Awardee by the Infectious Diseases Society of America. In the EnACT trial, MAT2203 exceeded the primary endpoint threshold for early fungicidal activity (EFA) of 0.20 $\log_{10}$ CFU/mL/day, with a mean EFA achieved of 0.30 $\log_{10}$ CFU/mL/day with 95% confidence intervals from 0.22 – 0.38.

Cohort 4 also yielded key secondary endpoints, including overall survival and safety. For 40 patients receiving MAT2203 treatment, overall survival remained at 90% through 18 weeks, while the survival rate at Week 2 was 95%. Importantly, the incidence of adverse events relating to kidney function and anemia were significantly lower for MAT2203 compared to the conventional IV amphotericin B standard of care treatment across the entirety of the EnACT trial, with no evidence of kidney toxicity even with up to 6 weeks of oral MAT2203 treatment.

In February 2024, we announced agreement with the FDA on the design of a single Phase 3 registration trial of MAT2203 in patients with invasive aspergillosis who have limited treatment options, including consensus on all critical elements of the ORALTO trial. In its correspondence, FDA agreed that the ORALTO trial would potentially be sufficient to support the registration of MAT2203 for an initial indication for the treatment of invasive aspergillosis in patients with limited treatment options, when and if conducted. Approval would be subject to normal FDA review of all aspects of this clinical trial.

ORALTO is planned to be a Phase 3, randomized, multicenter, open-label, adjudicator-blinded study to evaluate the efficacy and safety of MAT2203 as an oral step-down treatment following treatment with AmBisome® (liposomal IV-amphotericin B) compared with the standard of care in patients with invasive aspergillosis who have limited treatment options. The primary efficacy endpoint would be all-cause mortality at study day 42.

Key secondary objectives would include:

[1]**Clin Infect Dis.* 2020;71(5):e45-49

(a) demonstration of superiority of oral-step down treatment with MAT2203 compared with AmBisome for treatment-related toxicities leading to changes in treatment (i.e., dose adjustment/discontinuations or changes to treatment regimens);

(b) long-term survival benefit of MAT2203 using all-cause mortality at study day 84;

(c) evaluation of the impact of MAT2203 on healthcare resource utilization and quality of life impact.

Enrollment was been planned to include approximately 216 adults with recently diagnosed probable or proven invasive aspergillosis who are being treated with AmBisome due to their inability to receive an IV mold-active azole and with limited alternative treatment options. Following up to two days of initial treatment with AmBisome, eligible study participants would be entered into the study and randomized in a 2:1 ratio to receive either oral MAT2203 or continued AmBisome treatment followed by standard of care.

All study participants would receive up to 12 weeks of treatment starting from the first day of treatment with AmBisome. It is anticipated that all study participants would be hospitalized during the initial AmBisome treatment period. After step-down to oral MAT2203, study participants may be discharged from the hospital to continue treatment on an outpatient basis, as clinically appropriate.

An independent Data Review Committee, who will be blinded to treatment, would adjudicate primary and secondary endpoints, including clinical, radiological, and mycological responses. Once approximately 75% of participants are enrolled, an independent Data Safety Monitoring Board would review the overall pooled all-cause mortality rate in a blinded fashion to ensure that the sample size assumptions are reasonable and that the study is adequately powered. Should the pooled event differ substantially from expected levels, a sample size adjustment can be made to the trial.

ORALTO was planned to be conducted at approximately 65 investigator sites in the U.S., Europe, South America, Middle East, and Asia Pacific. Enrollment is expected to require approximately 24 months, if commenced.

We remain engaged in an ongoing partnership process for MAT2203, seeking one or more development and/or commercialization partners. We will require either (i) the consummation of a partnership transaction, or (ii) raising additional capital, prior to commencing the ORALTO trial. In the event a partnership is consummated, the partner may seek to revise the ORALTO trial or could determine a completely new development program and pathway for MAT2203. There can be no assurance that we will be successful in consummating a transaction involving MAT2203.

In addition to conducting the EnACT trial, a MAT2203 Compassionate/Expanded Use Access Program was established to provide MAT2203 on a compassionate use basis. Enrollment into the Program requires that patient applicants meet certain criteria for eligibility, including:

- the patient has no other treatment options.
- the invasive fungal infection is serious and/or life-threatening.
- the patient is expected to benefit from oral MAT2203 treatment and can tolerate oral medication; and
- the patient has a reasonable life expectancy, and their underlying conditions are under control.

A total of 37 patients to date have been enrolled in the Program at multiple healthcare institutions, including the University of Michigan, Johns Hopkins, Nationwide Children's Hospital, City of Hope, Vanderbilt University Medical Center, the National Institutes of Health, Children's Hospital of Philadelphia, Memorial Sloan Kettering Cancer Center, and the University of California, San Diego School of Medicine. The majority of enrolled patients are post-transplant or are undergoing treatment for underlying malignancies. 7 of the patients have been treated for invasive aspergillosis, each with positive results. The infections being treated with MAT2203 include a variety of micro-organisms (including *Aspergillus*, *Mucorales species*, *Candidiasis*, *Fusarium* and suspected *Coccidioides*) occurring at multiple sites of infection, including brain, bladder/colon, bone, lung, sinus, and skin. Most patients were receiving AmBisome® prior to enrollment but developed treatment-limiting nephrotoxicity and most also required treatment for either azole-resistant organisms or had clinically failed azole therapy and had no other treatment options.

Of the 15 patients enrolled in the Program who completed treatment with MAT2203 (median treatment of 16 weeks with a range of 2 to 49 weeks), 8 had a complete response and 7 were improved. Response to treatment was assessed by the treating physician. Nine additional patients continued to receive longer-term treatment with positive ongoing effects and 5 initiated treatment in the third and fourth quarter of 2024. To date, only 2 patients have discontinued MAT2203, both occurring during the first week of treatment, with one due to an intolerance and the other due to a terminal condition not otherwise related to the underlying fungal infection.

Importantly, all patients who experienced renal toxicity following treatment with AmBisome saw their renal function return to baseline after transitioning to MAT2203 therapy and suffered no further renal side effects over the course of extended treatment with MAT2203. While we have temporarily suspended the availability of MAT2203 under this program, we continue to monitor patients and provide ongoing support through external clinical medical consultants.

Strategy

We had been focused on redefining the intracellular delivery of nucleic acids and small molecules through our LNC Platform and its application to overcome current challenges in safely and effectively delivering small molecules, nucleic acids, gene therapies, proteins/peptides, and vaccines.

Key elements of our strategy now include:

- Securing one or more partners to monetize the value of MAT2203 and raising additional non-dilutive capital through the licensing or sale of our lead LNC Platform product candidate. A partnership, whether through a license, sale or other transaction, would likely seek to advance MAT2203 into Phase 3 development as quickly as possible, which could position a partner to commercialize MAT2203 upon approval.

- Conserving our cash resources while identifying and evaluating other strategic options for the Company, which could include the in-licensing of one or more assets or seeking a merger partner for the Company.

MAT2203 Regulatory Designations

The FDA has granted MAT2203 designations for Qualified Infectious Disease Product, or QIDP, and Fast Track for the treatment of invasive candidiasis and aspergillosis, for the prevention of IFIs in patients on immunosuppressive therapy, and the treatment of cryptococcosis. We recently also received Orphan Drug Designation for MAT2203 for the treatment of cryptococcosis and associated (CM) from the FDA and the European Medicines Agency (the "EMA"). The FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. The orphan drug designation provides eligibility for orphan drug exclusivity in the United States upon FDA approval if a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation. For a product that obtains orphan drug designation based on a plausible hypothesis that it is clinically superior to the same drug that is already approved for the same indication, to obtain orphan drug exclusivity upon approval, clinical superiority of such product to this same drug that is already approved for the same orphan indication must be demonstrated. Orphan drug exclusivity means that the FDA may not approve any other applications, including a NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similarly, the FDA can subsequently approve a drug with the same active moiety for the same condition during the exclusivity period if the FDA concludes that the later drug is clinically superior, meaning the later drug is safer, more effective or makes a major contribution to patient care. Orphan drug designation also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, a waiver from payment of user fees, an exemption from performing clinical studies in pediatric patients unless the FDA requires otherwise by regulation, and tax credits for the cost of the clinical research.

The QIDP designation, provided under the Generating Antibiotic Incentives Now Act, or the GAIN Act, offers certain incentives for the development of new antibacterial or antifungal drugs, including eligibility for Fast Track designation, priority review and, if approved by the FDA, eligibility for an additional five years of marketing exclusivity. Fast Track designation enables more frequent interactions with FDA to expedite drug development and review. Fast Track designation does not change the standards for approval, and we can provide no assurances that we can maintain Fast Track designation for MAT2203 or that such designation will result in faster regulatory review. The seven-year period of marketing exclusivity provided through orphan designation, if granted, combined with an additional five years of marketing exclusivity provided by the QIDP designation positions MAT2203 with a potential for a total of 12 years of marketing exclusivity in the United States to be granted at the time of FDA approval.

Antifungal Market Opportunity

The overall global antifungal market was valued at approximately $15.8 billion in 2023 and is expected to reach approximately $20.5 billion by 2030. In 2021, the global invasive fungal infection market was valued at more than $7.2 billion and is expected to reach $10.4 billion in 2030. This includes therapies used as active treatment or prophylaxis (preventative) in the inpatient and outpatient setting, therapies used for the treatment of hospitalized patients and therapies used for the treatment of patients who are being discharged from the hospital. Importantly, private insurance costs per visit range from approximately $40k to $150K per patient (2019 Benedict) mostly due to extended length of stay. We estimate that, each year, there are over 1.5 million cases of IFIs caused by various species of *Candida, Aspergillus* and *Cryptococcus,* the three most common invasive fungal pathogens, globally. The estimated incidence in the U.S. for these conditions is approximately 46,000 for invasive candidiasis, 15,000 for invasive aspergillosis, and 4,900 for CM. For example, aspergillosis-associated hospitalizations in the U.S. alone came at an estimated treatment cost of more than $1.3 billion, with indirect costs amounting to an additional $485 million. The rapid progression of disease and high mortality rates (20% - 50%) associated with documented IFIs often result in antifungal therapy being administered in suspected (unconfirmed) cases or as a preventative measure in patients at high risk. Also, the increasingly widespread use of immune suppressive drugs as cancer chemotherapy or for organ transplantation or treatment of autoimmune disease has resulted in an increasing population of patients at risk for IFIs. Furthermore, the limited number of systemic antifungal drug classes, consisting of azoles, echinocandins and polyenes, and their extensive use, has led to increased numbers of infections with drug-resistant strains. The Centers for Disease Control and Prevention (“CDC”) has listed fluconazole-resistant *Candida* as a serious threat requiring prompt and sustained action and has also identified a rise in echinocandin resistance, especially among *Candida glabrata.* In 2022, the World Health Organization issued a fungal priority pathogens list including cryptococcal neoformans, aspergillus fumigatus and c. auris and c. albicans as critical priority for antifungal development due to the high unmet need. We believe this underscores the urgent need for new agents with demonstrated activity against resistant strains and that can be administered with significantly less toxicity and the potential to discharge patients earlier to reduce hospital stays and associated costs.

Exclusive License Agreement with Rutgers University

Through our acquisition of Aquarius Biotechnologies Inc., we acquired a license from Rutgers University (“Rutgers”) for certain patents related to the LNC Platform. We subsequently changed the name of Aquarius Biotechnologies Inc. to Matinas BioPharma Nanotechnologies, Inc., and in February of 2022, the parties agreed to a Second Amended and Restated Exclusive License Agreement. The agreement provides for (1) royalties on a tiered basis between low single digits and the mid-single digits of net sales of products using such licensed technology, (2) a one-time sales milestone fee of $100,000 when and if sales of products using the licensed technology reach the specified sales threshold and (3) an annual license fee of $50,000 over the term of the license agreement. There was also a reduction in the consideration paid to Rutgers in the event of a sublicense to a third party of the exclusive patent rights granted pursuant to the Agreement. In consideration of the concessions made by Rutgers in the amended license agreement, the Company issued Rutgers 400,000 shares of common stock in February 2022. We also agreed to continue to assume the responsibility to pay required patent prosecution and maintenance fees covering the technology.

Unless otherwise terminated by either party, the term of the license, on a country-by-country basis, shall be the longer of 8-1/2 years from the date of first commercial sale of a product in a country using the licensed technology or until the expiration of the last-to-expire patent rights licensed under the agreement, whichever is longer. Rutgers has the right to terminate the license agreement if we have not commenced commercial sales of at least one product using the licensed technology within eight years of the effective date of the Second Amended and Restated License Agreement. We have discussed the elimination of this termination right with Rutgers through an amendment to the license agreement while we seek a partner for MAT2203.

Intellectual Property

The proprietary nature of, and protection for, our product candidates and our discovery programs, processes and know-how are important to our business. We will seek to protect our products and associated technologies for their manufacturing and development through a combination of patents, trade secrets, proprietary know-how, FDA exclusivity and contractual restrictions on disclosure. Our policy is to pursue, maintain and defend patent rights and to protect the technology, inventions and improvements that are commercially important to the development of our business. Our success will significantly depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology and inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely heavily on know-how and continuing technological innovation to develop and maintain our proprietary position.

Exclusively Licensed and Matinas-Owned Intellectual Property Relating to Our Proprietary LNC Platform and MAT2203

The patents and patent applications that we exclusively license from Rutgers provide some patent protection for the proprietary chemistry technology used in certain of our processes to make our lipid nanocrystal and geodate cochleates and formulate the active pharmaceutical ingredients delivered inside this delivery technology, as in MAT2203, our lead product utilizing the LNC Platform. Pursuant to our license agreement, we acquired rights to a portfolio that as of January 31, 2026 included 1 pending U.S. non-provisional patent application, 6 U.S. patents, and 34 granted foreign patents, which extends patent protection until at least 2033, excluding patent term adjustments or extensions. The in-licensed patents have been granted in countries including Europe, China, India, Brazil, Russia, Canada, Japan, Korea, Australia and Mexico.

The Matinas-owned patent portfolio covers our LNC Platform and users. As of January 31, 2026, this patent portfolio includes 1 U.S. patent, 3 pending U.S. non-provisional applications, 10 pending foreign applications, and 19 granted foreign patents. The foreign pending applications and granted patents are in countries including Europe, China, Brazil, Canada, Japan, Korea, Australia and Mexico

As of January 31, 2026, we owned one issued U.S. patent, and 7 issued foreign patents in Australia, Canada, Europe, and Japan, directed to compositions and methods for enhancing tissue penetration of an active agent in an LNC. The patents are expected to expire in 2036, and patents issuing from or claiming priority to the pending application are also expected to expire in 2036, excluding patent term adjustments or extensions.

As of January 31, 2026, we owned 9 issued foreign patents in Australia, Europe, and Japan, directed to LNC compositions and methods for treating mycobacteria infection. The patents are expected to expire in 2036, excluding patent term adjustments or extensions.

As of January 31, 2026, we owned one U.S. issued patent, one pending non-provisional U.S. patent application, 2 issued foreign patents in Japan and Australia, and 3 pending applications in China, Canada, and Europe, directed to LNC compositions and methods for treating cryptococcus infections. The patents are expected to expire in 2037, and patents issuing from or claiming priority to the pending application are also expected to expire in 2037, excluding patent term adjustments or extensions.

As of January 31, 2026, we owned one pending non-provisional U.S. patent application, and 6 pending applications in Australia, Brazil, Canada, China, Europe, Hong Kong, Japan, and Mexico, directed to LNC compositions and methods for treating cryptococcus infections. Patents issuing from or claiming priority to the pending applications are also expected to expire in 2040, excluding patent term adjustments or extensions.

As of January 31, 2026, we owned one pending non-provisional U.S. patent application and one pending application in Europe directed to LNC compositions and methods for treating mucormycosis. Patents issuing from or claiming priority to the pending applications are also expected to expire in 2043, excluding patent term adjustments or extensions.

We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see “Risk Factors—Risks Relating to Our Intellectual Property and Regulatory Exclusivity.”

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, significant aspects of our proprietary LNC Platform are based on unpatented trade secrets and know-how. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We also plan to seek trademark protection in the United States and outside of the United States where available and when appropriate. We intend to use these registered marks in connection with our pharmaceutical research and development as well as our product candidates.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Many of these companies have far greater human and financial resources and may have product candidates in more advanced stages of development and many will reach the market before our product candidates. Competitors may also develop products that are more effective, safer or less expensive or that have better tolerability or convenience.

Although we believe that our proprietary LNC Platform, experience, and knowledge in our areas of focus provide us with competitive advantages, potential competitors could reduce our commercial opportunities. For many of our product candidates, we anticipate facing competition from other products that are available on a generic basis and offered at low prices. Many of these generic products have been marketed by third parties for many years and are well accepted by physicians, patients, and payers.

We believe that MAT2203 provides us with competitive advantages over our peers. However, we face potential competition from various sources, including larger and better-funded pharmaceutical, specialty pharmaceutical, and biotechnology companies, as well as from generic drug manufacturers, academic institutions, governmental agencies, and public and private research institutions.

MAT2203, if approved by FDA, will primarily compete with antifungal classes approved for the treatment of fungal and mold infections, which include polyenes, azoles and echinocandins. The approved branded therapies for these indications include Cancidas (caspofungin, marketed by Merck & Co.), Eraxis (anidulafungin, marketed by Pfizer, Inc.), Mycamine (micafungin, marketed by Astellas Pharma US, Inc.), Diflucan (fluconazole, marketed by Pfizer, Inc.), Noxafil (posaconazole, marketed by Merck & Co.), Vfend (voriconazole, marketed by Pfizer, Inc.), Sporanox (itraconazole, marketed by Jansen Pharmaceuticals, Inc.), Cresemba (isavuconazole, marketed by Astellas Pharma US, Inc.), Ambisome (liposomal amphotericin B, marketed by Astellas Pharma US, Inc.), Abelcet (lipid complex amphotericin B, marketed by Leadiant Biosciences), Rezzayo (rezafungin, marketed byCorMedix Therapeutics), Brexafemme (Ibrexafungerp marketed by GlaxoSmithKline) and amphotericin B deoxycholate (marketed by X-Gen Pharmaceuticals, Inc.). There currently are and may be more generic versions of these products available at the time of MAT2203 market approval, which will create added competition. In addition to approved therapies, we expect that MAT2203 may compete with product candidates that we are aware of in clinical development by third parties, such olorofim (being developed by F2G, Ltd), fosmanogepix (being developed by Basilea), and EL219, a derivative of amphotericin B being developed by Elion Therapeutics.

Manufacturing

We currently lease in-house manufacturing capabilities for our lead LNC Platform product candidate, MAT2203. However, following our reduction in force in October 2024, we no longer produce MAT2203 or any other clinical trial material at this facility. We are currently searching for a partner to takeover development of MAT2203 and this partner will be required to identify and secure one or more third-party contract manufacturers for the formulation and manufacture of MAT2203. As part of any partnership, a transfer of our manufacturing technology and any associated information to our partner or to a third-party manufacturer would be required in order to manufacture the drug necessary for additional clinical work and any supplies required for the commercialization of MAT2203, if approved.

There are several potential third-party suppliers for amphotericin B, the generic active pharmaceutical ingredient in our lead clinical stage product candidate – MAT2203. Although to date we have not entered into formal supply agreements to secure sufficient supply of amphotericin B to support our clinical programs for MAT2203, we believe we will be able to secure supply of amphotericin B to support our clinical programs for MAT2203 from one or more third-party suppliers.

Sales and Marketing

We currently do not have any sales and marketing infrastructure and do not plan to develop this infrastructure in the future.

Review and Approval of Drugs in the United States

In the United States, FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA and the Department of Justice (DOJ) or other governmental entities.

Our product candidates must be approved by FDA through the NDA or biologics license application (BLA), in the case of biologic product candidates, process before they may be legally marketed in the United States. An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies in compliance with FDA's good laboratory practice (cGLP), regulations;
- submission to FDA of an investigational new drug applications (IND), which must take effect before human clinical trials may begin;
- approval by an independent institutional review board (IRB) representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices (GCP), to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to FDA of an NDA or BLA;

- review of the product by an FDA advisory committee, where appropriate or if applicable;

- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices (cGMP), requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- payment of user fees and securing FDA approval of the NDA or BLA; and

- compliance with any post-approval requirements, including a risk evaluation and mitigation strategy (REMS), and post-approval studies required by FDA.

Nonclinical Studies

Nonclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of nonclinical studies is subject to federal regulations and requirements, including cGLP regulations. The results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to FDA as part of an IND.

Companies usually must complete some long-term nonclinical testing, such as animal tests of reproductive AEs and carcinogenicity, and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Human Clinical Trials in Support of a Regulatory Approval

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practice, or GCP, requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to FDA as part of the Investigational New Drug application, or IND. An IND automatically becomes effective 30 days after receipt by FDA, unless before that time FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and FDA must resolve any outstanding concerns before the clinical trial can begin. Accordingly, submission of an IND may or may not result in FDA allowing clinical trials to commence.

In addition, an Institutional Review Board, or IRB, representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to FDA in support of an NDA or IND so long as the clinical trial is conducted in accordance with GCP and if FDA is able to validate the data from the clinical trial through an on-site inspection if FDA deems it necessary.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

Phase 1: The drug is initially introduced into a small number of healthy human subjects or patients with the target disease (e.g. cancer) or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

Phase 2: The drug is administered to a larger number of trial participants, up to several hundred, who usually have the disease or condition that the experimental drug is intended to treat, to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: These clinical trials are commonly referred to as "pivotal" studies, which typically denotes a study which presents the data that FDA or another relevant regulatory agency will use to determine whether or not to approve a drug. In Phase 3 clinical trials, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to FDA and more frequently if serious Adverse Events, or AEs, occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Submission of an NDA to FDA

Regulatory approval for most new drug or biologic products is based on two adequate and well-controlled Phase 3 clinical trials that provide evidence of the safety and efficacy of the proposed new product. Assuming successful completion of required clinical testing and other requirements, the results of the nonclinical and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls, and proposed labeling, among other things, are submitted to FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee and the sponsor of an approved NDA is also subject to annual prescription drug program fees and establishment user fees. These fees are typically increased annually.

FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before FDA accepts it for filing. Once the submission is accepted for filing, FDA begins an in-depth substantive review. FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by FDA for various reasons, and for various time periods, including for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by FDA following the original submission.

Before approving an NDA, FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections cover all facilities associated with an NDA submission, including drug component manufacturing (such as Active Pharmaceutical Ingredients), finished drug product manufacturing and control testing laboratories. FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast Track, Breakthrough Therapy and Priority Review Designations

FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with FDA and FDA may initiate review of sections of a fast-track product's NDA before the application is complete. This rolling review may be available if FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, FDA's time goal for reviewing a Fast Track application does not begin until the last section of the NDA is submitted. In addition, the Fast Track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Improvement Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. FDA determines, on a case-by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten FDA's goal for taking action on a marketing application from ten months to six months.

Under Section 524 of the FDCA, the FDA is authorized to award a priority review voucher to sponsors of certain tropical disease product applications that meet the criteria specified in the Act. A priority review voucher may be used by the sponsor who obtains it, or it may be transferred to another sponsor who may use it to obtain priority review for a different application. Priority review vouchers can result in the acceleration of review and approval of a product candidate by up to four months. In order to be eligible for a tropical disease priority review voucher, the application must be: for a listed tropical disease; submitted under Section 505(b)(1) of the FDCA or Section 351 of the Public Health Service Act; for a product that contains no active ingredient that has been approved in any other application under those statutory provisions; and must qualify for priority review. FDA has identified in guidance those product applications for the prevention or treatment of tropical diseases that may qualify for a priority review voucher.

Accelerated Approval Pathway

FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by FDA.

FDA's Decision on an NDA

Based on FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information for FDA to reconsider the application. When those deficiencies have been addressed to FDA's satisfaction in a resubmission of the NDA, FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions which can materially affect the potential market and profitability of the product. In addition, as a condition of approval, FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential AEs and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals and elements to assure safe use, which may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with FDA and state agencies and are subject to periodic unannounced inspections by FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on post-approval clinical trials;
- refusal of FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application ("ANDA"), to the agency. In support of such applications, a generic manufacturer may rely on the nonclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug ("RLD").

Specifically, for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug.

Upon approval of an ANDA, the FDA indicates whether the generic product is therapeutically equivalent to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutically equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, FDA's designation of therapeutic equivalence often results in automatic substitution of the generic drug by the pharmacist without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be submitted to FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Hatch-Waxman Patent Certification and the 30 Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant submits its application to the FDA, the applicant is required to certify to FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting a NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product with orphan status receives the first the FDA approval for the disease or condition for which it has such designation, the product will be entitled to orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Other Health Care Regulations

Health Privacy Laws

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., principal investigators involved in our clinical trials) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, or HIPPA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH. HIPAA generally requires that covered entities (healthcare providers, health plans and healthcare clearinghouses) obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient's information and our research efforts could be impaired or delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). Among other things, HITECH makes HIPAA's privacy and security standards, as well as the various penalties or failure to comply, directly applicable to "business associates"—independent contractors or agents of covered entities performing certain functions involving the creation or use of protected health information on behalf of a covered entity or providing services to a covered entity. While we do not believe we are a "business associate" under HIPAA, regulatory agencies may disagree.

The General Data Protection Regulation, or GDPR, adopted in 2016, establishes a regulatory framework designed to protect the security of personal data collected about residents of the EU and the movement of such personal data across the national borders of the EU Member States, including, but not limited to, requirements to obtaining consent of the individuals to whom the personal data relates, the nature and scope of notifications provided to the individuals, the security and confidentiality of the personal data, data breach notification and using third party processors in connection with the processing of the personal data. Failure to comply with the EU Directive and the GDPR could subject us to regulatory sanctions, delays in clinical trials, criminal prosecution and/or civil fines or penalties. Additionally, GDPR creates a direct cause of action by individual data subjects.

Fraud and Abuse Laws

In addition to the FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal prosecution, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback statute and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Affordable Care Act

The Affordable Care Act ("ACA") among other things, imposes individual and employer health insurance requirements, provides certain insurance subsidies (e.g., premiums and cost sharing), mandates extensive insurance market reforms, creates new health insurance access points (e.g., State and federal-based health insurance exchanges), expands the Medicaid program, promotes research on comparative clinical effectiveness of different technologies and procedures, and makes a number of changes to how products and services will be reimbursed by the Medicare program. Amendments to the Federal False Claims Act under the ACA have made it easier for private parties to bring "qui tam" (whistleblower) lawsuits against companies, under which the whistleblower may be entitled to receive a percentage of any money paid to the government.

Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of the ACA. There is continued uncertainty about the implementation of the ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA. If the ACA is repealed or further modified, or if implementation of certain aspects of the ACA are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal, modification or delay in the implementation of the ACA on us at this time. Due to the substantial regulatory changes that will need to be implemented by CMS and others, and the numerous processes required to implement these reforms, we cannot predict which healthcare initiatives will be implemented at the federal or state level, the timing of any such reforms, or the effect such reforms or any other future legislation or regulation will have on our business.

Designation of and Exclusivity for Qualified Infectious Disease Products

In 2012, Congress passed legislation known as the Generating Antibiotic Incentives Now Act, or GAIN Act. This legislation is designed to encourage the development of antibacterial and antifungal drug products that treat pathogens that cause serious and life-threatening infections. To that end, the law grants an additional five years of marketing exclusivity upon the approval of an NDA for a drug product designated by FDA as a Qualified Infectious Disease Product, or QIDP. Thus, for a QIDP, the periods of five-year new chemical entity exclusivity, three-year new clinical investigation exclusivity and seven-year orphan drug exclusivity, would become 10 years, eight years, and 12 years, respectively.

A QIDP is defined in the GAIN Act to mean "an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by —(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens;" or (2) certain "qualifying pathogens." A "qualifying pathogen" is a pathogen that has the potential to pose a serious threat to public health (e.g., resistant gram-positive pathogens, multi-drug resistant gram-negative bacteria, multi-drug resistant tuberculosis and *Clostridium difficile*) and that is included in a list established and maintained by FDA. A drug sponsor may request FDA to designate its product as a QIDP any time before the submission of an NDA. FDA must make a QIDP determination within 60 days of the designation request. A product designated as a QIDP will be granted priority review by FDA and can qualify for "fast track" status.

The additional five years of market exclusivity under the GAIN Act for drug products designated by FDA as QIDPs applies only to a drug that is first approved on or after July 9, 2012. Additionally, the five-year exclusivity extension does not apply to: a supplement to an application under Section 505(b) of the FDCA for any QIDP for which an extension is in effect or has expired; a subsequent application submitted with respect to a product approved by FDA for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength; or a product that does not meet the definition of a QIDP under Section 505(g) based upon its approved uses.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of a NDA, plus the time between the submission date of a NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with FDA.

Review and Approval of Drug Products in the European Union

To market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable non-U.S. regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a drug under European Union regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not received marketing approval in any European Union member states before. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one-member state designated by the applicant, known as the reference member state. Under this procedure, an applicant applies based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Third party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the HIPPA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the HITECH and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the ACA requires manufacturers of drugs to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests and the reported information will be made publicly available on a searchable website; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Employees

As of March 31, 2026, we had two full time employees and retained the services of two independent contractors/consultants.

Research and Development

For the years ended December 31, 2025 and 2024, we incurred $85 and $11,433, respectively, on research and development activities. These expenses include cash and non-cash expenses relating to the development of our clinical and pre-clinical programs, including our anti-infective product candidates, MAT2203 as well as support and enhancement of our LNC Platform.

Corporate and Available Information

We were incorporated in Delaware under the name Matinas BioPharma Holdings, Inc. in May 2013. We have two operating subsidiaries: Matinas BioPharma, Inc., a Delaware corporation originally formed on August 12, 2011 as Nereus BioPharma LLC, and Matinas BioPharma Nanotechnologies, Inc., a Delaware corporation originally formed on January 29, 2015 as Aquarius Biotechnologies, Inc.

Our principal executive offices are located at 1545 Route 206 South, Suite 203A, Bedminster, New Jersey 07921, and our telephone number is (908) 484-8805. Our website address is www.matinasbiopharma.com. Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our SEC reports can be accessed through the Investors section of our internet website. Further, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Rooms at 100 F Street, N.E., Washington, D. C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at http://www.sec.gov.

Item 1A. Risk Factors

An investment in our common stock is speculative and involves a high degree of risk, including a risk of loss of your entire investment. You should carefully consider the risks described below and the other information in this Annual Report before purchasing shares of our common stock. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties may also adversely impair our business operations. If any of the events described in the risk factors below actually occur, our business, financial condition or results of operations could suffer significantly. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our common stock.

Summary of Risk Factors

- We have paused clinical development of our lead product candidate, MAT2203, and are devoting significant time and resources to identifying and evaluating strategic alternatives, which may not be successful.
- We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Raising additional capital may cause dilution to stockholders, restrict operations or require us to relinquish rights to our technologies or product candidates.
- Our operating history to date may make it difficult to evaluate the success of our business and assess our future viability.
- We are early in our development efforts, which may not be successful.
- We cannot market our product candidates without regulatory approval, and any delay in this process will harm our business
- We depend in part on third-party technology, the loss of which could harm our business.
- We may not have or be able to obtain sufficient quantities of our products to meet our supply and clinical studies obligations and our business, financial condition and results of operation may be adversely affected.
- If we are unable to successfully commercialize our products our ability to generate revenue will be limited.
- If our studies or trials produce negative results, are delayed, or identify serious side effects, we may face delays, additional costs, and be unable to commercialize our product candidates.
- If we cannot enroll enough patients to complete our clinical trials, our business, financial condition and results of operations may be adversely affected.
- We may not be able to maintain orphan drug designation or exclusivity for our anti-infective product candidates.
- Fast Track designation or priority review status by the FDA may not speed up development, review, or approval, nor guarantee approval and our current or future product candidates may also treat indications that do not qualify for priority review vouchers.
- Any breakthrough therapy designation granted by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

- Designation of our current or future product candidates as qualified infectious disease products is not assured and, in any event, even if granted, may not actually lead to a faster development or regulatory review, and would not assure FDA approval of our product candidates.
- We may not obtain or maintain orphan drug, Fast Track, qualified infection disease, or breakthrough therapy designations for our product candidates and, even if granted, these designations may not speed up development or review and do not guarantee FDA approval.
- If we are unsuccessful in identifying and developing additional product candidates, our potential for growth may be impaired.
- We lack a sales and marketing organization. Without establishing these capabilities, we may not successfully commercialize our product candidates, even with regulatory approval.
- If we cannot file for MAT2203 approval under Section 505(b)(2) of the FDCA or need additional safety and efficacy data, development and commercialization timelines may be delayed.
- We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.
- Even with marketing approval, we will face ongoing regulatory obligations and reviews, potentially incurring significant expenses. Our product candidates could face labeling restrictions, market withdrawal, and penalties for non-compliance or unforeseen issues.
- Future legislation, and/or regulations and policies adopted by the FDA may increase the time and cost required for us to conduct and complete clinical trials.
- Changes in health care law and implementing regulations may have a material adverse effect on us.
- Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.
- If we market our product candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.
- Reductions in staffing and funding at FDA and other federal agencies could cause delays in the development and approval of our current or future product candidates.
- We have been and expect to be significantly dependent on our collaborative agreements for the development of MAT2203, which exposes us to the risk of reliance on the performance of third parties.
- We expect that we will rely on third parties to conduct clinical trials for our product candidates, which exposes us to the risk of reliance on the performance of third parties.
- We will be completely dependent on third parties to manufacture MAT2203 and any future product candidates, and our commercialization efforts could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of any product candidate or fail to do so at acceptable quality levels or prices.
- Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives could harm our business.
- Outbreaks of communicable diseases may materially and adversely affect our business, financial condition and results of operations.
- Adverse global conditions, including economic uncertainty, may negatively impact our financial results.
- We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from discovering, developing and commercializing product candidates.
- It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.
- If we fail to obtain or maintain patent or trade secret protection for our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.
- Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.
- We will need to increase the size of our organization to grow our business, and we may experience difficulties in managing this growth.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.
- Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

- We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.
- Pursuant to the terms of our Series A Preferred Stock, we may be obligated to pay significant royalties.
- The rights of the holders of common stock may be impaired by the potential issuance of preferred stock.
- We do not intend to pay dividends on our common stock in the foreseeable future.
- An active public trading market for our common stock may not be sustained.
- Our share price has been and could remain volatile.
- Any issuance of shares of our common stock upon conversion of the shares of Preferred Stock will cause dilution to our then existing stockholders and may depress the market price of our common stock.
- If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.
- If we are unable to maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be adversely affected.
- We could be delisted from the NYSE American, which could seriously harm the trading price of our common stock, the liquidity of our stock and our ability to raise capital.
- Upon dissolution of our Company, you may not recoup all or any portion of your investment.
- Our Certificate of Incorporation allows for our Board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.
- Anti-takeover provisions of our Certificate of Incorporation, bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our Board and management.
- Stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees could be limited.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Risks Related to Our Financial Position and Need for Additional Capital

Our business to date has been significantly dependent on the success of MAT2203, and we have decided to pause further development of MAT2203 and devote significant time and resources to identifying and evaluating strategic alternatives, which may not be successful.

To date, we have invested significant efforts and financial resources in the research and development of MAT2203, which was our lead product candidate in clinical trials. In October 2024, we announced that negotiations under a previously disclosed non-binding term sheet regarding global rights to MAT2203 have been terminated following notification from the prospective partner. As a result, we implemented an 80% workforce reduction effective as of October 31, 2024 and ceased all clinical development activities to conserve cash. We are also evaluating other strategic alternatives. There can be no assurance that efforts to identify and evaluate a potential buyer or partner for MAT2203 will result in any definitive offer to consummate a strategic transaction, or if made what the terms thereof will be or that any transaction will be approved or consummated. If any definitive offer to consummate a sale is received, there can be no assurance that a definitive agreement will be executed or that, if a definitive agreement is executed, the transaction will be consummated. In addition, there can be no assurance that any transaction, involving our company and/or assets, that is consummated would enhance shareholder value. There also can be no assurance that we will conduct further drug research or development activities in the future.

Any such strategic transaction may require us to incur non-recurring or other charges, may increase our near-and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our business.

If we do not successfully consummate a transaction involving MAT2203, our Board may decide to pursue a winddown or dissolution of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such dissolution as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a transaction involving MAT2203 will be consummated, and previous efforts to do so have not been successful. If no transaction is completed, the Board may decide to pursue a winddown or dissolution. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such a decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our limited operations while we evaluate our options. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a winddown or dissolution of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) obligations under our employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of our company; (ii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business; and (iii) non-cancelable facility lease obligations. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a winddown or dissolution of our company. If a winddown or dissolution were pursued, our Board, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a winddown or dissolution of our company.

We have expressed substantial doubt about our ability to continue as a going concern and we have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

As discussed in Note 2 to the consolidated financial statements for the fiscal year ended December 31, 2025, our consolidated financial statements for the fiscal year ended December 31, 2025 were prepared assuming that we will continue as a going concern. A going concern basis assumes that we will continue our operations for the foreseeable future and contemplates the realization of assets and the settlement of liabilities in the normal course of business.

Consequently, management is pursuing various financing alternatives to fund our operations so we can continue as a going concern. Management plans to secure the necessary financing through the issue of new equity or through a potential licensing partnership of MAT2203 and/or the entering into alternative strategic arrangements. However, our ability to raise capital could be affected by various risks and uncertainties. We may not be able to raise sufficient additional capital and there can be no assurance that these initiatives will be successful.

The financial statements do not give any effect to any adjustments in the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Some adjustments could be material.

We have incurred significant operating losses in every year since inception and expect to incur net operating losses for the foreseeable future. Our net loss was $10.3 million and $24.3 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $210.8 million. We do not know whether or when we will become profitable. To date, we have not generated any revenues from product sales and have financed our operations through private placements and public offerings of our equity securities and, to a lesser extent, through funding from the Cystic Fibrosis Foundation, or CFF, and the National Institutes of Health, or the NIH. We have devoted substantially all our financial resources and efforts to the research and development of potential product candidates. All our product candidates are in the development stage, and we have not completed development of any product candidate. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' deficit and working capital. If we resume the development of MAT2203 or any other product candidates, we anticipate that our expenses will increase substantially as we:

- conduct further clinical and preclinical studies of MAT2203, our lead LNC product candidate;
- support the conduct of further clinical studies of MAT2203, even if such studies are partially financed with non-dilutive funding;
- seek to discover and develop additional product candidates;

- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- require the manufacture of larger quantities of product candidates for clinical development and potentially commercialization;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts and personnel and infrastructure necessary to help us comply with our obligations as a public company.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue until we are able to obtain marketing approval for, and successfully commercialize, one or more of our product candidates. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing, and selling any products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. We are only in the preliminary stages of most of these activities and have not yet commenced other of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we resume development activities and are required by the FDA or comparable non-U.S. regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates, or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

We expect our expenses to be lower during 2026 compared to 2025 until we secure additional funding, but generally we expect our expenses to increase over time if we resume the development of MAT2203. Our expenses could further increase if we initiate new research and preclinical development efforts for other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. Furthermore, we expect to incur significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with continued operations. If we are unable to raise capital when needed or on attractive terms, it could have a material adverse effect on our business and our ability to continue as a going concern.

In addition, based on the aggregate market value of our common stock held by non-affiliates ("public float") as of the date of the filing of this Annual Report, and for so long as our public float is less than $75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using Form S-3 is limited to an aggregate of one-third of our public float. If our public float meets or exceeds $75 million at any time, we will no longer be subject to the restrictions set forth in General Instruction I.B.6 of Form S-3. Unless and until our public float meets or exceeds $75 million, our ability to raise capital using a shelf registration statement will be constrained by General Instruction I.B.6 of Form S-3, which may affect the timing of and amounts we can raise.

We do not believe that our existing cash and cash equivalents, excluding restricted cash, of $3,999 thousand as of December 31, 2025 will enable us to fund our operating expenses beyond the next twelve months from the filing date of this Annual Report. We have based this estimate on assumptions that may prove to be wrong in the future, and we could use our capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. Our future capital requirements, both short-term and long-term, will depend on many factors, including, in the event we resume development activities:

- the progress, timing, costs, and results of our clinical trials of our current and future product candidates, if any;
- the scope, progress, timing, costs, and results of clinical trials of, and research and preclinical development efforts for, other product candidates, including MAT2203, any future product candidates based upon our LNC Platform, and any preclinical or clinical work done to further validate our LNC Platform, generally;
- our ability to enter into and the terms and timing of any collaborations, licensing or other arrangements that we may establish;
- the number and development requirements of other product candidates that we pursue;
- the costs, timing, and outcome of regulatory review of our product candidates by the FDA and comparable non-U.S. regulatory authorities;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our headcount growth and associated costs if we expand our research and development and establish a commercial infrastructure;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies;
- the costs of operating as a public company; and
- the effect of competing technological and market developments.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, government or other third-party funding, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, your ownership interest may be materially diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends, that could adversely impact our ability to conduct our business. Securing additional financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

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

Our stockholders may be subject to substantial dilution by exercises of outstanding options and warrants.

As of December 31, 2025, we had outstanding options to purchase an aggregate of 457,219 shares of our common stock at a weighted average exercise price of $34.76 per share and outstanding warrants to purchase an aggregate of 10,516,543 shares of our common stock at a weighted average exercise price of $0.97 The exercise of such outstanding options and warrants will result in dilution of the value of our shares.

Our operating history to date may make it difficult to evaluate the success of our business and to assess our future viability.

We commenced active operations in 2013 and our product candidates are in early stages of clinical development. We have not yet demonstrated our ability to successfully obtain regulatory approvals for any of our product candidates, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. Even if we obtain regulatory approval, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

We are early in our development efforts, which may not be successful.

Because we are still in the clinical stage of our development efforts and are in the process of determining the overall clinical development path for our current and future product candidates, the timing and costs of the regulatory paths we will follow. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of MAT2203 and any other product candidates we may develop will depend on many factors, including the following:

- successful completion of preclinical studies;
- successful enrollment in, and completion of, clinical trials:

- demonstrating safety and efficacy;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates and technologies;
- launching commercial sales of the product candidates, if approved, whether alone or selectively in collaboration with others;
- acceptance of the product candidates, if approved, by patients, the medical community and third-party payers;
- effectively competing with other therapies;
- a continued acceptable safety profile of the products following approval; and
- enforcing and defending intellectual property rights and claims.

If we do not accomplish one or more of these goals in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

We cannot be certain that any of our product candidates will receive regulatory approval, without which we will not be able to market any of our product candidates. Any delay in the approval process will harm our business.

We expect to invest most of our capital in maintaining the regulatory status of MAT2203 and prosecuting associated intellectual property while we look for a partner to continue clinical development of MAT2203. Our ability to generate revenue related to product sales, which we do not expect will occur for at least the next several years, if ever, will depend on the successful development and regulatory approval of one or more of our product candidates. All our product candidates require regulatory review and approval prior to commercialization. Any delays in the regulatory review or approval of our product candidates would delay market launch, increase our cash requirements and result in additional operating losses. This failure to obtain regulatory approvals would prevent our product candidate from being marketed and would have a material and adverse effect on our business.

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Furthermore, this approval process is extremely complex, expensive, and uncertain. We may be unable to submit any NDA in the United States or any marketing approval application in foreign jurisdictions for any of our products. If we submit an NDA including any amended NDA or supplemental NDA, to the FDA seeking marketing approval for any of our product candidates, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any of these submissions will be accepted for filing and reviewed by the FDA, or that the marketing approval application submissions to any other regulatory authorities will be accepted for filing and review by those authorities. We cannot be certain that we will be able to respond to any regulatory requests during the review period in a timely manner, or at all, without delaying potential regulatory action. We also cannot be certain that any of our product candidates will receive favorable recommendations from any FDA advisory committee or foreign regulatory bodies or be approved for marketing by the FDA or foreign regulatory authorities. In addition, delays in approvals or rejections of marketing applications may be based upon many factors, including regulatory requests for additional analyses, reports, data and studies, regulatory questions regarding data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding such product candidates.

Data obtained from preclinical studies and clinical trials are subject to different interpretations, which could delay, limit, or prevent regulatory review or approval of any of our product candidates. Furthermore, regulatory attitudes towards the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, policy changes and agency funding, staffing and leadership. We do not know whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

In addition, the environment in which our regulatory submissions may be reviewed changes over time. For example, average review times at the FDA for NDAs have fluctuated in recent years, and we cannot predict the review time for any of our submissions with any regulatory authorities. Review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes. Moreover, considering widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of the U.S. Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of REMS measures that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or may result in approval for a more limited indication than originally sought.

We depend in part on technology owned or licensed to us by third parties, the loss of which would terminate or delay the further development of our product candidates, injure our reputation, or force us to pay higher royalties.

We rely heavily on the LNC Platform and certain of the patents that we have exclusively licensed from Rutgers. The loss of access to these patents could materially impair our business and future viability, and could result in delays in developing, introducing, or maintaining our product candidates and formulations until equivalent technology, if available, is identified, licensed and integrated. In addition, any defects in the intellectual property that we license could prevent the implementation or impair the functionality of our product candidates or formulation, delay new product or formulation introductions or injure our reputation. If we are required to enter into license agreements with third parties for replacement technology, we could be subject to higher royalty payments.

We may not have or be able to obtain sufficient quantities of our products to meet our supply and clinical studies obligations and our business, financial condition and results of operation may be adversely affected.

To date, we have only developed limited in-house manufacturing capabilities for the LNC Platform needed for the clinical development our MAT2203 product candidates. We previously entered into an agreement with Patheon, a wholly owned subsidiary of ThermoFisher, to prepare for the commercial manufacture of MAT2203, but this agreement ended with the reduction in force implemented in 2024. If we, or a partner, do not develop a long-term manufacturing capability for our LNC Platform product candidates sufficient to produce product for continued development and, if regulatory approval is obtained, then commercialization of these products, we will be dependent on a small number of third-party manufacturers for the manufacture of our product candidates. We may not have long-term agreements with any of these third parties, and if they are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers or formulators or enter into favorable agreements with them. Any inability to acquire enough of our products in a timely manner from these third parties could delay clinical trials and prevent us from developing our products in a cost-effective manner or on a timely basis. In addition, manufacturers of our product candidates are subject to cGMP and similar foreign standards, and we would not have control over compliance with these regulations by our manufacturers. If one of our contract manufacturers fails to maintain compliance, the production of our products could be interrupted, resulting in delays and additional costs. In addition, if the facilities of such manufacturers do not pass a pre-approval or post-approval plant inspection, the FDA will not grant approval and may institute restrictions on the marketing or sale of our products.

We may be reliant on third party manufactures and suppliers to meet the demands of our clinical supplies. Delays in receipt of materials, scheduling, release, custom's control, and regulatory compliance issues may adversely impact our ability to initiate, maintain, or complete clinical trials that we are sponsoring. Commercial manufacturing and supply agreements have not been established. Issues arising from scale-up, environmental controls, public health crises, such as pandemics and epidemics, equipment requirements, or other factors, may have an adverse impact on our ability to manufacture our product candidates.

If we are unable to successfully commercialize our current or future product candidates our ability to generate revenue will be limited.

Even if we obtain regulatory approval for our product candidates, our long-term viability and growth depend on the successful commercialization of products which lead to revenue and profits. Pharmaceutical product development is an expensive, high risk, lengthy, complicated, resource intensive process. To succeed, among other things, we must be able to:

- identify potential drug product candidates;
- design and conduct appropriate laboratory, preclinical and other research;
- submit for and receive regulatory approval to perform clinical studies;
- design and conduct appropriate preclinical and clinical studies according to good laboratory and good clinical practices;
- select and recruit clinical investigators;
- select and recruit subjects for our studies;
- collect, analyze, and correctly interpret the data from our studies;
- submit for and receive regulatory approvals for marketing; and
- manufacture the drug product candidates according to cGMP.

The development program with respect to any given product will take many years and thus delay our ability to generate profits. In addition, potential products that appear promising at early stages of development may fail for several reasons, including the possibility that the products may require significant additional testing or turn out to be unsafe, ineffective, too difficult or expensive to develop or manufacture, too difficult to administer, or unstable. Failure to successfully commercialize our products will adversely affect our business, financial condition, and results of operations.

If our preclinical and clinical studies do not produce positive results, if our clinical trials are delayed or if serious side effects are identified during such studies or trials, we may experience delays, incur additional costs and ultimately be unable to commercialize our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct, generally at our own expense, extensive preclinical tests to demonstrate the safety of our product candidates in animals, and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Preclinical and clinical testing is expensive, difficult to design and implement and can take many years to complete. A failure of one or more of our preclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to obtain regulatory approval or commercialize our product candidates, including:

- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we expect to be promising;
- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- conditions imposed on us by the FDA or any non-U.S. regulatory authority regarding the scope or design of our clinical trials may require us to resubmit our clinical trial protocols to institutional review boards for re-inspection due to changes in the regulatory environment;

- the number of patients required for our clinical trials may be larger than we anticipate, or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors or clinical investigators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner;
- we might have to suspend or terminate one or more of our clinical trials if we, the regulators or the institutional review boards determine that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate or we may not be able to reach agreements on acceptable terms with prospective clinical research organizations; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

In addition, if we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining, or may not be able to obtain, marketing approval for one or more of our product candidates;
- obtain approval for indications that are not as broad as intended or entirely different than those indications for which we sought approval; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any preclinical tests or clinical trials will be initiated as planned, will need to be restructured or will be completed on schedule, if at all. Significant preclinical or clinical trial delays also could shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Such delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

If we cannot enroll enough patients to complete our upcoming clinical trials, our business, financial condition, and results of operations may be adversely affected.

The completion rate of clinical studies of our products is dependent on, among other factors, the patient enrollment rate. Patient enrollment is a function of many factors, including:

- investigator identification and recruitment;
- regulatory approvals to initiate study sites;
- patient population size;
- the nature of the protocol to be used in the trial;
- patient proximity to clinical sites;

- eligibility criteria for the study;
- competition from other companies' clinical studies for the same patient population; and
- ability to obtain comparator drug/device.

We believe that historically our procedures for enrolling patients have been appropriate; however, delays in patient enrollment would increase costs and delay ultimate commercialization and sales, if any, of our products. Such delays could materially adversely affect our business, financial condition, and results of operations.

Reductions in staffing and funding at FDA and other federal agencies could cause delays in the development and approval of our current and future product candidates.

Under the FDCA, our products cannot be investigated in humans or marketed without approval from FDA. In addition, companies developing new therapies routinely seek and receive guidance from FDA regarding their methods and plans for developing their products. We and companies like us may also benefit from FDA-administered programs like orphan drug designation and expedited development pathways, e.g., breakthrough designation. Any material reductions in the ability of FDA to perform these and other functions may delay development and approval of our product candidates. Recent actions by the United States federal government have caused concern in the industry that this may occur. For example, beginning on February 13, 2025, the Department of Health and Human Services began firing a large number of its probationary employees, a category that includes new federal employees and employees recently promoted or transferred to new positions or agencies. Larger layoffs may follow, according to a memorandum issued by the Office of Personnel Management on February 26, 2025. These terminations, if they withstand legal challenges, may significantly delay and impede our interactions with FDA. Similar results may stem from the recent confirmed resignations of some senior FDA employees with responsibility for regulation of drugs and biologics, as well as possible future layoffs and resignations. There are also reports that the United States federal government intends to request Congress to reduce FDA funding in upcoming budgets. Such funding cuts may also delay the development and approval of our products.

We may not be able to maintain orphan drug designation or exclusivity for our anti-infective product candidates.

We have received orphan drug designation for MAT2203 in the United States and may seek additional orphan drug designation for other product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of regulatory or marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same indication for that drug during that time. For a product that obtains orphan drug designation on the basis of a plausible hypothesis that it is clinically superior to the same drug that is already approved for the same indication, in order to obtain orphan drug exclusivity upon approval, clinical superiority of such product to this same drug that is already approved for the same orphan indication must be demonstrated. The exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We cannot assure you that the application for orphan drug designation of MAT2203 or any future application with respect to any other product candidate, will be maintained or granted. If we are unable to maintain orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Any Fast Track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We have received Fast Track designation for MAT2203 for the treatment of invasive candidiasis, the treatment of aspergillosis, the prevention of invasive fungal infections due to immunosuppressive therapy and the treatment of cryptococcosis and may seek Fast Track designation for some of our other product candidates or priority review of applications for approval of our product candidates for certain indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even if we do receive Fast Track designation or priority review, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

Any breakthrough therapy designation granted by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval if the relevant criteria are met.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Designation of our product candidates as qualified infectious disease products is not assured and, in any event, even if granted, may not actually lead to a faster development or regulatory review, and would not assure FDA approval of our product candidates.

We have received a qualified infectious disease product, or QIDP, designation for MAT2203 for certain indications and we may be eligible for designation of future product candidates as QIDPs. A QIDP is "an antibacterial or antifungal drug intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or certain "qualifying pathogens." A product designated as a QIDP will be granted priority review by the FDA and may qualify for "fast track" status. Upon the approval of an NDA for a drug product designated by the FDA as a QIDP, the product is granted a period of five years of regulatory exclusivity in addition to any other period of regulatory exclusivity for which the product is eligible. The FDA has broad discretion whether to grant these designations, so even if we believe a particular product candidate is eligible for such designation or status, the FDA could decide not to grant it. Moreover, even if we do receive such a designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures and there is no assurance that our product candidate, even if determined to be a QIDP, will be approved by the FDA.

If we are unsuccessful in identifying and developing additional product candidates, our potential for growth may be impaired.

Even if we receive regulatory approval for MAT2203 or any other future product candidates we may develop, we still may not be able to successfully commercialize such products and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of MAT2203 or any other product candidates we may develop will depend upon its acceptance by the medical community, including physicians, patients, and health care payors. The degree of market acceptance of MAT2203 or such other product candidate will depend on several factors, including:

- demonstration of clinical safety and efficacy of such product candidate;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe such product candidates and of the target patient population to try new therapies;
- pricing and cost-effectiveness;
- the inclusion or omission of such product candidate in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

If MAT2203 or any other product candidates we may develop is approved but does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of such product candidate may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize such product candidate successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render such product candidate not commercially viable. For example, regulatory authorities may approve such product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for such product candidate, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve such product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA may place conditions on approvals including potential requirements or risk management plans and the requirement for a REMS to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of such product candidate. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of such product candidate.

We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities, we may not successfully commercialize any of our product candidates, even if regulatory approval is obtained.

At present, we have no sales or marketing personnel. To commercialize products that are approved for commercial sales, we must either develop a sales and marketing infrastructure or collaborate with third parties that have such commercial infrastructure. If we elect to develop our own sales and marketing organization, we do not intend to begin to hire sales and marketing personnel until the time of NDA submission to the FDA at the earliest, and we do not intend to establish our own sales organization in the United States until shortly prior to FDA approval of MAT2203 or any of our other product candidates.

We may not be able to establish a direct sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize MAT2203 or any of our other product candidates in the United States without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty successfully commercializing MAT2203 or any other product candidates we may develop, which would adversely affect our business, operating results and financial condition. Outside the United States, we may commercialize our product candidates by entering into collaboration agreements with pharmaceutical partners. We may not be able to enter into such agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties.

If we are unable to file for approval of MAT2203 under Section 505(b)(2) of the FDCA or if we are required to generate additional data related to safety and efficacy to obtain approval under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

Current plans for filing the NDA for MAT2203 include efforts to minimize the data we will be required to generate to obtain marketing approval for this product candidate and therefore reduce the development time. We intend to rely on the history of efficacy of amphotericin B, and although we met with the FDA in 2019, 2021 and again in 2022 to discuss our development plans for MAT2203, there is no assurance we will satisfy FDA's requirements for approval of MAT2203 under a 505(b)(2) pathway. The timeline for filing and review of our NDA for MAT2203 is based on our plan to submit the NDA under Section 505(b)(2) of the FDCA, which would enable us to rely in part on data in the public domain or elsewhere. We have not yet filed an NDA under Section 505(b)(2) for any product candidate. Depending on the data that may be required by the FDA for approval, some of the data may be related to products already approved by the FDA. If the data relied upon is related to products already approved by the FDA and covered by third-party patents, we would be required to certify that we do not infringe the listed patents or that such patents are invalid or unenforceable. As a result of the certification, the third-party would have 45 days from notification of our certification to initiate an action against us.

If an action is brought in response to such a certification, the approval of our NDA could be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of our product candidates under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents to our product candidates. Alternatively, we may elect to generate sufficient additional clinical data so that we no longer rely on data which triggers a potential stay of the approval of our product candidates. Even if no exclusivity periods apply to our applications under Section 505(b)(2), the FDA has broad discretion to require us to generate additional data on the safety and efficacy of our product candidates to supplement third-party data on which we may be permitted to rely. In either event, we could be required, before obtaining marketing approval for any of our product candidates, to conduct substantial new research and development activities beyond those we currently plan to engage to obtain approval of our product candidates. Such additional new research and development activities would be costly and time consuming.

We may not be able to realize a shortened development timeline for any of our product candidates, and the FDA may not approve our NDA based on their review of the submitted data. If our desired reference-listed drug containing products are withdrawn from the market by the FDA for any safety reason, we may not be able to reference such products to support a 505(b)(2) NDA for our product candidates, and we may need to fulfill the more extensive requirements of Section 505(b)(1). If we are required to generate additional data to support approval, we may be unable to meet our anticipated development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval of our lead product candidates.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in several jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Established competitors may invest heavily to quickly discover and develop novel compounds that could make MAT2203 or any other product candidates we may develop obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability, and safety to be commercially successful. Other competitive factors, including generic competition, which could force us to lower prices or result in reduced sales, particularly those products that have been marketed by third parties for many years and are well accepted by physicians, patients, and payers. In addition, new products developed by others could emerge as competitors to MAT2203 or any of our other product candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer.

Further, although we believe that our proprietary LNC Platform, experience, and knowledge in our areas of focus provide us with competitive advantages, potential competitors for MAT2203 could reduce our commercial opportunities.

Even if we obtain marketing approval for any product candidate, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our future products.

Even if we obtain United States regulatory approval of MAT2203 or any other product candidates that we may develop, FDA may still impose significant restrictions on its indicated uses or marketing or the conditions of approval or impose ongoing requirements for potentially costly and time-consuming post-approval studies, and post-market surveillance to monitor safety and efficacy. Our future products will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of AEs and other post-market information. These requirements include registration with FDA, as well as continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continuous review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

FDA has the authority to require a REMS, as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state, and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, our product labeling, advertising, and promotion would be subject to regulatory requirements and continuing regulatory review. FDA strictly regulates the promotional claims that may be made about prescription products. A product may not be promoted for uses that are not approved by FDA as reflected in the product's approved labeling. If we receive marketing approval for our product candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions, including revocation of its marketing approval. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;

- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize MAT2203 or any of our other product candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Future legislation, and/or regulations and policies adopted by the FDA may increase the time and cost required for us to conduct and complete clinical trials.

FDA has established regulations to govern the drug development and approval process, as have foreign regulatory authorities. The policies of FDA and other regulatory authorities may change, and additional laws or government regulations may be promulgated that could prevent, limit, delay but also accelerate regulatory review of our product candidates. For example, in December 2016, the Cures Act was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation. We cannot predict what if any effect the Cures Act or any existing or future guidance from FDA will have on development of our product candidates.

Changes in health care law and implementing regulations may have a material adverse effect on us.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in the United States, the Patient Protection and Affordable Care Act of 2010 ("ACA") substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of the ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS.

Additionally, the Inflation Reduction Act of 2022, which took effect in 2023, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government. This legislation contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs covered by Medicare or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs.

Legislative, administrative, and private payor efforts to control drug costs span a range of proposals, including drug price negotiation, Medicare Part D redesign, drug price inflation rebates, international mechanisms, generic drug promotion and anticompetitive behavior, manufacturer reporting, and reforms that could impact therapies utilizing the accelerated approval pathway. We cannot predict the ultimate content, timing or effect of any changes to the ACA, the Inflation Reduction Act, or other federal and state healthcare policy reform efforts including those aimed at drug pricing. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare policy will affect our business.

We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for our product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted, or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs or could reduce the potential commercial value of our product candidates. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs. Such legislation, or similar regulatory changes or relaxation of laws that restrict imports of products from other countries, could reduce the net price we receive for any future marketed products. As a result, our future products might not ultimately be considered cost-effective. We cannot be certain that reimbursement will be available for any of our product candidates. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any future products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any product candidates that we develop.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize MAT2203 or any other product candidates that we may develop in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;

- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the impact of tariffs and the cost of doing business in foreign markets;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

If we market our product candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct can subject that company to significant liability. Similarly, industry codes in the EU and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

We have been and expect to be significantly dependent on our collaborative agreements for the development of MAT2203, which exposes us to the risk of reliance on the performance of third parties.

In conducting our research and development activities for MAT2203, we currently rely, and expect to continue to rely, on collaborative agreements with universities, governmental agencies, and not-for-profit organizations for both strategic and financial resources. The loss of, or failure to perform by us or our partners under any applicable agreements or arrangements, or our failure to secure additional agreements for our product candidates, would substantially disrupt or delay our research and development activities, including our in-process and anticipated clinical trials. Any such loss would likely increase our expenses and materially harm our business, financial condition, and results of operation.

We expect that we will rely on third parties to conduct clinical trials for our product candidates, which exposes us to the risk of reliance on the performance of third parties.

We expect to enter into agreements with third-party CROs, or governmental entities like the NIH, to conduct and manage our clinical programs. We rely heavily on these parties for execution of clinical studies for MAT2203 and our other product candidates and can control only certain and very limited aspects of their activities. Nevertheless, we would be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the NIH or CROs would not relieve us of our regulatory responsibilities. We, the NIH and our CROs would be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or the NIH or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require many test subjects. Our failure or the failure of the NIH or our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the NIH or the CROs may not perform all their obligations under their arrangements with us or in compliance with regulatory requirements. If NIH or the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of MAT2203 or any other product candidates that we may develop may be delayed or our development program may be materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs would devote to our program or our product candidates. If we are unable to rely on the clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. As a result of the foregoing, our financial results, and the commercial prospects for MAT2203 and our other product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We are, and will be, completely dependent on third parties to manufacture our product candidates, and our commercialization of efforts could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of any product candidate or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredient, or API, in MAT2203, or any of our product candidates, for use in our clinical trials or for commercial product, if any. As a result, we will rely on contract manufacturers throughout the development process and then if MAT2203, or any of our product candidates are approved for commercialization. We have not entered into any agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of MAT2203, or any of our product candidates, on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture any of our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of a product candidate or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market such product candidate , if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We do not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our product candidates , delays, suspensions or withdrawals of approvals, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our product candidates.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished product or should cease doing business with us, we could experience significant interruptions in product supply or may not be able to create a supply of any product candidate at all. Were we to encounter manufacturing issues, our ability to produce a sufficient product supply might be negatively affected. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third-party manufacturing partners, could impair our ability to supply any product candidate at required levels. Because of the significant regulatory requirements that we would need to satisfy to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in product supply if we decided to transfer manufacturing to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability, and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of our product candidates, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of any product candidate over time. If commercial-scale manufacturing costs are higher than expected, these costs may significantly impact our operating results. To reduce costs, we may need to develop and implement process improvements. However, to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

Outbreaks of communicable diseases may materially and adversely affect our business, financial condition and results of operations.

We face risks related to health epidemics or outbreaks of communicable diseases. Since some of our business partners are outside of the U.S., in China and other Asian countries, including manufacturing operations for our active pharmaceutical ingredient, an outbreak of communicable diseases in Asia or elsewhere, or the perception that such an outbreak could occur, and the measures taken by the governments of countries affected could adversely affect our business, financial condition or results of operations. For example, an outbreak could significantly disrupt our business by limiting our ability to travel or ship materials within or outside China and forcing temporary closure of facilities that we rely upon.

Adverse global conditions, including economic uncertainty, may negatively impact our financial results.

Global conditions, dislocations in the financial markets, or inflation could adversely impact our business. In addition, the global macroeconomic environment has been and may continue to be negatively affected by, among other things, instability in global economic markets, increased U.S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment and political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets, which may adversely affect our business.

Risks Relating to Our Intellectual Property Rights and Regulatory Exclusivity

We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from discovering, developing and commercializing product candidates.

We rely upon our LNC Platform and certain of the patents which are exclusively licensed to us by Rutgers. We do not exclusively own some of the patents that underly the LNC Platform. Our rights to use upon the patents we exclusively license are subject to the negotiation of, continuation of and compliance with the terms of our license agreement with Rutgers. Pursuant to the terms of our license agreement with Rutgers, we control the prosecution, maintenance, or filing of the patents to which we hold licenses, as well as the enforcement of these patents against third parties. However, some of our patents and patent applications were either acquired from another company who acquired those patents and patent applications from yet another company or are licensed from a third party. Thus, these patents and patent applications were not written by us or our attorneys, and we did not have control over the drafting and prosecution of certain of these patents. The former patent owners and our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. We cannot be certain that drafting and/or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Our rights to use the technology we license are subject to the validity of the owner's intellectual property rights. Enforcement of our licensed patents or defense or any claims asserting the invalidity of these patents is often subject to the control or cooperation of our licensors. Legal action could be initiated against the owners of the intellectual property that we license and an adverse outcome in such legal action could harm our business because it might prevent such companies or institutions from continuing to license intellectual property that we may need to operate our business. In addition, such licensors may resolve such litigation in a way that benefits them but adversely affects our ability to use the licensed technology for our products.

Certain of our licenses contained in our agreement with Rutgers contain provisions that allow the licensor to terminate the license if (i) we breach any payment obligation or other material provision under the agreement and fail to cure the breach within a fixed time following written notice of termination, (ii) we or any of our affiliates, licensees or sub licensees directly or indirectly challenge the validity, enforceability, or extension of any of the licensed patents or (iii) we declare bankruptcy or dissolve. Our rights under the licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Termination of these licenses may prevent us from discovering, developing, and commercializing product candidates based on the LNC Platform, including our lead anti-infective product candidate MAT2203. Determining the scope of the license and related royalty obligations can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we might be barred from discovering, developing and commercializing product candidates based on the LNC Platform, including our lead anti-infective product candidates.

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our commercial success will depend, in part, on obtaining and maintaining patent protection for our technologies, products and processes, successfully defending these patents against third-party challenges, and successfully enforcing these patents against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific, and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents (including patents owned and licensed by us). We currently own or have rights to 30 issued patents relating to our LNC Platform, as well as pending patent applications for our LNC Platform that may never be approved by the United States or foreign patent offices. Furthermore, any patents which may eventually be issued from existing patent applications for any of our technologies, may be challenged, invalidated, or circumvented by third parties and might not protect us against competitors with similar products or technologies.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before the United States or foreign patent offices.

We also rely on trade secrets to protect technology, especially in cases where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants, and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to obtain or maintain patent or trade secret protection for our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We may also develop trademarks to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks.

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of MAT2203 or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize MAT2203 or any future product candidate and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties against us would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent MAT2203 from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to MAT2203 or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market our current product candidates or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign, MAT2203 or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing MAT2203 or a future product candidate, which could harm our business, financial condition, and operating results.

We anticipate that competitors may from time to time oppose our efforts to obtain patent protection for new technologies or to submit patented technologies for regulatory approval. Competitors may seek to oppose our patent applications to delay the approval process or to challenge our granted patents, for example, by requesting a reexamination of our patent at the United States Patent and Trademark Office, or the USPTO, or by filing an opposition in a foreign patent office, even if the opposition or challenge has little or no merit. Such proceedings are generally highly technical, expensive and time consuming, and there can be no assurance that such a challenge would not result in the narrowing or complete revocation of any patent of ours that was so challenged.

General Company-Related Risks

We will need to increase the size of our organization to grow our business, and we may experience difficulties in managing this growth.

We have two full time employees and retained the services of two independent contractors/consultants as of March 16, 2026. If our development and commercialization plans and strategies develop, we may need to expand the size of our employee base for managerial, development, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate, and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees would adversely impact our business prospects.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees, including Jerome D. Jabbour, our Chairman, Chief Executive Officer and President could adversely affect our business prospects.

Our ability to compete in the highly competitive pharmaceutical industry depends in large part upon our ability to attract highly qualified managerial, scientific, and medical personnel. To induce valuable employees to remain with us, we intend to provide employees with stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that we will not be able to control and may at any time be insufficient to counteract more lucrative offers from other companies.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face a potential risk of product liability because of the clinical testing of MAT2203 or any future product candidates and will face an even greater risk if we commercialize MAT2203 or any other future product. For example, we may be sued if any product we develop or any material that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of MAT2203. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for MAT2203 or any future products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing, or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We have obtained product liability insurance covering our clinical trials in the amount of greater than or equal to $5 million in the aggregate. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage or disruption from computer viruses, software bugs, unauthorized access, natural disasters, terrorism, war, and telecommunication, equipment and electrical failures. While we have not, to our knowledge, experienced any significant system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, our information security systems and those of our CROs are also subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information gathered and used in our business. For example, HIPAA and its implementing regulations impose, among other requirements, certain regulatory and contractual requirements regarding the privacy and security of personal health information. In the European Union the General Data Protection Regulation, or GDPR, is even more restrictive with respect to all personal information, including information masked by a coding system. In addition to HIPAA and GDPR, numerous other federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, and storage of personal information. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure or theft of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed, our competitive position could be compromised, or our business reputation could be harmed.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Risks related to our Securities

Pursuant to the terms of our Series A Preferred Stock, we may be obligated to pay significant royalties.

Pursuant to the terms of the Certificate of Designations of Preferences, Rights and Limitations (the "Series A Certificate of Designations") for our Series A Preferred Stock, we are required to pay royalties of up to $35 million per year. If and when we obtain FDA or EMA approval of MAT2203, which we do not expect to occur before 2030, if ever, and/or if we generate sales of such products, or we receive any proceeds from the licensing or other disposition of MAT2203, we are required to pay to certain former holders of our Series A Preferred Stock, in aggregate, a royalty equal to (i) 4.5% of Net Sales (as defined in the Series A Certificate of Designations), subject in all cases to a cap of $25 million per calendar year, and (ii) 7.5% of Licensing Proceeds (as defined in the Series A Certificate of Designations), subject in all cases to a cap of $10 million per calendar year. The Royalty Payment Rights will expire when the patents covering the applicable product expire, which is currently expected to be in 2033.

Our common stock ranks junior to the Preferred Stock in the event of a liquidation, dissolution or winding-up of the Company.

In the event of any liquidation, dissolution or winding-up of the Company, a holder of shares of the Preferred Stock will be entitled to receive an amount equal to 100% of the stated value before any distribution or payment may be made with respect to the common stock.

Any issuance of shares of our common stock upon conversion of the shares of Preferred Stock will cause dilution to our then existing stockholders and may depress the market price of our common stock.

Each share of Preferred Stock is convertible into a number of shares of common stock calculated by dividing (i) stated value by (ii) a fixed conversion price of $0.586.

The issuance of shares of our common stock upon conversion of the Preferred Stock will result in immediate and substantial dilution to the interests of holders of our shares of common stock and may depress the market price of our common stock.

We do not intend to pay dividends on our common stock in the foreseeable future.

The Board will determine, in its sole discretion, our dividend policy after considering our financial condition, results of operations and capital requirements, as well as other factors. We do not anticipate paying cash dividends on our common stock in the foreseeable future and you should not invest in us with the anticipation of receiving dividend income.

An active public trading market for our common stock may not be sustained.

Although our common stock is listed on the NYSE American, the market for our shares has demonstrated varying levels of trading activity, and we cannot assure you that an active trading market will be sustained. A lack of an active market may impair your ability to sell shares of our common stock at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the price of shares of our common stock. An inactive market may also impair our ability to raise capital by selling shares of capital stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration.

Our share price has been and could remain volatile.

The market price of our common stock has historically experienced and may continue to experience significant volatility. Our progress in developing our product candidates, the impact of government regulations on our products and industry, the potential sale of a large volume of our common stock by stockholders, our quarterly operating results, changes in general conditions in the economy or the financial markets and other developments affecting us or our competitors could cause the market price of our common stock to fluctuate substantially with significant market losses. If our stockholders sell a substantial number of shares of common stock, especially if those sales are made during a short period of time, those sales could adversely affect the market price of our common stock and could impair our ability to raise capital. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has affected the market prices of securities issued by many companies for reasons unrelated to their operating performance and may adversely affect the price of our common stock. In addition, we could be subject to a securities class action litigation as a result of volatility in the price of our stock, which could result in substantial costs and diversion of management’s attention and resources and could harm our stock price, business, prospects, results of operations and financial condition.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. Our research coverage by industry and financial analysts is currently limited. Even if our analyst coverage increases, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

If we are unable to maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be adversely affected.

We have identified a material weakness in our internal control over financial reporting. If we are not able to remediate this material weakness and otherwise maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be adversely affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of SOX, or Section 404, requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and provide a management report on internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

Management assessed the effectiveness of our internal control over financial reporting based on criteria established in "Internal Control—Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has concluded as of December 31, 2025, our internal control over financial reporting was not effective, as management identified a deficiency in internal control over financial reporting that was determined to be a material weakness.

We did not maintain an effective internal control environment to ensure the processing of and reporting of non-routine transactions are complete, accurate and timely. Specifically, we did not have the accounting resources necessary to ensure the timely preparation and review of the Company's annual indefinite lived assets impairment assessment.

If our steps are insufficient to successfully remediate the material weakness and otherwise establish and maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be materially and adversely affected. Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Moreover, we do not expect that disclosure controls or internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially adversely impact us.

We could be delisted from the NYSE American, which could seriously harm the trading price of our common stock, the liquidity of our stock and our ability to raise capital.

Our common stock is listed on the NYSE American. We must satisfy the continued listing requirements of the NYSE American to maintain the listing of our common stock on the NYSE American.

We had in the past, and may have in the future, difficulty satisfying NYSE American continued listing requirements for our common stock. On September 21, 2023, we received a deficiency letter from the NYSE American indicating that the Company was not in compliance with the NYSE American continued listing standard set forth in Section 1003(f)(v) of the NYSE American Company Guide due to its shares of common stock selling for a substantial period of time at a low price per share, which NYSE American determined to be a 30 trading day average price of less than $0.20 per share. On March 22, 2024, we announced that on March 21, 2024, we received a letter from the NYSE American indicating that the Company had regained compliance with the NYSE American continued listing standard set forth in Section 1003(f)(v) of the NYSE American Company Guide due to its shares of common stock demonstrating sustained price improvement. On August 27, 2024, we received notice that trading of our shares of common stock had been halted by the NYSE American due to its low trading price. The trading halt remained in effect until after we consummated the communicated reverse stock split of the common stock and the market opened on September 3, 2024. On January 10, 2025, we announced that we received the January 2025 NYSE Notice from the NYSE American stating that the Company failed to hold an annual meeting of stockholders during the fiscal year ended December 31, 2024, as required by Section 704 of the NYSE American Company Guide. We received a letter from the NYSE American on June 23, 2025 that we had resolved the deficiency set forth in the January 2025 NYSE Notice by virtue of holding our Annual Meeting for the fiscal year ended December 31, 2023 on June 23, 2025. As a result, the BC indicator was removed from our stock symbol.

There can be no assurance that we will be able to maintain compliance with the NYSE American continued listing requirements, and if we are unable to maintain compliance with such continued listing requirements, including any minimum trading price or market capitalization requirements, our shares may be delisted from the NYSE American, which could reduce the liquidity of our common stock materially and result in a corresponding material reduction in the price of our common stock.

In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees, suppliers, customers and business development opportunities. Such a delisting likely would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from the NYSE American, our common stock may no longer be recognized as a "covered security," and we would be subject to regulation in each state in which we offer our securities. Delisting can also lead a termination that our common stock is stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common stock. Thus, delisting from the NYSE American could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common stock.

Upon dissolution of our company, you may not recoup all or any portion of your investment.

In the event of a liquidation, dissolution or winding-up of our company, whether voluntary or involuntary, the proceeds and/or assets of our company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities will be distributed first to the holders of our preferred stock and thereafter to the stockholders of common stock (including the holders of our preferred stock on an "as converted" basis) on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding-up of our Company. In this event, you could lose some or all of your investment.

Our Certificate of Incorporation allows for our Board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our Board has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board has the authority to issue up to 10,000,000 shares of our preferred stock without further stockholder approval. As a result, our Board could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

Anti-takeover provisions of our Certificate of Incorporation, bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our Board and management.

Certain provisions of our amended and restated Certificate of Incorporation and bylaws could discourage, delay, or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your Shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our Board. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

- they provide that special meetings of stockholders may be called only by the Board, President, or our Chairman of the Board of Directors, or at the request in writing by stockholders of record owning at least fifty (50%) percent of the issued and outstanding voting shares of common stock;

- they do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in our Board; and

- they allow us to issue, without stockholder approval, up to 10,000,000 shares of preferred stock (all of which remain available for issuance) that could adversely affect the rights and powers of the holders of our common stock.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

Stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees may be limited.

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our Certificate of Incorporation or our bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. Our Certificate of Incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery and federal district courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find either choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. For example, the Court of Chancery of the State of Delaware recently determined that the exclusive forum provision of federal district courts of the United States of America for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. As a result of this decision, we do not currently intend to enforce the federal forum selection provision in our Certificate of Incorporation, unless the decision is reversed on appeal. However, if the decision is reviewed on appeal and ultimately overturned by the Delaware Supreme Court, we would enforce the federal district court exclusive forum provision.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Our ability to utilize our U.S. federal net operating loss, carryforwards and U.S. federal tax credits may be limited under Sections 382 of the Internal Revenue Code of 1986, as amended. The limitations apply if an "ownership change," as defined by Section 382 and Section 383, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). In addition, future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 and Section 383 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, the Tax Act, among other things, imposes significant additional limitations on the deductibility of interest and limits net operating loss (NOL) deductions to 80% of net taxable income for losses arising in taxable years beginning after December 31, 2017.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We, like other companies in our industry, face several cybersecurity risks in connection with our business. Our business strategy, results of operations, and financial condition have not, to date, been affected by risks from cybersecurity threats. During the reporting period, we have not experienced any material cyber incidents, nor have we experienced a series of immaterial incidents, which would require disclosure.

In the ordinary course of our business, we use, store and process data including data of our employees, trial participants, partners, clients, and vendors. We have implemented a cybersecurity risk management program that is designed to identify, assess, and mitigate risks from cybersecurity threats to this data and our systems. Our cybersecurity risk management program incorporates several components, including information security program assessments, continuous monitoring of cyber risks and threats using automated tools, written incident response and disaster recovery policies and procedures, and employee training. Under the direction of our Chief Executive Officer, our cyber risk management program is led by a third-party IT consultant with more than 30 years of technology engineering experience and several advanced degrees. We also deploy endpoint detection software and device management in conjunction with other reputable cybersecurity software. Additionally, we require multifactor authentication across all systems.

We periodically engage third parties to conduct risk assessments and other vulnerability analyses. Lastly, our program includes cybersecurity training for all employees. The semi-annual training focuses on cyber threat awareness, including phishing.

Governance Related to Cybersecurity Risks

Under the ultimate direction of our Chief Financial Officer, the Board is updated on our cybersecurity risk management program, including any critical cybersecurity risks, ongoing cybersecurity initiatives and strategies, and applicable regulatory requirements and industry standards, on an as-needed basis. The CEO also notifies the Board of any cybersecurity incidents (suspected or actual) and provides updates on the incidents as well as cybersecurity risk mitigation activities as appropriate.

Item 2. Properties

Our administrative offices consist of approximately 500 square feet of office space in Bedminster, NJ that we occupy under a lease that expires in December 2026. We also lease laboratory space approximating 14,000 square feet in Bridgewater, NJ, that expires in September 2027.

Item 3. Legal Proceedings

Other than as set forth below, we are not currently a party to any legal proceedings, and we are not aware of any claims or actions pending or threatened against us. In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

The Company filed a complaint against COE Bridgewater, LLC (its "Landlord") in the Superior Court of New Jersey, Somerset County, Chancery Division on July 11, 2025 alleging principally that Landlord illegally locked the Company out of its leased premises in Bridgewater, New Jersey. As a result of the illegal lockout, the Company seeks (among other things) a declaration that the lease and all obligations thereunder, including rent, terminated as of the date of the lockout. On September 5, 2025, Landlord filed an answer with counterclaims, which it amended on December 12, 2025. In the counterclaims, Landlord seeks a declaration that there was no lockout, or that the lockout was justified, and therefore the lease remains in effect. Landlord also seeks damages for the Company's alleged failure to pay approximately $205,000 in rent (as of December 31, 2025) following the lockout, and alleged conversion of certain furniture, fixtures, and equipment (FF&E) items within the premises belonging to Landlord. The amounts potentially payable under the lease have been reserved until the matter is resolved. The Company is currently in settlement negotiations with the Landlord, however there can be no assurance such a settlement will be achieved.

Item 4. Mine Safety Disclosures

Not applicable

PART II

Item 5. Market For Registrant's Common Equity, Related Stockholder Matters And Issuer Purchases Of Equity Securities

Our common stock is quoted on the NYSE American under the symbol "MTNB."

On March 26, 2026, the closing sale price of our common stock, as reported by the NYSE American, was $0.60 per share and we had approximately 91 record holders of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. VStock Transfer, LLC is the transfer agent and registrar for our common stock.

Dividends

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our Board and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our Board deems relevant.

Item 6. [Reserved]

Item 7. Management's Discussion And Analysis Of Financial Condition And Results Of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and financing needs, includes forward-looking statements that involve risks and uncertainties and should be read together with the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report and in other reports we file with the Securities and Exchange Commission, particularly those under "Risk Factors." All dollars amounts stated in the tabular and paragraph formats are presented in thousands, except per share data, or otherwise indicated.

Overview

We are a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using our lipid nanocrystal (LNC) platform delivery technology (LNC Platform).

Key elements of our strategy now include:

- Securing one or more partners to monetize the value of MAT2203 in the short term and raise additional non-dilutive capital through the licensing or sale of our lead LNC Platform product candidate. A partnership would likely seek to advance MAT2203 into Phase 3 development as quickly as possible, which could position a partner to commercialize MAT2203 upon approval and which could bring additional longer-term value to the Company and its shareholders.

- Conserving our cash resources while identifying and evaluating other strategic options for the Company, which could include the in-license of one or more assets or seeking a merger partner for the Company.

On October 31, 2024, we announced that negotiations under the MAT2203 Term Sheet were terminated following notification from the perspective partner for reasons unrelated to MAT2203. As a result, we implemented an immediate 80% workforce reduction, eliminating 15 positions, including three members of senior management, and paused clinical development of MAT2203 to preserve cash while it evaluated a potential sale of MAT2203 and/or other strategic alternatives, including a potential winddown or dissolution of the Company.

On February 13, 2025, we entered into a securities purchase agreement (the "February 2025 Agreement") with a certain group of investors (the "February 2025 Investors"), pursuant to which they agreed to purchase from the Company 3,300 shares of our Series C Convertible Preferred Stock, par value $0.0001 per share (the "Preferred Stock"), and warrants to purchase up to 11,262,808 shares of common stock (the "2025 Warrants") at a purchase price of $1,000 per share of Preferred Stock and accompanying 2025 Warrants for aggregate gross proceeds of $3.3 million before deducting offering expenses payable by the Company. The February 2025 Investors purchased 1,650 shares of Preferred Stock and accompanying 2025 Warrants to purchase up to 5,631,404 shares of common stock for gross proceeds to the Company of $1.65 million at an initial closing on February 13, 2025. Subject to the satisfaction of certain closing conditions, the February 2025 Investors purchased an additional 1,650 shares of Preferred Stock and accompanying 2025 Warrants to purchase up to 5,631,404 shares of common stock for gross proceeds to the Company of $1.65 million at a second closing on April 8, 2025. The shares of Preferred Stock are convertible into common stock at a conversion price of $0.586, and each share of Preferred Stock is initially convertible into 1,706 shares of common stock. The 2025 Warrants have an exercise price of $0.6446 per share. The 2025 Warrants purchased in the initial closing became exercisable on April 4, 2025, the effective date of the approval by our shareholders of the Stock Issuance Proposal (as defined below) (the "Shareholder Approval") and will expire five years from the effective date of the Shareholder Approval, or April 4, 2030. The 2025 Warrants purchased in the second closing were immediately exercisable and will expire on April 8, 2030. In connection with the February 2025 Agreement, Dr. Robin L. Smith, MD, MBA was appointed to the Board.

For the years ended December 31, 2025 and 2024, our net loss was $10,345 and $24,251, respectively. We have incurred losses for each period from our inception and expect to incur additional losses for the foreseeable future. We do not believe that the cash and cash equivalents on hand are sufficient to fund planned operations beyond the next twelve months from the filing date of this Annual Report. We will seek to fund our operations through public or private equity offerings, debt financings, government or other third-party funding, collaborations, and licensing arrangements. These financing alternatives may not be available to us on acceptable terms, or at all. As a result, substantial doubt exists about our ability to continue as a going concern.

Financial Operations Overview

Revenue

We did not generate any revenue during the years ended December 31, 2025 and 2024. Our ability to generate product revenue, which we do not expect to occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our early-stage product candidates.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of product candidate MAT2203, and advancement of our LNC Platform, which include:

- the cost of acquiring, developing, and manufacturing pre-clinical and human clinical trial materials;
- costs for consultants and contractors associated with Chemistry and Manufacturing Controls (CMC), pre-clinical and clinical activities and regulatory operations;
- expenses incurred under agreements with contract research organizations, or CROs, including the NIH, that conduct our pre-clinical or clinical trials;
- employee-related expenses, including salaries and stock-based compensation expense for those employees involved in the research and development process; and
- the reimbursement of certain expenses related to the CFF award agreement.

Research and development activities are central to our business model. We expect our research and development expenses to increase over time because product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage human trials. During 2025 our research and development expenses are lower compared with expenses incurred during 2024 as commencement of additional activities, was and continues to be subject to our ability to secure additional funding to support initiation of our Phase 3 registration trial for MAT2203, or to secure one or more partners to assume clinical development activities for MAT2203 and advance our LNC Platform delivery technology.

The table below summarizes our direct research and development expenses for our product candidates and development platform for the years ended December 31, 2025 and 2024. Our direct research and development expenses consist principally of external costs, such as fees paid to contractors, consultants, analytical laboratories and CROs and/or the NIH, in connection with our development work. We historically use our employee and infrastructure resources for manufacturing clinical trial materials, conducting product analysis, study protocol development and overseeing outside vendors. Included in "Internal Staffing, Overhead and Other" below is the cost of laboratory space, supplies, research and development (R&D) employee costs (including stock option expenses), travel and medical education.

	Years Ended December 31,	
	2025	**2024**
Direct research and development expenses:		
Manufacturing process development	$ —	$ 892
Preclinical trials	14	1,074
Clinical development	3	405
Regulatory	61	285
Internal staffing, overhead and other	7	8,777
Total research & development	$ 85	$ 11,433

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive and finance functions. Other general and administrative expenses include facility costs, insurance, investor relations expenses, professional fees for legal, patent review, consulting, and accounting/audit services. We anticipate that our general and administrative expenses during 2026 will decrease slightly compared to expenses incurred during 2025 as a result of cost-cutting measures implemented to conserve cash.

Asset Impairment Charges

During the fourth quarter of 2024, we identified impairment indicators for certain long-lived assets, primarily due to the terminated partnership negotiations for the future development and commercialization of MAT2203 and the subsequent cost-cutting measures. We remeasured the fair value of the Company's long-lived assets and recognized non-cash impairment charges of $4,431, $1,336 of which related to goodwill, $757 related to IPR&D and $2,338 related to other assets. These amounts are reflected as impairment charges in the consolidated statements of operations and comprehensive loss for 2024. We did not record an asset impairment charge in 2025.

Change in fair value of warrant liability

In a series of transactions on February 13, 2025, and April 8, 2025, we closed a private placement investment with certain investors in which the investors received shares of Preferred Stock and 2025 Warrants. The 2025 Warrants were initially classified as a liability upon each issuance date with the fair value estimated using a Monte Carlo simulation model. On June 26, 2025, we entered into a warrant amendment with the February 2025 Investors. Under such amendment, the terms of the 2025 Warrants were amended enabling for reclassification of the 2025 Warrants to equity.

Other (Expense)/Income, net

Other (expense)/income, net for the year ended December 31, 2025 and 2024 were ($261) and $262, respectively. Other (expense)/income, net decreased compared to the prior period primarily due to recording issuance costs of $251 in connection with the transactions contemplated by the February 2025 Agreement.

Application of Critical Accounting Policies and Accounting Estimates

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

For a description of our significant accounting policies, refer to "Note 3 – *Summary of Significant Accounting Policies*." Of these policies, the following are considered critical to an understanding of our Audited Consolidated Financial Statements as they require the application of the most difficult, subjective and complex judgments: (i) Other intangible assets, and (ii) Warrants.

Recent Accounting Pronouncements

Refer to "Note 3 – *Summary of Significant Accounting Policies"* in the accompanying notes to the consolidated financial statements for a discussion of recently adopted and issued accounting pronouncements and their impact or expected impact on our financial positions and results of operations.

Current Operating Trends

Our current R&D efforts are focused on advancing our lead LNC product candidate, MAT2203. Our R&D expenses consist of fees paid to consultants for work related to clinical trial design and regulatory activities, fees paid to providers for conducting various clinical studies as well as for the analysis of the results of such studies, and for other medical research addressing the potential efficacy and safety of our drugs. We believe that significant investment in product development is a competitive necessity, and we are seeking a partner to assist us in continuing to make these investments to be in a position to realize the potential of our product candidates and proprietary technologies.

We expect that most of our R&D expenses in the near-term, if any, will be incurred in support of MAT2203 and positioning that drug for a partnership with a well-funded and experienced third party biotech or pharmaceutical company.

Financial impact of events beyond our control

Our financial condition and results of operations may be impacted by factors we may not be able to control, such as pandemics, global supply chain disruptions, global trade disputes, tariffs and/or political instability. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks. Additionally, rising inflation rates may affect us by increasing operating expenses.

The Company's financial results for the years ended December 31, 2025 and 2024 were not significantly impacted by factors beyond our control, such as those described above. However, the Company cannot predict the impact of any of these factors on future results or the Company's ability to raise capital due to a variety of factors, including but not limited to the continued good health of Company employees, the ability of service providers and suppliers to continue to operate and deliver, the ability of the Company to maintain operations, and any government and/or public actions taken in response to these factors.

Results of Operations

Years Ended December 31, 2025 and 2024

The following table summarizes our operating results for the years ended December 31, 2025 and 2024:

	Years Ended December 31,	
	2025	**2024**
Expenses:		
Research and development	$ 85	$ 11,433
General and administrative	6,875	8,729
Impairment charges of goodwill and other intangible assets	—	2,093
Impairment charges of other assets	—	2,338
Operating Expenses	$ 6,960	$ 24,593

Research and Development expenses. R&D expense for the years ended December 31, 2025 and 2024 was $85 and $11,433, respectively. The decrease of $11,348 was due to a decrease of $2,584 of clinical trial expenses, primarily related to the pause of our MAT2203 development program, $8,764 decrease in total compensation expenses related to the reduction in force.

General and Administrative expenses. G&A expense for the years ended December 31, 2025 and 2024 was $6,875 and $8,729, respectively. The decrease of $1,854 over the prior year was primarily attributable to lower stock-based compensation expense and decreased headcount.

Impairment charges. For the year ended December 31, 2025, we did not record impairment charges. For the year ended December 31, 2024, we recorded $4,431 of impairment charges, $1,336 of which related to goodwill, $757 related to IPR&D and $2,338 related to other long-lived assets, primarily due to the terminated partnership negotiations for the future development and commercialization of MAT2203 and subsequent cost-cutting measures.

Liquidity and capital resources

Sources of Liquidity

We have funded our operations since inception primarily through private placements of our preferred stock and our common stock and common stock warrants. As of December 31, 2025, we have raised a total of $170,336 in gross proceeds and $156,594, net proceeds, from sales of our equity securities since inception in 2013.

As of December 31, 2025, we had cash and cash equivalents, excluding restricted cash, totaling $3,999.

2025 Private Placement

On February 13, 2025, we entered into the February 2025 Agreement, pursuant to which we agreed to issue and sell, in a private placement, an aggregate of 3,300 shares of Preferred Stock, initially convertible into up to 5,631,404 shares of our common stock, with a stated value of $1,000 per share, and 2025 Warrants to purchase up to an aggregate of 200% of the shares of common stock into which the shares of Preferred Stock are initially convertible, or 11,262,808 shares of common stock, for an offering price of $1,000 per share of Preferred Stock and accompanying 2025 Warrants.

Pursuant to the February 2025 Agreement, on February 13, 2025, we issued and sold in an initial closing 1,650 shares of Preferred Stock, initially convertible into up to 2,815,702 shares of common stock, and accompanying 2025 Warrants, initially exercisable for up to 5,631,404 shares of common stock, for gross proceeds of $1.65 million. On April 4, 2025, we obtained stockholder approval for the issuance of the Preferred Stock and 2025 Warrants, as required by the rules and regulations of NYSE American, including Section 713 of the NYSE American Company Guide, and issued and sold, in a second closing, an additional 1,650 shares of Preferred Stock, initially convertible into up to 2,815,702 shares of common stock, and accompanying 2025 Warrants, initially exercisable for up to 5,631,404 shares of common stock, for gross proceeds of $1.65 million.

2024 Registered Direct Offering

On April 5, 2024, the Company closed a registered direct offering of 666,667 shares of its common stock and warrants to purchase up to an aggregate of 666,667 additional shares of common stock, at a combined purchase price of $15.00 per share and accompanying warrant. The Company generated gross proceeds of approximately $10,000 and net proceeds of approximately $9,179, after deducting underwriting discounts and commissions and other offering expenses.

2020 At-The-Market Sales Agreement

On July 2, 2020, we entered into an At-The-Market Sales Agreement (the "Sales Agreement") with BTIG, LLC ("BTIG"), pursuant to which we may offer and sell, from time to time, through BTIG, as sales agent and/or principal, shares of our common stock having an aggregate offering price of up to $50 million, subject to certain limitations on the amount of common stock that may be offered and sold by us set forth in the Sales Agreement. BTIG will be paid a 3% commission on the gross proceeds from each sale. We may terminate the Sales Agreement at any time; BTIG may terminate the Sales Agreement in certain limited circumstances. During 2024, we sold 218,000 shares of our common stock under the Sales Agreement generating gross proceeds of $56 thousand. We did not sell any shares under the Sales Agreement during 2025. At December 31, 2025, the Sales Agreement's available capacity was $44,191. However, such capacity is limited by the restrictions imposed by General Instruction I.B.6 to Form S-3, which limits the amount we can raise through primary public offerings of securities in any twelve-month period using Form S-3 to an aggregate of one-third of our public float.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Years Ended December 31	
	2025	**2024**
Cash used in operating activities	$ (7,011)	$ (15,885)
Cash provided by investing activities	335	9,208
Cash provided by financing activities	3,391	9,174
Net (decrease)/increase in cash and cash equivalents and restricted cash	$ (3,285)	$ 2,497

Operating Activities

Net cash used in operating activities for the year ended December 31, 2025 was $7,011, compared to $15,885 in the prior year. Net losses of $10,345 and $24,251 for the years ended December 31, 2025 and 2024, respectively, were partially offset by working capital adjustments due to the timing of receipts and payments in the ordinary course of business, adjustments for non-cash stock based compensation expense, impairment charges and change in fair value of the warrant liability.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2025 was $335, compared to $9,208 of net cash provided by investing activities for the year ended December 31, 2024. The decrease in cash provided by investing activities was primarily due to a year over year decrease of $9,208 in net maturities of marketable debt securities, partially offset by $335 from the net sales of assets in 2025.

Financing Activities

Net cash provided by financing activities was $3,391 and $9,174 for the years ended December 31, 2025 and 2024, respectively. The decrease in cash provided by financing activities is primarily due to the net proceeds from the sale of our Preferred Stock and 2025 Warrants of $3,271 and the exercise of warrants $129 during the year-ending December 31, 2025, being less than the net proceeds from the registered direct sale of our common stock of $9,179 during the year-ended December 31, 2024.

Going Concern

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future.

We do not believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditures requirements beyond the next twelve months from the filing date of this Annual Report. As a result, substantial doubt exists about the Company's ability to continue as a going concern.

Until such time, if ever, that we can generate revenues sufficient to achieve profitability, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, government or other third-party funding, collaborations, and licensing arrangements. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interest of our stockholders may be materially diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights of our common stockholders. Debt financing and preferred equity financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends, that could adversely impact our ability to conduct our business. Securing additional financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to secure one or more partners to monetize the value of MAT2203 or future product candidates

If we raise additional funds through collaborations, strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

Our financial condition and results of operations may also be impacted by other factors we may not be able to control, such as global supply chain disruptions, global trade disputes and/or political instability. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks. Additionally, rising inflation rates may affect us by increasing operating expenses, such as employee-related costs and other expenses, negatively impacting our future results of operations.

Contractual Obligations and Commitments

Refer to Note 11 – *"Commitments"* in the accompanying notes to the consolidated financial statements for a discussion of the Company's contractual obligations and commitments.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

RECENT ACCOUNTING PRONOUNCEMENTS

Refer to Note 3 - "*Summary of Significant Accounting Policies*," in the accompanying notes to the consolidated financial statements for a discussion of recent accounting pronouncements.

Item 7A. Quantitative And Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements And Supplementary Data

Our financial statements, together with the independent registered public accounting firm report thereon, are incorporated by reference from the applicable information set forth in Part IV Item 15, "Exhibits, Financial Statement Schedules" of this Annual Report on Form 10-K which includes the report of EisnerAmper LLP (PCAOB ID: 274).

Item 9. Changes In And Disagreements With Accountants On Accounting And Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure Controls and Procedures:

As of December 31, 2025, under the supervision and with the participation of our principal executive officer and principal financial officer we have evaluated, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon such evaluation, our principal executive and financial officers have concluded that, as of December 31, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we filed or submitted under the Exchange Act is recorded, processed, summarized and reported within time periods specified by the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to our management, including principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting:

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. Our control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, any projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting based on criteria established in "Internal Control—Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has concluded as of December 31, 2025, our internal control over financial reporting was effective.

During 2024, we did not maintain an effective internal control environment to ensure the processing of and reporting of non-routine transactions are complete, accurate and timely. Specifically, we did not have the accounting resources necessary to ensure the timely preparation and review of the Company's indefinite-lived assets impairment assessment. During 2025, the Company engaged third party financial resources to assist in its evaluation of its indefinite-lived assets for impairment. Based on these additional resources, the Company has concluded that it has remediated the material weaknesses that existed for the year ended December 31, 2024.

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

Changes in Internal Control Over Financial Reporting:

Except for changes being implemented by the Company to address the material weakness identified above, there was no change in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") that occurred during the quarter ended December 31, 2025 covered by this report that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information

None of the Company's directors and officers adopted, modified, or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the Company's fiscal quarter ended December 31, 2025 (each as defined in Item 408 of Regulation S-K under the Exchange Act).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers And Corporate Governance

All directors hold office for one-year terms until the election and qualification of their successors. Officers are appointed by our Board and serve at the discretion of the Board, subject to applicable employment agreements. The following table sets forth information regarding our executive officers and the members of our Board.

Name	Age	Position(s)
Jerome D. Jabbour	51	Chairman, Chief Executive Officer, President and Interim Chief Financial Officer
Evelyn D'An	64	Director
Keith Murphy	55	Director
Edward Neugeboren	58	Director
Robin L. Smith	65	Director

Management

Jerome D. Jabbour, JD was appointed Chief Executive Officer in March 2018 and was named Chairman in March 2025. He has served as our President since March 2016. Prior to that he served as our Executive Vice President, Chief Business Officer, General Counsel and Secretary since October 2013 and as one of our directors from April 2012 until November 2013. Mr. Jabbour is also a Co-founder of Matinas BioPharma. Jabbour has also served on the board of directors of Indaptus Therapeutics, Inc. (Nasdaq: INDP), a clinical stage biotechnology company dedicated to pioneering innovative cancer and viral infection treatments since February 2026. Prior to joining our management team, he was the Executive Vice President and General Counsel of MediMedia USA, or MediMedia, from 2012 to October 2013, a privately held diversified healthcare services company. Prior to MediMedia, he was the Senior Vice President, Head of Global Legal Affairs of Wockhardt Limited (2008-2012), a global pharmaceutical and biotechnology company, and Senior Counsel and Assistant Secretary at Reliant (2004-2008). Earlier in his career, he held positions as Commercial Counsel at Alpharma, Inc. (2003-2004) and as a Corporate Associate at Lowenstein Sandler LLP (1999-2003). Mr. Jabbour earned his J.D. from Seton Hall University School of Law in New Jersey and a B.A. in Psychology from Loyola University in Baltimore.

Directors

Jerome D. Jabbour. See description under "Management."

Evelyn D'An Ms. D'An has served on the Board since February 2025. She is an experienced board director and financial leader with extensive corporate governance, financial oversight, and accounting experience with a range of companies She is President of D'An Financial Services, a strategic consulting firm she established in 2004 and has been serving on corporate boards since 2006. From 1998 through 2004, Ms. D'An served as partner of Ernst & Young, an accounting and professional services firm, where she spent 18 years serving clients in retail, consumer products, technology, financial services, media and other sectors. Ms. D'An serves on the board of directors of Zoomcar Holdings, Inc., a publicly-traded car sharing platform company (NASDAQ: ZCAR), where she has served since April 2023, GHD Group Pty Ltd., a privately-held technical professional services firm, where she has served since March 2020, and Backblaze, Inc., a publicly-traded open cloud storage platform (NASDAQ: BLZE), where she has served since August 2021. Ms. D'An is the chair of the audit committee of all three companies, a member of the compensation committee of Backblaze, Inc. and Zoomcar Holdings, Inc. and a member of the nominating committee of GHD Group Pty Ltd. Ms. D'An served on the board of directors of Renovaro Inc. (NASDAQ: REND) (formerly Enochian BioSciences Inc.) from April 2018 through June 2021, where she was a member of the audit committee and the nominating committee. Ms. D'An graduated with a B.S. in Accounting from the State University at Albany. We believe Ms. D'An is qualified to serve on our Board due to her extensive expertise and experience in a variety of public companies and because of her demonstrated financial expertise and experience serving on boards of directors and as Chair of audit committees.

Keith Murphy has served on the Board since March 2025 and is currently a Director and Executive Chairman of VivoSim Labs, Inc. (Nasdaq: VIVS) (formerly Organovo Holdings, Inc. (Nasdaq: ONVO). Mr. Murphy re-joined the VivoSim board of directors in July 2020 and has served as its Executive Chairman since September 2020. Mr. Murphy is also the Chief Executive Officer and Chairman of Viscient Bio ("Viscient"), a private company that he founded in 2017 that is focused on drug discovery and development utilizing 3D tissue technology and multi-omics (genomics, transcriptomics, metabolomics). Mr. Murphy previously served as the President and Chief Executive Officer of Organovo from February 2012 through April 2017, and as Chairman from February 2012 through August 2017. Mr. Murphy also previously served as President, Chief Executive Officer, and Chairman of Organovo, Inc., Organovo's primary operating company prior to its going-public transaction, from August 2007 to February 2012. Prior to founding Organovo, Mr. Murphy served in various roles at Amgen, Inc. from August 1997 to July 2007 including as Global Operations Leader for the osteoporosis/bone cancer drug Prolia/Xgeva (denosumab). Prior to joining Amgen, Mr. Murphy served at Alkermes, Inc., a biotechnology company, from July 1993 to July 1997, where he played a role on the development team for their first approved product, Nutropin (hGH) Depot. Mr. Murphy served as a member of the board of directors of Kintara Therapeutics, Inc. from August 2020 to February 2022, and served on its compensation committee and nominating and corporate governance committee. He holds a B.S. in Chemical Engineering from the Massachusetts Institute of Technology (MIT) and is an alumnus of the UCLA Anderson School of Management. We believe Mr. Murphy's previous experience in the biotechnology field, especially in developing novel products, his experience and expertise in product development opportunities and strategy, and his educational experience qualify him to be a member of our board of directors.

Edward Neugeboren. Mr. Neugeboren has served on the Board since March 2025. Mr. Neugeboren is Founder and Managing Partner of QuadView Healthcare Advisors LLC, a healthcare investment banking advisory and business development firm. From 2015 to 2025, Mr. Neugeboren was Chief Strategy Officer of Cronus Pharma, LLC, a fully integrated R&D, manufacturing and sales & marketing animal health pharmaceutical company. Mr. Neugeboren led commercial operations, strategic planning and acquisitions and was also responsible for developing and executing overall corporate strategy as well as corporate and portfolio acquisitions and licensing. Mr. Neugeboren currently serves on the Board of Directors of Grace Therapeutics (Nasdaq: GRCE), a late-stage biopharmaceutical company addressing rare and orphan diseases where he is a member of the Audit, Compensation and Nominating & Governance Committees. He served as an Advisor to Healthcare Capital Corp., Inc., and its merger with Alpha Tau Medical Ltd., a NASD listed radiopharmaceutical company. Previously, Mr. Neugeboren was the Chief Strategy Officer for Cronus' parent pharmaceutical group comprised of Rising Pharma Holdings, Inc., a generic pharmaceutical company and Casper Pharma, LLC, a specialty pharmaceutical company. Mr. Neugeboren was previously a Managing Director of Ledgemont Capital Group, LLC, an investment banking firm providing strategic and financial advisory services to emerging healthcare and technology companies. Mr. Neugeboren also served as Chief Administrative Officer and Director of Equity Research Operations at Lehman Brothers and prior, he was Deputy Director of Equity Research at UBS, formerly Warburg Dillon Read and Director of Equity Research Operations. Mr. Neugeboren began his career in 1992 as an equity research analyst covering the Specialty Pharmaceuticals industry, including Generic Drugs and Drug Delivery at Dillon, Read & Co., Kidder, Peabody & Co., and Furman, Selz, Inc. He was a member of the top ranked Greenwich Associates Mid-Cap Pharmaceuticals Team. Mr. Neugeboren has graduated with a BA in Economics from Union College. He holds Series 24, 7 and 63 FINRA security licenses. We believe Mr. Neugeboren is qualified to serve as a director due to his extensive experience in drug development, business management and knowledge of the pharmaceutical, health care and securities industries.

Robin L. Smith, MD, MBA. Dr. Smith has served on the Board since February 2025. Dr. Smith has been a Managing Partner of BRM Holdings, a privately-held strategic and investment advisory firm, since 2015. She also founded two privately-held biotechnology companies, Spiritus Therapeutics and Exotropin LLC. Dr Smith also served as an independent director of the Western Acquisition Ventures Corp., a special purpose acquisition company, from 2022-2023, where she served on the audit and compensation committees. From 2006 until 2015, Dr. Smith was chairman and chief executive officer of Lisata Therapeutics, Inc., a publicly-traded stem-cell bank (NASDAQ: LSTA) (formerly Neostem, Inc.). From October 2019 to December 2023, Dr. Smith served on the board of directors of Celularity Inc, a publicly-traded cellular and regenerative medicine company (NASDAQ: CELU). From February 2020 to May 2022, Dr. Smith served on the board of directors of ServiceSource International, Inc., a publicly-traded customer journey experience company (NASDAQ: SREV) that was acquired in 2022 by Concentrix Corporation, and served on its nominating and governance committee. From December 2019 to November 2021, Dr. Smith served on the board of directors of Sorrento Therapeutics, a former publicly-traded clinical and commercial stage biopharmaceutical company (NASDAQ: SRNE). From February 2019 to May 2020, Dr. Smith served on the board of directors of Seelos Therapeutics, a publicly-traded clinical-stage biopharmaceutical company (NASDAQ: SEEL), and served on its audit and compensation committees. Prior to 2019, Dr. Smith served on the boards of multiple publicly-traded biopharmaceutical companies. Dr. Smith received her B.A. from Yale University and her M.D. from the Yale School of Medicine. She holds an M.B.A. from the Wharton School of Business, completed the Stanford University Directors Program, and received an honorary Doctor of Science degree from Thomas Jefferson Medical College. We believe Dr. Smith is qualified to serve on our board of directors because of her extensive management experience in the pharmaceutical industry and her clinical, drug development and regulatory experience.

There are no family relationships among any of our directors or executive officers.

Director Independence

Based on information requested from and provided by each of our directors, the Board has determined that Messrs. Keith Murphy and Edward Neugeboren and Mses. Evelyn D'An and Robin L. Smith are "independent directors" as such term is defined in the rules of the NYSE American corporate governance requirements and Rule 10A-3 promulgated under the Exchange Act of 1934. Mr. Jabbour is not an independent director under these rules because he is an executive officers of the Company. Each of Messrs. Herbert Conrad, Eric Ende, James Scibetta and Matthew Wikler and Ms. Natasha Giordano, who served as directors during 2025 and resigned in 2025, were determined to be "independent directors."

Board Committees

Our Board has three standing committees — an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee.

Audit Committee. The Audit Committee oversees and monitors our financial reporting process and internal control system, reviews and evaluates the audit performed by our registered independent public accountants and reports to the Board any substantive issues found during the audit. The Audit Committee is directly responsible for the appointment, compensation and oversight of the work of our registered independent public accountants. The Audit Committee reviews and approves all transactions with affiliated parties. Evelyn D'An, Robin L. Smith and Edward Neugeboren currently serve as members of the Audit Committee, with Ms. D'An serving as its chair. All current and past members of the Audit Committee have been determined to be financially literate and are considered independent directors as defined under the NYSE American's listing standards and applicable SEC rules and regulations. Ms. D'An qualifies as an audit committee "financial expert" as that term is defined by SEC regulations. Our Board has adopted an Audit Committee Charter, which is available for viewing at *www.matinasbiopharma.com*.

Compensation Committee. The Compensation Committee provides advice and makes recommendations to the Board in the areas of employee salaries, benefit programs and director compensation. The Compensation Committee also reviews the compensation of our executive officers, including our chief executive officer, and makes recommendations in that regard to the Board as a whole. Edward Neugeboren and Keith Murphy currently serve as members of the Compensation Committee, with Mr. Neugeboren serving as its chair. All current and past members of the Compensation Committee are considered independent directors as defined under the NYSE American's listing standards. Our Board has adopted a Compensation Committee Charter, which is available for viewing at *www.matinasbiopharma.com*.

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee nominates individuals to be elected to the full Board by our stockholders. The Nominating and Corporate Governance Committee considers recommendations from stockholders if submitted in a timely manner in accordance with the procedures set forth in our Bylaws and applies the same criteria to all persons being considered. Keith Murphy, Evelyn D'An and Robin L. Smith currently serve as members of the Nominating and Corporate Governance Committee, with Mr. Murphy serving as its chair. All current and past members of the Nominating and Corporate Governance Committee are considered independent directors as defined under the NYSE American's listing standards. Our Board has adopted a Nominating and Corporate Governance Charter, which is available for viewing at *www.matinasbiopharma.com*.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers, and employees, including our principal executive officer, principal financial and accounting officer, or persons performing similar functions. A copy of the code is posted on the corporate governance section of our website, which is located at www.matinasbiopharma.com. If we make any substantive amendments to, or grant waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website.

Insider Trading Policy

We have adopted an insider trading policy (the "Trading Policy") that is designed to promote compliance with federal securities laws, rules and regulations, as well as the rules and regulations of the NYSE American. The Trading Policy provides the Company's standards on trading and causing the trading of our securities or securities of other publicly traded companies while in possession of confidential information. It prohibits trading in certain circumstances and applies to all of our directors, officers and employees as well as independent contractors or consultants who have access to material nonpublic information of Matinas. Additionally, our Trading Policy imposes special additional trading restrictions applicable to all of our directors and executive officers. A copy of the Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report.

Item 11. Executive Compensation

Summary Compensation Table – 2025

Our named executive officers for the year ended December 31, 2025 were Jerrome D. Jabbour, Chief Executive Officer, President and Interim Chief Financial Officer; Keith Kucinski, former Chief Financial Officer; and James J. Ferguson, Former Chief Medical Officer.

The following table sets forth information regarding the compensation awarded to, earned by or paid to the named executive officers for the years ended December 31, 2025 and December 31, 2024.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($) (1)	All Other Compensation ($)	Total ($)
Jerome D. Jabbour	2025	598,000	—	57,044	—	655,044
Chief Executive Officer, President and Interim Chief Financial Officer	2024	598,000	—	—	—	598,000
Keith Kucinski	2025	416,000	—	—	—	416,000
Former Chief Financial Officer	2024	416,000	168,160	—	—	584,160
James J. Ferguson	2025	390,000	—	—	—	390,000
Former Chief Medical Officer	2024	468,000	121,680	—	—	589,680

(1) Amounts reflect the grant date fair value of option awards granted in 2025 and 2024 in accordance with Accounting Standards Codification Topic 718. These amounts do not correspond to the actual value that will be recognized by the named executive officers.

Narrative Disclosure to Summary Compensation Table

Employment Agreements with Our Named Executive Officers

Jabbour

On March 22, 2018, we entered into an employment agreement with Mr. Jabbour, as subsequently amended on March 3, 2023, April 30, 2025 and December 12, 2025. Under the terms of Mr. Jabbour's employment agreement, Mr. Jabbour received a signing bonus of $84,000 and a base salary of $350,000 per year. Mr. Jabbour's current salary is $598,000. In addition, Mr. Jabbour is eligible to receive an annual bonus, which is targeted at 50% of his base salary but which may be adjusted by our Compensation Committee based on his individual performance and our performance as a whole. Mr. Jabbour is also eligible to receive option grants at the discretion of our Compensation Committee. In addition, Mr. Jabbour is eligible for a cash retention bonus in the event of a change in control of the Company, as such term is defined in the employment agreement, on or before June 30, 2026, equal to the greater of (i) Mr. Jabbour's target annual bonus for the fiscal year in which the change in control occurs, or (ii) $299,000 if Mr. Jabbour remains employed with the Company through the date that of such change in control. Two-thirds of the retention bonus will be paid upon the Company's execution of a definitive agreement that, if consummated, would result in a change in control, and the remaining one-third would be paid immediately prior to the closing of such change in control, so long as for each payment Mr. Jabbour has not resigned without good reason nor been terminated by the Company for cause (each as defined in the employment agreement). If Mr. Jabbour resigns for good reason or is terminated by the Company other than for Cause, he will be entitled to the retention bonus (or any remaining portion thereof), payable within ten days following such termination and in any event not later than immediately prior to the closing of a change in control. Mr. Jabbour received $150,000 of his 2025 annual bonus in January 2026 with the remaining $150,000 to be paid upon the signing of a definitive agreement related to MAT2203. If we terminate Mr. Jabbour's employment without cause or Mr. Jabbour resigns with good reason (absent a change of control), we are required to pay him severance of up to twelve months of his base salary plus COBRA benefits for twelve months, and his target annual bonus for the year pro rated to the date of termination. In addition, the vesting of 50% of his outstanding options issued prior to December 31, 2021 will be accelerated in full upon such termination and Mr. Jabbour will be provided with an extension through two years after the separation date of the exercise period for his vested stock options. If we terminate Mr. Jabbour's employment without cause during the 24-month period immediately following a change of control or Mr. Jabbour resigns with good reason during the 24-month period immediately following a change of control, we are required to pay him severance of 18 months of his base salary and 1.5 times his target annual bonus plus 18 months of COBRA benefits. In addition, his outstanding options will be vested in full and Mr. Jabbour will be provided with an extension through two years after the separation date of the exercise period for his vested stock options. Mr. Jabbour is also subject to a customary non-disclosure agreement, pursuant to which Mr. Jabbour has agreed to be subject to a non-compete during the term of his employment and for a period of eighteen months following termination of his employment.

Kucinski

On December 31, 2018, we entered into an employment agreement with Mr. Kucinski which was effective as of January 2, 2019, as subsequently amended on March 3, 2023 and April 30, 2025. Under the terms of Mr. Kucinski's employment agreement, Mr. Kucinski's base salary was $250,000 per year, and was $416,000 at the time of his resignation. In addition, Mr. Kucinski was eligible to receive an annual bonus, which is targeted at 40% of his base salary but which may be adjusted by our Compensation Committee based on his individual performance and our performance as a whole. Mr. Kucinski was also eligible to receive option grants at the discretion of our Compensation Committee. In addition, Mr. Kucinski was entitled cash retention bonus in the event of a change in control of the Company, as such term is defined in the employment agreement, on or before March 31, 2026, equal to the greater of (i) Mr. Kucinski's target annual bonus for the fiscal year in which the change in control occurs, or (ii) $166,400 if Mr. Kucinski remained employed with the Company through the date that of such change in control. If we terminated Mr. Kucinski's employment without cause or Mr. Kucinski resigned with good reason, we would have been required to pay him severance of up to twelve months of his base salary plus benefits. In addition, the vesting of 50% of his outstanding options issued prior to December 31, 2021 would have been accelerated in full upon such termination. If we terminated Mr. Kucinski's employment without cause during the 12-month period immediately following a change of control or Kucinski resigned with good reason during the 12-month period immediately following a change of control, we would have been required to pay him severance of 12 months of his base salary and his target annual bonus plus 12 months of COBRA benefits. In addition, his outstanding options would have been vested in full. Mr. Kucinski was also subject to a customary non-disclosure agreement, pursuant to which Mr. Kucinski has agreed to be subject to a non-compete during the term of her employment and for a period of eighteen months following termination of his employment.

On November 18, 2025, Mr. Kucinski resigned from his position as Chief Financial Officer, effective January 17, 2026. Mr. Kucinski was not entitled to a retention bonus or severance under his employment agreement.

Ferguson

On February 22, 2019, we entered into an employment agreement with Mr. Ferguson which was effective as of February 25, 2019, as subsequently amended on March 3, 2023. Mr. Ferguson's employment with the Company was terminated without cause in October 2024, and Mr. Ferguson was eligible to receive the severance benefits described below for a termination by us without cause. Under the terms of Mr. Ferguson's employment agreement, Mr. Ferguson's base salary was $375,000 per year, and was $468,000 at the time of his termination. Mr. Ferguson was eligible to receive an annual bonus, targeted at 40% of his base salary and subject to adjustment by our Compensation Committee based on his individual performance and our performance as a whole. Mr. Ferguson was also eligible to receive option grants at the discretion of our Compensation Committee. Under the terms of his employment agreement, if Mr. Ferguson's employment was terminated by us without cause or by Mr. Ferguson with good reason, we are required to pay him severance of up to twelve months of his base salary plus benefits. In addition, the vesting of 50% of his outstanding options issued prior to December 31, 2021 was accelerated in full upon such termination. Under the terms of his employment agreement, if we terminated Mr. Ferguson's employment without cause during the 12-month period immediately following a change of control or Mr. Ferguson resigned with good reason during such period, we were required to pay him severance of 12 months of his base salary and his target annual bonus plus 12 months of COBRA benefits. In addition, his outstanding options would be vested in full. Mr. Ferguson is also subject to a customary non-disclosure agreement, pursuant to which Mr. Ferguson has agreed to be subject to a non-compete during the term of his employment and for a period of eighteen months following termination of his employment. All severance payments have been made to Mr. Ferguson as of October 31, 2025.

Outstanding Equity Awards at Fiscal Year-End Table – 2025

The following table summarizes, for each of the named executive officers, the number of shares of common stock underlying outstanding stock options held as of December 31, 2025.

	Option Awards			
Name	**Number of securities underlying unexercised options (#) exercisable**	**Number of securities underlying unexercised options (#) unexercisable**	**Option exercise price ($)**	**Option expiration date**
Jerome D. Jabbour	-	70,100	$ 0.59	Apr 29, 2035
	36,457	33,544	$ 12.35	Dec 14, 2033
	30,653	9,114	$ 26.50	Dec 19, 2032
	33,163	-	$ 46.00	Dec 13, 2031
	32,001	-	$ 68.00	Dec 31, 2030
	20,001	-	$ 113.50	Dec 31, 2029
	15,001	-	$ 54.00	Feb 10, 2029
	20,000	-	$ 49.02	Mar 21, 2028
	8,001	-	$ 166.00	Feb 20, 2027
	7,001	-	$ 21.50	Feb 4, 2026
Keith Kucinski	10,417	9,584	$ 12.35	Dec 14, 2033
	9,636	2,865	$ 26.50	Dec 19, 2032
	10,001	-	$ 46.00	Dec 13, 2031
	10,001	-	$ 68.00	Dec 31, 2030
	7,001	-	$ 113.50	Dec 31, 2029
	5,501	-	$ 54.00	Feb 10, 2029
	5,000	-	$ 30.50	Jan 1, 2029

2013 Equity Compensation Plan

General

2013 Plan

On August 2, 2013, our Board adopted the 2013 Equity Compensation Plan (as amended to date, the "2013 Plan") pursuant to the terms described herein. The 2013 Plan was approved by the stockholders on August 7, 2013. Effective May 8, 2014, upon the approval of our Board and our stockholders, we amended and restated the 2013 Plan, primarily to include "evergreen" provisions, which provided that the number of shares of common stock available for issuance under the 2013 Plan is subject to an automatic annual increase on January 1 of each year beginning in 2015; to amend the definition of "fair market value"; and to increase the limits on awards under the Plan. The 2013 Plan, which expired on May 7, 2024, provided for the granting of incentive stock options, nonqualified stock options, restricted stock units, performance units, and stock purchase rights. No additional awards will be made under the 2013 Plan.

2025 Plan

On April 30, 2025, the Board, subject to the approval of our stockholders, which was received on June 23, 2025, adopted a new 2025 Equity Incentive Plan (the "2025 Plan") to succeed the 2013 Plan. The general purpose of the 2025 Plan is to provide an incentive to our employees, directors, consultants and advisors by enabling them to share in the future growth of our business. The term of the 2025 Plan is 10 years.

As of December 31, 2025, there were 116,500 options outstanding and 646,548 remaining shares available for grant under the 2025 Plan, and there are 434,334 awards, including both restricted stock grants and option grants, issued and exercised under the 2013 Plan.

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

We do not have any formal policy that requires us to grant, or avoid granting, stock options at particular times. Consistent with our annual compensation cycle, if options are to be granted, the Compensation Committee generally seeks to grant annual stock option awards in connection with our conducting and completing such annual review, which typically occurs in approximately the fourth quarter of each year. Equity awards were awarded to our non-employee directors pursuant to our 2013 Plan and 2025 Plan. The timing of any stock option grants in connection with new hires, promotions, or other non-routine grants may be tied to the event giving rise to the award (such as an employee's commencement of employment or promotion effective date), and in other cases such grants may be awarded at the same time with other annual grants. As a result, in all cases, the timing of grants of stock options occurs independent of the release of any material nonpublic information, and we do not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

As required by SEC rules, the following table presents information regarding awards issued to our Named Executive Officers in fiscal year 2025 during any period beginning four business days before the filing of a periodic report or current report disclosing material non-public information and ending one business day after the filing or furnishing of such report with the SEC.

Name	Grant Date	Number of Securities Underlying the Award	Exercise Price of the Award	Grant Date Fair Value of the Award [1]	Percentage Change in the Closing Market Price of the Securities Underlying the Award Between the Trading Day Ending Immediately Prior to the Disclosure of Material Nonpublic Information and the Trading Day Beginning Immediately Following the Disclosure of Material Nonpublic Information
Jerome D. Jabbour	4/30/2025	70,100	$ 0.59	$ 57,044	4.92%

(1) Amount reflects the grant date fair value of option awards granted in accordance with Accounting Standards Codification Topic 718. This amount does not correspond to the actual value that will be recognized by the named executive officer.

Tax Withholding

The Company has the power and right to deduct or withhold, or require a participant to remit to the Company, the minimum statutory amount to satisfy federal, state, and local taxes, domestic or foreign, required by law or regulations to be withheld.

Director Compensation

We maintain a policy pursuant to which our non-employee directors receive annualized compensation. The policy provides for the following compensation amounts payable in cash, or upon election by such non-employee director, in shares of unrestricted common stock: (i) each non-employee director is entitled to receive an annual fee of $50,000; (ii) the chairman of the board is entitled to receive an additional annual fee of $25,000; (iii) the vice chair, if one is appointed, is entitled to receive an additional annual fee of $20,000; (iv) the chair of our audit committee is entitled to receive an annual fee of $15,000 and other members of our audit committee are entitled to receive $7,500; (v) the chair of our compensation committee is entitled to receive an annual fee of $10,000 and other members of our compensation committee are entitled to receive $6,000; and (vi) the chair of our nominating and corporate governance committee is entitled to receive an annual fee of $8,000 and other members are entitled to receive $4,000.

All fees under the director compensation policy are paid on a quarterly basis in arrears and no per meeting fees are paid. All fees may be paid in unrestricted shares of common stock at the election of the director. We also reimburse non-employee directors for reasonable expenses incurred in connection with attending board of director and committee meetings.

Director Compensation Table – 2025

The following table summarizes the annual compensation for our non-employee directors during 2025 and for each who resigned from our Board during 2025.

Name	Cash Compensation ($)
Herbert Conrad	6,321
Eric Ende	16,019
Natasha Giordano	12,736
James S. Scibetta	4,375
Matthew Wikler	10,889
Evelyn D'An (1)	62,867
Edward Neugeboren (1)	54,563
Keith Murphy (1)	51,733
Robin Smith (1)	54,154

(1) As of December 31, 2025, Ms. D' An, Mr. Neugeboren, Mr. Murphy and Ms. Smith each held options to purchase 11,600 shares of common stock.

Compensation Committee Interlocks and Insider Participation

The Compensation Committee of the Board is currently composed of the following two non-employee directors: Edward Neugeboren, Chair, and Keith Murphy. No member of the Compensation Committee is or was formerly an officer or an employee of the Company during the last fiscal year. In addition, no executive officer of the Company serves on the Compensation Committee or board of directors of a company for which any of the Company's directors serve as an executive officer. See Item 13.

Item 12. Security Ownership Of Certain Beneficial Owners And Management And Related Stockholder Matters.

The following table sets forth the number of shares of common stock beneficially owned as of March 16, 2026 by:

- each of our stockholders who is known by us to beneficially own 5% or more of our common stock;

- each of our executive officers;
- each of our directors; and
- all of our directors and current executive officers as a group.

Beneficial ownership is determined based on the rules and regulations of the SEC. A person has beneficial ownership of shares if such individual has the power to vote and/or dispose of shares. This power may be sole or shared and direct or indirect. Applicable percentage ownership in the following table is based on 6,406,191 shares outstanding as of March 16, 2026. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock that are subject to options or warrants held by that person and exercisable as of, or within 60 days of, March 16, 2026 are counted as outstanding. These shares, however, are not counted as outstanding for the purposes of computing the percentage ownership of any other person(s). Except as may be indicated in the footnotes to this table and pursuant to applicable community property laws, each person named in the table has sole voting and dispositive power with respect to the shares of common stock set forth opposite that person's name. Unless indicated below, the address of each individual listed below is c/o Matinas BioPharma Holdings, Inc., 1545 Route 206 South, Suite 302, Bedminster, NJ 07921.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders		
David E. Lazar (1)	545,000	8.51%
Sanitam Partners LLC (2)	687,359(3)	9.99%
Directors and Named Executive Officers		
Jerome D. Jabbour	231,157(4)	3.49%
Evelyn D'An	11,600(5)	*%
Keith Murphy	11,600(6)	*%
Edward Neugeboren	11,600(7)	*%
Robin Smith	11,600(8)	*%
Keith A. Kucinski	59,447(9)	*%
James Furgurson	-	-
Directors and Current Executive Officers as a group (5 persons)	277,557(10)	4.16%

* Less than 1%

(1) Based solely on information contained in a Schedule 13G filed on August 19, 2025. The address of David E. Lazar is 44, Tower 100, The Towers, Winston Churchill, San Francisco, Paitilla, Panama City, Panama 07196.

(2) Based on information contained in a Schedule 13D/A filed on April 10, 2025 by Sanitam Partners LLC, Adam K Stern, Platinum Point Capital, LLC, Brian Freifeld, Pembroke & Partners LLC and Robert J. Eide and other information known to the Company.

(3) Includes (i) 28,260 shares of common stock owned by Mr. Stern, (ii) 118,577 shares of common stock owned by A.K.S. Family Partners LP ("AKSLP"), (ii) 26,500 shares of common stock owned by AKS Family Foundation ("AKS"), (iii) 21,350 shares of common stock owned by Stern Aegis Ventures, LLC Defined Benefit Plan for the Benefit of Adam K Stern, (iv) 6,000 shares of common stock owned by Pavillion Capital Partners LLC, (v) 6,000 shares of common stock owned by Piper Venture Partners LLC, (vi) 1,000 shares of common stock owned by IRA Adam K Stern - Rollover IRA, (vii) 3,000 shares of common stock owned by Stern Aegis Ventures LLC 401k Plan for the Benefit of Adam K Stern and (viii) 476,672 shares of common stock issuable upon exercise of Preferred Stock and 2025 Warrants beneficially held by Sanitam Partners LLC. Platinum Point Capital, LLC and Pembroke & Partners LLC. Excludes shares of common stock underlying the Preferred Stock and 2025 Warrants, which are subject to a beneficial ownership blocker. Mr. Stern has voting and investment control of the securities held by AKSLP, AKS, Stern Aegis Ventures, LLC Defined Benefit Plan for the Benefit of Adam K Stern, Pavillion Capital Partners LLC, Piper Venture Partners LLC,. IRA Adam K Stern - Rollover IRA, Stern Aegis Ventures LLC 401k Plan for the Benefit of Adam K Stern and Sanitam Partners LLC. Brian Freifeld has voting and investment control of the securities held by Platinum Point Capital, LLC. Robert J. Eide has voting and investment control of the securities held by Pembroke & Partners LLC.

(4) Includes 221,950 shares of common stock issuable upon exercise of options that are exercisable within 60 days of March 16, 2026. Does not include 86,085 shares of common stock issuable upon exercise of options that are not exercisable within 60 days of March 16, 2026.

(5) Includes 11,600 shares of common stock issuable upon exercise of options that are exercisable within 60 days of March 13, 2026.

(6) Includes 11,600 shares of common stock issuable upon exercise of options that are exercisable within 60 days of March 16, 2026.

(7) Includes 11,600 shares of common stock issuable upon exercise of options that are exercisable within 60 days of March 16, 2026.

(8) Includes 11,600 shares of common stock issuable upon exercise of options that are exercisable within 60 days of March 16, 2026.

(9) Includes 57,557 shares of common stock issuable upon exercise of options that are exercisable within 60 days of March 16, 2026.

(10) See notes (4), (5), (6), (7) and (8).

Securities Authorized for Issuance under Equity Compensation Plans

The following table summarizes information about our equity compensation plans as of December 31, 2025.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of Outstanding Options (b)	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)(2)
Equity compensation plans approved by stockholders	457,219(1)	$ 34.76(1)	646,548
Equity compensation plans not approved by stockholders	—	—	—
Total	457,219	$ 34.76	646,548

(1) The amounts include securities issued under the 2013 Plan and the 2025 Plan.

(2) In accordance with the "evergreen" provision in our 2025 Plan, an additional 256,248 shares were automatically made available for issuance on the first trading day of 2026, which represents 4.0% of the number of shares outstanding on December 31, 2025; these shares are excluded from this calculation. The 2013 Plan expired and no further grants will be made thereunder.

Item 13. Certain Relationships, Related Transactions, And Director Independence

Certain Relationships and Related Party Transactions

The following is a description of transactions since January 1, 2024, and each currently proposed transaction in which:

- the amounts involved exceeded or will exceed the lesser of (i) $120,000 and (ii) one percent of the average of our total assets at year-end for the last two completed fiscal years; and

- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

2025 Offering

On February 13, 2025, we entered into the February 2025 Agreement with the February 2025 Investors, pursuant to which we agreed to issue and sell, in a private placement, an aggregate of 3,300 shares of Preferred Stock, initially convertible into up to 5,631,404 shares of our common stock, with a stated value of $1,000 per share, and 2025 Warrants to purchase up to an aggregate of 200% of the shares of common stock into which the shares of Preferred Stock are initially convertible, or 11,262,808 shares of common stock, for an offering price of $1,000 per share of Preferred Stock and accompanying 2025 Warrants (the "2025 Private Placement").

Pursuant to the February 2025 Agreement, on February 13, 2025, we issued and sold in an initial closing 1,650 shares of Preferred Stock, initially convertible into up to 2,815,702 shares of common stock, and accompanying 2025 Warrants, initially exercisable for up to 5,631,404 shares of common stock, for gross proceeds of $1.65 million. On April 4, 2025, we obtained stockholder approval for the issuance of the Preferred Stock and 2025 Warrants, as required by the rules and regulations of NYSE American, including Section 713 of the NYSE American Company Guide, and issued and sold, in a second closing, an additional 1,650 shares of Preferred Stock, initially convertible into up to 2,815,702 shares of common stock, and accompanying 2025 Warrants, initially exercisable for up to 5,631,404 shares of common stock, for gross proceeds of $1.65 million.

Pursuant to the February 2025 Agreement, until such time as the February 2025 Investors no longer own at least 10% of the outstanding shares of common stock on a fully diluted, as-converted basis, the February 2025 Investors will be entitled to nominate one director to serve on the Board, who is initially Dr. Smith. Until such time as the February 2025 Investors no longer own at least 30% of the outstanding shares of common stock on a fully diluted, as-converted basis, the February 2025 Investors are entitled to nominate one additional director to serve on the Board.

Sanitam Partners LLC, a current holder of more than 5% of our common stock, purchased 1,406 shares of Preferred Stock and 2025 Warrants to purchase 4,798,636 shares of common stock in the 2025 Private Placement.

Pembroke & Partners LLC, a current holder of more than 5% of our common stock, purchased 984 shares of Preferred Stock and 2025 Warrants to purchase 3,358,364 shares of common stock in the 2025 Private Placement.

Platinum Point Capital LLC, a current holder of more than 5% of our common stock, purchased 410 shares of Preferred Stock and 2025 Warrants to purchase 1,399,320 shares of common stock in the 2025 Private Placement.

HEZBAY Holdings LLC, a former holder of more than 5% of our common stock purchased 500 shares of Preferred Stock and 2025 Warrants to purchase 1,706,488 shares of common stock in the 2025 Private Placement.

April 2024 Offering

On April 2, 2024, we entered into a securities purchase agreement (the "April 2024 Purchase Agreement") with certain institutional investors, pursuant to which we issued and sold an aggregate of: (i) 666,667 shares of common stock and (ii) warrants to purchase up to 666,667 shares of common stock The offering price per share and accompanying warrant was $15.00. Pursuant to the April 2024 Purchase Agreement, affiliates of Highbridge Capital Management, LLC, a former holder of more than 5% of our common stock, purchased 466,666 shares of common stock and warrants to purchase 466,666 shares of common stock, for $7.0 million. On August 15, 2025, we entered into Warrant Exchange Agreements (the "Exchange Agreements") with affiliates of Highbridge Capital Management, LLC. Pursuant to the Exchange Agreements, on August 15, 2025, the Company issued to affiliates of Highbridge Capital Management, LLC one share of common stock for each April 2024 Warrant held, for an aggregate of 466,666 shares of common stock.

Indemnification Agreements

We entered into indemnification agreements with certain of our directors and executive officers. The indemnification agreements provide for indemnification against expenses, judgments, fines and penalties actually and reasonably incurred by an indemnitee in connection with threatened, pending or completed actions, suits or other proceedings, subject to certain limitations. The indemnification agreements also provide for the advancement of expenses in connection with a proceeding prior to a final, non-appealable judgment or other adjudication, provided that the indemnitee provides an undertaking to repay to us any amounts advanced if the indemnitee is ultimately found not to be entitled to indemnification by us. The indemnification agreement set forth procedures for making and responding to a request for indemnification or advancement of expenses, as well as dispute resolution procedures that apply to any dispute between us and an indemnitee arising under the Indemnification Agreements.

Policies and Procedures for Related Party Transactions

We have adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock, any members of the immediate family of any of the foregoing persons and any firms, corporations or other entities in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest, which we refer to collectively as related parties, are not permitted to enter into a transaction with us without the prior consent of our Board acting through the audit committee or, in certain circumstances, the chairman of the audit committee. Any request for us to enter into a transaction with a related party, in which the amount involved exceeds $100,000 and such related party would have a direct or indirect interest must first be presented to our audit committee, or in certain circumstances the chairman of our audit committee, for review, consideration and approval. In approving or rejecting any such proposal, our audit committee, or the chairman of our audit committee, is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, the extent of the benefits to us, the availability of other sources of comparable products or services and the extent of the related party's interest in the transaction.

Director Independence

Based on information requested from and provided by each of our directors, the Board has determined that Messrs. Keith Murphy and Edward Neugeboren and Mses. Evelyn D'An and Robin L. Smith are "independent directors" as such term is defined in the rules of the NYSE American corporate governance requirements and Rule 10A-3 promulgated under the Exchange Act of 1934. Mr. Jabbour is not an independent director under these rules because he is an executive officers of the Company. Each of Messrs. Herbert Conrad, Eric Ende, James Scibetta and Matthew Wikler and Ms. Natasha Giordano, who served as directors during 2025 and resigned in 2025, were determined to be "independent directors."

Item 14. Principal Accounting Fees And Services

The following table represents aggregate fees billed to the Company for the fiscal years ended December 31, 2025 and 2024, by EisnerAmper LLP, the Company's independent registered public accounting firm.

	Years Ended December 31,	
	2025	**2024**
Audit Fees	$ 279	$ 255
Audit-Related Fees	—	—
Tax Fees	—	—
Total Fees	$ 279	$ 255

Audit Fees consist of fees billed for professional services rendered for the audit of our annual financial statements, audit of internal controls over financial reporting, review of our interim consolidated financial statements, comfort and consent letters.

Audit-Related Fees consist of fees billed for professional services rendered for assurance related services that are reasonably related to the performance of the audit or review of our financial services.

Tax Fees are for tax-related services related primarily to tax consulting and tax planning.

The Audit Committee pre-approves all auditing services and any non-audit services that the independent registered public accounting firm is permitted to render under Section 10A (h) of the Exchange Act. The Audit Committee may delegate the pre-approval to one of its members, provided that if such delegation is made, the full Audit Committee must be presented at its next regularly scheduled meeting with any pre-approval decision made by that member.

Part IV

Item 15. Exhibits And Financial Statement Schedules

Exhibit No.	Description
2.1	Merger Agreement, dated July 11, 2013, by and among the Company, Matinas Merger Sub, Inc., and Matinas BioPharma, Inc. (incorporated by reference to Exhibit 2.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
2.2	Agreement and Plan of Merger with Aquarius Biotechnologies, Inc., a Delaware corporation, Saffron Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company and J. Carl Craft, as the stockholder representative (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on January 30, 2015).
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
3.2	Bylaws (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
3.3	Certificate of Amendment to Certificate of Incorporation , dated October 29, 2015 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on November 5, 2015).
3.4	Certificate of Amendment of Certificate of Incorporation, dated August 30, 2024 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2024.
3.6	Certificate of Amendment of Certificate of Incorporation, dated August 6, 2025 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 6, 2025).
3.7	Amendment No. 1 to Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on May 2, 2025).
3.8	Certificate of Designation of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on February 13, 2025).
4.1	Common Stock Specimen (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on March 31, 2017).
4.2	Description of Securities.*
4.3	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on April 5, 2024).
4.4	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on February 13, 2025).
4.5	Form of Amendment to Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2025).

10.1	Matinas BioPharma Holdings, Inc. Amended and Restated 2013 Equity Compensation Plan (incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2015). †
10.2	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.7 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014). †
10.3	Form of Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.8 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).†
10.4	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.14 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014). †
10.5	Lease, effective as of November 4, 2013, by and between the company and A-K Bedminster Associates, L.P. (incorporated by reference to Exhibit 10.17 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
10.6	Amended and Restated Exclusive License Agreement dated as of January 29, 2015, by and between Rutgers, the State University of New Jersey and Aquarius Biotechnologies, Inc. (incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2015).+
10.7	Lease Agreement, dated as of December 15, 2016, by and between CIP II/AR Bridgewater Holdings LLC, and Matinas BioPharma Holdings, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on April 28, 2017).
10.8	Employment Agreement, dated March 22, 2018, between the Company and Jerome D. Jabbour (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on March 27, 2018).†
10.9	Employment Agreement, dated January 3, 2019, between Matinas Biopharma Holdings, Inc. and Keith Kucinski (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 3, 2019).†
10.10	Employment Agreement, dated February 25, 2019, between Matinas Biopharma Holdings, Inc. and James J. Ferguson III (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 25, 2019). †
10.11	At-The-Market Sales Agreement, dated July 2, 2020, between Matinas BioPharma Holdings, Inc. and BTIG, LLC (incorporated by reference to Exhibit 1.02 to the Company's Registration Statement on Form S-3 filed with the SEC on July 2, 2020).
10.12	Therapeutic Development Award Agreement, dated November 19, 2020, between Matinas BioPharma Holdings, Inc. and the Cystic Fibrosis Foundation (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K filed with the SEC on March 29, 2021).
10.13	Amendment to Employment Agreement, dated March 3, 2023, between Matinas Biopharma Holdings, Inc. and Jerome Jabbour (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2023).†
10.14	Amendment to Employment Agreement, dated March 3, 2023, between Matinas Biopharma Holdings, Inc. and Theresa Matkovits (incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2023).†
10.15	Amendment to Employment Agreement, dated March 3, 2023, between Matinas Biopharma Holdings, Inc. and Keith Kucinski (incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2023).†
10.16	Amendment to Employment Agreement, dated March 3, 2023, between Matinas Biopharma Holdings, Inc. and James Ferguson (incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2023).†
10.17	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 13, 2025).
10.18	Amendment to Employment Agreement, dated as of April 30, 2025, between the Company and Jerome D. Jabbour (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 2, 2025). †
10.19	Amendment to Employment Agreement, dated as of April 30, 2025, between the Company and Keith Kucinski (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on May 2, 2025). †
10.20	Matinas BioPharma Holdings, Inc. 2025 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 23, 2025). †

10.21	Form of Warrant Exchange Agreement, dated August 15, 2025 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 18, 2025).
10.22	Third Amendment to Employment Agreement, dated as of December 12, 2025, between the Company and Jerome D. Jabbour (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 12, 2025). †
19.1	Matinas BioPharma Holdings Corp. Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K filed with the SEC on March 27, 2024).
21.1	Subsidiaries Index*
23.1	Consent of EisnerAmper LLP.*
31.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Section 1350 Certification.**
97.1	Matinas BioPharma Holdings, Inc. Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K filed with the SEC on April 15, 2025).
101	The following financial information from the Annual Report on Form 10-K for the fiscal year ended December 31, 2025, formatted in XBRL (eXtensible Business Reporting Language), is filed electronically herewith: (i) Consolidated Balance Sheets as of December 31, 2025 and 2024; (ii) Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2025 and 2024; (iii) Consolidated Statement of Changes in Stockholders' Equity (Deficit) for the Years Ended December 31, 2025 and 2024; (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2025 and 2024; and (v) Notes to Consolidated Financial Statements.*
104	The cover page from this Annual Report on Form 10-K, formatted as Inline XBRL.

+	Confidential treatment has been requested for certain provisions of this Exhibit pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.
†	Indicates a management contract or compensation plan, contract or arrangement.
*	Filed herewith.
**	The information in this exhibit is furnished and deemed not filed with the SEC for purposes of section 18 of the Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of Matinas Biopharma Holdings, Inc. under the Securities Act or the Exchange Act of whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Bedminster, State of New Jersey on March 31, 2026.

MATINAS BIOPHARMA HOLDINGS, INC.

By: */s/ Jerome D. Jabbour*
Name: Jerome D. Jabbour
Title: Chairman, Chief Executive Officer, President & Interim Chief Financial Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Person	Capacity	Date
/s/ Jerome D. Jabbour Jerome D. Jabbour	Chairman, Chief Executive Officer, President & Interim Chief Financial Officer (Principal Executive Officer and Principal Financial and Accounting Officer)	March 31, 2026
/s/ Evelyn D'An Evelyn D'An	Director	March 31, 2026
/s/ Keith Murphy Keith Murphy	Director	March 31, 2026
/s/ Edward Neugeboren Edward Neugeboren	Director	March 31, 2026
/s/ Robin L. Smith Robin L. Smith	Director	March 31, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Matinas BioPharma Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Matinas BioPharma Holdings, Inc. and Subsidiaries as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2025 and 2024, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has recurring net losses and net cash flow used in operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

In-process Research and Development

As described in Notes 3, 7, and 12 to the financial statements, In-process Research and Development ("IPR&D") is tested for impairment on an annual basis, or more frequently if indicators of impairment exist. Impairment exists if the carrying value of the IPR&D exceeds its fair value. The Company performed a quantitative assessment as of December 31, 2025, and estimated the fair value of the IPR&D with the income approach using a discounted cash flow method. Management's cash flow projections included significant judgments and assumptions relating to the plans contemplated for the commercialization of the IPR&D, along with the amount and timing of projected future cash flows and discount rates.

We identified the impairment assessment of IPR&D as a critical audit matter due to the significant judgment by management when developing the fair value estimates. This led to a high degree of auditor judgment and subjectivity and effort in performing procedures and evaluating management's significant assumptions related to amount and timing of projected future cash flows and discount rates. Additionally, the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included, among others (i) understanding management’s process for developing the fair value estimate; (ii) evaluating the appropriateness of the discounted cashflow model used by management; and (iii) evaluating the reasonableness of the significant assumptions used by management related to the amount and timing of projected future cash flows and discount rates. Evaluating management's assumptions related to the amount and timing of projected future cash flows and discount rates involved evaluating whether the assumptions used by management were reasonable considering the consistency with external market and industry data. Professionals with specialized skill and knowledge were used to assist in evaluating (i) the appropriateness of the discounted cash flow model, (ii) the reasonableness of the discount rates assumption, and (iii) the appropriateness of probability and assumptions used in evaluating the reasonableness of the fair value of the IPR&D asset.

/s/ EisnerAmper LLP

We have served as the Company’s auditor since 2011.

EISNERAMPER LLP
Iselin, New Jersey
March 31, 2026

Matinas BioPharma Holdings, Inc.
Consolidated Balance Sheets
(in thousands, except for share data)

	December 31,	
	2025	**2024**
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 3,999	$ 7,284
Restricted cash – security deposit	50	50
Prepaid expenses and other current assets	26	691
Total current assets	4,075	8,025
Non-current assets:		
Leasehold improvements and equipment - net	138	468
Operating lease right-of-use assets - net	531	1,680
Finance lease right-of-use assets - net	4	8
In-process research and development	2,260	2,260
Restricted cash - security deposit	200	200
Total non-current assets	3,133	4,616
Total assets	$ 7,208	$ 12,641
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 315	$ 95
Accrued expenses and other liabilities	452	1,805
Operating lease liabilities - current	694	761
Financing lease liabilities - current	2	5
Total current liabilities	1,463	2,666
Non-current liabilities:		
Deferred tax liability	257	257
Operating lease liabilities - net of current portion	653	2,116
Financing lease liabilities - net of current portion	5	12
Total non-current liabilities	915	2,385
Total liabilities	2,378	5,051
Stockholders' equity:		
Series C Convertible preferred stock, stated value $1,000 per share, par value $0.0001 per share, 10,000,000 shares authorized at December 31, 2025 and 2024; 3,155 and 0 issued and outstanding as of December 31, 2025 and 2024, respectively. Liquidation preference of $3,155,000 as of December 31, 2025.	—	—
Common stock par value $0.0001 per share, 500,000,000 and 250,000,000 shares authorized at December 31, 2025 and 2024, respectively; 6,406,191 and 5,086,985 issued and outstanding as of December 31, 2025 and 2024, respectively	1	1
Additional paid-in capital	215,616	207,413
Accumulated deficit	(210,787)	(199,824)
Total stockholders' equity	4,830	7,590
Total liabilities and stockholders' equity	$ 7,208	$ 12,641

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

Matinas BioPharma Holdings, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	For the Year Ended December 31,	
	2025	**2024**
Costs and Expenses:		
Research and development	$ 85	$ 11,433
General and administrative	6,875	8,729
Impairment charges of goodwill and other intangible assets	—	2,093
Impairment charges of other assets	—	2,338
Total costs and expenses	6,960	24,593
Loss from operations	(6,960)	(24,593)
Change in fair value of warrant liability	(3,161)	—
Gain on sale of assets	37	—
Other (expenses)/income, net	(261)	262
Loss before tax	$ (10,345)	$ (24,331)
Income tax benefit	—	80
Net loss	$ (10,345)	$ (24,251)
Deemed dividend relating to warrant exchange	(618)	—
Net loss attributable to common shareholders	$ (10,963)	$ (24,251)
Net loss per share – basic and diluted	$ (2.00)	$ (4.98)
Weighted average common shares outstanding:		
Basic and diluted	5,474,129	4,865,829
Other comprehensive gain, net of tax		
Unrealized gain on securities available-for-sale	—	221
Other comprehensive gain, net of tax	—	221
Comprehensive loss	$ (10,345)	$ (24,030)

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

Matinas BioPharma Holdings, Inc.
Consolidated Statements of Changes in Stockholders' Equity
(in thousands, except for share data)

	Convertible Preferred Stock Series C		Common Stock		Additional Paid - in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares*	Amount	Capital	Deficit	(loss)/Income	Equity
Balance, December 31, 2023	—	$ —	4,345,291	$ —	$ 195,040	$ (175,573)	$ (221)	$ 19,246
Stock-based compensation	—	—	—	—	3,195	—	—	3,195
Issuance of common stock and warrants in public offering, net of stock issuance cost ($877)	—	—	671,033	1	9,178	—	—	9,179
Issuance of common stock in reverse stock split	—	—	70,661	—	—	—	—	—
Other comprehensive income	—	—	—	—	—	—	221	221
Net loss	—	—	—	—	—	(24,251)		(24,251)
Balance, December 31, 2024	—	$ —	5,086,985	$ 1	$ 207,413	$ (199,824)	$ —	$ 7,590
Stock-based compensation	—	—	—	—	1,023	—	—	1,023
Issuance of preferred stock and warrants in public offering, net of stock issuance costs ($29)	3,300	—	—	—	330	—	—	330
Reclassification of warrants from liability to equity	—	—	—	—	6,103	—	—	6,103
Issuance of Common Stock in exchange for warrants	—	—	466,666	—	618	—	—	618
Deemed dividend	—	—	—	—	—	(618)	—	(618)
Issuance of Common Stock upon conversion of preferred stock	(145)	—	247,440	—	—	—	—	—
Issuance of Common Stock upon exercise of warrants	—	—	605,100	—	129	—	—	129
Net loss	—	—	—	—	—	(10,345)		(10,345)
Balance, December 31, 2025	3,155	$ —	6,406,191	$ 1	$ 215,616	$ (210,787)	$ —	$ 4,830

* Adjusted to reflect the impact of the 1-for-50 reverse stock split effective as of August 30, 2024.

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

Matinas BioPharma Holdings, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	For the Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (10,345)	$ (24,251)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	32	365
Net gain on disposal of assets	(37)	—
Stock-based compensation expense	1,023	3,195
Loss on operating lease right-of-use assets modification	241	—
Amortization of operating lease right-of-use assets	420	602
Amortization of finance lease right-of-use assets	4	5
Amortization of bond premium	—	(17)
Change in fair value of warrant liability	3,161	—
Impairment charges of goodwill and other intangible assets	—	2,093
Impairment charges of other assets	—	2,338
Income tax benefit	—	(84)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	665	587
Accounts payable	220	(419)
Accrued expenses and other liabilities	(1,353)	356
Operating lease liabilities	(1,042)	(655)
Net cash used in operating activities	(7,011)	(15,885)
Cash flows from investing activities:		
Proceeds from sale of assets	335	—
Purchases of marketable debt securities	—	(8,437)
Proceeds from sales of marketable debt securities	—	17,645
Net cash provided by investing activities	335	9,208
Cash flows from financing activities:		
Gross proceeds from private placement of preferred stock and common stock warrants	3,300	—
Transaction costs paid pursuant to private placement	(29)	—
Net proceeds from exercise of warrants	129	—
Net proceeds from public offerings of common stock and warrants	—	9,179
Payments of capital lease liability – principal	(9)	(5)
Net cash provided by financing activities	3,391	9,174
Net (decrease)/increase in cash, cash equivalents and restricted cash	(3,285)	2,497
Cash, cash equivalents and restricted cash at beginning of period	7,534	5,037
Cash, cash equivalents and restricted cash at end of period	$ 4,249	$ 7,534
Supplemental non-cash financing and investing activities:		
Reclassification of warrants from liability to equity	$ 6,103	$ —
Unrealized gain on marketable debt securities	$ —	$ 221
Exchange of warrants for shares of common stock	$ 618	$ —
Reduction of right-of-use assets and lease liabilities on lease termination	$ 488	—

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

Note 1 – Description of Business

Matinas BioPharma Holdings Inc. ("Holdings") is a Delaware corporation formed in 2013. Holdings is the parent company of Matinas BioPharma, Inc. ("BioPharma"), and Matinas BioPharma Nanotechnologies, Inc. ("Nanotechnologies," formerly known as Aquarius Biotechnologies, Inc.), its operating subsidiaries ("Nanotechnologies", and together with "Holdings" and "BioPharma", "the Company"). The Company is a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology (LNC Platform).

The Company's lead product candidate is MAT2203 (oral amphotericin B), a highly potent antifungal drug which, by virtue of LNC delivery, has been made oral, safe, and well-tolerated for prolonged administration in patients with life-threatening invasive fungal infections. Following the successful EnACT Phase 2 trial in the treatment of cryptococcal meningitis, MAT2203 is now positioned for a single, Phase 3 registration trial (the "ORALTO trial") in support of a New Drug Application ("NDA") for the treatment of invasive aspergillosis in patients with limited treatment options.

The Company had also been seeking to develop an internal pipeline of products utilizing the LNC Platform to encapsulate small molecules and small oligonucleotides and facilitate targeted and extrahepatic delivery to desired cells and tissues without toxicity, with a focus on small molecule oncology applications as well as the formulation and delivery of small oligonucleotides with a primary therapeutic focus on inflammation.

Following an 80% reduction in workforce implemented in late October 2024, the Company has been reassessing its strategic plan while implementing a cost-cutting strategy and paused further clinical development of MAT2203 with the goal of consummating a licensing, sale or other similar transaction as soon as possible to advance the development of MAT2203 into Phase 3. In addition, the Company continues to engage with the FDA to keep the MAT2203 Investigational New Drug Application ("IND") active and is actively maintaining and prosecuting intellectual property relating to MAT2203 and to the LNC Platform generally as well as maintaining all of its obligations under its license agreement with Rutgers University. The Company also continues to support the patients in its Expanded/Compassionate Use Access Program with the assistance of outside medical clinician consultants, although the Company is no longer supplying patients with MAT2203. As a result of the reduction in force, the Company has paused the internal development of a pipeline of products utilizing the LNC Platform as it evaluates strategic alternatives for those early-stage programs in oncology and inflammatory diseases.

The Company remains engaged in an ongoing partnership process for MAT2203, seeking one or more development and/or commercialization partners. The Company will require either (i) the consummation of a partnership transaction, or (ii) raising additional capital, prior to commencing the ORALTO trial. In the event a partnership is consummated, the partner may seek to revise the ORALTO trial or could determine a completely new development program and pathway for MAT2203. There can be no assurance that the Company will be successful in consummating a transaction involving MAT2203.

Note 2 – Going Concern

The Company has experienced net losses and negative cash flows from operations each period since its inception. Through December 31, 2025, the Company had an accumulated deficit of $210,787. The Company's net loss for the years ended December 31, 2025 and 2024 was $10,345 and $24,251, respectively.

The Company expects operating expenses to be lower in the near term compared to recent years until such time as it is able to consummate a licensing, sale or other similar transaction with a prospective partner that will provide funding to support initiation of the Phase 3 registration trial for MAT2203 and advancement of the LNC Platform delivery technology. The Company expects that its research and development expenses will increase if it moves forward with additional clinical studies for its current product candidates and development of additional product candidates. If the Company obtains U.S. Food and Drug Administration ("FDA") approval for one or more of its product candidates, the Company expects that its expenses will continue to increase once the Company reaches commercial launch. As a result, the Company expects to continue to incur substantial losses for the foreseeable future.

As of December 31, 2025, the Company had cash and cash equivalents of $3,999 and restricted cash of $250. The Company does not believe that the cash and cash equivalents on hand are sufficient to fund planned operations beyond the next twelve months from the filing date of these financial statements. As a result, substantial doubt exists about the Company's ability to continue as a going concern.

The ability of the Company to continue as a going concern is dependent upon securing one or more partners to monetize the value of MAT2203, the ability to control its operating expenses, future sales of common stock through the At-The-Market Sales Agreement ("Sales Agreement") with BTIG, LLC and securing additional financing. While the Company believes in the viability of this strategy and believes the actions presently being taken by the Company provide the opportunity for it to continue as a going concern, there can be no assurance the Company will be successful in its implementation. In particular, utilization of the Sales Agreement may not be viable due to market conditions and new financing may not be available on acceptable terms, or at all. These consolidated financial statements do not include any adjustments related to the recoverability and classification of asset amounts or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

Note 3 – Summary of Significant Accounting Policies

Basis of presentation and principles of consolidation

The accompanying consolidated financial statements include the consolidated accounts of Holdings and its wholly owned subsidiaries, BioPharma, and Nanotechnologies. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and reflect the operations of the Company and its wholly owned subsidiaries. All intercompany transactions have been eliminated in consolidation.

Reverse Stock Split

On August 30, 2024, the Company effected a 1-for-50 reverse stock split of its issued and outstanding common stock (the "Reverse Stock Split"). The Company's common stock began trading on a split adjusted basis on September 3, 2024. No fractional shares were issued as a result of the Reverse Stock Split as fractional shares of Common Stock were rounded up to the nearest whole share. Unless otherwise noted in these consolidated financial statements, all shares of common stock, warrants convertible into shares of common stock, stock options, per share information, and related parameters specified in this annual report have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented. Refer to Note 14 – *Stockholders' Equity* for additional information related to the Reverse Stock Split.

Use of estimates

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

Significant items subject to such estimates and assumptions include, but are not limited to, the Company's research and development expenses and the assessment of the impairment of long-lived assets, including goodwill, intangible assets, other long-lived assets and the fair value of the Company's warrant liability.

Segment and geographic information

Accounting Standard Update ("ASU") 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures was adopted by the Company during the year ended December 31, 2024. This ASU requires disclosure of significant segment expenses that are regularly provided to the chief operating decision maker ("CODM"), an amount for other segment items with description of composition, and disclosure of the title and position of the CODM.

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decisionmaker ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance. The Company considers its chief executive officer to be the Company's CODM. The CODM manages its operations and allocates resources based on the Company's consolidated results and therefore operates as one segment.

Segment revenue, profit or loss, significant segment expenses and other segment items - The accounting policies of the Company's single operating and reportable segment are the same as those described in this Summary of Significant Accounting Policies. The Company's method for measuring segment profitability includes net income(loss), which the CODM uses to assess performance and make decisions for resource allocation, consistent with the measurement principals for net income (loss) as reported on the Company's consolidated statement of operations. The significant assets and expenses regularly reviewed by the CODM are consistent with those reported on the Company's consolidated balance sheet, statement of operations. The measure of segment assets is reported in the consolidated balance sheet as total assets. Segment revenues and expenses are identical to that disclosed in the accompanying consolidated statement of operations and comprehensive loss.

The adoption of these disclosure requirements did not have a material impact on its consolidated financial statements and related disclosures.

Cash, cash equivalents and restricted cash

The Company considers all highly liquid financial instruments with original maturities of three months or less when purchased to be cash and cash equivalents and all investments with maturities of greater than three months from date of purchase are classified as marketable debt securities. Cash and cash equivalents consisted of cash in bank checking and savings accounts, money market funds and short-term U.S. treasury bonds that mature within three months of settlement date. The Company presents restricted cash with cash and cash equivalents in the Consolidated Statements of Cash Flows. Restricted cash represents funds the Company is required to support a letter of credit to cover building operating leases. For a complete disclosure of the Company's cash, cash equivalents and restricted cash, see Note 4 – Cash, Cash Equivalents, Restricted Cash and Marketable Debt Securities.

Marketable Debt Securities

Marketable debt securities, all of which were available-for-sale, consisted of U.S. treasury bonds, U.S. government notes and corporate debt securities and were carried at fair value, with unrealized gains and losses reported as accumulated other comprehensive loss, except for losses from impairments which are determined to be other-than-temporary. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense over the life of the instrument. The Company reviewed its portfolio of available-for-sale debt securities, using both qualitative and quantitative factors, to determine if declines in fair value below cost have resulted from a credit-related loss or other factors. Realized gains and losses and declines in value judged to be other-than-temporary are included in the determination of net loss and are included in other income, net. Fair values are based on quoted market prices at the reporting date. Interest and dividends on available-for-sale securities are included in other income, net. For a complete disclosure of the Company's marketable debt securities, see Note 4 – Cash, Cash Equivalents, Restricted Cash and Marketable Debt Securities.

Concentration of credit risk

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash, cash equivalents, restricted cash and marketable debt securities. The Company's investment policy is to invest only in institutions that meet high credit quality standards and establishes limits on the amount and time to maturity of investments with any individual counterparty. Balances are maintained at U.S. financial institutions and may from time to time exceed the Federal Deposit Insurance Corporation ("FDIC") insurance limit of $250 per depositor, per insured bank for each account ownership category. The Company has not experienced any credit losses associated with its balances in such accounts for the years ended December 31, 2025 and 2024.

Leasehold improvements and equipment

Leasehold improvements and equipment are stated at cost less accumulated depreciation and amortization, and impairment. Depreciation on equipment is computed using the straight-line method over the estimated useful lives of the assets, which range from three to ten years, except for certain equipment that has been reduced to salvage value in connection with the Company's impairment analysis and is no longer being depreciated, see Note 12 – Impairment Charges. Capitalized costs associated with leasehold improvements are amortized on a straight-line basis over the lesser of the estimated useful life of the asset or the remaining term of the lease.

Upon retirement or sale, the cost of assets disposed of and related accumulated depreciation and amortization is removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are charged to expense as incurred. For a complete disclosure of the Company's leasehold improvements and equipment, see Note 6 – Leasehold Improvements and Equipment.

Goodwill and Other Intangible assets

Goodwill is recorded when consideration paid for an acquired entity exceeds the fair value of the net assets acquired. Goodwill is not amortized but rather is assessed for impairment at least annually on a reporting unit basis, or more frequently when events and circumstances indicate the goodwill may be impaired.

The goodwill impairment test is performed at the reporting unit level. The fair value of the Company's reporting unit is determined using an income approach, which involves the use of estimates and assumptions, including projected future operating results and cash flows, the cost of capital, and financial measures derived from observable market data of comparable public companies. The Company estimates and compares the fair value of its reporting unit to its carrying value including goodwill. If the fair value is less than the carrying value, an impairment expense is recorded for the difference between those values and limited to the total carrying amount of goodwill.

Indefinite lived intangible assets are comprised of in-process research and development ("IPR&D") and represent projects acquired in a business combination that have not reached technological feasibility or that lack regulatory approval at the time of acquisition. These IPR&D assets are reviewed for impairment annually, or sooner if events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable.

The assessment of the Company's indefinite lived intangible asset involves comparing the fair value of the asset, determined using the income approach which is based on discounted cash flow techniques, to the carrying value of the asset. The fair value determination is based on the concept of evaluating the highest and best use of the asset (group) in the hands of a market participant and considers the current use and any other use that is financially feasible, justifiable, and reasonably probable. If the fair value is less than the carrying value, an impairment expense is recorded for the difference between those values.

During the fourth quarter of 2024, the Company identified impairment indicators for its goodwill and other intangible assets, primarily due to the terminated partnership negotiations for the future development & commercialization of MAT2203 and subsequent cost-cutting measures. The Company completed the required quantitative impairment test which resulted in recognizing a full non-cash impairment charge equal to the carrying amount of goodwill and a partial impairment charge related to IPR&D. See Notes 7 - Goodwill and Other Intangible Assets and 12 – Impairment Charges. The Company elected to perform a quantitative analysis as of December 31, 2025 and determined that no impairment charges needed to be recorded related to IPR&D.

Long-lived assets

The Company reviews leasehold improvements and equipment, operating lease right-of-use assets and other long-lived asset for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Recoverability is measured by comparing its carrying amount with the future net undiscounted cash flows the assets expected to generate. If such assets are considered to be impaired, the impairment is measured as the difference between the carrying amount of the assets and the Level 3 fair value of assets using the present value of the future net cash flows generated by the respective long-lived assets.

Determining fair value requires the use of estimates and assumptions. Such estimates and assumptions include revenue growth rates, estimated cost structure and operating expense, weighted average costs of capital, and future market conditions, market rental rate, among others.

Following a triggering event in the fourth quarter of 2024, the Company completed an impairment test for long-lived assets, which resulted in non-cash impairment charges. See Note 12 – Impairment Charges. There was a triggering event in September 2025, and management performed a quantitative analysis and concluded that no additional impairment was necessary. The Company did not record an impairment charge related to its long-lived assets during the year ended December 31, 2025.

Leases

The Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 842, "Leases", establishes a right-of-use ("ROU") model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. ROU assets are evaluated for impairment as a long-lived asset. Lessor accounting under the new standard is substantially unchanged. Additional qualitative and quantitative disclosures are also required. For a complete disclosure of the Company's leases, see Note 9 – Leases.

Income taxes

Deferred taxes are provided on a liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates in the period that includes the enactment date.

The Company adopted the provisions of ASC 740-10 and has analyzed its filing positions in 2025 and 2024 in jurisdictions where it may be obligated to file returns. The Company believes that its income tax filing position and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties as of December 31, 2025.

Since the Company incurred net operating losses in every tax year since inception, the 2015 through 2024 income tax returns are subject to examination and adjustments by the Internal Revenue Service for at least three years following the year in which the tax attributes are utilized.

Fair Value Measurements

As defined in ASC 820 "Fair Value Measurement", fair value measurements should be disclosed separately by three levels of the fair value hierarchy. For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs (quoted prices in active markets) and minimized the use of unobservable inputs (the Company's assumptions) when developing fair value measurements, in accordance with the established fair value hierarchy. For a complete disclosure of the Company's fair value measurements, see Note 5 – Fair Value Measurements.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity and ASC 815, Derivatives and Hedging. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their initial valuation are subsequently made. Warrants that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and are revalued on each subsequent balance sheet date until such instruments are exercised or expired, with any changes in the fair value between reporting periods recorded on the consolidated statement of operations. The assessment of whether the warrants are accounted for as equity-classified or liability-classified instruments is re-evaluated on a periodic basis. See Note 14 - *Stockholders' Equity* for a discussion on the Company's warrants.

Stock-based compensation

Stock-based compensation to employees consists of stock option grants. The Company accounts for stock-based compensation under the provisions of ASC 718-10, *Compensation – Stock Compensation*, which requires all share-based payments to employees, non-employees and directors, including grants of stock options and restricted shares, to be recognized in the consolidated statements of operations and comprehensive loss based on their fair values on the date of grant over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. Generally, the Company issues stock option awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company classifies stock-based compensation expense in the same manner in which the awards recipient's payroll or service provider's costs are classified.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of ASC Topic 505, subtopic 50, *Equity-Based Payments to Non-Employees* based upon the fair-value of the underlying instrument. The equity instruments, consisting of stock options granted to consultants, are valued using the Black-Scholes valuation model. The Company calculates the fair value of option grants utilizing the Black-Scholes pricing model and estimates the fair value of restricted stock based upon the estimated fair value or the common stock.

The resulting compensation expense for both employee and non-employee awards is generally recognized on a straight-line basis over the requisite service period of the award.

Net Loss Per Share

The following table sets forth the computation of basic and dilutive net loss per share:

	Years Ended December 31,	
	2025	**2024**
Numerator:		
Net loss attributable to common stockholders	$ (10,345)	$ (24,251)
Adjustment for deemed dividend (*)	(618)	—
Adjusted net loss used for basic and diluted calculation	$ (10,963)	$ (24,251)
Denominator:		
Weighted-average common shares, basic and diluted	5,474,129	4,865,829
Net loss per common share:		
Basic and diluted	$ (2.00)	$ (4.98)

(*) Deemed dividend represents the excess of fair value of common stock issued over the fair value of warrants immediately prior to exchange, which reduces income available to common stockholders used for the basic and diluted net loss per common share calculation.

Basic and diluted net loss per common share

Net loss per share information is determined using the two-class method. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income (loss) available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in the earnings as if all income (loss) for the period had been distributed. The Company's convertible preferred stock and outstanding warrants participate in any dividends declared by the Company on common stock on a one-for-one basis and are therefore considered to be participating securities. The participating securities are not required to participate in the losses of the Company, and therefore during periods of loss there is no allocation required under the two-class method.

Under the two-class method, basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share attributable to common stockholders is computed by adjusting net loss per share attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period including potential dilutive common shares. For purposes of this calculation, outstanding options and warrants to purchase common stock, and shares of convertible preferred stock are considered potential dilutive common shares. The Company has generated net loss in all periods presented, and therefore the basic and diluted net loss per share attributable to common stockholders are the same as the inclusion of the potentially dilutive securities would be anti-dilutive.

During the years ended December 31, 2025 and 2024, diluted earnings per common share is the same as basic earnings per common share because, as the Company incurred a net loss during each period presented, the potentially dilutive securities from the assumed exercise of all outstanding stock options and warrants would have an anti-dilutive effect. The reconciliation of the anti-dilutive shares as of December 31, 2025 and 2024 are as follows:

	As of December 31,	
	2025	**2024**
Stock options	457,219	687,356
Preferred stock conversion to common stock	5,383,964	—
Warrants	10,516,543	666,667
Total	16,357,726	1,354,023

Research and development expenses

Research and development expenses primarily consist of costs associated with the preclinical and clinical development of our product candidate portfolio, including the following:

- external research and development expenses incurred under arrangements with third parties, such as contract research organizations ("CROs") and other vendors and contract manufacturing organizations ("CMOs") for the production of drug substance and drug product; and

- employee-related expenses, including salaries, benefits and share-based compensation expense.

Research and development expenses also include costs of acquired product licenses and related technology rights where there is no alternative future use, costs of prototypes used in research and development, consultant fees and amounts paid to certain of our collaborative partners.

All research and development expenses are charged to operations as incurred in accordance with FASB ASC Topic 730, Research and Development. The Company accounts for non-refundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received, rather than when the payment is made.

Accrued Research and Development Expenses

As part of the process of preparing the Company's financial statements, the Company is required to estimate its accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost. Certain of the Company's service providers invoice the Company monthly in arrears for services performed or when contractual milestones are met. The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known to the Company at that time. The Company periodically confirms the accuracy of its estimates with the service providers and adjusts if necessary. The significant estimates in the Company's accrued research and development expenses are related to expenses incurred with respect to CROs, CMOs and other vendors in connection with research and development and manufacturing activities.

The Company bases its expense related to CROs and CMOs on its estimates of the services received and efforts expended pursuant to quotations and contracts with such vendors that conduct research and development and manufacturing activities on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of the applicable research and development or manufacturing expense. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from its estimate, the Company adjusts the accrual or prepaid expense accordingly. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. There have been no material changes in estimates for the periods presented.

Patent expenses

Legal fees and other direct costs incurred in obtaining and protecting patents are also expensed as incurred and are included in general and administrative expenses in the consolidated statements of operations.

Other comprehensive gains

Other comprehensive gains consist of net gains/(losses) and unrealized gains on marketable debt securities available-for-sale and is presented in the Consolidated Statements of Operations and Comprehensive Loss.

Recent accounting pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which expands annual disclosure requirements related to the rate reconciliation and income taxes paid disclosures. ASU 2023-09 requires consistent categories and greater disaggregation of information in the rate reconciliation and income taxes paid to be disaggregated by jurisdiction. The updated standard is effective for fiscal years beginning after December 15, 2024. Early adoption is permitted and the update may be applied on a prospective basis with retrospective application permitted. The Company adopted the ASU on January 1, 2025 and the adoption had no material impact on the Company's financial statements.

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses (DISE)*, which specifies additional disclosure requirements. The new guidance requires additional disclosures, including the composition of certain income expense line items (such as purchases of inventory, employee compensation, and "other expenses") and a separate disclosure for selling expenses. This change is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, however, early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on the consolidated financial statements and disclosures.

The Company's management has considered all recent accounting pronouncements issued and believes that these recent pronouncements will not have a material effect on the Company's financial statements.

Note 4 – Cash, Cash Equivalents, Restricted Cash and Marketable Debt Securities

Cash, Cash Equivalents and Restricted Cash

The Company presents restricted cash with cash and cash equivalents in the Consolidated Statements of Cash Flows. Restricted cash at December 31, 2025 and 2024 of $250 represents funds the Company is required to set aside as collateral, primarily for one of the Company's operating leases and other purposes.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported in the Consolidated Balance Sheets to the total of the amounts in the Consolidated Statements of Cash Flows as of December 31, 2025, December 31, 2024 and December 31, 2023:

	December 31, 2025	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 3,999	$ 7,284	$ 4,787
Restricted cash included in current/non-current assets	250	250	250
Cash, cash equivalents and restricted cash in the statement of cash flows	$ 4,249	$ 7,534	$ 5,037

Marketable Debt Securities

The Company classified its investments in marketable debt securities as available-for-sale and as a current asset. The Company's investments in marketable debt securities were carried at fair value, with unrealized gains and losses included as a separate component of stockholders' equity. Unrealized losses and gains were classified as other comprehensive (loss)/income and costs are determined on a specific identification basis. Realized gains and losses from marketable debt securities are recorded in other income, net. The Company did not incur any realized gains and losses during the years ended December 31, 2025 and 2024. For the years ended December 31, 2025 and 2024, the Company recorded unrealized gains of $0 and $221, respectively.

The Company did not own any marketable debt securities at December 31, 2025 and 2024.

Note 5 - Fair Value Measurements

The Company uses the fair value hierarchy to measure the value of its financial instruments. The fair value hierarchy is based on inputs to valuation techniques that are used to measure fair value that are either observable or unobservable. Observable inputs reflect assumptions market participants would use in pricing an asset or liability based on market data obtained from independent sources, while unobservable inputs reflect a reporting entity's pricing based upon its own market assumptions. The basis for fair value measurements for each level within the hierarchy is described below:

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

- Level 2 – Quoted prices for identical or similar assets and liabilities in markets that are not active; or other model-derived valuations whose inputs are directly or indirectly observable or whose significant value drivers are observable.

- Level 3 – Valuations derived from valuation techniques in which one or more significant inputs to the valuation model are unobservable and for which assumptions are used based on management estimates.

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

The carrying amounts of cash equivalents, current portion of restricted cash, prepaid expenses and other current assets, accounts payable, current portion of lease liabilities and accrued expenses approximate fair value due to the short-term nature of these instruments.

The Company did not have any financial assets or liabilities that were carried at fair value using the hierarchy as of December 31, 2025 and 2024. During 2025, the Company had liability classified warrants that were carried at fair value. During 2024, the Company did not have any assets or liabilities carried at fair value.

The table below presents a summary of changes in fair value of the warrant liability that was measured at fair value on a recurring basis:

	Warrant Liability
Balance at December 31, 2024	$ —
Issuance of warrants reported at fair value	2,942
Change in fair value	3,161
Reclassification to equity	(6,103)
Balance at December 31, 2025	$ —

On February 13, 2025, the Company entered into a securities purchase agreement with certain investors and, pursuant to an initial and second closing under the agreement, issued and sold to the investors an aggregate of (i) 3,300 shares of convertible preferred stock and (ii) warrants (the "Warrants") to purchase up to 11,262,808 shares of the Company's common stock (see Note 14).

The Company classified the Warrants as a liability upon issuance. Accordingly, proceeds from the transaction were first allocated to the Warrants which were recorded at fair value at issuance, and any residual value allocated to preferred stock. Subsequent changes in fair value of the Warrants were recognized in the Company's consolidated statements of operations and comprehensive loss.

On June 26, 2025, the terms of the Warrants were amended to remove the provision that provided for a potential adjustment to the Warrants that did not meet the indexation requirements. The Company determined that the Warrants then satisfied the conditions to be accounted for as equity instruments. The change in fair value of the Warrants until June 26, 2025 was recorded in the income statement and fair value of the Warrants on June 26, 2025, was reclassified to equity. There will be no subsequent measurement for the equity classified Warrants as long as the indexation and equity classification criteria continue to be met.

For each reporting period during which the Warrants were classified as a liability, the Company's warrant liability was measured at fair value utilizing a Monte Carlo simulation model, which required assumptions including the value of the stock on the measurement date, exercise price, expected term, expected volatility, and the risk-free interest rate. Certain assumptions, including the expected term and expected volatility, were subjective and require judgment to develop.

The warrant liabilities were valued on the various measurement dates during the year ended December 31, 2025 using the following range of assumptions:

Expected volatility		54.0% - 61.0%
Risk-free interest rate		3.77% – 4.39%
Stock price on valuation date	$	0.52 - 0.94
Exercise price	$	0.64
Dividend yield		0.00%
Expected term		4.8 - 5.0 years

Fair Values Measured on a Non-recurring Basis

The Company's non-financial assets, such as property, plant and equipment, and intangible assets, including IPR&D, are recorded at fair value upon acquisition and are remeasured only if an impairment charge is recognized. The Company remeasured the fair value of its long-lived assets upon the occurrence of triggering events in the fourth quarter of 2024 and in the third quarter of 2025. See Note 12 - Impairment Charges for more information on the impairment losses recorded during the year ended December 31, 2025 and 2024 for assets measured on a non-recurring basis.

Note 6 – Leasehold Improvements and Equipment

Leasehold improvements and equipment, summarized by major category, consist of the following for the years ended December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Equipment	$ —	$ 1,535
Leasehold improvements	166	993
Total	166	2,528
Less: accumulated depreciation and amortization	28	2,060
Leasehold improvements and equipment, net	$ 138	$ 468

Depreciation and amortization expense for the years ended December 31, 2025 and 2024 was $32 and $365, respectively. During the year ended December 31, 2025, the Company recorded net asset write-offs of $2,082, including $2,064 of related accumulated depreciation.

Assets sales and disposals

On April 19, 2025, the Company initiated a process to sell certain unused laboratory equipment that was previously impaired and carried a net book value of $280. During the year end ended December 31, 2025, the Company sold all $280 of the equipment, generating proceeds of $335 resulting in a gain of $55. In addition, the Company incurred an $18 loss on the disposal of leasehold improvements.

Impairment of Long-Lived Assets

During the fourth quarter of 2024, the Company recorded in its consolidated statement of operations and comprehensive loss a $1,090 charge for an impairment loss associated with its leasehold improvements and equipment. The Company did not record an impairment charge during the year ended December 31, 2025.

Note 7 – Goodwill and Other Intangible Assets

The following table provides the gross and net carrying value of goodwill as follows:

	Amounts
Balance at December 31, 2023	$ 1,336
Impairment of goodwill	(1,336)
Balance at December 31, 2024	$ —

The Company completed its annual impairment test for goodwill during the fourth quarter of 2024, which resulted in full impairment of the Company's $1,336 of goodwill. The goodwill impairment is reflected in impairment charge of goodwill and other intangible assets in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2024. For the year ended December 31, 2025, there were no additions to goodwill.

The following table provides the gross and net carrying value of IPR&D as follows:

	Amounts
Balance at December 31, 2023	$ 3,017
Impairment of IPR&D	(757)
Balance at December 31, 2024	$ 2,260
Impairment of IPR&D	—
Balance at December 31, 2025	$ 2,260

The Company completed its impairment test for IPR&D during the fourth quarter of 2024, which resulted in partial impairment of $757 of the Company's of IPR&D. The IPR&D impairment is reflected in impairment charge of goodwill and other intangible assets in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2024. The Company completed its quantitative impairment test for IPR&D during the fourth quarter of 2025, and noted the fair value exceeded the carrying value. Consequently, the Company did not record an IPR&D impairment charge during the year ended December 31, 2025.

Note 8 – Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities, summarized by major category, consist of the following for the years ended December 31, 2025 and 2024:

	As of December 31,	
	2025	2024
Severance	$ —	$ 1,509
General and administrative expenses	452	296
Total	$ 452	$ 1,805

Note 9 – Leases

The Company has various lease agreements including leases of office space, a laboratory and manufacturing facility, and various equipment. Some leases include purchase, termination or extension options for one or more years. These options will be included in the lease term when it is reasonably certain that the option will be exercised. Certain of the Company's lease agreements contain rent escalation clauses.

Operating and finance leases are presented in the Company's consolidated balance sheets as right-of-use assets from leases, current lease liabilities and long-term lease liabilities. The assets and liabilities from our leases are recognized at the lease commencement date based on the present value of remaining lease payments over the lease term using the Company's incremental borrowing rates or implicit rates, when readily determinable. Short-term leases, which have an initial term of 12 months or less, are not recorded on the balance sheet. As the Company's operating leases do not provide implicit rates, the Company has utilized its incremental borrowing rate, determined based on the long-term borrowing costs of companies with similar credit profiles, to record its lease obligations. The Company's finance leases provide readily determinable implicit rates. For operating leases, the Company recognizes the minimum rental expense on a straight-line basis based on the fixed components of a lease arrangement. The Company will amortize this expense over the term of the lease beginning with the lease commencement date.

Operating lease obligations

On November 1, 2013, the Company entered into a 7-year lease for office space in Bedminster, New Jersey which commenced in June 2014 at a monthly rent of approximately $13, increasing to approximately $14 toward the end of the term. The lease was subsequently amended on September 13, 2022 to provide additional space and to extend the term of the lease until June 30, 2029 at a monthly rent of approximately of approximately $20, increasing to approximately $23 toward the end of the term. On October 3, 2025, the Bedminster lease was amended to decrease the lease term to 15 months, beginning in October 2025 and ending December 31, 2026. The amendment included a one-time payment of $323 in full satisfaction of the Company's rental obligations through the end of the amended term date. The lease amendment also included a provision which provided the landlord the right to relocate the Company to mutually acceptable space within the building. In November 2025, the Company was moved to another space in the building which is approximately 500 square feet and approximately 94% less space than the prior leased office space. The decrease in office space generated a right-of-use asset write-off of $207. This partial lease termination resulting in the recognition of the loss in the amount of $241 in the accompanying consolidated statement of operation and comprehensive loss. There is no renewal option, no security deposit, no residual value or significant restrictions or covenants other than those customary in such arrangements. Except as expressly provided, all other terms, covenants, conditions and agreements as set forth in the lease will remain unchanged and in full force and effect.

On December 15, 2016, the Company entered into a 10-year, 3-month lease of laboratory and manufacturing space in Bridgewater, New Jersey. The lease began August 2017. The monthly rent started at approximately $43, increasing to approximately $64 in the final year. To obtain the lease, the Company provided an initial security deposit of $586 which was subsequently reduced and is currently $200 at December 31, 2025. The Bridgewater lease is currently in dispute, please see Bridgewater lease proceedings in Note: 11- Commitments and Contingencies.

The Company incurred lease expense for its operating leases of $634 and $902 for the years ended December 31, 2025 and 2024, respectively. The Company incurred amortization expense on its operating lease right-of-use assets of $420 and $602 for the years ended December 31, 2025 and 2024, respectively.

Finance Leases

The Company incurred interest expense on its finance leases of $1 and $2 for the years ended December 31, 2025 and 2024, respectively. The Company incurred amortization expense on its finance lease right-of-use assets of $4 and $5 for the years ended December 31, 2025 and 2024, respectively.

The following table presents information about the amount and timing of liabilities arising from the Company's operating leases and finance leases as of December 31, 2025:

Maturity of Lease Liabilities	Operating Lease Liabilities	Finance Lease Liabilities
2026	$ 781	$ 4
2027	678	4
Total undiscounted operating lease payments	$ 1,459	$ 8
Less: Imputed interest	112	1
Present value of operating lease liabilities	$ 1,347	$ 7
Weighted average remaining lease term in years	1.8	1.9
Weighted average discount rate	8.4%	11.6%

The following table presents information about the amount and timing of liabilities arising from the Company's operating leases and finance leases as of December 31, 2024:

Maturity of Lease Liabilities	Operating Lease Liabilities	Finance Lease Liabilities
2025	$ 998	$ 7
2026	1,040	7
2027	944	7
2028	273	—
2029	138	—
Total undiscounted operating lease payments	$ 3,393	$ 21
Less: Imputed interest	516	4
Present value of operating lease liabilities	$ 2,877	$ 17
Weighted average remaining lease term in years	3.3	2.9
Weighted average discount rate	9.3%	11.6%

Impairment of right-of-use assets

During the fourth quarter of 2024, the Company determined that the net book value of Bridgewater facility lease right-of-use asset might not be recoverable, primarily due to the terminated partnership negotiations for the future development and commercialization of MAT2203 and subsequent cost-cutting measures. The Company conducted a recoverability test by comparing the projected undiscounted future cash flows associated with the right-of-use asset to its carrying amount and concluded that an impairment charge must be recognized. The charge was subsequently determined based on the excess of the carrying amount of the asset over its estimated fair value. The Company recorded impairment charges related to its Bridgewater facility lease right-of-use asset of $782, and a related finance lease of right-of-use asset of $8. The lease impairment charges were included in the impairment charges of other assets line in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2024.

During 2025, the Company endeavoured to secure a sub-tenant for the Bridgewater facility. In the third quarter of 2025, the Company determined, due to the passage of time without securing a sub-tenant, the carrying amount of the Bridgewater facility lease right of use asset might not be recoverable. The Company performed a recoverability test by comparing the projected undiscounted future cash flows associated with the right-of-use asset to its carrying amount and concluded that the carrying amount was recoverable. The Company also assessed the asset for impairment in the fourth quarters of 2025 and concluded there were no events or circumstances where Bridgewater facility right of use asset was not recoverable. Accordingly, the Company did not record an impairment charge during the fourth quarter of 2025.

Note 10 – Research and Development Agreements

License Agreement

Through the acquisition of Aquarius, the Company acquired a license from Rutgers University, The State University of New Jersey (successor in interest to the University of Medicine and Dentistry of New Jersey) for certain patents related to the LNC Platform (the "License Agreement"). The Second Amended and Restated Exclusive License Agreement provides for, among other things, the payment of (1) royalties on a tiered basis between low single digits and the mid-single digits of net sales of products using such licensed technology, (2) a one-time sales milestone fee of $100 when and if sales of products using the licensed technology reach the specified sales threshold and (3) an annual license fee of $50 over the term of the License Agreement. The term of the License Agreement will remain in effect until the expiration of the last-to-expire patent rights licensed or seven and one-half years from the date of the first commercial sale of a licensed product under this agreement, whichever is later.

Note 11 – Commitments and Contingencies

Royalty payment rights

Pursuant to the terms of the Certificate of Designations of Preferences, Rights and Limitations (the "Certificate of Designations") for our Series A Preferred Stock, the Company may be required to pay royalties of up to $35 million per year. If and when the Company obtains FDA or EMA approval of MAT2203 and/or MAT2501, which we do not expect to occur before 2030, if ever, and/or if the Company generates sales of such products, or receives any proceeds from the licensing or other disposition of MAT2203 or MAT2501, the Company will be required to pay to certain former holders of its Series A Preferred Stock, in aggregate, a royalty equal to (i) 4.5% of Net Sales (as defined in the Certificate of Designations), subject in all cases to a cap of $25 million per calendar year, and (ii) 7.5% of Licensing Proceeds (as defined in the Certificate of Designations), subject in all cases to a cap of $10 million per calendar year. The Royalty Payment Rights will expire when the patents covering the applicable product expire, which is currently expected to be in 2033.

Employment agreements

The Company also has employment agreements with certain employees which require the funding of a specific level of payments, if certain events, such as a change in control, termination without cause or retirement, occur.

Other normal business operating agreements

In addition, in the course of normal business operations, the Company enters into agreements with contract service providers to assist in the performance of research and development and manufacturing activities. Expenditures to these third parties represent significant costs in clinical development and may require upfront payments and long-term commitments of cash. Subject to required notice periods and obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time.

Bridgewater lease proceedings

The Company filed a complaint against COE Bridgewater, LLC (its "Landlord") in the Superior Court of New Jersey, Somerset County, Chancery Division on July 11, 2025 alleging principally that Landlord illegally locked the Company out of its leased premises in Bridgewater, New Jersey. As a result of the illegal lockout, the Company seeks (among other things) a declaration that the lease and all obligations thereunder, including rent, terminated as of the date of the lockout. On September 5, 2025, Landlord filed an answer with counterclaims, which it amended on December 12, 2025. In the counterclaims, Landlord seeks a declaration that there was no lockout, or that the lockout was justified, and therefore the lease remains in effect. Landlord also seeks damages for the Company's alleged failure to pay approximately $205,000 in rent (as of December 31, 2025) following the lockout, and alleged conversion of certain furniture, fixtures, and equipment (FF&E) items within the premises belonging to Landlord. The amounts potentially payable under the lease have been accrued until the matter is resolved. The Company is currently in settlement negotiations with the Landlord, however there can be no assurance such a settlement will be achieved.

Legal proceedings

Besides the Bridgewater lease proceedings above, the Company is not currently a party to any legal proceedings, and the Company is not aware of any claims or actions pending or threatened against its business. In the future, the Company might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Note 12 – Impairment Charges

The Company reviews property, plant and equipment and other long-lived assets, including leasehold improvements, for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable in accordance with ASC 360, "Property, Plant and Equipment."

During the fourth quarter of 2024, the Company identified impairment indicators for certain long-lived assets, primarily due to the terminated partnership negotiations for the future development and commercialization of MAT2203 and subsequent cost-cutting measures.

In accordance with ASC 360-10, long-lived assets that are held and used are tested for impairment at the asset group level, which represents the lowest level for which identifiable cash flows are largely independent of the cash flows of other groups of assets and liabilities. The Company has historically determined that its long-lived assets are sufficiently interdependent to constitute one asset group and performed impairment testing at the reporting unit level. However, the workforce reduction implemented in October 2024 and related pause of product development activities indicates a change in the interdependency of the Company's cash flows. The Company's long-lived assets have subsequently been evaluated as three asset groups:

- an asset group including all long-lived assets associated with the development of MAT2203 and not otherwise included in the following two asset groups;
- an asset group including the ROU asset associated with the Bridgewater facility lease, including the related leasehold improvements; and
- an asset group including machinery & equipment located at the Bridgewater facility.

ASC 360-10-35 provides that impairment testing for specific assets should be performed in the following order:

- Test other assets (e.g., accounts receivable, inventory) under applicable guidance and indefinite-lived intangible assets (other than goodwill) under ASC 350-30
- Test long-lived assets (asset group) under ASC 360-10
- Test goodwill of a reporting unit that includes the aforementioned assets under ASC 350-20

Indefinite-lived intangible assets

IPR&D

The Company's indefinite-lived intangible assets are comprised of in-process research and development ("IPR&D"). For the years ended December 31, 2025 and 2024, the Company assessed IPR&D impairment by performing a quantitative analysis which involved comparing the fair value of the asset, determined using an income approach which is based on discounted cash flow techniques, to the carrying value of the asset.

During the fourth quarter of 2024, the Company identified impairment indicators for its IPR&D and recorded an impairment charge of $757, which represented the excess of the carrying value of the asset over the calculated fair value. The impairment charge has been included in the Company's Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2024. The Company elected to perform a quantitative analysis to determine if its IPR&D asset was impaired as of December 31, 2025. The results of the quantitative analysis indicated the fair value of the IPR&D asset exceeded its carrying value and as such the Company did not record an impairment charge of IPR&D during the year ended December 31, 2025.

Goodwill

For the year ended December 31, 2024, the Company assessed goodwill impairment by performing a quantitative analysis for its reporting unit. As part of the quantitative review, the Company considered whether its fair value, determined as the price a market participant would be willing to pay in a potential acquisition of the Company, exceeds its carrying value, including goodwill.

During the fourth quarter of 2024, the Company identified impairment indicators for its goodwill and recorded an impairment charge of $1,336, which represented the carrying value of goodwill. The impairment charge has been included in the impairment charges of goodwill line item in the Company's Consolidates Statement of Operations and Comprehensive Loss for the year ended December 31, 2024.

Long-lived assets

The recoverability test for the Company's long-lived assets was performed by comparing the carrying amount of each asset group to its estimated future undiscounted pre-tax cash flows over the remaining useful life of the primary long-lived asset within each group. As a result of this analysis, the Company concluded that the carrying value of the asset group including the ROU asset associated with the Bridgewater facility lease and related leasehold improvements, and the asset group including machinery & equipment located at the Bridgewater facility, were not fully recoverable. The Company determined the fair value of the asset group which includes the ROU asset associated with the Bridgewater facility lease and related leasehold improvements using the discounted cash flow method, considering cash flows associated with a potential sublease of the facility. Significant assumptions used include estimated sublease payments, a period of vacancy before the sublease begins and expenses incurred to facilitate the sublease. The Company determined the fair value of the asset group which includes machinery & equipment at the Bridgewater facility by considering its potential salvage value, determined by estimating a salvage rate of proceeds which could be realized in the sale of equipment to a third party. These analyses led to the recognition of impairment charges totalling $2,338. The impairment charges have been included in the Impairment charges of other assets line item in the Company's Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2024. An impairment test of its ROU asset associated with the Bridgewater facility lease during the third quarter of 2025 due to the identification of a triggering event. The quantitative recoverability test performed indicated the asset's carrying value was fully recoverable. As such no additional impairment was recorded in 2025 related to this asset.

The following table provides the total amount of impairment charges of other assets as follows:

	Amounts
Leasehold improvement and equipment (including amounts recorded within prepaid expenses)	$ 1,546
Operating and finance leases right of use assets	790
Impairment charges of other assets at December 31, 2024	$ 2,338

Note 13 – Income Taxes

The Company utilizes the liability method of accounting for deferred income taxes. Under this method, deferred tax liabilities and assets are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities. A valuation allowance is established against deferred tax assets when, based on 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's policy is to record interest and penalties on uncertain tax positions as income tax expense. As of December 31, 2025 and 2024, the Company does not believe any material uncertain tax positions were present. Accordingly, interest and penalties have not been accrued due to an uncertain tax position.

The components of the income tax provision are as follows:

	Year Ended December 31,	
	2025	2024
Current expense (benefit):		
Federal	$ —	$ —
State	7	4
Foreign	—	—
Total current expense (benefit):	$ 7	$ 4
Deferred expense (benefit):		
Federal	$ —	$ (84)
State	—	—
Foreign	—	—
Total deferred expense (benefit):	$ —	$ (84)
Total income tax expense (benefit):	$ 7	$ (80)

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate after the adoption of ASU 2023-09 is as follows:

	Year Ended December 31,	
	2025	
U.S. Federal Statutory Tax Rate	$ (2,171)	21.00%
State and Local Income Taxes, Net of Federal Income Tax Effect (a)	6	(0.06)%
Change in Valuation Allowances	1,405	(13.59)%
Nontaxable or Nondeductible Items		
Warrants	717	(6.94)%
Other	50	(0.48)%
Effective Tax Rate	$ 7	(0.07)%

(a) State taxes in New Jersey made up the majority (greater than 50 percent) of the tax effect in this category.

As previously disclosed for the year ended December 31, 2024 prior to the adoption of ASU 2023-09, the following is a reconciliation of the difference between the effective income tax rate and federal statutory rate:

	Year Ended December 31, 2024
Income at U.S. Statutory Rate	21.00%
State Taxes, net of Federal benefit	6.53%
Permanent Differences	(1.87)%
Tax Credits	0.00%
Valuation Allowance	(25.35)%
Discrete Items	0.02%
	0.33%

The following table presents income taxes paid (net of refunds received) during the year ended December 31, 2025 by jurisdiction:

	Year Ended December 31, 2025
U.S. federal taxes	$ —
State and local taxes	
Massachusetts	1
New Jersey	6
Total income taxes paid	$ 7

The Company has no current income taxes payable other than certain state minimum taxes which are included in general and administrative expenses. The $80 income tax benefit recognized during the year ended December 31, 2024, primarily relates to a reduction in the deferred tax liability associated with the Company's IPR&D, which was impaired during the year.

Significant components of the Company's deferred tax assets (liabilities) for 2025 and 2024 consist of the following:

	Year Ended December 31,	
	2025	2024
Share-based Compensation	$ 2,931	$ 5,282
Depreciation and Amortization	213	451
Accrued Liability	42	279
Net Operating Loss Carry-forwards	33,362	28,270
R&D Credit Carryforwards	4,469	4,469
R&D Section 174 Costs	4,713	7,511
Other	1	31
IPR&D	(637)	(637)
ROU Asset	(151)	(476)
ROU Liability	380	811
Total Deferred tax assets	$ 45,323	$ 45,991
Valuation allowance	(45,580)	(46,248)
Net deferred tax asset (liability)	$ (257)	$ (257)

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible and is impacted by the Company's ability to carryforward losses to years in which the Company has taxable income. Due to the Company's history of losses and lack of other positive evidence to support taxable income, the Company has recorded a valuation allowance against those deferred tax assets that are not expected to be realized. The valuation allowances were $45,580 and $46,248 as of December 31, 2025 and 2024, respectively, representing decrease of $668.

As of December 31, 2025, the Company had Federal net operating loss carryforwards of $38,080 which will begin to expire in 2032. In addition, the Company has federal net operating loss carryforwards of $106,217 which have an indefinite carryforward period. The Company also had federal and state research and development tax credit carryforwards of $4,469. The federal net operating loss and tax credit carryforwards will expire at various dates beginning in 2032, if not utilized. The difference between the statutory tax rate and the effective tax rate is primarily attributable to the valuation allowance offsetting deferred tax assets.

Utilization of the net operating losses and general business tax credits carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 due to changes in ownership of the Company that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating losses and general business tax credits carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company has not completed a study to determine whether it had undergone an ownership change since the Company's inception.

Under the Tax Cuts and Jobs Act of 2017, research and development costs are no longer fully deductible and are required to be capitalized and amortized for U.S. tax purposes effective January 1, 2022. The mandatory capitalization requirement increases our deferred tax assets. The One Big Beautiful Bill Act (the "OBBBA") was enacted into law on July 4, 2025. Included in the OBBBA were provisions where certain research and development expenses could be immediately expensed rather than capitalized. The Company considered the effects of the OBBBA and determined there was not a material effect on the Company's financial statements as of December 31, 2025.

Note 14 – Stockholders' Equity

Common Stock

As of December 31, 2025, in accordance with the Certificate of Incorporation, the Company was authorized to issue 500,000,000 shares of common stock and 10,000,000 shares of preferred stock, each share having a par value of $0.0001.

Reverse Stock Split

On August 30, 2024, the Company effected the Reverse Stock Split. Accordingly, each of the Company's stockholders received one share of the Company's common stock for every 50 shares of the Company's common stock that such stockholder held immediately prior to the effective time of the Reverse Stock Split. The Reverse Stock Split affected all of the Company's issued and outstanding shares of common stock equally provided that no fractional shares of common stock were issued as a result of the Reverse Stock Split as fractional shares of common stock were rounded up to the nearest whole share. The Reverse Stock Split also affected the Company's outstanding stock-based awards, warrants and other exercisable or convertible securities and resulted in the shares of common stock underlying such instruments being reduced and the exercise price or conversion price being increased proportionally by the Reverse Stock Split ratio.

As a result of the Reverse Stock Split, the number of shares of common stock authorized for issuance was adjusted from 500,000,000 to 250,000,000, and the par value of $0.0001 per share was not affected. Additionally, the number of issued and outstanding shares of the Company's common stock was adjusted from 250,816,164 shares to 5,086,985 shares on August 30, 2024, including the issuance of an additional 70,661 shares to those stockholders that would otherwise would have been entitled to a fractional share of common stock as a result of the Reverse Stock Split.

On June 23, 2025, the Company received shareholder approval to increase the number of shares of common stock authorized for issuance to 500,000,000. On August 6, 2025, the Company filed a Certificate of Amendment (the "Certificate of Amendment") to the Company's Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to increase the number of authorized shares of the Company's common stock from 250,000,000 shares to 500,000,000 shares. The Certificate of Amendment became effective upon filing.

April 2024 Purchase Agreement

During the year ended December 31, 2024, the Company sold 671,033 shares of its common stock. On April 5, 2024, the Company closed a registered direct offering of 666,667 shares of its common stock and warrants to purchase up to an aggregate of 666,667 additional shares of common stock, at a combined purchase price of $15.00 per share and accompanying warrant. The Company generated gross proceeds of $10,000 and net proceeds of $9,179, after deducting underwriting discounts and commissions and other offering expenses.

At-The-Market Equity Offering

On July 2, 2020, the Company entered into an At-The-Market Sales Agreement (the "Sales Agreement") with BTIG, LLC ("BTIG"), pursuant to which the Company may offer and sell, from time to time, through BTIG, as sales agent and/or principal, shares of its common stock having an aggregate offering price of up to $50,000, subject to certain limitations on the amount of common stock that may be offered and sold by the Company set forth in the Sales Agreement. BTIG will be paid a 3% commission on the gross proceeds from each sale. The Company may terminate the Sales Agreement at any time; BTIG may terminate the Sales Agreement in certain limited circumstances. During the year ended December 31, 2024, the Company sold 4,366 shares of its common stock generating net proceeds of $54. The Company did not sell any shares of its common stock during the year ended December 31, 2025. At December 31, 2025, the Sales Agreement's available capacity was $44,191. As of the filing of this Form 10-K, the Company is subject to the General Instructions I.B.6 to Form S-3, known as the "*baby shelf* rules," which limit the number of securities it can sell under its registration statements on Form S-3.

Preferred Stock

In accordance with the Certificate of Incorporation, the Company is authorized to issue 10,000,000 preferred shares at a par value of $0.0001.

On February 13, 2025, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain investors (the "Purchasers"), pursuant to which the Company sold, in a private placement (the "Offering"), an aggregate of 3,300 shares of the Company's Series C Convertible Preferred Stock, par value $0.0001 per share (the "Preferred Stock"), initially convertible into up to 5,631,404 shares of the Company's common stock with a stated value of $1,000 per share (the "Stated Value"), and warrants (the "Warrants") to purchase up to an aggregate of 200% of the shares of Common Stock into which the shares of Preferred Stock are initially convertible, or 11,262,808 shares of Common Stock, for an offering price of $1,000 per share of Preferred Stock and accompanying Warrants in two equal tranches, the second of which closed on April 8, 2025.

Pursuant to the Purchase Agreement, on February 13, 2025, the Company issued and sold in an initial closing of the Offering (the "Initial Closing"), 1,650 shares of Preferred Stock, initially convertible into up to 2,815,702 shares of Common Stock, and accompanying Warrants, initially exercisable for up to 5,631,404 shares of Common Stock, for gross proceeds to the Company of $1.65 million. On April 4, 2025, the Company obtained shareholder approval ("Shareholder Approval") for the issuance of the Preferred Stock and Warrants, as required by the rules and regulations of NYSE American LLC (the " NYSE"), including Section 713 of the NYSE American Company Guide, and issued and sold, in a second closing of the Offering (the "Second Closing"), an additional 1,650 shares of Preferred Stock, initially convertible into up to 2,815,702 shares of Common Stock, and accompanying Warrants, initially exercisable for up to 5,631,404 shares of Common Stock, for gross proceeds to the Company of $1.65 million.

The following is a summary of the principal terms of Preferred Stock:

Voting. The holders of the Preferred Stock (the "Series C Holders") are entitled to vote with the holders of common stock, voting together as a single class, on all matters presented to stockholders. In any such vote, each share of the Preferred Stock is entitled to a number of votes equal to the Stated Value divided by $0.6393, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock.

Dividends. The Series C Holders are entitled to receive dividends on an as-converted basis, disregarding for such purpose any conversion limitations stated below, to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock. No other dividends shall be paid on shares of the Preferred Stock.

Liquidation Rights. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the Series C Holders are entitled to receive out of the assets available for distribution to stockholders, (i) after and subject to the payment in full of all amounts required to be distributed to the holders of another class or series of stock of the Company ranking on liquidation prior and in preference to the Preferred Stock, (ii) ratably with any class or series of stock designated as ranking on liquidation on parity with the Preferred Stock and (iii) in preference and priority to the holders of the shares of junior securities, an amount equal to one hundred percent (100%) of the Stated Value receive. If the Company's assets are insufficient to pay in full such amounts, then the entire assets to be distributed to the Series C Holders will be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Conversion Rights. Each share of the Preferred Stock is convertible at any time at the option of the Series C Holder thereof, into that number of shares of common stock, subject to the limitations described below, determined by dividing the Stated Value by the conversion price.

A Series C Holder will not have the right to convert any portion of its preferred stock if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such conversion. A holder may increase or decrease the beneficial ownership limitation up to 9.99%, provided, however, that any increase in the beneficial ownership limitation shall not be effective until 61 days following notice of such change to the Company.

Conversion Price. The conversion price for the Preferred Stock is $0.586, subject to anti-dilution adjustment.

Preemptive and Similar Rights. The Series C Holders have no preemptive or similar rights.

Redemption/Put Rights. There are no redemption or sinking fund provisions applicable to the Preferred Stock. All of the outstanding shares of the Preferred Stock are fully paid and non-assessable.

The following table summarizes the changes in Preferred Stock outstanding for the year ended December 31, 2025:

	Shares
Outstanding at December 31, 2024	—
Issued	3,300
Converted to Common Stock	(145)
Outstanding at December 31, 2025	3,155

Warrants

As of December 31, 2025, the Company had outstanding warrants to purchase 10,516,543 shares of common stock, 200,001 shares at an exercise price of $17.50 per share (the "2024 Warrants") and 10,316,542 shares at an exercise price of $0.64 (the "2025 Warrants").

The 2024 Warrants have an exercise price of $17.50, were exercisable beginning October 2, 2024, and expire on the five-and-one-half year anniversary of the date of issuance, or October 5, 2029.

The 2025 Warrants have an exercise price of $0.64 per share. The 2025 Warrants purchased in the Initial Closing of the Private Placement became exercisable on April 4, 2025, the effective date of the Shareholder Approval and will expire five years from the effective date of the Shareholder Approval, or April 4, 2030. The 2025 Warrants purchased in the Second Closing of the Private Placement were immediately exercisable and will expire on April 8, 2030.

On August 15, 2025, we entered into Warrant Exchange Agreements (the "Exchange Agreements") with certain holders (the "Exchanging Holders") of 2024 Warrants to purchase an aggregate of 466,666 shares of common stock. Pursuant to the Exchange Agreements, on August 15, 2025, the Company issued to the Exchanging Holders one share of common stock for each April Warrant, for an aggregate of 466,666 shares of common stock (the "Exchange Shares"), in exchange for the 2024 Warrants (the "Exchange"), in reliance on an exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended (the "Securities Act"). Following the consummation of the Exchange, the 2024 Warrants were cancelled, and no further shares are issuable pursuant to the 2024 Warrants.

The fair value of the 2024 Warrants immediately prior to Exchange was $483 and the total fair value of common stock issued was $1,101. The Company determined that the excess of fair value of the common stock issued over the fair value of the 2024 Warrants is not associated with anything other than the Exchange. Thus, the excess amount of $618 was recognized as a deemed dividend. As the Company does not have retained earnings, the dividend will be recognized through accumulated deficit. For purposes of calculating earnings per share, the Company reduced the income available to common stockholders by $618.

Once exercisable, the warrants may be exercised at any time in whole or in part upon payment of the applicable exercise price until expiration of the Warrants. No fractional shares will be issued upon the exercise of the Warrants. The exercise price and the number of warrant shares purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of certain events, which may include stock dividends, stock splits, combination and reclassifications of the Company capital stock or other similar changes to the equity structure of the Company. The warrants do not have a redemption feature. They may be exercised on a cashless basis at the holder's option and are classified as equity instruments. The warrants to purchase shares of common stock were valued on the date of issuance using the Black-Scholes option pricing model for the 2024 Warrants and the Monte Carlo Simulation model for the 2025 Warrants with the following assumptions:

2024 Warrants

Expected volatility		122.66%
Risk-free interest rate		4.38%
Stock price on date of grant	$	15.00
Exercise price	$	17.50
Dividend yield		0.00%
Expected term		0.5 to 5.5 years

2025 Warrants

Expected volatility		54.0% - 58.0%
Risk-free interest rate		3.84% -4.39%
Stock price on date of grant	$	0.51 -0.60
Exercise price	$	0.64
Dividend yield		0.00%
Expected term		5.0 years

A summary of warrants outstanding as of December 31, 2025 and 2024 were as follows:

	Shares
Outstanding at December 31, 2023	—
Issued	666,667
Exercised	—
Expired	—
Outstanding at December 31, 2024	666,667
Issued	11,262,808
Exercised	(946,266)
Exchanged	(466,666)
Expired	—
Outstanding at December 31, 2025	10,516,543

Note 15 – Accumulated Other Comprehensive Income/(Loss)

The following table summarizes the changes in accumulated other comprehensive income/(loss) by components during the years ended December 31, 2024:

	Net Unrealized Gains/(Losses) on Available-for-Sale Securities	**Accumulated Other Comprehensive Income/(Loss)**
Balance, December 31, 2023	$ (221)	$ (221)
Net unrealized gain on securities available-for-sale	221	221
Balance, December 31, 2024	$ —	$ —

All components of accumulated other comprehensive income/(loss) are net of tax and there was no activity during 2025.

Note 16 – Stock-based Compensation

2013 Plan

On August 2, 2013, the Company's Board adopted the 2013 Equity Compensation Plan (as amended to date, the "2013 Plan") pursuant to the terms described herein. The 2013 Plan was approved by the stockholders on August 7, 2013. Effective May 8, 2014, upon the approval of the Company's Board and its stockholders, the Company amended and restated the 2013 Plan, primarily to include "evergreen" provisions, which provided that the number of shares of common stock available for issuance under the 2013 Plan is subject to an automatic annual increase on January 1 of each year beginning in 2015; to amend the definition of "fair market value"; and to increase the limits on awards under the Plan. The 2013 Plan, which expired on May 7, 2024, provided for the granting of incentive stock options, nonqualified stock options, restricted stock units, performance units, and stock purchase rights.

As of December 31, 2025, there were 434,334 awards, including both restricted stock grants and option grants, issued and exercised under the 2013 Plan and no remaining shares available for grant under the 2013 Plan.

2025 Plan

On April 30, 2025, the Company's Board, subject to the approval of its stockholders, which was received on June 23, 2025, adopted a new 2025 Equity Incentive Plan (the "2025 Plan") to succeed the 2013 Plan. The general purpose of the 2025 Plan is to provide an incentive to its employees, directors, consultants and advisors by enabling them to share in the future growth of our business. The term of the 2025 Plan is 10 years.

As of December 31, 2025, there were 116,500 options outstanding and 646,548 remaining shares available for grant under the 2025 Plan.

The Company recognized stock-based compensation expense (options and restricted share grants) in the following expense categories of its consolidated statements of operations as follows:

	Year Ended December 31,	
	2025	**2024**
Research and Development	$ 85	$ 1,087
General and Administrative	938	2,108
Total	$ 1,023	$ 3,195

Stock Options

The following table summarizes the Company' stock option activity and related information for the period from January 1, 2024 to December 31, 2025:

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term in Years
Outstanding at January 1, 2024	934,243	$ 41.67	7.4
Granted	—	—	
Exercised	—	—	
Forfeited	(188,618)	18.97	
Expired	(58,269)	56.76	
Outstanding at December 31, 2024	687,356	$ 46.71	4.6
Granted	116,500	0.59	
Exercised	—	—	
Forfeited	(3,101)	20.19	
Expired	(343,536)	47.19	
Outstanding at December 31, 2025	457,219	$ 34.76	6.5

The following table summarizes outstanding options at December 31, 2025, by their exercise price:

Range of Exercise Prices	Number Outstanding	Weighted Average Exercise Price Per Share
$0.59 - $12.35	207,102	$ 5.73
$21.50 - $30.50	69,571	$ 25.96
$46.00 - $68.00	139,871	$ 55.14
$113.50 - $166.00	40,675	$ 127.53
	457,219	$ 34.76

As of December 31, 2025, the number of vested shares underlying outstanding options was 285,211 at a weighted average exercise price of $34.76. None of these outstanding options were in-the-money as of December 31, 2025, therefore they had no intrinsic value. As of December 31, 2025, there was $773 of total unrecognized share-based compensation. Such costs are expected to be recognized over a weighted average period of approximately 1.7 years.

All outstanding options expire ten years from date of grant. Options granted to employees prior to 2018 vest in equal monthly installments over three years. Beginning in 2018, options granted to employees vest over four years, with 25% of the shares vesting on the first annual anniversary of grant and the remaining shares vesting in 36 equal monthly installments over the following 3 years.

The resulting compensation expense for stock options is generally recognized on a straight-line basis over the requisite service period of the award. No awards were granted under the Plan during the year ended December 31, 2024. The following weighted-average assumptions were used to calculate share-based compensation for awards granted under the Plan during the year ended December 31, 2025:

Volatility	119.5% - 128.9%
Risk-free interest rate	4.00% - 4.35%
Grant date fair value for options awarded during 2025	$ 0.82
Dividend yield	0.0%
Expected life	6.0 - 10.0 years

The Company does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. Hence, the Company uses the “simplified method” described in Staff Accounting Bulletin (SAB) 107 to estimate the expected term of share option grants.

The expected stock price volatility assumption is based on the Company’s historical stock price volatility.

Exhibit 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following is a description of our common stock and preferred stock, as set forth in our certificate of incorporation, as amended to date (the "Certificate of Incorporation"), our bylaws, as amended to date (the "Bylaws"), and the Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (the "Certificate of Designation"), each of which is incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.2 is a part. This summary does not purport to be complete and is qualified in its entirety by the full text of the Certificate of Incorporation, Bylaws and Certificate of Designation, as well as to the applicable provisions of the Delaware General Corporation Law (the "DGCL"). We encourage you to read our Certificate of Incorporation, Bylaws, the Certificate of Designation and the applicable portions of the DGCL carefully.

General

Our authorized capital stock consists of 500,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

Common Stock

Voting. The holders of our common stock are entitled to one vote for each share held of record on all matters on which the holders are entitled to vote (or consent to), including the election of directors. Our Certificate of Incorporation and Bylaws do not provide for cumulative voting rights. As a result, the holders of a plurality of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election, if they should so choose. With respect to matters other than the election of directors, at any meeting of the stockholders at which a quorum is present or represented, the affirmative vote of a majority of the votes properly cast on such matter shall be the act of the stockholders, except as otherwise required by law, the Certificate of Incorporation, the Bylaws or the rules or regulations of any stock exchange applicable to the Company. One-third of the voting power of the shares entitled to vote at the meeting, present in person or represented by proxy, shall constitute a quorum at any meeting of stockholders.

Dividends. Subject to applicable law and the rights, if any, of the holders of any outstanding series of preferred stock or any class or series of stock having a preference over or the right to participate with the common stock with respect to the payment of dividends, dividends may be declared and paid or set apart for payment upon the common stock out of any assets or funds of the Company legally available for the payment of dividends, but only when and as declared by our board of directors or any authorized committee thereof.

Liquidation Rights. Upon the dissolution, liquidation or winding up of the Company, after payment or provision for payment of the debts and other liabilities of the Company and subject to the rights, if any, of the holders of any outstanding series of preferred stock or any class or series of stock having a preference over or the right to participate with the common stock with respect to the distribution of assets of the Company, upon such dissolution, liquidation or winding up of the Company, the holders of common stock shall be entitled to receive the remaining assets of the Company available for distribution to its stockholders ratably in proportion to the number of shares held by them.

Conversion Rights. The holders of our common stock have no conversion rights.

Preemptive and Similar Rights. The holders of our common stock have no preemptive or similar rights.

Redemption/Put Rights. There are no redemption or sinking fund provisions applicable to the common stock. All of the outstanding shares of our common stock are fully paid and non-assessable.

Transfer Agent and Registrar. The transfer agent and registrar for our common stock is VStock Transfer, LLC.

Listing. Our common stock is listed on the NYSE American LLC under the ticker symbol "MTNB."

Preferred Stock

We are authorized to issue up to 10,000,000 shares of preferred stock, par value $0.0001 per share, with such designations, rights and preferences as may be determined from time to time by our board of directors. Accordingly, our board of directors has the authority, within the limitations and restrictions prescribed by law and without stockholder approval, to provide by resolution for the issuance of shares of preferred stock, and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference and the number of shares constituting any series of the designation of such series. The issuance of preferred stock could have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, decreasing the market price of the common stock, impeding or delaying a possible takeover or change in control of our company, and adversely affecting the voting and other rights of the holders of our common stock, all without further action by our stockholders.

If we offer a specific series of preferred stock, we will describe the terms of the preferred stock in the prospectus supplement for such offering and will file a copy of the certificate of designation establishing the terms of the preferred stock with the Securities and Exchange Commission. To the extent required, this description will include:

- the title and stated value;
- the number of shares offered, the liquidation preference per share and the purchase price;
- the dividend rate(s), period(s) and/or payment date(s), or method(s) of calculation for such dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption, if applicable;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price (or how it will be calculated) and conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price (or how it will be calculated) and exchange period;
- voting rights, if any, of the preferred stock;
- a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of the affairs of the Company; and
- any material limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of the Company.

Series C Convertible Preferred Stock

The following is a summary of the principal terms of our Series C Convertible Preferred Stock (the "Series C Preferred") as set forth in the Certificate of Designation.

On February 13, 2025, we issued 1,650 shares of Series C Preferred, and on April 8, 2025, we issued an additional 1,650 shares of Series C Preferred. As of December 31, 2025, 3,155 shares of Series C Preferred were outstanding.

Voting. The holders of our Series C Preferred (the "Series C Holders") are entitled to vote with the holders of common stock, voting together as a single class, on all matters presented to stockholders. In any such vote, each share of Series C Preferred is entitled to a number of votes equal to the stated value per share of the Series C Preferred ($1,000) divided by $0.6393, subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the common stock.

Dividends. The Series C Holders are entitled to receive dividends on an as-converted basis, disregarding for such purpose any conversion limitations stated below, to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock. No other dividends shall be paid on shares of Series C Preferred.

Liquidation Rights. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the Series C Holders are entitled to receive out of the assets available for distribution to stockholders, (i) after and subject to the payment in full of all amounts required to be distributed to the holders of another class or series of stock of the Company ranking on liquidation prior and in preference to the Series C Preferred, (ii) ratably with any class or series of stock designated as ranking on liquidation on parity with the Series C Preferred and (iii) in preference and priority to the holders of the shares of junior securities, an amount equal to one hundred percent (100%) of the stated value and no more, in proportion to the full and preferential amount that all shares of the Series C Preferred are entitled to receive. If the Company's assets are insufficient to pay in full such amounts, then the entire assets to be distributed to the Series C Holders will be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Conversion Rights. Each share of Series C Preferred is convertible at any time at the option of the Series C Holder thereof, into that number of shares of common stock, subject to the limitations described below, determined by dividing the stated value by the conversion price.

A Series C Holder will not have the right to convert any portion of its preferred stock if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such conversion. A holder may increase or decrease the beneficial ownership limitation up to 9.99%, provided, however, that any increase in the beneficial ownership limitation shall not be effective until 61 days following notice of such change to the Company.

Conversion Price. The conversion price for the Series C Preferred is $0.586, subject to anti-dilution adjustment as set forth in the Certificate of Designation.

Preemptive and Similar Rights. The Series C Holders have no preemptive or similar rights.

Redemption/Put Rights. There are no redemption or sinking fund provisions applicable to the Series C Preferred. All of the outstanding shares of the Series C Preferred are fully paid and non-assessable.

Transfer Agent and Registrar. The transfer agent and registrar for our Series C Preferred is VStock Transfer, LLC.

Anti-takeover Effects of Delaware Law and of the Certificate of Incorporation

The following paragraphs summarize certain provisions of the DGCL, the Certificate of Incorporation and the Bylaws that may have the effect of discouraging an acquisition of our Company. The summary does not purport to be complete and is subject to and qualified in its entirety by reference to the DGCL, the Certificate of Incorporation and the Bylaws.

Section 203 of the DGCL

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary and the interested stockholder;
- any sale, lease, mortgage, pledge, transfer or other disposition to or with the interested stockholder of assets of the corporation or any direct or indirect majority-owned subsidiary having an aggregate value equal to 10% or more of (x) the fair value of the corporation's consolidated assets or (y) the aggregate market value of all outstanding stock of the corporation;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or any direct or indirect majority-owned subsidiary of any stock of the corporation or such subsidiary to the interested stockholder;
- any transaction involving the corporation or any direct or indirect majority-owned subsidiary that has the effect of increasing the interested stockholder's proportionate share of the stock or any class or series of the corporation or such subsidiary; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation or any direct or indirect majority-owned subsidiary.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the price of our common stock.

Certificate of Incorporation and Bylaws

Our Certificate of Incorporation and Bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control of our company. These provisions are as follows:

- They provide that special meetings of stockholders may be called only (i) by the board of directors pursuant to a resolution adopted by a majority of our board of directors, or (ii) by the Secretary upon the written request of stockholders of record who, in the aggregate, own at least 20% of the voting power of the outstanding shares entitled to vote at such meeting. The board of directors may postpone or reschedule any previously scheduled special meeting of stockholders;
- They do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in our board of directors;
- They allow us to issue "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- Our Bylaws require stockholders who wish to nominate directors to deliver a timely written notice to the Secretary at our principal executive offices. For an annual meeting, notice must be received during the window beginning 120 days and ending 90 days before the anniversary of the prior year's annual meeting, with adjustments if the meeting is advanced by more than 30 days or delayed by more than 60 days (or if no meeting was held the prior year), in which case the deadline is the later of 90 days before the meeting or 10 days after public announcement of the meeting date. For a special meeting at which directors are to be elected pursuant to the Company's notice of meeting, nominations may be made only by the board of directors (or a committee thereof) or by a stockholder of record who delivers notice during the window beginning 120 days before the meeting and ending on the later of 90 days before the meeting or 10 days after the first public announcement of the meeting and the nominees to be elected. These procedures may preclude the conduct of business if not followed and may discourage or deter a potential acquirer from soliciting proxies to elect its own slate of directors or otherwise seeking to obtain control of our company;
- Our Certificate of Incorporation authorizes only our board of directors to fill vacant directorships; and

- Our Certificate of Incorporation provides that, unless we consent in writing to an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, creditors or other constituents, (iii) any action asserting a claim against us or any of our directors or officers arising under, or relating to the interpretation or application of, the DGCL, the Certificate of Incorporation or the Bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine, in each case subject to that court's having personal jurisdiction over indispensable parties. If, and only if, the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state court sitting in the State of Delaware. Any person or entity purchasing or otherwise acquiring any interest in our capital stock is deemed to have notice of, and consented to, this provision. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act of 1933, as amended (the "Securities Act"), or the Securities Exchange Act of 1934, as amended (the "Exchange Act") or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

Potential Effects of Authorized but Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the DGCL and subject to any limitations set forth in the Certificate of Incorporation. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

Exhibit 21.1

Subsidiaries of Matinas BioPharma Holdings, Inc.

Name	State of Incorporation
Matinas BioPharma, Inc.	Delaware
Matinas BioPharma Nanotechnologies, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Matinas BioPharma Holdings, Inc. on Form S-3 (No. 333-272580 and 333-286686) and Form S-8 (Nos. 333-198488, 333-203141, 333-210495, 333-215456, 333-222912, 333-237315, 333-253659, 333-264095, 333-271059 and 333-288245) of our report dated March 31, 2026, on our audits of the financial statements as of December 31, 2025 and 2024 and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 31, 2026. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ EISNERAMPER LLP

EISNERAMPER LLP
Iselin, New Jersey
March 31, 2026

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER

I, Jerome D. Jabbour, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2025 of Matinas BioPharma Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(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; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2026

/s/ Jerome D. Jabbour
Jerome D. Jabbour
Chairman, Chief Executive Officer, President and Interim Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF
THE PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(b)
OF THE SECURITIES EXCHANGE ACT OF 1934 AND 18 U.S.C. SECTION 1350

In connection with the Annual Report on Form 10-K of Matinas BioPharma Holdings, Inc. (the "Company") for the fiscal year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Jerome D. Jabbour, Chief Executive Officer and Interim Chief Financial Officer, hereby certifies, to the knowledge of the undersigned, pursuant to 18 U.S.C. Section 1350, 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.

Date: March 31, 2026

/s/ Jerome D. Jabbour
Jerome D. Jabbour
Chairman, Chief Executive Officer, President and Interim Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

This Certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.