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, 2023

☐ 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 001-41159

IMMIX BIOPHARMA, INC.
(Exact name of registrant as specified in charter)

Delaware	**45-4869378**
(State or jurisdiction of Incorporation or organization)	I.R.S. Employer Identification No.
11400 West Olympic Blvd., Suite 200, Los Angeles, CA	**90064**
(Address of principal executive offices)	(Zip code)

(310) 651-8041
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, $0.0001 par value	IMMX	The Nasdaq Stock Market LLC

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 definition 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 by Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter ended June 30, 2023 was $27,964,126 based upon the closing price of the registrant's common stock of $2.69 on The Nasdaq Capital Market as of that date.

Number of common shares outstanding as of March 29, 2024 was 26,396,420 shares.

Documents Incorporated by Reference: Portions of the registrant's definitive proxy statement (the "2024 Proxy Statement") relating to its 2043 annual meeting of stockholders (the "2024 Annual Meeting of Stockholders") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2024 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by such forward-looking terminology as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. Our forward-looking statements are based on a series of expectations, assumptions, estimates and projections about our company, are not guarantees of future results or performance and involve substantial risks and uncertainty. We may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Our business and our forward-looking statements involve substantial known and unknown risks and uncertainties, including the risks and uncertainties inherent in our statements regarding:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operations;
- the success, cost and timing of our clinical trials;
- our dependence on third parties in the conduct of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize our product candidates;
- the potential that results of pre-clinical and clinical trials indicate our current product candidates or any future product candidates we may seek to develop are unsafe or ineffective;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current and future product candidates;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;
- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against claims against us;
- our reliance on third-party suppliers and manufacturers;
- the success of competing therapies and products that are or become available;
- our ability to expand our organization to accommodate potential growth and our ability to retain and attract key personnel;
- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our product candidates;
- market acceptance of our product candidates, the size and growth of the potential markets for our current product candidates and any future product candidates we may seek to develop, and our ability to serve those markets; and
- the successful development of our commercialization capabilities, including sales and marketing capabilities.

All of our forward-looking statements are as of the date of this Annual Report on Form 10-K only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of, or any material adverse change in, one or more of the risk factors or risks and uncertainties referred to in this Annual Report on Form 10-K or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the U.S. Securities and Exchange Commission (the "SEC") could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Annual Report on Form 10-K, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Annual Report on Form 10-K that modify or impact any of the forward-looking statements contained in this Annual Report on Form 10-K will be deemed to modify or supersede such statements in this Annual Report on Form 10-K.

This Annual Report on Form 10-K may include market data and certain industry data and forecasts, which we may obtain from internal company surveys, market research, consultant surveys, publicly available information, reports of governmental agencies and industry publications, articles and surveys. Industry surveys, publications, consultant surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. While we believe that such studies and publications are reliable, we have not independently verified market and industry data from third-party sources.

RISK FACTOR SUMMARY

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors," together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

Risks Relating to Our Financial Position and Capital Needs

- We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.
- We need significant additional financing to fund our operations and complete the development and, if approved, the commercialization of our product candidates. 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 our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

Risks Relating to the Development and Regulatory Approval of Our Product Candidates

- We have a limited number of product candidates, all which are still in early clinical or pre-clinical development. If we do not obtain regulatory approval of one or more of our product candidates, or experience significant delays in doing so, our business will be materially adversely affected.
- Clinical trials are expensive, time consuming, difficult to design and implement, and involve uncertain outcomes. Results of previous pre-clinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or other regulatory authorities.
- We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidates are being studied which could delay or prevent the start of clinical trials for our product candidates.

- Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

- We are dependent on third parties for manufacturing and marketing of our product candidates. If we are not able to secure favorable arrangements with such third parties or the third parties upon whom we rely do not perform, including failure to perform to our specifications or comply with applicable regulations, our business and financial condition could be harmed.

- If any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, in which case revenue generated from their sales would be limited.

- Even if we receive regulatory approval to commercialize any of the product candidates that we develop, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

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

- Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain for such product candidates. If we fail to comply with regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

Risks Relating to our Business and Operations

- If the market opportunities for our current and potential future product candidates are smaller than we believe they are, our ability to generate product revenue may be adversely affected and our business may suffer.

- Our products will face significant competition, and if they are unable to compete successfully, our business will suffer.

- Any international operations we undertake may subject us to risks inherent with operations outside of the United States.

Risks Relating to our Intellectual Property

- We may be subject to claims that our employees or consultants have wrongfully used or disclosed alleged trade secrets.

- Our intellectual property may not be sufficient to protect our product candidates from competition, which may negatively affect our business. We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights.

- We conduct certain research and development operations through our Australian wholly-owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations could suffer.

Risks Related to Owning our Common Stock

- We are currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on Nasdaq or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

- Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

- We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.

PART I

Throughout this Annual Report on Form 10-K, references to "we," "our," "us," the "Company," "Immix," or "Immix Biopharma" refer to Immix Biopharma, Inc., individually, or as the context requires, collectively with its subsidiaries.

ITEM 1. BUSINESS

Overview

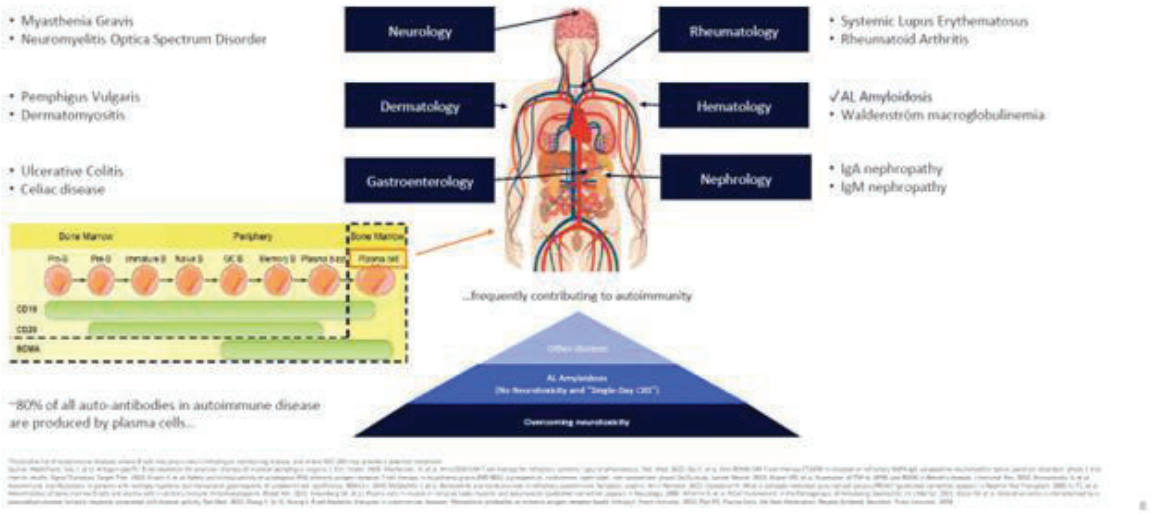
Immix Biopharma, Inc. is a clinical-stage biopharmaceutical company focused on the application of chimeric antigen receptor cell therapy ("CAR-T") in light chain (AL) Amyloidosis and autoimmune disease. Our lead cell therapy candidate is U.S. Food and Drug Administration ("FDA") investigational new drug ("IND") cleared CAR-T NXC-201, currently being evaluated in our ongoing Phase 1b/2a NEXICART-1 (NCT04720313) clinical trial. Based on early clinical data, we believe NXC-201 has the potential to be the world's first "Single-Day Cytokine Release Syndrome", or "Single-Day CRS" CAR-T (CRS median onset day 1, median duration 1 day), enabling the potential for a faster return home for patients. NXC-201 has been awarded Orphan Drug Designation ("ODD") by the FDA in both AL Amyloidosis and multiple myeloma, and ODD by the European Commission ("EMA") in AL Amyloidosis.

Our strategy is to:

- Develop our lead candidate CAR-T NXC-201 in AL Amyloidosis and other autoimmune diseases
- Pursue development of NXC-201 and additional cell therapy candidates in other applicable indications where CAR-T is not an approved therapy today

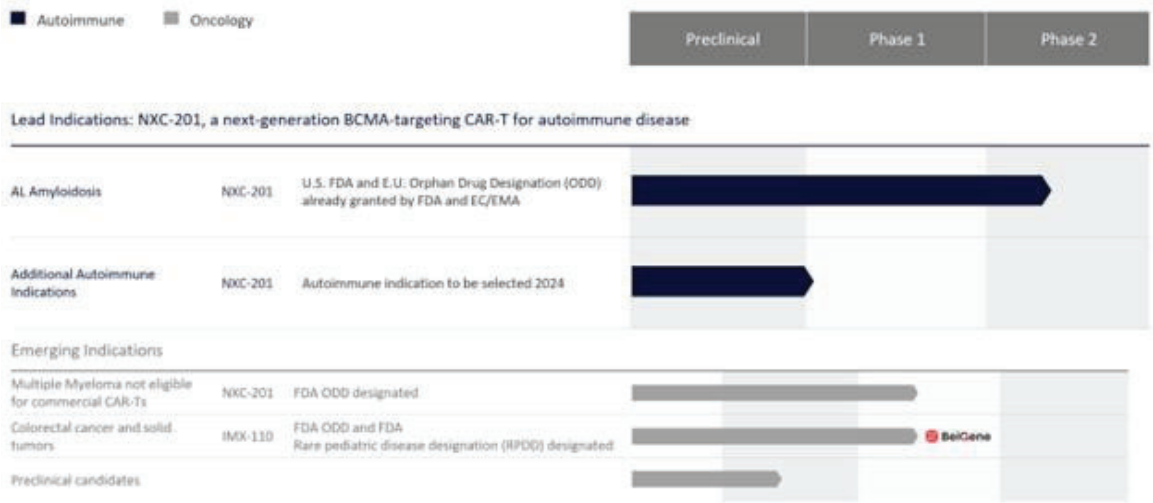
Our mission is to harness the immune system through innovative cell therapies and other modalities to deliver widely accessible cures in autoimmune and other indications, as we believe patients are waiting.

Figure 1: Select ImmixBio Possible Autoimmune Target Indications



Our N-GENIUS platform has produced our clinical-stage lead candidate NXC-201, a next-generation CAR-T for AL Amyloidosis and autoimmune disease, complemented by emerging programs.

Figure 2: ImmixBio Pipeline



NXC-201 is in clinical trials to treat relapsed/refractory AL Amyloidosis.

As of February 2024, we have treated 73 patients in our ongoing Phase 1b/2a NEXICART-1 (NCT04720313), of which 63 were relapsed/refractory multiple myeloma patients, and 10 were relapsed/refractory AL Amyloidosis patients.

In September 2023, the FDA granted ODD to NXC-201 for the treatment of AL Amyloidosis. If a product that has ODD subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications to market the same drug for the same indication for 7 years (except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity).

In November 2023, the U.S. FDA cleared an IND application for NXC-201 to enroll U.S. patients into NXC-201 clinical trials.

In December 2023, NXC-201 clinical data in relapsed/refractory AL Amyloidosis was presented in an oral presentation at the 65th annual American Society of Hematology ("ASH") meeting, covering 10 relapsed/refractory AL Amyloidosis patients treated with NXC-201, indicating an overall response rate of 100% (10/10) and a complete response rate of 70% (7/10).

In February 2024, the European Commission ("EC") granted orphan drug designation to NXC-201 for the treatment of AL Amyloidosis. Benefits of European ODD include: 10 years of market exclusivity once authorized in the EU; Access to the EU centralized authorization procedure; and reduced fees for EU protocol assistance, marketing authorization applications, inspections before authorization, applications for changes to marketing authorizations made after approval, and reduced annual fees.

Our Other Programs

Our other programs include NXC-201 for autoimmune diseases, a $25 billion combined annual market size according to Grand View Research and Fortune Business Insights; NXC-201 for relapsed/refractory multiple myeloma, a $14 billion market size growing to $27 billion according to Wilcock, et al, Nature Reviews; IMX-110 for soft tissue sarcoma, a $3 billion market size according to Medgadget, and in combination with anti-PD-1 for colorectal cancer, a $27 billion market size according to IndustryARC.

Our Platform and Technologies

We believe our N-GENIUS platform has broad potential utility in hematologic and autoimmune diseases.

Our N-GENIUS platform, which has produced NXC-201, consists of three key elements: (1) Purpose-Built Cell Therapy Evidence Capture Engine + Relational Database, which relates ImmixBio internal data to external to accelerate therapy design, manufacture, and preclinical; (2) proprietary EXPAND technology, which is applied to multiple cell therapy indications, already utilized to create NXC-201; and (3) Atomized, Novel Binding Scaffold Generation Engine, which allows for optimal molecule binding. We believe key characteristics of NXC-201 may apply to other products candidates produced by the N-GENIUS Platform. Those 3 key characteristics are: (a) high transduction efficiency (supporting efficient manufacturing), (b) low tonic signaling (lower off-target toxicity may lead to lower toxicity), and (c) anti-exhaustion capability (increased persistence may lead to activity over an extended period of time).

Our Lead Program: NXC-201 in relapsed/refractory AL Amyloidosis

Market Opportunity

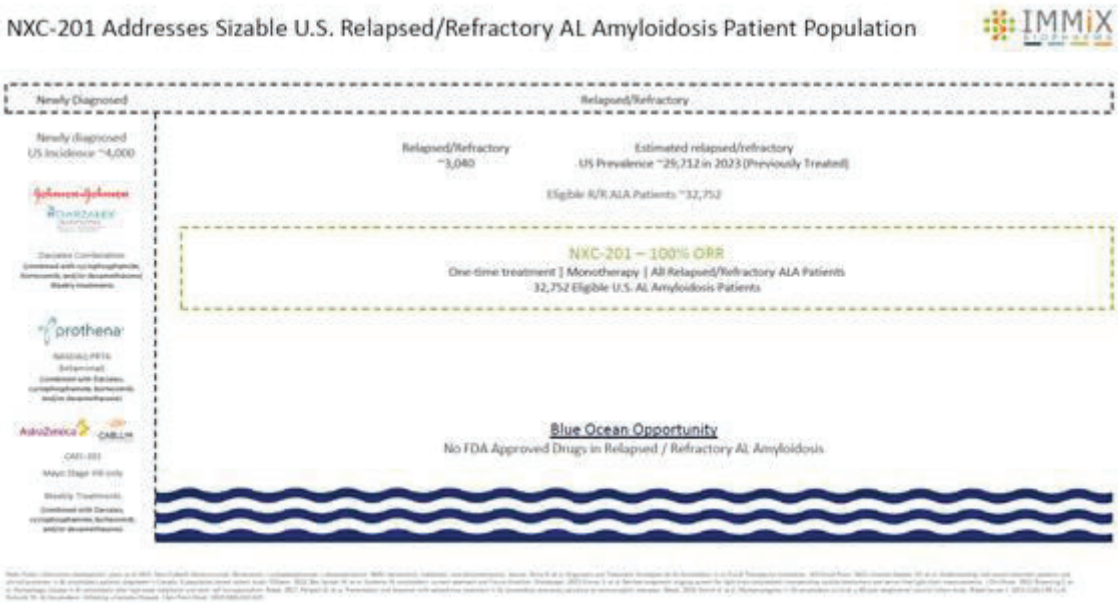
The first indication we intend to pursue for NXC-201 is relapsed/refractory AL Amyloidosis.

AL amyloidosis is a life-threatening immunological disorder in which an abnormal protein called amyloid builds up in tissues and organs. This abnormal protein is produced by long-lived plasma cells ("LLPCs"), a type of immune B-cell. The signs and symptoms of AL amyloidosis vary among patients because build-up may occur in the heart (most frequent cause of mortality), liver, kidneys, intestines, muscles, joints, nerves, or spleen, according to the National Institutes of Health ("NIH"). Diagnosis is frequently delayed, due to varied and non-specific symptoms including: fatigue, weight loss, shortness of breath, dizziness, and numbness in hands and feet. Upon diagnosis, many patients already have late-stage disease, and are not aware of available treatment options and clinical trials.

The U.S. observed prevalence of relapsed/refractory AL Amyloidosis is growing 12% per year according to Staron, et al Blood Cancer Journal, estimated to reach 29,712 patients in 2023. AL amyloidosis has a one-year mortality rate of 47 percent, 76 percent of which is caused by cardiac amyloidosis, according to Alexion. The current market size for amyloidosis therapies is $3.6 billion, expected to reach $6 billion in 2027, according to Grand View Research.

As of February 2024, there are no FDA approved drugs for AL Amyloidosis.

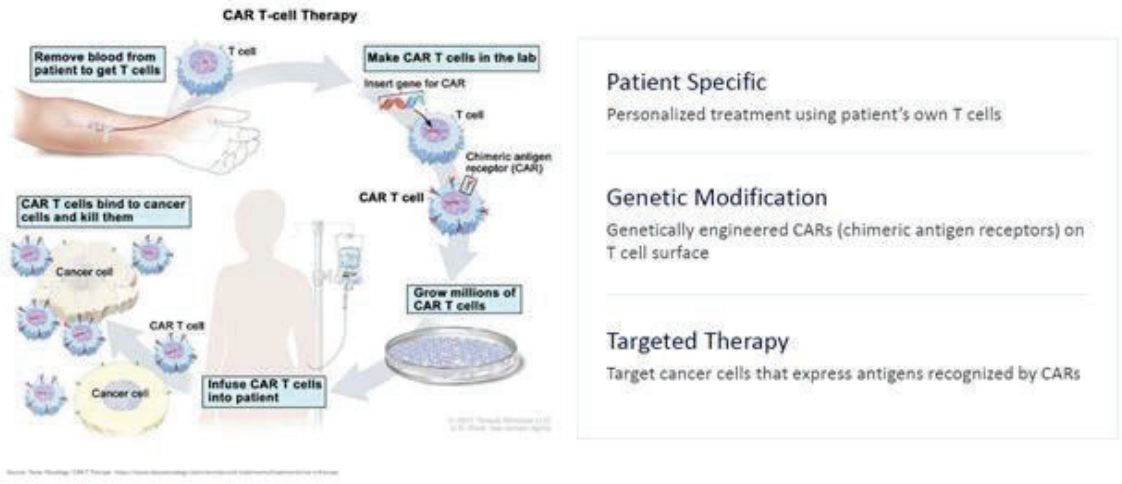
Figure 3: NXC-201 "Blue Ocean Opportunity" in AL Amyloidosis



NXC-201 Composition and Mechanism of Action

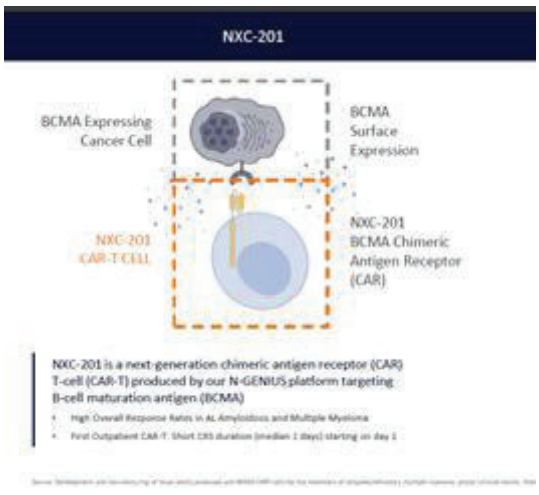
NXC-201 is a next-generation CAR-T targeting B-cell maturation antigen ("BCMA"). CAR-T cell therapy is a type of immunotherapy that uses the patient's own immune cells, modified with our proprietary technology, to create NXC-201, which is then introduced into the patient's body. Then the patient's modified NXC-201 CAR-T cells are able to recognize and eliminate diseased cells.

Figure 4: NXC-201: What is CAR-T Cell Therapy?



Our N-GENIUS cell engineering platform with EXPAND technology has already produced clinical-stage CAR-T NXC-201, targeting BCMA, which we believe is the first and only autologous CAR-T being developed to treat light-chain (AL) Amyloidosis. NXC-201 is currently being evaluated in our ongoing Phase 1b/2a NEXICART-1 (NCT04720313) clinical trial.

Figure 5: NXC-201: First CAR-T Generated by the N-GENIUS Platform

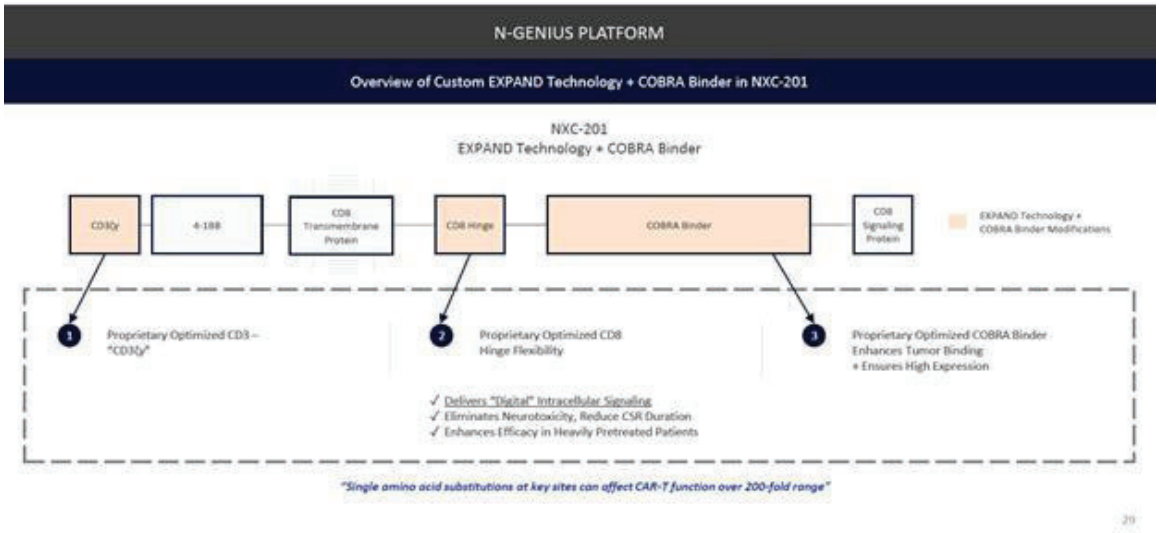


Those 3 key characteristics of NXC-201 are: (a) high transduction efficiency (supporting efficient manufacturing), (b) low tonic signaling (lower off-target toxicity may lead to lower toxicity), and (c) anti-exhaustion capability (increased persistence may lead to activity over an extended period of time).

Figure 6: NXC-201: Key Characteristics

NXC-201 has been designed with a proprietary, optimized C3ζγ for enhanced signal transduction, proprietary, optimized modified-stiffness CD8 hinge, and proprietary, optimized COBRA binder for enhanced signal binding. We believe the combination of these modifications has the potential to allow for NXC-201 to deliver "digital" intracellular signaling, potentially eliminating neurotoxicity and reducing CRS duration to 1 day.

Figure 7: N-GENIUS Platform – EXPAND Technology + COBRA Binder



NXC-201 was designed for high activity against disease-causing AL Amyloidosis LLPCs, which are also the source of autoimmune antibodies in a variety of autoimmune disorders.

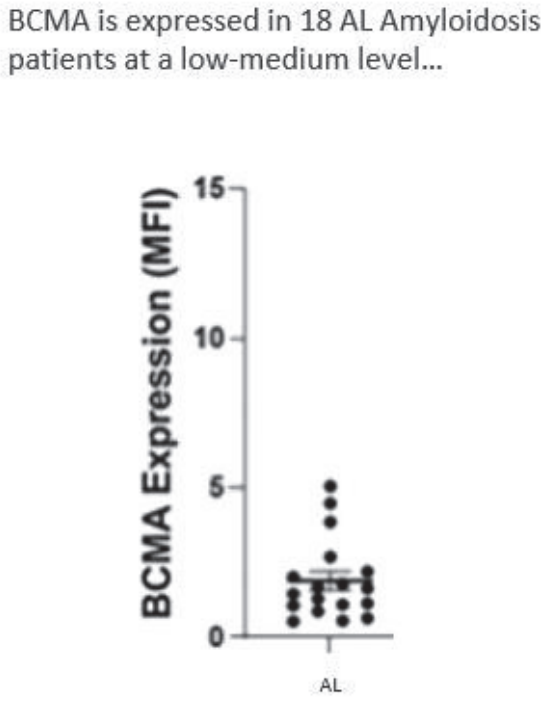
NXC-201 Pre-clinical Data

In AL Amyloidosis, we believe there are two primary challenges with CAR-T patient dosing:

a) Uneven BCMA expression across disease-causing LLPCs; and
b) frail patient due to pre-existing organ (heart) damage.

Published in *Clinical Cancer Research* in 2022, NXC-201 was tested preclinical and clinically in AL Amyloidosis.

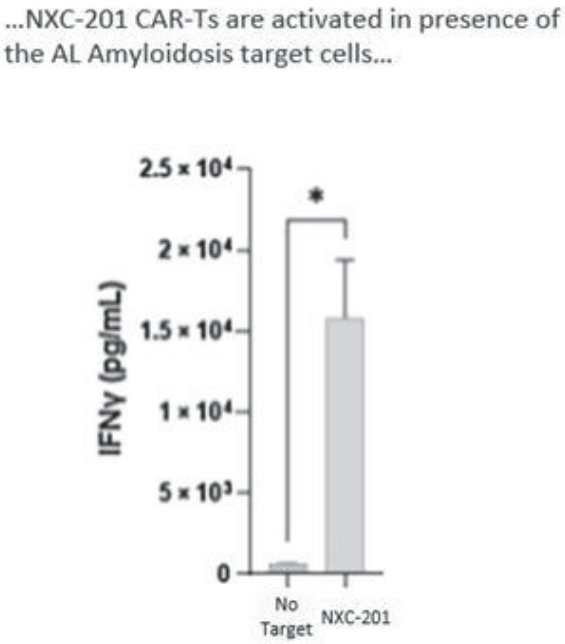
Figure 8: In AL Amyloidosis, BCMA expression is at a low-to-medium level



Source: *Clinical Cancer Research, Kfir-Erenfeld,et al, 2022*

Our testing demonstrated low-to-medium expression of BCMA in 18 AL Amyloidosis patient samples.

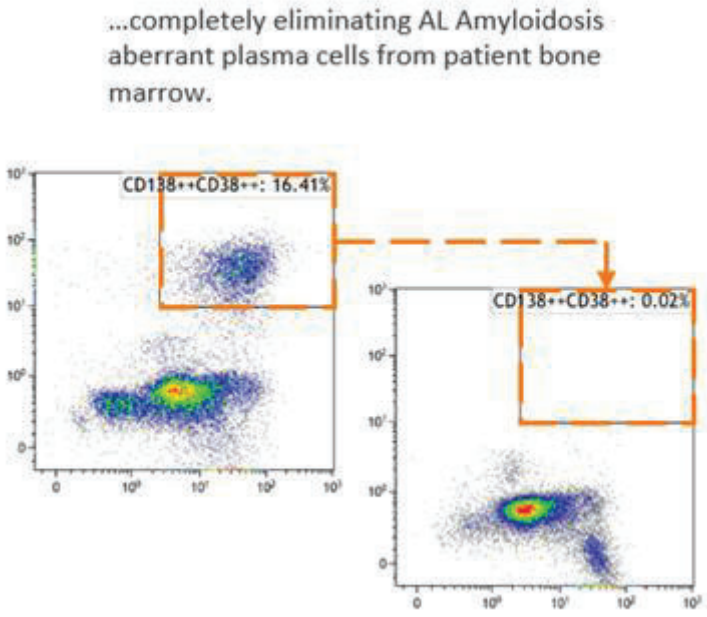
Figure 9: High Activity Level of NXC-201 in AL Amyloidosis



Source: *Clinical Cancer Research, Kfir-Erenfeld,et al, 2022*

NXC-201 demonstrated high activity in the presence of AL Amyloidosis diseased plasma cells.

Figure 10: NXC-201 Targets Diseased AL Amyloidosis LLPCs in Patient Bone Marrow



Source: *Clinical Cancer Research, Kfir-Erenfeld,et al, 2022*

Near-complete elimination of diseased AL Amyloidosis LLPCs was observed in relapsed/refractory AL Amyloidosis patients treated with NXC-201.

NXC-201 Clinical Data – Relapsed/refractory AL Amyloidosis

In December 2023, NXC-201 clinical data in relapsed/refractory AL Amyloidosis was presented in an oral presentation at the 65th annual ASH meeting, covering 10 relapsed/refractory AL Amyloidosis patients treated with NXC-201. These data represent the largest cohort of AL patients treated with CAR T-based therapy reported in the literature thus far.

Clinical Results

Enrolled AL amyloidosis patients presented with organ involvement and were heavily pretreated with prior lines of therapy (median 6, range 3-10). All patients had refractory, progressive disease. No patients received bridging therapy.

NXC-201 was administered at cell doses of either 150×10^6, 450×10^6, and 800×10^6 per patient.

Patient characteristics:

- 90% (9/10) had high-risk cytogenetics
- 80% (8/10) had cardiac involvement
- 50% (5/10) had New York Heart Association ("NYHA") stage 3 or 4 heart failure (3 stage 4, 2 stage 3)
- 40% (4/10) had Mayo stage 3 (1 stage 3b, 3 stage 3a) AL amyloidosis disease
- 40% (4/10) had t(11;14) translocation
- Relapsed/refractory to a median 6 lines of prior therapy (range: 3-10)

Clinical data:

- Overall response rate of 100% (10/10)
- Complete response + very good partial response rate of 90% (9/10)
- Complete response rate of 70% (7/10) (6 out of 7 were minimum residual disease ("MRD") 10^{-5})
- Organ response rate of 60% (6/10)
- Best responder had a duration of response of 23.7 months as of December 10, 2023, with response ongoing
- There were no immune effector cell-associated neurotoxicity syndrome (ICANS) events
- "Single Day CRS": Median CRS duration was 1 day (range: 1-4):
    - No grade 4 CRS events
    - 2 experienced no CRS; 2 experienced grade 1 CRS; 4 Experienced grade 2 CRS; 2 experienced grade 3 CRS

For the 8 patients with cardiac involvement:

- Overall response rate of 100% (8/8)
- Complete response rate of 63% (5/8) (4 out of 5 were MRD 10^{-5})
- Organ response rate of 63% (5/8)

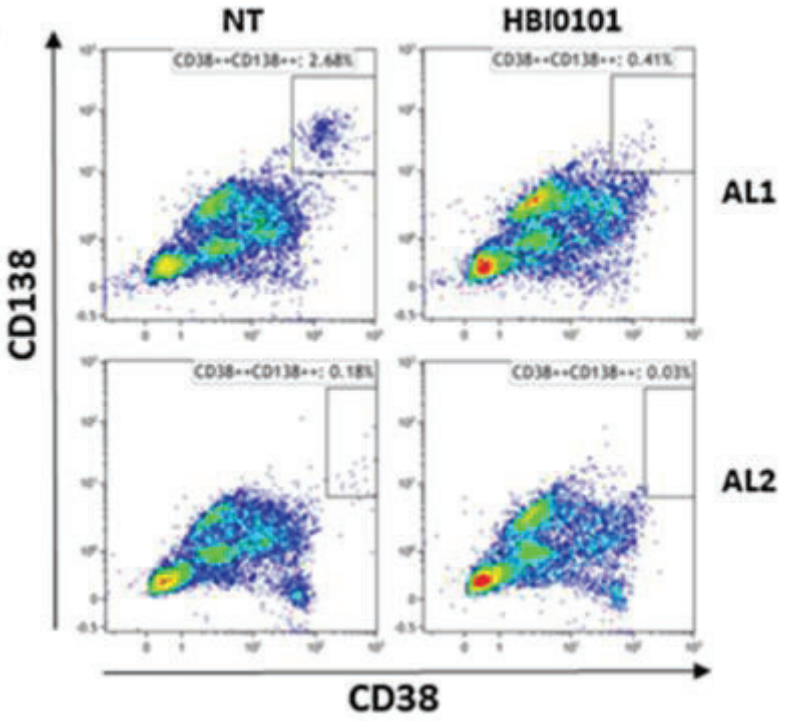
For the 4 patients with t(11;14) disease:

- Overall response rate of 100% (4/4)
- Complete response rate of 75% (3/4) (MRD 10^{-5})
- Organ response rate of 50% (2/4)

In Vitro Studies

NXC-201 has demonstrated efficient eradication of plasma cells from patients with AL amyloidosis (Kfir-Erenfeld et al. 2022). Co-cultures of plasma cells from AL amyloidosis patients and NXC-201 resulted in an almost complete eradication of the plasma cells. A control of AL amyloidosis plasma cells with non-transduced ("NT") cells, in contrast, did not result in a similar elimination of the plasma cells.

Figure 11. Elimination of Plasma Cells After Co-culture with NXC-201 Compared to NT Cells



Abbreviations: AL: amyloid light chain; NT: non-transduced; HBI0101 = NXC-201. **Source:** (Kfir-Erenfeld et al. 2022).

This data suggest that NXC-201 cells were able to recognize the AL amyloidosis plasma cells and exert specific BCMA-directed antitumoral effect, as further evidenced by the fact that following co-culture with AL amyloidosis plasma cells, NXC-201 cells underwent significant activation, demonstrated by upregulation of the 4-1BB cell marker and increased secreted levels of inflammatory cytokines (interferon gamma: IFNγ, tumour necrosis factor alpha: TFNα), which was not seen in NT cells. Furthermore, non-tumour bone marrow derived mononuclear cells were not affected by co-culture with NXC-201, demonstrating the targeted effect of this therapy.

Figure 12: NXC-201 Activation Following Overnight Co-culture with Amyloid Light Chain Amyloidosis Plasma Cells

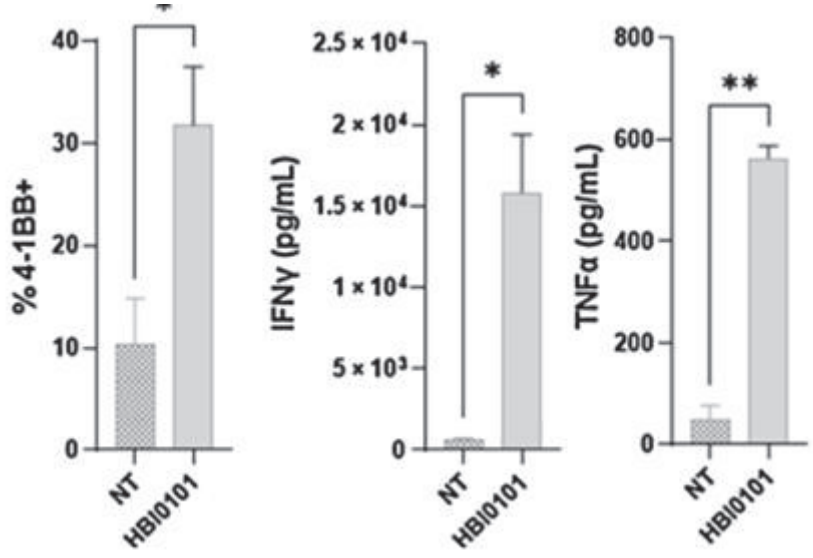
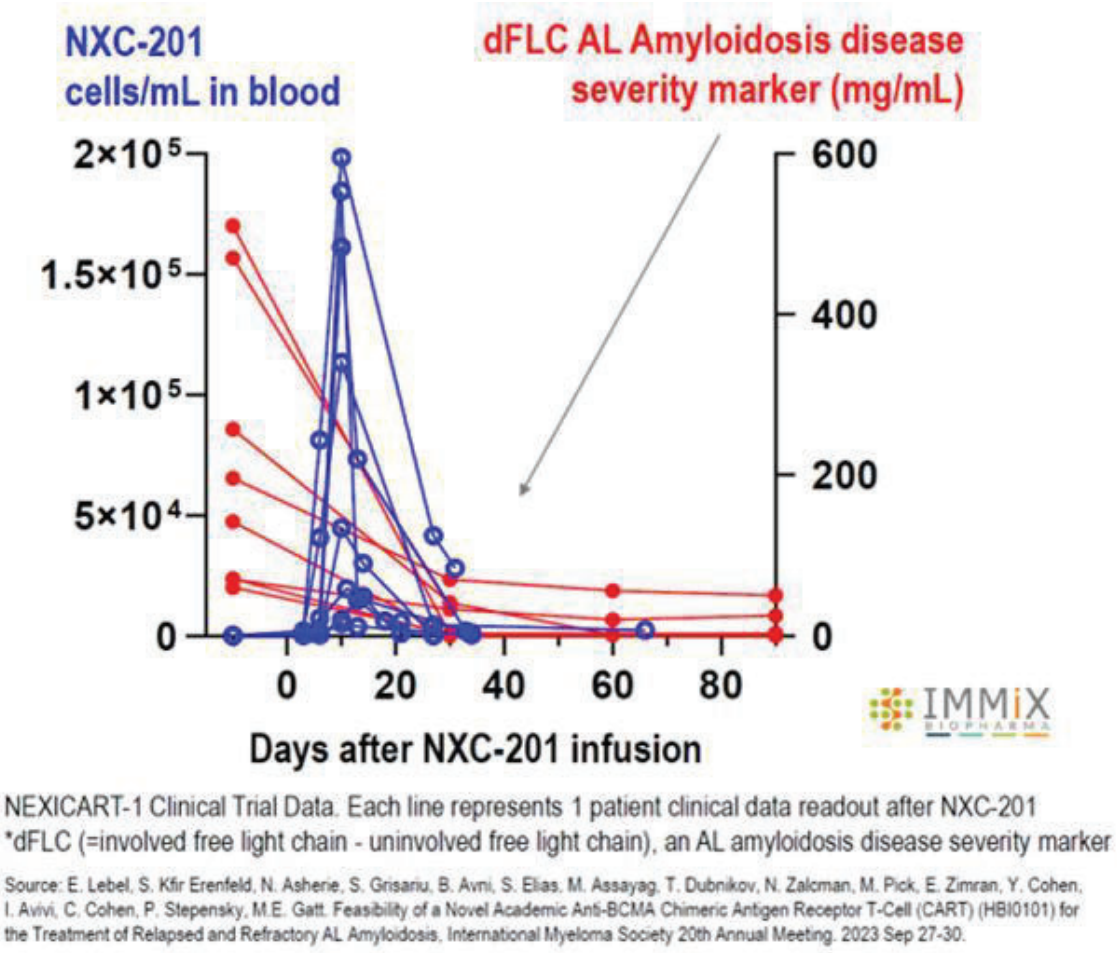


Figure 13: 65th ASH NXC-201 presentation: Rapid elimination of disease-causing amyloid chains by NXC-201 within ~30 days was observed



NEXICART-1 Clinical Trial Data. Each line represents 1 patient clinical data readout after NXC-201
*dFLC (=involved free light chain - uninvolved free light chain), an AL amyloidosis disease severity marker

Source: E. Lebel, S. Kfir Erenfeld, N. Asherie, S. Grisariu, B. Avni, S. Elias, M. Assayag, T. Dubnikov, N. Zalcman, M. Pick, E. Zimran, Y. Cohen, I. Avivi, C. Cohen, P. Stepensky, M.E. Gatt. Feasibility of a Novel Academic Anti-BCMA Chimeric Antigen Receptor T-Cell (CART) (HBI0101) for the Treatment of Relapsed and Refractory AL Amyloidosis. International Myeloma Society 20th Annual Meeting. 2023 Sep 27-30.

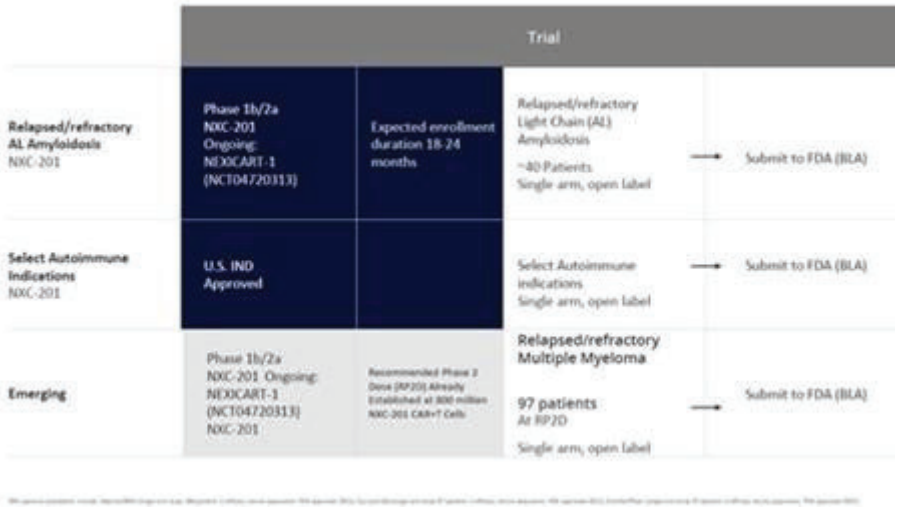
NXC-201 in Relapsed/refractory multiple myeloma

As of February 2024, 63 patients with triple-refractory relapsed/refractory multiple myeloma with median 4 lines of prior therapy (range: 3-13) have been treated with NXC-201. A 95% overall response rate to NXC-201 treatment was observed in relapsed/refractory multiple myeloma patients not previously treated with BCMA-targeted therapy (98% overall response rate observed in relapsed/refractory multiple myeloma patients without extra-medullary disease). “Single-Day CRS” was demonstrated – median duration of CRS of 1 day, median onset day 1. Multiple myeloma is a $14 billion market size growing to $27 billion according to Wilcock, et al, Nature Reviews.

NXC-201 Development Strategy

In our lead program, NXC-201 for relapsed/refractory AL Amyloidosis, we plan to enroll 40 patients in our open label, single-arm clinical trial, and then submit a biologics license application (“BLA”) for FDA approval.

Figure 14: NXC-201 Clinical Development Plan Through FDA BLA Submissions



The primary objectives in relapsed/refractory AL Amyloidosis are to study the safety and efficacy of NXC-201. The efficacy endpoints are to evaluate response rates according to consensus recommendations for AL amyloidosis treatment response criteria in AL (Palladini et al. 2012).

The expected primary endpoints are complete response rate and overall response rate in our NXC-201 relapsed/refractory AL Amyloidosis clinical trial.

Our strategy is to pursue orphan drug indications in which open-label, single-arm clinical trials may lead to possible BLA submissions, or indications with large populations with remaining unmet medical need.

IMX-110 – Tissue-Specific Therapeutic™ with tissue micro environment ("TME") Normalization™ Technology

IMX-110 in Colorectal Cancer

The first potential indication we intend to pursue for IMX-110 (in combination with anti-PD-1 antibody) is relapsed/refractory colorectal cancer ("CRC"). CRCs are cancers that arise from the colon and rectum. According to American Cancer Society, there were roughly 153,020 new cases of colorectal cancer in the United States in 2023. The five-year survival rate in the United States for all stages of CRC is 65.1%, but this falls to 15.1% for patients with late-stage metastatic disease according to the National Cancer Institute ("NCI").

The CRC market is estimated to reach approximately $31.2 billion by 2025 from the estimated $26.3 billion in 2019 according to IndustryARC. Drugs used to treat CRC include conventional irinotecan, oxaliplatin, 5-fluorouracil, pembrolizumab (marketed as Keytruda®, by Merck & Co.), nivolumab (marketed as Opdivo®, by Bristol Meyers Squibb), bevacizumab (marketed as Avastin®, by Roche), ramucirumab (marketed as Cyramza®, by Eli Lilly), and regorafenib (marketed as Stivarga® by Bayer). $41.11 billion is the total publicly disclosed combined annual sales of pembrolizumab (Keytruda®, Merck & Co.), nivolumab (Opdivo®), bevacizumab (Avastin®), and ramucirumab (Cyramza®) according to 2023 available annual reports. In relapsed/refractory proficient mismatch repair (pMMR) (microsatellite-stable - MSS) relapsed/refractory mCRC, regorafenib (marketed as Stivarga® by Bayer) produced a median progression free survival ("mPFS") of 2.0 months according to the FDA approval label.

As of February 2024, we continue to dose escalate IMX-110 + BeiGene anti-PD-1 Tislelizumab in our IMMINENT-01 (NCT05840835) study. In July 2023, we reported the following clinical data for IMX-110 + Tislelizumab in proficient mismatch repair ("pMMR", or microsatellite-stable – "MSS") relapsed/refractory mCRC in IMMINENT-01: Out of 4 relapsed/refractory metastatic colorectal cancer patients treated with IMX-110 + tislelizumab: 3 out of 4 (75%) patients experienced tumor shrinkage at 2 months; 1 out of 4 (25%) patients experienced tumor control at 2 months; 1 out of 4 patients remain on IMX-110 + tislelizumab therapy as of July 7, 2023; Median progression-free survival and overall survival not yet reached; Patients received a median of 8 earlier anti-cancer treatments that failed to halt cancer growth (lines of therapy) prior to receiving IMX-110 + tislelizumab.

IMX-110 in Soft Tissue Sarcoma ("STS")

The second potential indication we intend to pursue for IMX-110 is relapsed/refractory STS. STSs are cancers that arise from muscle, fat, nerves, fibrous tissues, blood vessels or deep skin tissues. According to American Cancer Society, there were roughly 13,000 new cases of soft tissue sarcomas in the United States during 2020 and about 13,400 new cases of soft tissue sarcomas in the United States are anticipated in 2023. Approximately 160,000 people live with soft tissue cancers in the United States. The five-year survival rate for all stages of STS is 65.4% in the United States, but this falls to 17.1% for patients with late-stage metastatic disease according the NCI. The global soft tissue sarcoma market is estimated to reach approximately $6.5 billion by 2030 from the estimated $2.9 billion in 2019 according to Medgadget. Drugs used to treat STS include conventional doxorubicin, eribulin (marketed as Halaven®, by Eisai Co, Ltd), pazopanib (marketed as Votrient®, by Novartis), and trabectedin (marketed as Yondelis®, by Janssen/Johnson & Johnson).

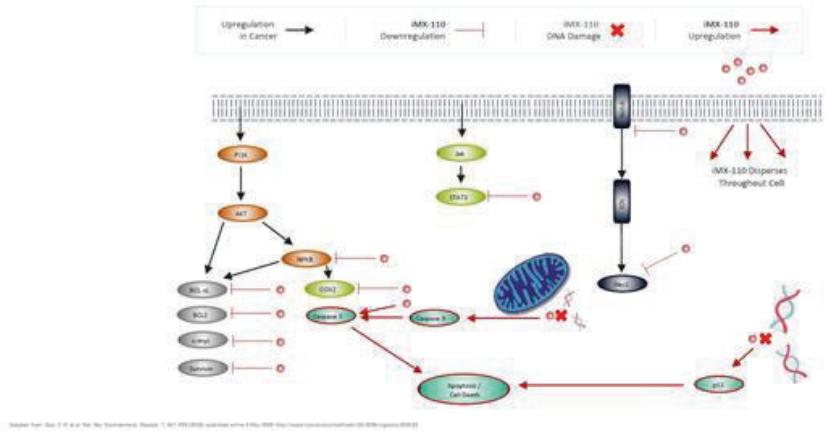
Objective response rates are increasingly considered as poor surrogates of clinical activity in STS. Therefore, lack of progression, or progression free survival ("PFS"), is used as the primary measure of treatment success in STS. Conventional doxorubicin, in three separate studies as a first-line therapy, produced a mPFS (meaning the time patients live without their cancer progressing) in STS patients of 2.5 months, 4.6 months, and 2.7 months according to Lorigan et al., 2007, Judson et al., 2014 and Chawla et al., 2015. Eribulin (Halaven®), was trialed in a study producing a mPFS in STS patients of 2.6 months according to Schöffski et al., 2016. Pazopanib (Votrient®), was trialed in a study producing a mPFS in STS patients of 4.6 months according to van der Graaf et al., 2012. Trabectedin (Yondelis®) was trialed in a study producing a mPFS in STS patients of 4.2 months according to Demetri et al., 2016.

As of February 2024, we have treated 21 patients in our ongoing IMX-110 Phase 1b/2a clinical trial in the United States and Australia, of which clinical analysis has been completed for the initial 14 patients. Of those 14 patients, 8 patients completed a tumor measurement after the enrollment measurement. Of those 8 patients, a range of late-stage STSs were represented, including: leiomyosarcoma, cholangiocarcinoma, carcinosarcoma, and poorly differentiated sarcoma. 4 months was the mPFS observed in STS patients treated with IMX-110 in the United States in our ongoing Phase 1b/2a clinical trial. 6 months of radiological PFS was observed in 50% of our STS patients treated with IMX-110. 100% of these patients received between 3 and 13 lines of therapy prior to IMX-110. Zero drug-related serious adverse events and zero dose interruptions due to toxicity have been observed in our 1b/2a clinical trial to-date.

IMX-110 Composition and Mechanism of Action

IMX-110, currently in Phase 1b/2a clinical trials, is a Tissue-Specific Therapeutic™ with TME Normalization™, a technology that we are developing initially for mCRC and STS. Tumor growth is sustained by hypoxia (low oxygen concentration) and acidosis (an excessively acidic condition) which produce recurring waves of activation of multiple kinases that upregulate NF-κB, STAT3 and other key transcriptional factors which cause recurrent inflammation. This inflammatory environment activates the TME to provide metabolic and structural support to the tumor and to recruit Treg T-cells (immune cells suppressing immune response) to suppress anti-tumor immune response. IMX-110's poly-kinase inhibitor polyphenol curcuminoid complex ("PCC") halts this fundamental tumor-sustaining inflammation by blocking multiple kinases and interfering with NF-κB and STAT3 activation, interrupting the positive feedback loop underlying the inflammatory cycle. With tumor-sustaining inflammation halted, IMX-110's apoptosis inducer (Polyethylene glycol – phosphatidylethanolamine ("PEG-PE")-doxorubicin complex) is then able to induce tumor cell death where conventional therapies have been hampered by resistance caused by NF-κB and STAT3 activation.

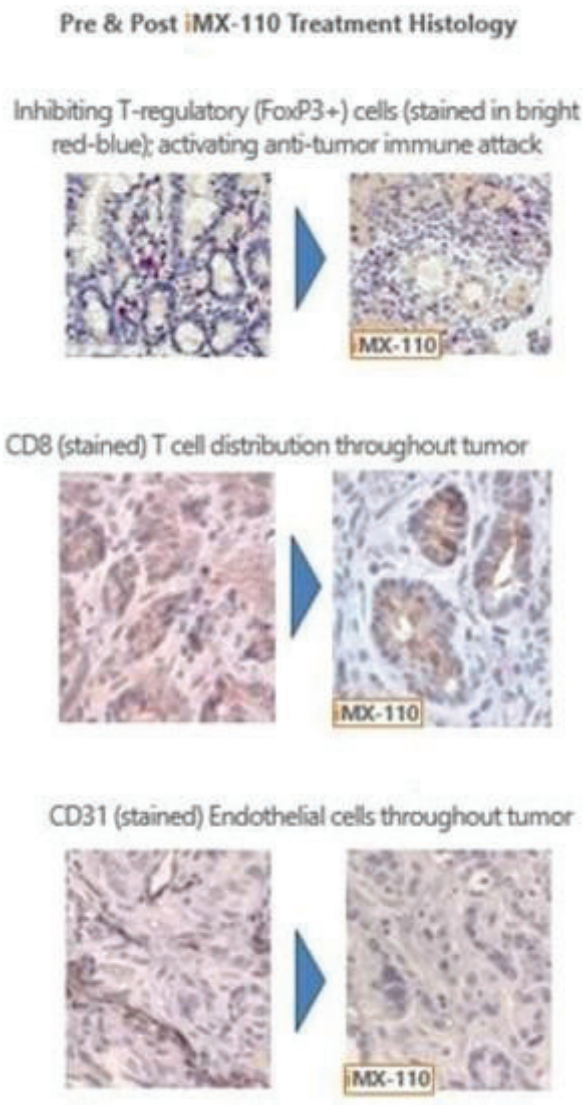
Figure 15: IMX-110 Induces Apoptosis while Blocking Multiple Escape Pathways



IMX-110 Immunomodulation Effects

In this pre-clinical study of IMX-110 monotherapy in the genetic Kras, p53, and Cre ("KPC") pancreatic mouse cancer model, our histological analysis showed that IMX-110 has the potential to transform "cold" tumors into "hot" tumors by eliminating immunosuppressive T-regulatory immune cells (top), enabling cytotoxic T-lymphocytes to enter the tumor (middle), and eliminating tumor vascularization (bottom).

Figure 16: IMX-110 Tissue-Specific Therapeutic™ with TME Normalization™ Technology Monotherapy Turns "Cold" Tumors "Hot" in Genetic (KPC) Pancreatic Cancer Pre-clinical Model



(See above paragraph for study description. ImmixBio unpublished results.)

Our Other Programs

We are also pursuing development of NXC-201 in autoimmune diseases, a $25 billion combined annual market size according to Grand View Research and Fortune Business Insights.

Manufacturing

We have a strong track record of successful manufacturing. We have already established a track record of producing NXC-201 for patient dosing and testing in the U.S. and ex-U.S. (73 patients dosed to-date). In addition, we have already developed a scalable, reliable manufacturing process for our TSTx according to current Good Manufacturing Practice ("cGMP").

We will continue to leverage our established technical, manufacturing, analytical, quality, cGMP, project management expertise and existing relationships to contract with appropriate CMOs to manufacture our cell therapies and TSTx moving forward.

In January 2024, the Company entered into a long-term operating lease agreement for biopharmaceutical manufacturing space located in California. To date, we have obtained active pharmaceutical ingredients ("API") and drug product for our product candidates from several third party contract manufacturers. We are in the process of developing our supply chain for each of our product candidates and have entered into agreements pursuant to which third-party contract manufacturers will provide us with necessary quantities of API and drug product on a project-by-project basis based upon our needs. We rely, and expect to continue to rely for the foreseeable future, on FDA, EMA, or other jurisdiction-registered third-party contract manufacturing organizations to produce our product candidates for pre-clinical and clinical testing, as well as for commercial manufacture if our product candidates receive marketing approval. As part of the manufacture and design process for our product candidates, we rely on internal, scientific and manufacturing know-how and trade secrets and the know-how and trade secrets of third-party manufacturers. We also contract with additional third parties for the filling, labeling, packaging, storage and distribution of investigational drug products. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our product candidates. We maintain agreements with our manufacturers that include confidentiality and intellectual property, and quality provisions to protect our proprietary rights related to our product candidates and satisfy regulatory requirements.

Competition

The biotechnology industry is extremely competitive in the race to develop new products. We currently face and will continue to face competition for our development programs from groups that are developing therapies for oncology and inflammation. The competition is likely to come from multiple sources, including larger pharmaceutical companies, biotechnology companies, and academic institutions.

Companies developing therapies for AL amyloidosis include, but are not limited to, Prothena Corp, Caelum Biosciences (Now Alexion/AstraZeneca), and Janssen/Johnson & Johnson.

Companies developing or intend to develop cell therapies for autoimmune indications include, but are not limited to: Kyverna Therapeutics, Inc.; Cabaletta Bio, Inc.; Fate Therapeutics Inc.; and Arcellx, Inc.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our strategy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, and product candidates that are important to the development and implementation of our business. Our patent portfolio is intended to cover our product candidates and related components, their methods of use and processes for their manufacture, our proprietary reagents and assays, and any other inventions that are commercially important to our business. We also rely on trademarks as well as trade secret protection of our confidential information and know-how relating to our proprietary technology platform, and product candidates. We believe that we have substantial know-how and trade secrets relating to our technology and product candidates.

As of March 15, 2024, our patent portfolio includes 12 U.S. and foreign granted patents, 11 pending U.S. and foreign patent applications, 2 pending international (PCT) patent applications related to our technology platform and our product candidates. Of those, 2 patents has been granted in the U.S. and 10 patents have been granted in the following countries: France, Germany, Ireland, Switzerland, and the United Kingdom. Two non-provisional patent applications are currently pending in the U.S. and 9 foreign patent applications are currently pending in Australia, Brazil, Canada, Europe, Hong Kong, Japan and Mexico. Certain platform patents are expected to remain in force until 2036.

The below patents and patent applications comprise our patent portfolio. All of the patents and patent applications listed below are owned by us.

Jurisdiction	Status	Number	Title	Expected Expiration Date	Type of Patent Protection
United States	Granted	9,833,508	CANCER THERAPEUTICS	3/15/2033*	Methods of treatment
United States	Granted	11,819,571	METHODS AND RELATED COMPOSITIONS FOR THE TREATMENT OF CANCER	3/15/2033*	Compositions and methods of treatment
United States	Pending	18/499,104	METHODS AND RELATED COMPOSITIONS FOR THE TREATMENT OF CANCER		Compositions and methods of treatment
EPO	Pending	20196191.9	MICELLE COMPRISING AN INHIBITOR OF NF-KB		Compositions and methods of treatment
Hong Kong	Pending	42021037058.1	MICELLE COMPRISING AN INHIBITOR OF NF-KB		Compositions and methods of treatment
Switzerland	Patent	13760370	GLUT-1 ZIELGERICHTETE UND MIT KURKUMIN BELADENE MIZELLEN	3/15/2033*	Compositions
Germany	Patent	2825198	GLUT-1 ZIELGERICHTETE UND MIT KURKUMIN BELADENE MIZELLEN	3/15/2033*	Compositions
France	Patent	13760370	CANCER THERAPEUTICS	3/15/2033*	
United Kingdom	Patent	13760370	GLUT-1 TARGETED AND CURCUMIN LOADED MICELLES	3/15/2033*	Compositions
Ireland	Patent	13760370.0	GLUT-1 TARGETED AND CURCUMIN LOADED MICELLES	3/15/2033*	Compositions
Switzerland	Patent	16858309.4	VERFAHREN UND VERWANDTE ZUSAMMENSETZUNGEN ZUR BEHANDLUNG VON KREBS	10/21/2036*	Compositions
Germany	Patent	16858309.4	VERFAHREN UND VERWANDTE ZUSAMMENSETZUNGEN ZUR BEHANDLUNG VON KREBS	10/21/2036*	Compositions
France	Patent	16858309.4	MÉTHODES ET COMPOSITIONS ASSOCIÉES POUR LE TRAITEMENT DU CANCER	10/21/2036*	Compositions
United Kingdom	Patent	16858309.4	METHODS AND RELATED COMPOSITIONS FOR	10/21/2036*	Compositions

Jurisdiction	Status	Number	Title	Expected Expiration Date	Type of Patent Protection
Ireland	Patent	16858309.4	THE TREATMENT OF CANCER METHODS AND RELATED COMPOSITIONS FOR THE TREATMENT OF CANCER	10/21/2036*	Compositions
Mexico	Pending	MX/a/2024/000302	NANOPARTICLES FOR CANCER TREATMENT	07/07/2042**	Compositions and methods of treatment
Japan	Pending	2024-500609	NANOPARTICLES FOR CANCER TREATMENT	07/07/2042**	Compositions and methods of treatment
Australia	Pending	2022308041	NANOPARTICLES FOR CANCER TREATMENT	07/07/2042**	Compositions and methods of treatment
Canada	Pending	3,224,127	NANOPARTICLES FOR CANCER TREATMENT	07/07/2042**	Compositions and methods of treatment
Brazil	Pending	11 2024 000075 3	NANOPARTICLES FOR CANCER TREATMENT	07/07/2042**	Compositions and methods of treatment
EPO	Pending	22748648.7	NANOPARTICLES FOR CANCER TREATMENT	07/07/2042**	Compositions and methods of treatment
United States	Pending	18/577,129	NANOPARTICLES FOR CANCER TREATMENT	07/07/2042**	Compositions and methods of treatment
PCT	Pending	PCT/US2022/044948	NANOPARTICLES FOR CANCER TREATMENT		Compositions and methods of treatment
Australia	Pending	2022352844	NANOPARTICLES FOR CANCER TREATMENT	09/27/2042**	Compositions and methods of treatment
PCT	Pending	PCT/US2023/69537	NANOPARTICLES FOR THE TREATMENT OF INFLAMMATORY DISEASES		Methods of treatment

* Provided all maintenance and renewal fees are timely paid.
** Any resulting patents in this family are expected to expire in 2042 (not including any patent term adjustment and patent term extension in the United States and equivalents in foreign countries).

Additionally, as of March 15, 2024, our subsidiary Nexcella, Inc. has global exclusive rights to PCT Application No. PCT/IL2023/050142 filed in 20023 and claiming priority to U.S. Provisional Patent Application Nos. 63/308,277 and 63/368,002. The application is directed to our N-GENIUS platform, EXPAND technology, and to our product candidates, including NXC-201. The application relates to a chimeric antigen receptor (CAR) molecule specific for B cell maturation antigen (BCMA), compositions and methods thereof for the treatment of immune-related disorders. We plan to enter the national phase of the PCT application in multiple countries. Any resulting patents in this family are expected to expire in 2043 (not including any patent term adjustment and patent term extension in the United States and equivalents in foreign countries).

We generally pursue multilayered patent protection covering the composition of matter including the formulations of the product candidates, and/or the functional characteristics of the product candidates. In addition to composition of matter coverage, we also generally pursue claims directed to methods of making, and methods of use of the product candidates.

IP License Agreement with Immix Biopharma Australia Pty Ltd.

On January 23, 2017, we entered into an IP License Agreement ("License Agreement") with Immix Biopharma Australia Pty Ltd., our wholly-owned subsidiary ("IBAPL"), pursuant to which we granted IBAPL a non-exclusive, non-transferable license to IMX-110 intellectual property that is necessary for the purpose of, among other things, conducting or facilitating the research, development or clinical trials relating to such intellectual property in the Commonwealth of Australia. Pursuant to the terms of the License Agreement, during the term of the License Agreement, IBAPL shall pay us a royalty equal to a mid single digit percentage of Net Sales (as defined in the License Agreement), subject to adjustment as set forth in the License Agreement. The License Agreement may be terminated by either party (i) upon 20 days prior written notice to the other party, (ii) if the other party breaches any provision of the License Agreement and fails to remedy such breach within 10 business days after receiving written notice of such breach or (iii) if the other party is the subject to an insolvency event as set forth in the License Agreement. To date, we have not received any payments pursuant to the License Agreement.

AxioMx Master Services Agreement

On December 22, 2014, we entered into a Master Service Agreement ("MSA") with AxioMx, Inc. ("AxioMx") which is in the business of developing and supplying custom affinity reagents. We entered into the MSA to serve as a master agreement governing multiple sets of projects as may be agreed upon us and AxioMx from time to time. Pursuant to the MSA, we granted AxioMx a non-exclusive, royalty-free, worldwide, non-transferable license to certain of our intellectual property to perform services pursuant to the MSA, and AxioMx granted us an exclusive product assignment option which grants us an exclusive, royalty-bearing right, with the right to sublicense, under the Deliverable (as defined in the MSA) to further research, develop, use, sell, offer for sale, import and export one or more assigned products pursuant to the MSA. We exercised the option in 2017. Pursuant to the MSA, AxioMx is entitled to royalties on the sale of any Deliverable that is used for diagnostic, prognostic or therapeutic purposes, in humans or animals, or for microbiology testing, including food safety testing or environmental monitoring. Specifically, we shall pay AxioMx a royalty of 3.5% of Net Sales (as defined in the MSA) of assigned products for each Deliverable used in licensed products for therapeutic purposes. In addition, we shall pay AxioMx a royalty of 1.5% of Net Sales of assigned products for each Deliverable used in licensed products for diagnostic or prognostic purposes; provided, however, if three Deliverables are used in an assigned product for diagnostic or prognostic purposes, the royalty shall be 4.5%. As of December 31, 2023, the MSA has expired and the Company does not intend to extend the MSA; however, the royalty obligations described herein shall survive the termination of the MSA.

Research and License Agreement with Hadasit and BIRAD

On December 8, 2022, our subsidiary Nexcella entered into a Research and License Agreement (the "Agreement") with Hadasit Medical Research Services & Development, Ltd. and BIRAD – Research and Development Company Ltd. (collectively, the "Licensors") pursuant to which the Licensors granted to Nexcella an exclusive, worldwide, royalty-bearing license throughout the world, except Israel, Cyprus and other countries in the Middle East (the "Territory"), to an invention entitled "Anti-BCMA CAR-T cells to target plasma cell" to develop, manufacture, have manufactured, use, market, offer for sale, sell, have sold, export and import the Licensed Product (as defined in the Agreement). Pursuant to the Agreement, Nexcella paid the Licensors an upfront fee of $1,500,000 in December 2022. Additional quarterly payments totaling approximately $13.0 million are due through September 2026 along with an annual license fee of $50,000. Nexcella has agreed to pay royalties to the Licensors equal to 5% of based on Net Sales (as defined in the Agreement) during the Royalty Period. "Royalty Period" means for each Licensed Product, on a country-to-country basis, the period commencing on December 8, 2022 and ending on the later of (a) the expiration of the last to expire Valid Claim (as defined in the Agreement) under a Licensed Patent (as defined in the Agreement), if any, in such country, (b) the date of expiration of any other Exclusivity Right (as defined in the Agreement) or data protection period granted by a regulatory or other governmental authority with respect to a Licensed Product or (c) 15 years from the date of First Commercial Sale (as defined in the Agreement) of a Licensed Product in such country.

In addition, Nexcella shall pay milestone payments of up to $20 million upon the achievement of certain Net Sales as set forth in the Agreement and Nexcella has committed to funding NXC-201 clinical trials in Israel over 4 years for an estimated total cost of approximately $13 million, spread on a quarterly basis over that period, which Nexcella believes will generate clinical trial data owned by Nexcella. The term of the Agreement commenced on December 8, 2022 and, unless earlier terminated pursuant to the terms thereof, shall continue in full force and effect until the later of the expiration of the last Valid Claim under a Licensed Patent or a Joint Patent (as defined in the Agreement) or Exclusivity Right covering a Licensed Product or the expiration of a continuous period of 15 years during which there shall not have been a First Commercial Sale of any Licensed Product in any country in the world. Licensors may terminate the Agreement immediately if Nexcella or its affiliates or sublicensees commences an action in which it challenges the validity, enforceability or scope of any of the Licensed Patents or Joint Patents. In addition, either party may terminate the Agreement if the other party materially breaches the Agreement and fails to cure such breach within 30 days. Additionally, Licensors may terminate the Agreement if Nexcella becomes insolvent or files for bankruptcy.

Agreements with Nexcella

Founders Agreement

Effective December 8, 2022, we entered a Founders Agreement with our subsidiary Nexcella (the "Nexcella Founders Agreement"). Pursuant to the Nexcella Founders Agreement, in consideration for the time and capital expended in the formation of Nexcella and the identification of specific assets, the acquisition of which benefit Nexcella, we received 250,000 shares of Nexcella's Class A Preferred Stock, 1,000,000 shares of Nexcella's Class A Common Stock, and 5,000,000 shares of Nexcella's common stock. In addition, pursuant to the Nexcella Founders Agreement, prior to a Qualified IPO (as defined in Nexcella's Amended and Restated Certificate of Incorporation, as amended (the "Nexcella COI")) or Qualified Change in Control (as defined in the Nexcella COI), we shall provide funds to Nexcella as requested by Nexcella, in good faith, to be evidenced by a senior unsecured promissory note. The Nexcella Founders Agreement has a term of 15 years, which, upon expiration, automatically renews for successive one-year periods unless terminated by us upon notice at least six months prior to the end of the term or upon the occurrence of a Change of Control (as defined in the Nexcella Founders Agreement). In exchange for the time and capital expended in the formation of Nexcella and the identification of specific assets, the acquisition of which benefit Nexcella, on December 21, 2022, the Company loaned Nexcella approximately $2.1 million, evidenced by a senior unsecured promissory note, which note matures on January 31, 2030, accrues interest at a rate of 7.875% per annum and is convertible into shares of common stock of Nexcella at a conversion price of $2.00 per share, subject to adjustment; provided, however, that such note shall automatically convert into shares of Nexcella common stock immediately prior to certain conversion triggers set forth in the note. Nexcella may not prepay the note without our prior written consent .

The Class A Preferred Stock is identical to the common stock other than as to conversion rights, the PIK Dividend right (as defined below) and voting rights.

Each share of Class A Preferred Stock is convertible, at our option, into one share of Nexcella's common stock, subject to certain adjustments. As a holder of Nexcella's Class A Preferred Stock, we will receive on each March 13 (each a "PIK Dividend Payment Date") until the date all outstanding Class A Preferred Stock is converted into Nexcella's common stock or redeemed (and the purchase price is paid in full), pro rata per share dividends paid in additional shares of Nexcella common stock ("PIK Dividends") such that the aggregate number of shares of common stock issued pursuant to such PIK Dividend is equal to 2.5% of Nexcella's fully-diluted outstanding capitalization on the date that is one business day prior to any PIK Dividend Payment Date. In addition, as a holder of Class A Preferred Stock, we shall be entitled to cast for each share of Class A Preferred Stock held as of the record date for determining stockholders entitled to vote on matters presented to the stockholders of Nexcella, the number of votes that is equal to 1.1 times a fraction, the numerator of which is the sum of (A) the shares of outstanding Nexcella common stock and (B) the whole shares of Nexcella common stock into which the shares of outstanding Nexcella Class A Common Stock and the Class A Preferred Stock are convertible and the denominator of which is number of shares of outstanding Nexcella Class A Preferred Stock.

Each share of Class A Common Stock is convertible, at our option, into one share of Nexcella's common stock, subject to certain adjustments. In addition, upon a Qualified IPO or Qualified Change in Control, the shares of Class A Common Stock, will automatically convert into one share of Nexcella's common stock; provided however, if at that time, the Class A Common Stock is not then convertible into a number of shares of Nexcella common stock (or such other capital stock or securities at the time issuable upon the conversion of the Class A Common Stock) that have a value of: (a) in the case of a Qualified IPO, at least $5,000,000 based on the initial offering price in such offering, or (b) in the case of a Qualified Change in Control, at least $5,000,000 in cash or at least $5,000,000 of equity based on the implied value of a share of Nexcella common stock resulting from the price paid upon the consummation of such Qualified Change of Control, the Class A Common Stock will automatically convert into such number of shares of Nexcella common stock (or such other capital stock or securities at the time issuable upon the conversion of the Class A Common Stock) that have a value of $5,000,000 based on the initial offering price in such offering or the implied value of a share of Nexcella common stock resulting from the price paid upon the consummation of such Qualified Change of Control (or if such Qualified Change of Control results in the Class A Shares being exchanged solely for cash, then $5,000,000 in cash). We shall be entitled to cast such number of votes equal to the number of whole shares of Nexcella common stock into which our Class A Common Stock are convertible as of the record date for determining stockholders entitled to vote on matters presented to the stockholders of Nexcella.

In addition to the foregoing, we shall be entitled to one vote for each share of Nexcella common stock held by us. Except as provided by law or by the Nexcella COI, holders of Nexcella Class A Common Stock and Class A Preferred Stock shall vote together with the holders of Nexcella common stock, as a single class.

As additional consideration under the Nexcella Founders Agreement, Nexcella will also: (i) pay an equity fee in shares of common stock, payable within five business days of the closing of any equity or debt financing for Nexcella or any of its respective subsidiaries that occurs after the effective date of the Nexcella Founders Agreement and ending on the date when we no longer have majority voting control in Nexcella's voting equity, equal to 2.5% of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to 4.5% of Nexcella's annual Net Sales (as defined in the Nexcella Founders Agreement), payable on an annual basis. In the event of a Change of Control, Nexcella will pay a one-time change in control fee equal to five times the product of (A) Net Sales for the 12 months immediately preceding the Change of Control and (B) 4.5%.

Management Services Agreement

Effective as of December 8, 2022, we entered into a Management Services Agreement (the "Nexcella MSA") with our subsidiary Nexcella. Pursuant to the terms of the Nexcella MSA, we will render management, advisory and consulting services to Nexcella. Services provided under the Nexcella MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Nexcella's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of Nexcella with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). At our request, Nexcella shall utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by us, provided those services are offered at market prices. In consideration for the Services, Nexcella will pay us an annual base management and consulting fee of $500,000 (the "Annual Consulting Fee"), payable in advance in equal quarterly installments; provided, however, that such Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which Nexcella has Net Assets (as defined in the Nexcella MSA) in excess of $100 million at the beginning of the calendar year. Notwithstanding the foregoing, the first Annual Consulting Fee payment shall be made on the first business day of the calendar quarter immediately following the completion of the first equity financing for Nexcella that is in excess of $10 million in gross proceeds. The first payment shall include all amounts in arrears from the effective date of the Nexcella MSA through such payment as well as the amounts in advance for such first quarterly payment. Actual and direct out-of-pocket expenses reasonably incurred by us in performing the Services shall be reimbursed to us by Nexcella. The Nexcella MSA shall continue for a period of five years from the effective date thereof and shall be automatically extended for additional five year periods unless we and Nexcella provide written notice to not extend the term at least 90 days prior to the end of the term, unless the Nexcella MSA is terminated earlier by mutual agreement between us and Nexcella.

Recent Developments

In February 2024, we conducted an underwritten public offering of 5,535,055 shares of common stock at the public offering price is $2.71 per shares, for the net proceeds, after underwriter discounts and offering expenses, of $13,566,697. Pursuant to the underwriting agreement, we granted the underwriter a 30-day over-allotment option to purchase up to an additional 783,970 shares of our common stock, which was exercised in full on March 1, 2024 for the net proceeds, after underwiring discounts and offering expenses, of $1,954,594.

In February 2024, the European Commission (EC) granted orphan drug designation to NXC-201 for the treatment of AL Amyloidosis. Benefits of European ODD include: 10 years of market exclusivity once authorized in the EU; Access to the EU centralized authorization procedure; and reduced fees for EU protocol assistance, marketing authorization applications, inspections before authorization, applications for changes to marketing authorizations made after approval, and reduced annual fees.

Government Regulations

United States Regulation of Drugs and Biologics

We expect that NXC-201 will be regulated by the FDA as a biologic by submitting a Biologic License Application ("BLA"). We expect that IMX-110 will be regulated by the FDA as a complex non-biologic by submitting a New Drug Application ("NDA"). We expect to pursue United States and global regulatory designations, vouchers, conditional approvals and accelerated approvals where appropriate.

Our business activities are subject to various laws, rules and regulations of the United States as well as of foreign governments.

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of drug products such as those we are developing. We, along with third-party contractors, will be required to navigate the various pre-clinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

The process required by the FDA before drug candidates may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practice ("GLP") regulation;
- submission to the FDA of an Investigational New Drug ("IND"), which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB"), or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug candidate for its intended purpose;
- preparation of and submission to the FDA of an NDA or BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP, and of selected clinical investigation sites to assess compliance with current good clinical practice ("cGCP"); and
- FDA review and approval of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

Pre-clinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCP, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under 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 separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

For purposes of NDA or BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase 1*—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- *Phase 2*—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. Some trials may combine aspects of Phase 1 and Phase 2 into a single clinical trial that can examine both safety in healthy volunteers and safety and preliminary efficacy in patients with a specific disease.

- *Phase 3*—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

A registrational trial is a clinical trial that adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the drug. Generally, registrational trials are Phase 3 trials but may be Phase 2 trials if the trial design provides a reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the NDA or BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

NDA or BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, non-clinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. The NDA or BLA must include all relevant data available from pertinent pre-clinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. A determination by the FDA within 60 days of the receipt of an NDA or BLA to file the application for review for its completeness is initiated at the time of submission. If the FDA determines there is significance to the missing or incomplete information in the context of the proposed drug product, the proposed indication(s) and the amount of time needed to address any given deficiency, it can issue a refusal-to-file letter. The submission of an NDA or BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once an NDA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews an NDA or BLA to determine, among other things, whether a product is safe and effective. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The 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 or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA or BLA and conducts inspections of manufacturing facilities where the product will be produced, the 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 will describe all of the deficiencies that the FDA has identified in the NDA or BLA. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the NDA or BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA or BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA or BLA with a Risk Evaluation and Mitigation Strategy ("REMS"), to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and 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. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

Fast Track Designation

The FDA offers several expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the review team during product development and, once an NDA or BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

Breakthrough Therapy Designation

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if 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. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Priority Review

Any product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, 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. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires, as a condition for accelerated approval, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Regenerative Medicine Advanced Therapy Designation

With passage of the Cures Act in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative medicine advanced therapies. A product is eligible for RMAT designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such disease or condition. Regenerative medicine therapies include cell therapy, therapeutic tissue engineering product, human cell and tissue products and combination products that use such products. The benefits of a regenerative medicine advanced therapy designation include early interactions with FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review, and accelerated approval based on surrogate or intermediate endpoints. RMAT designation may be rescinded if a product no longer meets the qualifying criteria.

Rare Pediatric Disease Priority Review Voucher Program

With enactment of the FDASIA in 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications that meet the criteria specified in the law. This provision is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application.

For the purposes of this program, a "rare pediatric disease" is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare disease or conditions within the meaning of the Orphan Drug Act. A sponsor may choose to request RPDD, but the designation process is entirely voluntary; requesting designation is not a prerequisite to requesting or receiving a priority review voucher. In addition, sponsors who choose not to submit a RPDD request may nonetheless receive a priority review voucher if they request such a voucher in their original marketing application and meet all of the eligibility criteria. The Rare Pediatric Disease Priority Review Voucher Program was extended as part of the 2021 Coronavirus Response and Relief Supplemental Consolidated Appropriations Act in December 2020. As part of this extension, after September 30, 2024, the FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has a RPDD for the drug that was granted by September 30, 2024. After September 30, 2026, the FDA may not award any additional rare pediatric disease priority review vouchers.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of 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 user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved NDA or BLA. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw 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 adverse events 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 restrictions or other restrictions under an REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a 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 the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics and drugs. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning or untitled letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Europe

European Drug Development

In the European Union, our future products also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority ("NCA"), and one or more Ethics Committees ("ECs"). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and Ecs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is expected that the new Clinical Trials Regulation (EU) No 536/2014 will apply following confirmation of full functionality of the Clinical Trials Information System, the centralized EU portal and database for clinical trials foreseen by the Regulation, through an independent audit, currently expected to occur in January 2022. The new Regulation will be directly applicable in all Member States (and so does not require national implementing legislation in each Member State), and aims at simplifying and streamlining the approval of clinical studies in the EU, for instance by providing for a streamlined application procedure via a single point and strictly defined deadlines for the assessment of clinical study applications.

European Drug Review and Approval

In the European Economic Area ("EEA"), which is comprised of the Member States of the European Union together with Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a marketing authorization ("MA"). There are two main types of Mas:

- The centralized MA is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP"), of the EMA, and is valid throughout the entire territory of the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicinal products (i.e. gene-therapy, somatic cell-therapy or tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union. Under the centralized procedure the maximum timeframe for the evaluation of a MA application by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of a MA application considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a MA application under the accelerated assessment procedure is of 150 days, excluding stop-clocks, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

- National Mas, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this national MA can be recognized in other Member States through the mutual recognition procedure. If the product has not received a national MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State ("RMS"). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SmPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States) for their approval. If the Concerned Member States raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Concerned Member States).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

European New Chemical Entity Exclusivity

In the EEA, medicinal products for human use qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization, for a period of eight years from the date on which the reference product was first authorized in the EEA. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. Even if an innovative medicinal product gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on an application with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

European orphan designation and exclusivity

In the EEA, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions which either affect no more than 5 in 10,000 persons in the European Union, or where it is unlikely that the marketing of the medicine would generate sufficient return to justify the necessary investment in its development. In each case, no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if such a method exists, the product in question would be of significant benefit to those affected by the condition).

In the EEA, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers, and ten years of market exclusivity is granted following marketing approval for the orphan product. This period may be reduced to six years if, at the end of the fifth year, it is established that the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. During the period of market exclusivity, marketing authorization may only be granted to a "similar medicinal product" for the same therapeutic indication if: (i) a second applicant can establish that its product, although similar to the authorized product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

European pediatric investigation plan

In the EEA, companies developing a new medicinal product must agree upon a pediatric investigation plan ("PIP"), with the EMA's Pediatric Committee ("PDCO"), and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when this data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP (even where such results are negative) are eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval). In the case of orphan medicinal products, a two year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

PRIME Designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority Medicines ("PRIME") scheme is a voluntary scheme intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation, where the marketing authorization application will be made through the centralized procedure. Eligible products must target conditions for which where is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EEA or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the EMA's CHMP or Committee for Advanced Therapies are appointed early in PRIME scheme facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

Australia

Our clinical trial for IMX-110 is being conducted in Australia and the United States. The Therapeutic Goods Administration ("TGA") and the National Health and Medical Research Council set the GCP requirements for clinical research in Australia, and compliance with these codes is mandatory. Australia has also adopted international codes, such as those promulgated by the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH"). The ICH guidelines must be complied with across all fields of clinical research, including those related to pharmaceutical quality, nonclinical and clinical data requirements and trial designs. The basic requirements for preclinical data to support a first-in-human trial under ICH guidelines are applicable in Australia. Requirements related to adverse event reporting in Australia are similar to those required in other major jurisdictions.

Clinical trials conducted using "unapproved therapeutic goods" in Australia, being those which have not yet been evaluated by the TGA for quality, safety and efficacy must occur pursuant to either the Clinical Trial Notification Scheme ("CTN Scheme") or the Clinical Trial Exemption Scheme ("CTX Scheme"). In each case, the trial is supervised by a Human Research Ethics Committee ("HREC"), an independent review committee set up under guidelines of the Australian National Health and Medical Research Council that ensures the protection of rights, safety and well-being of human subjects involved in a clinical trial. A HREC does this by reviewing, approving and providing continuing examination of trial protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

The CTN Scheme broadly involves:

- completion of preclinical laboratory and animal testing;

- submission to a HREC, of all material relating to the proposed clinical trial, including the trial protocol;

- the institution or organization at which the trial will be conducted, referred to as the "Approving Authority", giving final approval for the conduct of the trial at the site, having regard to the advice from the HREC; and

- the investigator submitting a 'Notification of Intent to Conduct a Clinical Trial' form, or CTN Form, to the TGA. The CTN form must be signed by the sponsor, the principal investigator, the chairman of the HREC and a person responsible from the Approving Authority. The TGA does not review any data relating to the clinical trial however CTN trials cannot commence until the trial has been notified to the TGA.

Under the CTX Scheme:

- a sponsor submits an application to conduct a clinical trial to the TGA for evaluation and comment; and

- a sponsor must forward any comments made by the TGA Delegate to the HREC(s) at the sites where the trial will be conducted.

A sponsor cannot commence a trial under the CTX Scheme until written advice has been received from the TGA regarding the application and approval for the conduct of the trial has been obtained from an ethics committee and the institution at which the trial will be conducted.

Approval for inclusion in the Australian Register of Therapeutic Goods ("ARTG") is required before a pharmaceutical product may be marketed (or imported, exported or manufactured) in Australia. In order to obtain registration of the product on the ARTG, it is required that:

- adequate and well-controlled clinical trials demonstrate the quality, safety and efficacy of the therapeutic product;

- evidence is compiled which demonstrates that the manufacture of the therapeutic product complies with the principles of cGMP;

- manufacturing and clinical data is derived to submit to the Advisory Committee on Prescription Medicines, which makes recommendations to the TGA as to whether or not to grant approval to include the therapeutic product in the ARTG; and

- an ultimate decision is made by the TGA whether to include the therapeutic product in the ARTG.

Regulation and Procedures Governing Approval of Products in Other Jurisdictions

The requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. In all cases, clinical trials must be conducted in accordance with applicable regulatory requirements. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which our drugs will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical drugs and services. 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 drugs.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property protection, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower-cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Even if favorable coverage and reimbursement status is attained for our product candidates, once approved, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country.

Healthcare Laws and Regulations

Sales of our product candidates, if approved, will be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we might conduct our business. The healthcare laws and regulations that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute, a criminal statute, makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The Civil Monetary Penalties Law also contains a provision that prohibits the payment of anything of value in return for referrals and provides for the imposition of civil penalties.

- the Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. § 1395nn) (the "Stark Law") prohibit referrals by a physician of "designated health services" which are payable, in whole or in part, by Medicare or Medicaid, to an entity in which the physician or the physician's immediate family member has an investment interest or other financial relationship, subject to several exceptions. The Stark Law also prohibits billing for services rendered pursuant to a prohibited referral. Several states have enacted laws similar to the Stark Law. These state laws may cover all (not just Medicare and Medicaid) patients. We consider the Stark Law in planning our products, marketing and other activities, and believe that our operations are in compliance with the Stark Law. If we violate the Stark Law, our financial results and operations could be adversely affected. Penalties for violations include denial of payment for the services, significant civil monetary penalties, and exclusion from the Medicare and Medicaid programs.

- Federal false claims and false statement laws, including the federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent.

- Health Insurance Portability and Accountability Act of 1996, the Health Information and Technology for Economic and Clinical Health Act and their implementing regulations at 45 C.F.R. Parts 160, 162 and 164, as amended ("HIPAA") created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their implementing regulations, imposes obligations on certain types of individuals and entities regarding the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information.

- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Also, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA. These laws are subject to extensive and increasing enforcement by numerous federal, state, and local government agencies including the Office of Inspector General, the Department of Justice, the CMS, the Office of Civil Rights, and various state authorities.

Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

Employees

As of March 15, 2024, we had 17 employees, 14 of which are full-time employees. Of such employees, 8 are engaged in research and development. None of our employees are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced work stoppages. We believe that relations with our employees are good.

Our Corporate History

We were incorporated as a California limited liability company in 2012 and converted to a Delaware corporation in January 2014. In August 2016, we established a wholly-owned Australian subsidiary, Immix Biopharma Australia Pty Ltd., in order to conduct various pre-clinical and clinical activities for the development of our product candidates. In November 2022, we established a Delaware corporation, Nexcella, Inc., in order to conduct various pre-clinical and clinical activities for the development of our product candidates. ImmixBio currently owns 95% of outstanding common stock on a fully diluted basis of Nexcella.

Available Information

Our website address is *www.immixbio.com*. The contents of, or information accessible through, our website are not part of this Annual Report on Form 10-K, and our website address is included in this document as an inactive textual reference only. We make our filings with the SEC, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC. The public may read and copy the materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is *www.sec.gov*. The information contained in the SEC's website is not intended to be a part of this filing.

ITEM 1A. RISK FACTORS.

An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and the other information in this Annual Report on Form 10-K before investing in our common stock. Our business and results of operations could be seriously harmed by any of the following risks. The risks set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following events occur, our business, financial condition and results of operations could be materially adversely affected. In such case, the value and trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Relating to Our Financial Position and Capital Needs

We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company focused on developing a novel class of TSTx in oncology and inflammation. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities and have not generated any revenues from collaboration or licensing agreements or product sales to date, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses since our inception. For the years ended December 31, 2023 and 2022, we reported net losses of $15,595,522 and $8,229,713, respectively. As of December 31, 2023, we had an accumulated deficit of $53,411,295.

We do not expect to generate revenues for many years, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop and seek regulatory approvals for our current product candidates and any additional product candidates we may acquire, and potentially begin to commercialize product candidates that may achieve regulatory approval. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our expenses will further increase as we:

- conduct pre-clinical and clinical trials of our product candidates;
- in-license or acquire the rights to, and pursue development of, other products, product candidates or technologies;
- hire additional clinical, manufacturing, quality control, quality assurance and scientific personnel;
- seek marketing approval for any product candidates that successfully complete clinical trials;
- establish sales, marketing and distribution capabilities, if we receive, or expect to receive, marketing approval for any product candidates;
- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management information systems and personnel.

We need significant additional financing to fund our operations and complete the development and, if approved, the commercialization of our product candidates. 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 will need to raise significant additional capital to complete development and obtain regulatory approval for our product candidates. Although we believe that our existing cash and cash equivalents balance of $17,509,791 as of December 31, 2023, plus the net proceeds of $15.5 million from our February 2024 offering of common stock, will be sufficient to meet our cash, operational and liquidity requirements for at least 12 months from the date of this report, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned.

We expect to expend substantial resources for the foreseeable future to continue the clinical development and manufacturing of our product candidates. These expenditures will include costs associated with research and development, potentially acquiring new product candidates or technologies, conducting pre-clinical studies and clinical trials and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. We have no committed source of additional capital. If adequate funds are not available to us on a timely basis, we may not be able to continue as a going concern or we may be required to delay, limit, reduce or terminate pre-clinical studies, clinical trials or other development activities for our product candidates or target indications, or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

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

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or through the issuance of shares under management or other types of contracts, or upon the exercise or conversion of outstanding derivative securities, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, anti-dilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of common stock in the event of a liquidation. In addition, debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends and may require us to grant security interests in our assets, including our intellectual property. 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, products 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 need to curtail or cease our operations.

We currently have no source of revenues. We may never generate revenues or achieve profitability.

Currently, we do not generate any revenues from product sales or otherwise. Even if we are able to successfully achieve regulatory approval for our product candidates, we do not know when we will generate revenues or become profitable, if at all. Our ability to generate revenues from product sales and achieve profitability will depend on our ability to successfully commercialize products, including our current product candidates and other product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenues and achieve profitability also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical trials;
- complete and submit either BLAs or NDAs to the FDA and obtain U.S. regulatory approval for indications for which there is a commercial market;
- complete and submit applications to foreign regulatory authorities;
- obtain regulatory approval in territories with viable market sizes;
- obtain coverage and adequate reimbursement from third parties, including government and private payors;
- set commercially viable prices for our products, if any;
- establish and maintain supply and manufacturing relationships with reliable third parties, legally globally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop distribution processes for our product candidates;
- develop commercial quantities of our product candidates, if approved, at acceptable cost levels;
- obtain additional funding if required to develop and commercialize our product candidates;
- develop sales, marketing and distribution capabilities for products we intend to sell;
- achieve market acceptance of our products;
- attract, hire and retain qualified personnel; and
- protect our intellectual property rights.

Our revenues for any product candidates for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which it gains regulatory approval, the accepted price for the products, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as our estimates, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenues from sales of such products, even if approved. In addition, we anticipate incurring significant costs associated with commercializing any approved product candidates. As a result, even if we generate revenues, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2023 we had federal net operating loss ("NOLs") carryforwards of approximately $11,800,000. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U.S. tax laws, and will begin to expire, if not utilized, beginning in 2034. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, federal NOLs incurred in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the Tax Act, or whether any further regulatory changes may be adopted in the future that could minimize its applicability. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and certain corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in the ownership of its equity over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited.

Risks Relating to the Development and Regulatory Approval of Our Product Candidates

We have a limited number of product candidates, all which are still in early clinical or pre-clinical development. If we do not obtain regulatory approval of one or more of our product candidates, or experience significant delays in doing so, our business will be materially adversely affected.

We currently have no products approved for sale or marketing in any country, and may never be able to obtain regulatory approval for any of our product candidates. As a result, we are not currently permitted to market any of our product candidates in the United States or in any other country until we obtain regulatory approval from the FDA or regulatory authorities outside the United States. Our product candidates are in early stages of development and we have not submitted an application, or received marketing approval, for any of our product candidates. Obtaining regulatory approval of our product candidates will depend on many factors, including, but not limited to, the following:

- successfully completing formulation and process development activities;
- completing clinical trials that demonstrate the efficacy and safety of our product candidates;
- receiving marketing approval from applicable regulatory authorities;
- establishing commercial manufacturing capabilities; and
- launching commercial sales, marketing and distribution operations.

Many of these factors are wholly or partially beyond our control, including clinical advancement, the regulatory submission process and changes in the competitive landscape. If we do not achieve one or more of these targets in a timely manner, we could experience significant delays or may be unable to develop our product candidates at all, which may have a material adverse effect on our business and results of operations.

Clinical trials are expensive, time consuming, difficult to design and implement, and involve uncertain outcomes. Results of previous pre-clinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or other regulatory authorities.

Positive or timely results from pre-clinical or early-stage trials do not ensure positive or timely results in late-stage clinical trials or product approval by the FDA or comparable foreign regulatory authorities. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercialization. Our planned clinical trials may produce negative or inconclusive results, and we or any of our current and future strategic partners may decide, or regulators may require us, to conduct additional clinical or pre-clinical testing.

Success in pre-clinical studies or early-stage clinical trials does not mean that future clinical trials or registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and foreign regulatory authorities, despite having progressed through pre-clinical studies and initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials or registration clinical trials. For example, a number of companies in the biopharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials. Similarly, pre-clinical interim results of a clinical trial are not necessarily predictive of final results.

If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to obtain regulatory approval and commercialize our product candidates on a timely basis, or at all, which would require us to incur additional costs and delay our receipt of any product revenue.

We may experience delays in our ongoing or future pre-clinical studies or clinical trials, and we do not know whether future pre-clinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients or be completed on schedule, if at all. The commencement or completion of these planned clinical trials could be substantially delayed or prevented by many factors, including, but not limited to:

- discussions with the FDA or other regulatory agencies regarding the scope or design of our clinical trials;
- the limited number of, and competition for, suitable sites to conduct our clinical trials, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- any delay or failure to obtain approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical trial;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to manufacture sufficient supplies of product candidates for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or clinical research organizations ("CROs"), the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs;
- delay or failure to obtain IRB approval to conduct a clinical trial at a prospective site;
- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- the inability to enroll a sufficient number of patients in studies to ensure adequate statistical power to detect statistically significant treatment effects;

- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- lack of efficacy during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;
- inability to monitor patients adequately during or after treatment;
- clinical study sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- inability to address any non-compliance with regulatory requirements or safety concerns that arise during the course of a clinical trial;
- the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications in testing; and
- our clinical trials may be suspended or terminated upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future strategic partners that have responsibility for the clinical development of any of our product candidates.

Changes in regulatory requirements, policies and guidelines may also occur and we may need to significantly amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. These changes may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us. Any failure or significant delay in commencing or completing clinical trials for our product candidates may adversely affect our ability to obtain regulatory approval and our commercial prospects and our ability to generate product revenue will be diminished.

The design or our execution of clinical trials may not support regulatory approval.

The design or execution of a clinical trial can determine whether its results will support regulatory approval and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in future clinical trials. The FDA or foreign regulatory authorities may disagree with our trial design and our interpretation of data from pre-clinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for clinical trial that has the potential to result in FDA or other agencies' approval. In addition, such regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates which may have a material adverse effect on our business.

We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidates are being studied which could delay or prevent the start of clinical trials for our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidate is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. If we experience delays in our clinical trials, the timeline for obtaining regulatory approval of our product candidates will most likely be delayed.

Many factors may affect our ability to identify, enroll and maintain qualified patients, including the following:

- eligibility criteria of our ongoing and planned clinical trials with specific characteristics appropriate for inclusion in our clinical trials;
- design of the clinical trial;
- size and nature of the patient population;
- patients' perceptions as to risks and benefits of the product candidate under study and the participation in a clinical trial generally in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the availability and efficacy of competing therapies and clinical trials;
- pendency of other trials underway in the same patient population;
- willingness of physicians to participate in our planned clinical trials;
- severity of the disease under investigation;
- proximity of patients to clinical sites;
- patients who do not complete the trials for personal reasons; and
- issues with CROs and/or with other vendors that handle our clinical trials.

We may not be able to initiate or continue to support clinical trials of our product candidates for one or more indications, or any future product candidates, if we are unable to locate and enroll a sufficient number of eligible participants in these trials as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our trials may be delayed or our trials could become too expensive to complete.

If we experience delays in the completion of, or termination of, any clinical trials of our product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of our product candidates could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales; no regulatory agency has made any such determination that any of our product candidates are safe or effective for use by the general public for any indication.

All of our product candidates are still in pre-clinical or early clinical development. Additionally, all of our product candidates are required to undergo ongoing safety testing in humans as part of clinical trials. Consequently, not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved by regulatory authorities, after the approved product has been marketed. Therefore, the results from clinical trials may not demonstrate a favorable safety profile in humans. The results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA or foreign regulatory authorities, or result in marketing approval from the FDA or foreign regulatory authorities with restrictive label warnings, limited patient populations or potential product liability claims. Even if we believe that our clinical trial and pre-clinical studies demonstrate the safety and efficacy of our product candidates, only the FDA and other comparable regulatory agencies may ultimately make such determination. No regulatory agency has made a determination that any of our product candidates are safe or effective for any indication.

If any of our product candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, and/or a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenue from the sale of any future products.

We are dependent on third parties for manufacturing and marketing of our product candidates. If we are not able to secure favorable arrangements with such third parties, our business and financial condition could be harmed.

We will not manufacture any of our product candidates for commercial sale nor do we have the resources necessary to do so. In addition, we currently do not have the capability to market our drug products ourselves. In addition to our internal sales force efforts, we have contracted with and intend to continue to contract with specialized manufacturing companies to manufacture our product candidates. In connection with our efforts to commercialize our product candidates, we will seek to secure favorable arrangements with third parties to distribute, promote, market and sell our product candidates. If our internal sales force is unable to successfully distribute, market and promote our product candidates and we are not able to secure favorable commercial terms or arrangements with third parties for the distribution, marketing, promotion and sales of our product candidates, we may have to retain promotional and marketing rights and seek to develop the commercial resources necessary to promote or co-promote or co-market certain or all of our drug candidates to the appropriate channels of distribution in order to reach the specific medical market that we are targeting. We may not be able to enter into any partnering arrangements on this or any other basis. If we are not able to secure favorable partnering arrangements, or are unable to develop the appropriate resources necessary for the commercialization of our product candidates, our business and financial condition could be harmed.

In addition, we, or our potential commercial partners, may not successfully introduce our product candidates or such candidates may not achieve acceptance by patients, health care providers and insurance companies. Further, it is possible that we may not be able to secure arrangements to manufacture, market, distribute, promote and sell our proposed product candidates at favorable commercial terms that would permit us to make a profit. To the extent that corporate partners conduct clinical trials, we may not be able to control the design and conduct of these clinical trials.

If a third-party contract manufacturing organization ("CMO") upon whom we rely to formulate and manufacture our product candidates does not perform, fails to manufacture according to our specifications or fails to comply with strict regulations, our pre-clinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated or we could incur significant additional expenses.

Although in January 2024, the Company entered into a long-term operating lease agreement for manufacturing space located in California, as of March 2024, we do not own or operate any operating manufacturing facilities. We rely on and intend to continue to rely on CMOs to formulate and manufacture our pre-clinical and clinical materials. Our reliance on a CMO exposes us to a number of risks, any of which could delay or prevent the completion of our pre-clinical studies or clinical trials, or the regulatory approval or commercialization of our product candidates, result in higher costs, or deprive us of potential product revenues. Some of these risks include:

- our CMO failing to develop an acceptable formulation to support later-stage clinical trials for, or the commercialization of, our product candidates;
- our CMO failing to manufacture our product candidate according to our specifications, the FDA's cGMP requirements, or otherwise manufacturing material that we, the FDA or other regulatory agencies may deem to be unsuitable in our clinical trials;
- our CMO being unable to increase the scale of, increase the capacity for, or reformulate the form of our product candidates. We may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it may adversely affect the cost of our product candidates. We cannot assure you that our CMO will be able to manufacture our product candidates at a suitable scale, or we will be able to find alternative manufacturers acceptable to us that can do so;
- our CMO placing a priority on the manufacture of their own products, or other customers' products;
- our CMO failing to perform as agreed upon or not remain in business; and
- our CMO's plants being closed as a result of regulatory sanctions, natural disasters, health epidemics or otherwise.

Manufacturers of pharmaceutical products are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Administration and corresponding state and foreign agencies to ensure strict compliance with FDA mandated cGMP, other government regulations and corresponding foreign standards. While we are obligated to audit their performance, we do not have control over our CMO's compliance with these regulations and standards. Failure by any of our CMOs, or us, to comply with applicable regulations could result in sanctions being imposed on us or the CMOs. These sanctions may include fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

In the event that we need to change our CMOs, our pre-clinical studies, clinical trials or the commercialization of our product candidates could be delayed, adversely affected or terminated, or such a change may result in significantly higher costs.

Various steps in the manufacture of our product candidates may need to be sole-sourced. In accordance with cGMP, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further pre-clinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future CMOs may be difficult for us and could be costly, which could result in our inability to manufacture our product candidates for an extended period of time and therefore a delay in the development of our product candidates. Further, in order to maintain our development time lines in the event of a change in our CMOs, we may incur significantly higher costs to manufacture our product candidates.

We may have conflicts with our future partners that could delay or prevent the development or commercialization of our product candidates.

We may have conflicts with our future partners, such as conflicts concerning the interpretation of pre-clinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due to us under a collaboration; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

We may not be able to conduct, or contract others to conduct, animal testing in the future, which could harm our research and development activities.

Certain laws and regulations relating to drug development require us to test our drug candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted or delayed.

If any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, in which case revenue generated from their sales would be limited.

The commercial success of our product candidates will depend upon their acceptance among physicians, patients and the medical community. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- limitations or warnings contained in the approved labeling for a product candidate;
- changes in the standard of care for the targeted indications for any of our product candidates;
- limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability of coverage and reimbursement amounts from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the cost-effectiveness of our product candidates;
- availability of alternative products at similar or lower cost, including generic and over-the-counter products;
- the extent to which the product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular diseases;

- whether the product can be used effectively with other therapies to achieve higher response rates;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- convenience and ease of administration of our products; and
- potential product liability claims.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients and the medical community, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

Even if we receive regulatory approval to commercialize any of the product candidates that we develop, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or subject to certain conditions of approval, and may contain requirements for potentially costly post-approval trials, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the marketed product.

For any approved product, we will be subject to ongoing regulatory obligations and extensive oversight by regulatory authorities, including with respect to manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product. These requirements include submissions of safety and other post-approval information and reports, as well as continued compliance with cGMP and cGCP for any clinical trials that we conduct post- approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product;
- withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA, European Medicines Agency ("EMA") or another competent regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations. Further, the FDA's or other regulatory authority's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which could adversely affect our business, prospects and ability to achieve or sustain profitability.

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

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients, and will face an even greater risk if product candidates are approved by regulatory authorities and commercialized. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in:

- decreased demand for any future approved products;

- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- increased regulatory scrutiny;
- significant litigation costs;
- substantial monetary awards to or costly settlement with patients or other claimants;
- product recalls or a change in the indications for which products may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operation.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain for such product candidates.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act ("MMA") changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our product candidates and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "Health Care Reform Law") is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products.

The Health Care Reform Law remains subject to legislative efforts to repeal, modify or delay the implementation of the law. However, if the Health Care Reform Law is repealed or modified, or if implementation of certain aspects of the Health Care Reform Law 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 Health Care Reform Law on us at this time. Due to the substantial regulatory changes that will need to be implemented by the Centers for Medicare & Medicaid Services 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.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce or eliminate our profitability.

If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

As a company involved in the healthcare industry, our business activities are subject to substantial governmental regulation. There are significant costs involved in complying with these laws and regulations. If we are found to have violated any applicable laws or regulations, we could be subject to civil or criminal damages, fines, sanctions or penalties, including exclusion from participation in government healthcare programs, such as Medicare, and we may be required to change our method of operations and business strategy. A federal, state, local or foreign government could determine that we are not operating in accordance with the law, or whether, when or how the laws, or the interpretation thereof, will change in the future and impact our business, financial condition, cash flows and results of operations. Any of these possibilities, if they occur, could adversely affect us.

The laws to which we will be subject and which could impact our business activities include the following.

- federal and state healthcare program anti-kickback laws (including the federal Anti-Kickback Statute and Civil Monetary Penalties Law) prohibit among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. Such anti-kickback laws can be implicated by, among other activities, marketing arrangements with ordering providers, discount or rebate programs or other inducements to purchase our products. Violation of these laws can result in criminal prosecution and imposition of criminal penalties and fines, as well civil monetary penalties and multiple damage judgments, and exclusion from participation in federal healthcare programs;

- the Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. § 1395nn) prohibit referrals by ordering by a physician of "designated health services" which include pharmaceuticals and drugs that are payable, in whole or in part, by Medicare or Medicaid, to an entity in which the physician or the physician's immediate family member has an investment interest or other financial relationship, subject to several exceptions. Financial relationships that are implicated by the Stark Law can include arrangements ranging from marketing arrangements and consulting agreements to medical director agreements with physicians who order our products. The Stark Law also prohibits billing for services rendered pursuant to a prohibited referral. Several states have enacted laws similar to the Stark Law. These state laws may cover all (not just Medicare and Medicaid) patients. If we violate the Stark Law, our financial results and operations could be adversely affected. Penalties for violations include denial of payment for the services, significant civil monetary penalties, and exclusion from the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

- HIPAA which imposes certain requirements relating to the privacy, security and transmission of protected health information which includes individually identifiable health information, demographic data, medical histories and test results;

- the Federal Food, Drug and Cosmetic Act which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- The Physician Payments Sunshine Act which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations;

- state law equivalents of each of the above federal laws, such as, Stark Law, anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If we are unable to effectively adapt to changes in the healthcare industry, our business may be harmed.

Federal, state and local legislative bodies frequently pass legislation and promulgate regulations relating to healthcare reform or that affect the healthcare industry. As has been the trend in recent years, it is reasonable to assume that there will continue to be increased government oversight and regulation of the healthcare industry in the future. We cannot predict the ultimate content, timing or effect of any new healthcare legislation or regulations, nor is it possible at this time to estimate the impact of potential new legislation or regulations on our business. It is possible that future legislation enacted by Congress or state legislatures, or regulations promulgated by regulatory authorities at the federal or state level, could adversely affect our business. It is also possible that the changes to federal healthcare program reimbursements to providers who purchase our products may serve as precedent to possible changes in other payors' reimbursement policies in a manner adverse to us. Similarly, changes in private payor reimbursements could lead to adverse changes in federal healthcare programs, which could have a material adverse effect on our business, financial condition, cash flows and results of operations.

There can be no assurance that we will be able to successfully address changes in the current regulatory environment. Some of the healthcare laws and regulations applicable to us are subject to limited or evolving interpretations, and a review of our business or operations by a court, law enforcement or a regulatory authority might result in a determination that could have a material adverse effect on us. Furthermore, the healthcare laws and regulations applicable to us may be amended or interpreted in a manner that could have a material adverse effect on our business, financial condition, cash flows and results of operations.

Risks Relating to our Business and Operations

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to prioritize our efforts on specific research and development programs, including clinical development of NXC-201, IMX-110, IMX-111 and IMX-120 or other future product candidates. As a result, we may forgo or delay pursuit of other opportunities, including with potential future product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable drug candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through partnership, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If the market opportunities for our current and potential future product candidates are smaller than we believe they are, our ability to generate product revenue may be adversely affected and our business may suffer.

Our understanding of the number of people who suffer from certain types of cancers, hematologic malignancies and inflammatory diseases as well as ulcerative colitis and Crohn's disease that our product candidates may have the potential to treat is based on estimates. These estimates may prove to be incorrect, and new studies may demonstrate or suggest a lower estimated incidence or prevalence of such diseases. The number of patients in the United States or elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our current or potential future product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business prospects and financial condition.

Our products will face significant competition, and if they are unable to compete successfully, our business will suffer.

We compete in an industry that is characterized by: (i) rapid technological change, (ii) evolving industry standards, (iii) emerging competition, (iv) new product introductions and (v) an emphasis on proprietary and novel products and product candidates. Our competitors, some of which include larger pharmaceutical companies, biotechnology companies, and academic institutions, have and may develop products and technologies that will compete with our products and technologies. Specifically, we face competition from companies developing therapies for AL amyloidosis which include Prothena Corp, Caelum Biosciences (Now Alexion/AstraZeneca), and Janssen/Johnson & Johnson. In addition, we face competition from companies developing cell therapies for autoimmune indications, some of which include Kyverna Therapeutics, Inc.; Cabaletta Bio, Inc.; Fate Therapeutics Inc.; and Arcellx, Inc. Moreover, companies with approved therapies for blood disorders include, but are not limited to, Novartis AG, Bristol Myers Squibb Co, and Janssen/Johnson & Johnson. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying new product candidates.

We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In addition, our products may need to compete with drugs physicians use off-label to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Because several competing companies and institutions have greater financial resources than us, they may be able to: (i) provide broader services and product lines, (ii) make greater investments in research and development and (iii) carry on larger research and development initiatives. Our competitors also have greater development capabilities than we do and have substantially greater experience in undertaking pre-clinical and clinical testing of products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. They may also have greater name recognition and better access to customers than us.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or protected health information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we may collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property and proprietary business information. We manage and maintain our applications and data by utilizing cloud-based data center systems. These applications and data may encompass a wide variety of business-critical information, including research and development information, commercial information and business and financial information. We face risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of being unable to adequately monitor our controls.

Our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the federal privacy rules for health information promulgated under HIPAA and regulatory penalties. There is no guarantee that we can continue to protect our systems from breach. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or providers, process claims and appeals, conduct research and development activities, collect, process and prepare company financial information, provide information about any future products, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

The U.S. Office of Civil Rights in the Department of Health and Human Services enforces the HIPAA privacy and security rules and may impose penalties for failure to comply with requirements of HIPAA. Penalties vary significantly depending on factors such as whether failure to comply was due to willful neglect. These penalties include civil monetary penalties of $100 to $50,000 per violation, up to an annual cap of $1,500,000 for identical violations. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 per violation and up to one-year imprisonment. The criminal penalties increase to $100,000 per violation and up to five-years imprisonment if the wrongful conduct involves false pretenses, and to $250,000 per violation and up to 10-years imprisonment if the wrongful conduct involves the intent to sell, transfer, or use identifiable health information for commercial advantage, personal gain, or malicious harm. The U.S. Department of Justice is responsible for criminal prosecutions under HIPAA. Furthermore, in the event of a breach as defined by HIPAA, there are reporting requirements to the Office of Civil Rights under the HIPAA regulations as well as to affected individuals, and there may also be additional reporting requirements to other state and federal regulators, including the Federal Trade Commission, and to the media. Issuing such notifications can be costly, time and resource intensive, and can generate significant negative publicity. Breaches of HIPAA may also constitute contractual violations that could lead to contractual damages or terminations.

In addition, the interpretation and application of consumer, health-related and data protection laws in the United States, the European Union, or EU, and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these data protection laws vary between states, may differ from country to country, and may vary based on whether testing is performed in the United States or in another country. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. For example, we may be subject to privacy laws and regulations such as the European Union's General Data Protection Regulation ("GDPR") and the California Consumer Privacy Act ("CCPA"). These laws mandate that companies satisfy requirements regarding the handling of personal and sensitive data, including its use, protection, and the ability of persons whose data is stored to correct or delete such data about themselves. Failure to comply with GDPR requirements could result in penalties of up to 4% of worldwide revenue. The GDPR, CCPA, and other similar laws and regulations, as well as any associated inquiries or investigations or any other government actions, may be costly to comply with, increase our operating costs, require significant management time and attention, and subject us to remedies that may harm our business, including fines, negative publicity, or demands or orders that we modify or cease existing business practices.

Furthermore, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could have a material adverse effect on our business.

Unfavorable geopolitical and macroeconomic developments could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by conditions in the U.S. and global economies, the United States and global financial markets and adverse geopolitical and macroeconomic developments, including rising inflation rates, the continuing impact of the COVID-19 pandemic, the Ukrainian/Russian and Israeli/Palestinian conflicts and related sanctions, bank failures, and economic uncertainties related to these conditions.

For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In response to rising inflation, the U.S. Federal Reserve has raised, and may again raise, interest rates, which, coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks.

While the COVID-19 pandemic has abated, many of the consequences of the COVID-19 pandemic continue to cause disruption and increased costs for businesses. In the case of clinical stage biopharmaceutical companies, we believe there continue to be, among other things, supply chain disruptions that are causing delays in the delivery of drug candidates and comparator products and healthcare staffing shortages that are causing delays in the establishment of test sites and the conduct of clinical trials.

Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022 and the eruption of the Israeli/Palestinian conflict in October 2023, including as a result of economic sanctions and export controls against Russia and countermeasures taken by Russia. The full economic and social impact of these sanctions and countermeasures, in addition to the ongoing military conflicts in Ukraine and Gaza, which could conceivably expand, remains uncertain; however, both the conflicts and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, and/or supply chain continuity, in both Europe and globally, and has introduced significant uncertainty into global markets. While we do not currently operate in Russia, Ukraine or the Middle East, as the adverse effects of these conflicts continue to develop our business and results of operations may be adversely affected.

Any international operations we undertake may subject us to risks inherent with operations outside of the United States.

We intend to obtain market clearance for our product candidates in foreign markets; however, even with the cooperation of a commercialization partner, conducting drug development in foreign countries involves inherent risks, including, but not limited to: difficulties in staffing, funding and managing foreign operations; unexpected changes in regulatory requirements; export restrictions; tariffs and other trade barriers; difficulties in protecting, acquiring, enforcing and litigating intellectual property rights; fluctuations in currency exchange rates; and potentially adverse tax consequences. If we were to experience any of the difficulties listed above, or any other difficulties, our international development activities and our overall financial condition may suffer and cause us to reduce or discontinue our international development and registration efforts.

We may not be successful in hiring and retaining key employees, including executive officers.

Our future operations and successes depend in large part upon the strength of our management team. We rely heavily on the continued service of each member of our management team. Accordingly, if any member of our management team were to terminate their employment with us, such departure may have a material adverse effect on our business. In addition, our future success depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified financial, managerial, technical, clinical and regulatory personnel. There can be no assurance that these professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and work force could adversely affect our ability to operate, grow and manage our business.

Our employees, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain approval of any of our product candidates from the FDA or any other foreign regulatory agency and begin commercializing those products in the United States or elsewhere, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA or other regulatory agencies, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

Risks Relating to our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidates, others could compete against us, which may have a material adverse effect on our business.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates, the processes used to manufacture them and the methods for using them, as well as successfully defending such patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the U.S. or in foreign jurisdictions outside of the U.S. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our products or technologies could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our future licensors will not be involved in interference, opposition, reexamination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices.

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 or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are similar to our product candidates, but that are not covered by the claims of our patents;

- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- our pending patent applications may not result in issued patents;
- the claims of our issued patents or patent applications when issued may not cover our products or product candidates;
- any patents that we may obtain from licensing or otherwise may not provide us with any competitive advantages;
- any granted patents that we rely upon may be held invalid or unenforceable as a result of legal challenges by third parties; and
- the patents of others may have an adverse effect on our business.

If we fail to comply with our obligations in the agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our potential licensors, we could lose rights that are important to our business.

We have and may, in the future, be required to enter into intellectual property license agreements that are important to our business. These license agreements may impose various diligence, milestone payment, royalty and other obligations on us. For example, we may enter into exclusive license agreements with various universities and research institutions, we may be required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products, and may need to satisfy specified milestone and royalty payment obligations. If we fail to comply with any obligations under any potential agreements with any of these licensors, we may be subject to termination of the license agreement in whole or in part; increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize products covered by the license agreement will be impaired.

In addition, disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third-party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to a third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize our product candidates.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights.

If we choose to commence a proceeding or litigation to prevent another party from infringing our patents, that party will have the right to ask the examiner or court to rule that such patents are invalid or should not be enforced against them. There is a risk that the examiner or court will decide that our patents are not valid and that we do not have the right to stop the other party from using the related inventions. There is also the risk that, even if the validity of such patents is upheld, the examiner or court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights. In addition, the U.S. Supreme Court has recently modified some tests used by the U.S. Patent and Trademark Office ("USPTO") in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge to any patents we obtain or may, in the future, license. Any proceedings or litigation to enforce our intellectual property rights or defend ourselves against claims of infringement of third-party intellectual property rights could be costly and divert the attention of managerial and scientific personnel, regardless of whether such litigation is ultimately resolved in our favor. We may not have sufficient resources to bring these actions to a successful conclusion. Moreover, if we are unable to successfully defend against claims that we have infringed the intellectual property rights of others, we may be prevented from using certain intellectual property and may be liable for damages, which in turn could materially adversely affect our business, financial condition or results of operations.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our product candidates, or manufacture or use of our product candidates, will not infringe third-party patents. Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. Some of these third parties may be better capitalized and have more resources than us. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable way around the patent and may need to halt commercialization of our product candidates. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our product candidates or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we are the first to invent the technology, because:

- some patent applications in the U.S. may be maintained in secrecy until the patents are issued;
- patent applications in the U.S. are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering products and technology similar to ours. Any such patent application may have priority over our patent applications, which could require us to obtain rights to issued patents covering such products or technologies. If another party has filed U.S. patent applications on inventions similar to us that claims priority to any applications filed prior to the priority dates of our applications, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the U.S. It is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar inventions prior to our inventions, resulting in a loss of our U.S. patent position with respect to such inventions which could in turn have a material adverse effect on our operations. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than us because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

We also rely on trade secrets to protect our proprietary products and technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our business.

We may be subject to claims that our employees or consultants have wrongfully used or disclosed alleged trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees or consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our intellectual property may not be sufficient to protect our product candidates from competition, which may negatively affect our business.

We may be subject to competition despite the existence of intellectual property we own or in the future may license. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or may in the future license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our product candidates.

We may elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license from a third party. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition, and the commercial viability of our products; and

- restructuring our Company or delaying or terminating select business opportunities, including, but not limited to, research and development, clinical trial, and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

A third party may also challenge the validity, enforceability or scope of the intellectual property rights that we own or in the future may license; and, the result of these challenges may narrow the scope or claims of or invalidate patents that are integral to our product candidates. There can be no assurance that we will be able to successfully defend patents we own or may license in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation, amongst other factors.

Intellectual property rights and enforcement may be less extensive in jurisdictions outside of the U.S.; thus, we may not be able to protect our intellectual property and third parties may be able to market competitive products that may use some or all of our intellectual property.

Changes to patent law, including the Leahy-Smith America Invests Act, AIA or Leahy-Smith Act, of 2011 and the Patent Reform Act of 2009 and other future article of legislation, may substantially change the regulations and procedures surrounding patent applications, issuance of patents, and prosecution of patents. We can give no assurances that our patents can be defended or will protect us against future intellectual property challenges, particularly as they pertain to changes in patent law and future patent law interpretations.

In addition, enforcing and maintaining our intellectual property protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by the USPTO, courts and foreign government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements which may have a material adverse effect on our business.

We conduct certain research and development operations through our Australian wholly-owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations could suffer.

In August 2016, we formed a wholly-owned Australian subsidiary, Immix Biopharma Australia Pty Ltd to conduct various pre-clinical and clinical activities for our product and development candidates in Australia. We may not be able to efficiently or successfully monitor, develop and commercialize our lead products in Australia, including conducting clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our product candidates in Australia will be accepted by the FDA or foreign regulatory authorities for development and commercialization approvals.

In addition, current Australian tax regulations provide for a refundable research and development tax credit equal to 43.5% of qualified expenditures. If we lose our ability to operate IBAPL in Australia, or if we are ineligible or unable to receive the research and development tax credit, or the Australian government significantly reduces or eliminates the tax credit, our business and results of operation may be adversely affected.

Breakthrough Therapy Designation, Fast Track Designation or RPDD by the FDA, and equivalents granted by indications, may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in any jurisdiction.

We may seek a Breakthrough Therapy Designation for some of our product candidates. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy 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 therapies 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. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. 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 therapies 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 such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek Fast Track Designation for some of our product candidates for therapeutic indications. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track Designation. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, 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. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

We may seek a RPDD for some of our product candidates. However, even if we believe a particular product candidate is eligible for this designation, we cannot guarantee that FDA would agree. The FDA may award priority review vouchers to sponsors of products that meet the definition of a "rare pediatric disease." A "rare pediatric disease" is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare disease or conditions within the meaning of the Orphan Drug Act. However, this designation is at the discretion of the FDA and, even if we do receive a Rare Pediatric Disease Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures and are still not guaranteed final approval of our product candidate by the FDA. Additionally, the benefits of a RPDD may not be available for future product candidates. After September 30, 2024, the FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has a RPDD for the drug that was granted by September 30, 2024. After September 30, 2026, the FDA may not award any additional rare pediatric disease priority review vouchers.

Risks Related to Owning our Common Stock

The price of our common stock may fluctuate substantially.

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, are:

- sales of our common stock by our stockholders, executives, and directors;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financing to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- possible delays in the expected recognition of revenue due to lengthy and sometimes unpredictable sales timelines;
- the timing and success of introductions of new products by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- network outages or security breaches;
- our ability to attract new customers;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our product candidates or any future clinical trials we may conduct;
- changes in the development status of our product candidates;

- any delays or adverse developments or perceived adverse developments with respect to the FDA or other regulatory agencies' review of our planned pre-clinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for our product candidates;
- unanticipated safety concerns related to the use of our product candidates;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy or future issuances of securities;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- competition from existing technologies and products or new technologies and products that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

We are currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on Nasdaq or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

Although our common stock is currently listed on The Nasdaq Capital Market, we may not be able to continue to meet the exchange's minimum listing requirements or those of any other national exchange. If we are unable to maintain listing on Nasdaq or if a liquid market for our common stock does not develop or is sustained, our common stock may remain thinly traded.

The Listing Rules of Nasdaq require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our shareholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of March 25, 2024, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 39% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our Company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, any future debt agreements may also preclude us from paying or place restrictions on our ability to pay dividends. Any future determination as to the declaration and payment of dividends will be at the discretion of our board of directors and will depend on factors the board of directors deems relevant, including among others, our results of operations, financial condition and cash requirements, business prospects, and the terms of any of our financing arrangements. Therefore, any return to stockholders may be limited to the increase, if any, of our share price. There is no guarantee that our stock will appreciate in value.

Our third amended and restated certificate of incorporation ("Amended and Restated Certificate of Incorporation") and our amended and restated bylaws (the "Amended and Restated Bylaws") and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 10 million shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter our Amended and Restated Bylaws without stockholder approval;
- place limitations on the removal of directors;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with the us or our directors, officers or employees.

Our Amended and Restated Certificate of Incorporation provides that unless we consent in writing to the selection of an alternative forum, the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of our Company to us or our stockholders, (iii) any action asserting a claim against us, our directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law (the "DGCL") or our Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws, or (iv) any action asserting a claim against us, our directors, officers, employees or agents governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act or 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.

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. However, our Amended and Restated Certificate of Incorporation contains a federal forum provision which provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock are deemed to have notice of and consented to this provision.

These choice of 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 and may result in increased costs to our stockholders, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find our choice of forum provisions contained in our Amended and Restated 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 harm our business, results of operations, and financial condition.

Failure to maintain ***effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.***

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. Our management concluded there was a material weakness in our internal control over financial reporting as of December 31, 2023 as, due to our small size, and our limited number of personnel, we did not have in place an effective internal control environment with formal processes and procedures, including journal entry processing and review, to allow for a detailed review of accounting transactions that would identify errors in a timely manner. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

We have implemented additional review procedures including addition of accounting consultants to remediate such weakness. While we believe that our remediation efforts will resolve the identified material weakness, there is no assurance that such efforts will be sufficient or that additional actions will not be necessary, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. Furthermore, if we remediate our current material weakness but identify new material weaknesses in our internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may be negatively affected. As a result of such failures, we could also become subject to investigations by Nasdaq, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our business.

General Risk Factors

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over medical epidemics, energy costs, geopolitical issues, the U.S. mortgage market and a deteriorating real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

Future sales and issuances of our common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall. In addition, the perception that sales of our common stock could occur, could cause our stock price to fall.

We expect that significant additional capital will be needed to continue our planned operations, including increased marketing, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. Furthermore, sales of a substantial number of our shares of common stock in the public markets or the perception that such sales could occur, could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

The number of shares of our common stock available for future issuance or sale could adversely affect the per share trading price of our common stock.

We cannot predict whether future issuances or sales of our common stock or the availability of shares for resale in the open market will decrease the per share trading price of our common stock. The issuance of a substantial number of shares of our common stock in the public market or the perception that such issuances might occur could adversely affect the per share trading price of our common stock.

We are an "emerging growth company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, pursuant to Section 107 of the JOBS Act, as an "emerging growth company" we intend to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

Financial reporting obligations of being a public company in the U.S. are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company we incur significant additional legal, accounting and other expenses. The obligations of being a public company in the U.S. require significant expenditures and place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of The Nasdaq Capital Market. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company" or a "smaller reporting company." Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy. We employ processes for assessing, identifying, and managing material risks from cybersecurity threats that are incorporated into our overall risk management system. These items are designed to help protect our information assets from internal and external threats and protect the integrity and confidentiality of our data. Our system includes procedural and technical safeguards, response plans, and reviews of our policies. We engage various external entities, including consultants, to improve and enhance our cybersecurity oversight. We provide all employees and consultants with cybersecurity and prevention training including timely and relevant topics covering social engineering, phishing, mobile security, and data protection and the need for reporting incidents and suspicious events immediately. With respect to third parties that assist in our cybersecurity oversight, we obtain reports to assess the security of their systems and processes. We engage in ongoing monitoring of all third-party providers to ensure compliance with our cybersecurity standards.

Although we develop and maintain systems and controls designed to prevent cybersecurity threats from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with service providers and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

As of the date of this report, we are not aware of any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition.

Governance. Our senior management team conducts the regular assessment and management of material risks from cybersecurity threats, including review with our IT team and third-party service providers. All employees and consultants are directed to report to our senior management any irregular or suspicious activity that could indicate a cybersecurity threat or incident. The Audit Committee of our Board of Directors evaluates our cybersecurity assessment and management policies, including quarterly interviews with our senior officers and independent registered accounting firm.

ITEM 2. PROPERTIES

Our executive office is located at 11400 West Olympic Blvd., Suite 200, Los Angeles, CA 90064, which the Company leases on an as needed basis. We believe that our existing facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

In January 2024, the Company entered into a long-term operating lease agreement for manufacturing space in California under a non-cancelable financing lease that expires in December 2033. Under the terms of the lease, we expect to make total lease payments of $1.6 million through December 2033.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

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

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "IMMX."

Stockholders

As of March 29, 2024, there were 19 stockholders of record of our common stock.

Dividend Policy

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 of directors 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 of directors deems relevant.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and plan of operations together with and our accompanying consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report on Form 10-K. All amounts in this report are in U.S. dollars, unless otherwise noted.

Overview

Immix Biopharma, Inc. is a clinical-stage biopharmaceutical company focused on the application of CAR-T in light chain (AL) Amyloidosis and autoimmune disease. Our lead cell therapy candidate is FDA IND cleared CAR-T NXC-201, currently being evaluated in our ongoing Phase 1b/2a NEXICART-1 (NCT04720313) clinical trial. Based on early clinical data, we believe NXC-201 has the potential to be the world's first "Single-Day CRS" CAR-T (CRS median onset day 1, median duration 1 day), enabling the potential for a faster return home for patients. NXC-201 has been awarded Orphan Drug Designation (ODD) by the FDA in both AL Amyloidosis and multiple myeloma, and ODD by the European Commission (EMA) in AL Amyloidosis.

Since inception, we have devoted substantially all of our resources to developing product and technology rights, conducting research and development, organizing and staffing our Company, business planning and raising capital. We operate as one business segment and have incurred recurring losses, the majority of which are attributable to research and development activities and negative cash flows from operations. We have funded our operations primarily through the sale of convertible debt and equity securities. Currently, our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. 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 incur costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenses on other research and development activities.

AxioMx Master Services Agreement

On December 22, 2014, we entered into a Master Service Agreement ("MSA") with AxioMx, Inc. ("AxioMx") which is in the business of developing and supplying custom affinity reagents. We entered into the MSA to serve as a master agreement governing multiple sets of projects as may be agreed upon us and AxioMx from time to time. Pursuant to the MSA, we granted AxioMx a non-exclusive, royalty-free, worldwide, non-transferable license to certain of our intellectual property to perform services pursuant to the MSA, and AxioMx granted us an exclusive product assignment option ("Option") which granted us an exclusive, royalty-bearing right, with the right to sublicense, under the Deliverable (as defined in the MSA) to further research, develop, use, sell, offer for sale, import and export one or more assigned products pursuant to the MSA. We exercised the Option in 2017. Pursuant to the MSA, AxioMx is entitled to royalties on the sale of any Deliverable that is used for diagnostic, prognostic or therapeutic purposes, in humans or animals, or for microbiology testing, including food safety testing or environmental monitoring. Specifically, we shall pay AxioMx a royalty of 3.5% of Net Sales (as defined in the MSA) of assigned products for each Deliverable used in licensed products for therapeutic purposes. In addition, we shall pay AxioMx a royalty of 1.5% of Net Sales of assigned products for each Deliverable used in licensed products for diagnostic or prognostic purposes; provided, however, if three Deliverables are used in an assigned product for diagnostic or prognostic purposes, the royalty shall be 4.5%. As of December 31, 2022, the MSA has expired and we do not intend to extend the MSA; however, the royalty obligations described herein shall survive the termination of the MSA.

Research and License Agreement with Hadasit and BIRAD

On December 8, 2022, Nexcella entered into the Agreement with the Licensors pursuant to which the Licensors granted to Nexcella an exclusive, worldwide, royalty-bearing license in the Territory to an invention entitled "Anti-BCMA CAR-T cells to target plasma cell" to develop, manufacture, have manufactured, use, market, offer for sale, sell, have sold, export and import Licensed Product. Pursuant to the Agreement, Nexcella paid the Licensors an upfront fee of $1,500,000 in December 2022. Additional quarterly payments totaling approximately $13.0 million are due through September 2026 along with an annual license fee of $50,000. Nexcella has agreed to pay royalties to the Licensors equal to 5% of Net Sales during the Royalty Period.

In addition, Nexcella shall pay sales milestone payments of up to $20 million for Net Sales exceeding $700 million and Nexcella has committed to funding NXC-201 clinical trials in Israel over 4 years for an estimated total cost of approximately $13 million, spread on a quarterly basis over that period, which Nexcella believes will generate clinical trial data owned by Nexcella. The term of the Agreement commenced on December 8, 2022 and, unless earlier terminated pursuant to the terms thereof, shall continue in full force and effect until the later of the expiration of the last Valid Claim under a Licensed Patent or a Joint Patent or Exclusivity Right covering a Licensed Product or the expiration of a continuous period of 15 years during which there shall not have been a First Commercial Sale of any Licensed Product in any country in the world. Licensors may terminate the Agreement immediately if Nexcella or its affiliates or sublicensees commences an action in which it challenges the validity, enforceability or scope of any of the Licensed Patents or Joint Patents. In addition, either party may terminate the Agreement if the other party materially breaches the Agreement and fails to cure such breach within 30 days. Additionally, Licensors may terminate the Agreement if Nexcella becomes insolvent or files for bankruptcy.

Recent Developments

In February 2024, we conducted an underwritten public offering of 5,535,055 shares of common stock at the public offering price is $2.71 per shares, for the net proceeds, after underwriter discounts and offering expenses, of approximately $13,529,999. Pursuant to the underwriting agreement, we granted the underwriter a 30-day over-allotment option to purchase up to an additional 783,970 shares of our common stock, which was exercised in full on March 1, 2024 for the net proceeds, after underwiring discounts and offering expenses, of $1,954,594.

Results of Operations

Year Ended December 31, 2023 compared to the Year Ended December 31, 2022

General and Administrative Expenses

General and administrative expenses were $7,406,082 for the year ended December 31, 2023 compared to $4,023,170 for the year ended December 31, 2022.

The expenses incurred in both periods were related to salaries, patent maintenance costs and general accounting and other general consulting expenses, which were higher for the year ended December 31, 2023 due to increased professional fees of $516,271, increased investor relations services of $1,041,458, of which $622,423 was non-cash from shares issued for services, increased compensation of $203,274, and increased stock-based compensation of $1,419,217 from additional equity awards issued to the officers, directors and consultants.

Research and Development Expenses

Research and development expenses were $8,735,031 for the year ended December 31, 2023 compared to $4,195,778 for the year ended December 31, 2022.

The increased research and development expenses relate to our ongoing Phase 1b/2a clinical trial, including, but not limited to, contract research organization (“CRO”) and related costs for maintaining and treating patients in the clinical trial. We were able to increase spending on research and development in 2023 as a result of our increased fundings from the various equity offerings.

Interest Income

Interest income was $572,006 for the year ended December 31, 2023 compared to $0 interest income for the year ended December 31, 2022. Interest income in the current period was related to interest earned on investments in a money market fund.

Provision for Income Taxes

Provision for income taxes for the year ended December 31, 2023 was $26,415 compared to $10,268 for the year ended December 31, 2022, due to withholding taxes relating to our Australian subsidiary.

Liquidity and Capital Resources

Sources of Liquidity

We do not have any approved products for commercial sale and have never generated revenue from product sales and have incurred significant net losses since our inception and expect to continue to incur net operating losses for the foreseeable future. We do not expect to receive any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our product candidates or enter into collaborative arrangements with third parties. We currently have no credit facility or committed sources of capital.

Material Cash Requirements

Our primary use of cash and cash equivalents is to fund operating expenses, which consist of clinical research and development expenses, manufacturing expenses, legal and compliance expenses, compensation and related expenses, and general overhead costs. Cash and cash equivalents used to fund operating expenses is impacted by the timing of when we pay or prepay these expenses. We expect our expenses to increase in connection with our ongoing activities, particularly as we expand our clinical programs, continue the research and development of, and seek marketing approval for our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

As of December 31, 2023, we had total assets of approximately $19.9 million and working capital of approximately $16.1 million. As of December 31, 2023, our liquidity included approximately $17.5 million of cash and cash equivalents. In February and March 2024, we conducted an underwritten public offering of 6,319,025 shares of our common stock, inclusive of the underwriter's exercise in full of its over allotment option, at $2.71 per share, for the net proceeds of approximately $15.5 million, after underwriting discounts and offering expenses. We believe that our cash and cash equivalents on hand as of the date of this report will be sufficient to fund our planned operations over the 12-month period following the date of this report; however, there can be no assurance we will not need additional capital sooner. In addition, we believe that we will need additional capital to continue our planned operations beyond the 12-month period following the date of this report. We intend to seek additional funds through various financing sources, including the sale of our equity and debt securities, licensing fees for our product candidates and technology and joint ventures with industry partners. In addition, we will consider alternatives to our current business plan that may enable us to achieve revenue producing operations and meaningful commercial success with a smaller amount of capital. However, there can be no guarantees that such funds will be available on commercially reasonable terms, if at all. If such financing is not available on satisfactory terms, we may be unable to further pursue our business plan and we may be unable to continue operations.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. 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 or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, 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.

The continuation of the Company as a going concern is dependent upon its ability to obtain continued financial support from its stockholders, necessary equity financing to continue operations and the attainment of profitable operations.

In January 2024, the Company entered into a long-term operating lease agreement for biopharmaceutical manufacturing space in California under a non-cancelable operating lease that expires in December 2033. Under the terms of the lease we expect to make total lease payments of $1.6 million through December 2033.

We enter into contracts in the normal course of business with third-party contract organizations for preclinical and clinical studies, manufacture and supply of our preclinical and clinical materials and providing other services and products for operating purposes. Contracts for preclinical and clinical studies and other services generally provide for termination following a certain period after notice, and therefore we believe that our non-cancelable obligations under these agreements are not material. We do not have any long-term manufacturing and supply agreements with our third-party contract manufacturers but enter into specific contracts on an as needed basis for individual batch production runs.

Cash Flows

Cash used in operating activities

Net cash used in operating activities was $11,371,438 for the year ended December 31, 2023 and $7,408,303 for the year ended December 31, 2022. Net cash used for the year ended December 31, 2023 was primarily related to our net loss of $15,595,522 offset by non-cash items of stock-based compensation expense of $2,565,708 and depreciation expense of $5,468. Operating activities also included an increase in accounts payable of $2,434,467, an increase in the tax receivable of $893,401, and a decrease in prepaid expenses of $111,842. Net cash used for the year ended December 31, 2022, was primarily related to our net loss of $8,229,713 offset by non-cash items of stock-based compensation expense of $624,069 and depreciation expense of $2,135. Operating activities also included an increase in accounts payable of $1,131,736 and an increase in the tax receivable of $236,384, offset by an increase in prepaid expenses of $691,047 and decrease in accrued interest of $9,099.

Cash used in investing activities

Net cash used in investing activities was $52,089 for the year ended December 31, 2023 and $0 for the year ended December 31, 2022. We purchased equipment during the year ended December 31, 2023.

Cash provided by financing activities

Net cash provided by financing activities was $15,463,512 for the year ended December 31, 2023 and $3,232,063 for the year ended December 31, 2022. Net cash provided by financing activities in 2023 was primarily related to $9,934,153 in net proceeds from the issuance of shares of our common stock and warrants in our August 2023 private placement and $5,438,970 in net proceeds from the sale of shares of our common stock pursuant to our ATM facilities.

Critical Accounting Policies

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to prepaid/accrued research and development expenses, stock-based compensation, value of deferred tax assets and related valuation allowances, and fair value of the embedded derivative financial instrument related to our convertible promissory notes. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Stock-Based Compensation - We measure all stock-based awards granted based on their estimated fair value on the date of the grant and recognize the corresponding compensation expense for those awarded to employees and directors over the requisite service period, which is generally the vesting period of the respective award, and for those awarded to nonemployees over the period during which services are rendered by nonemployees until completed. We have typically issued stock options with service-based vesting conditions and we record the expense for these awards using the straight-line method.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

The following table reflects the weighted average assumptions used to estimate the fair value of stock options granted during the years ended December 31, 2023 and 2022:

	2023	2022
Volatility	114-120%	117-124%
Expected life (years)	5.27-10	5.27-10.0
Risk-free interest rate	4.12-4.38%	1.70-3.06%
Dividend rate	—%	—%

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs consist primarily of clinical research fees paid to consultants and outside service providers, other expenses relating to design, development and testing of our therapy candidates, and for license and milestone costs related to in-licensed products and technology. Costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. Such licenses purchased by us require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and has no alternative future use.

Clinical trial costs are a component of research and development expenses. The Company estimates expenses incurred for clinical trials that are in process based on services performed under contractual agreements with clinical research organizations and actual clinical investigators. Included in the estimates are (1) the fee per patient enrolled as specified in the clinical trial contract with each institution participating in the clinical trial and (2) progressive data on patient enrollments obtained from participating clinical trial sites and the actual services performed. Changes in clinical trial assumptions, such as the length of time estimated to enroll all patients, rate of screening failures, patient drop-out rates, number and nature of adverse event reports, and the total number of patients enrolled can impact the average and expected cost per patient and the overall cost of the clinical trial. We monitor the progress of the trials and their related activities and adjust expense accruals, when applicable. Adjustments to accruals are charged to expense in the period in which the facts give rise to the adjustments become known.

Recent Accounting Pronouncements

See Note 2 to our audited consolidated financial statements found elsewhere in this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our consolidated financial statements.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have chosen to take advantage of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards until those standards would otherwise apply to private companies provided under the JOBS Act. As a result, our financial statements may not be comparable to those of companies that comply with public company effective dates for complying with new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including, without limitation, (i) providing an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with the requirement adopted by the Public Company Accounting Oversight Board ("PCAOB") regarding the communication of critical audit matters in the auditor's report on financial statements. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this item. As a smaller reporting company, we are not required to provide the information required by this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

IMMIX BIOPHARMA, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Immix Biopharma, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Immix Biopharma, Inc. and its subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

KMJ Corbin & Company LLP

We have served as the Company's auditor since 2021.

Irvine, California
March 29, 2024

Immix Biopharma, Inc.
Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,509,791	$ 13,436,714
Tax receivable	1,172,183	255,705
Prepaid expenses and other current assets	1,105,776	1,205,398
Total current assets	19,787,750	14,897,817
Deferred offering costs	87,229	6,724
Equipment, net	50,181	3,560
Total assets	$ 19,925,160	$ 14,908,101
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,721,783	$ 1,273,296
Total current liabilities	3,721,783	1,273,296
Funds held for subsidiary private offering	-	475,000
Total liabilities	3,721,783	1,748,296
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock, $0.0001 par value; 200,000,000 shares authorized; 19,994,719 shares issued and 19,922,356 shares outstanding at December 31, 2023, and 13,964,485 shares issued and 13,892,122 shares outstanding at December 31, 2022	2,000	1,397
Additional paid-in capital	69,779,706	51,156,597
Accumulated other comprehensive income	134,666	87,021
Accumulated deficit	(53,411,295)	(37,985,247)
Treasury stock at cost, 72,363 shares as of December 31, 2023 and 2022	(99,963)	(99,963)
Total Immix Biopharma, Inc. stockholders' equity	16,405,114	13,159,805
Non-controlling interests	(201,737)	-
Total stockholders' equity	16,203,377	13,159,805
Total liabilities and stockholders' equity	$ 19,925,160	$ 14,908,101

See accompanying notes to the consolidated financial statements.

Immix Biopharma, Inc.
Consolidated Statements of Operations and Comprehensive Loss

	For the Years Ended December 31,	
	2023	2022
Operating expenses:		
General and administrative expenses	$ 7,406,082	$ 4,023,170
Research and development	8,735,031	4,195,778
Total operating expenses	16,141,113	8,218,948
Loss from operations	(16,141,113)	(8,218,948)
Other income (expense):		
Interest income	572,006	-
Interest expense	-	(497)
Total other income (expense), net	572,006	(497)
Loss before provision for income taxes	(15,569,107)	(8,219,445)
Provision for income taxes	26,415	10,268
Net loss	(15,595,522)	(8,229,713)
Net loss attributable to non-controlling interests	169,474	-
Net loss attributable to Immix Biopharma, Inc. common stockholders	(15,426,048)	(8,229,713)
Other comprehensive income (loss):		
Foreign currency translation	47,645	(38,387)
Total other comprehensive income (loss)	47,645	(38,387)
Comprehensive loss	(15,378,403)	(8,268,100)
Less: comprehensive loss attributable to non-controlling interests	-	-
Comprehensive loss attributable to Immix Biopharma, Inc. common stockholders	$ (15,378,403)	$ (8,268,100)
Loss per common share - basic and diluted	$ (0.89)	$ (0.59)
Weighted average shares outstanding – basic and diluted	17,341,146	13,887,309

See accompanying notes to the consolidated financial statements.

Immix Biopharma, Inc.
Consolidated Statements of Stockholders' Equity
For the Years Ended December 31, 2023 and 2022

	Stockholders of Immix Biopharma, Inc.								
	Common Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Shares	Treasury Stock Amount	Non-Controlling Interests	Total Stockholders' Equity
Balance December 31, 2021	13,228,689	$ 1,323	$47,618,852	$ 125,408	$(29,755,534)	-	$ -	$ -	$ 17,990,049
Shares issued for cash proceeds, net of offering costs	630,000	63	2,913,687	-	-	-	-	-	2,913,750
Shares issued for cashless exercise of stock options	62,532	6	(6)	-	-	-	-	-	-
Shares issued for services	43,264	5	99,995	-	-	-	-	-	100,000
Repurchase of common shares	-	-	-	-	-	(72,363)	(99,963)	-	(99,963)
Stock-based compensation	-	-	524,069	-	-	-	-	-	524,069
Net loss	-	-	-	-	(8,229,713)	-	-	-	(8,229,713)
Foreign currency translation adjustment	-	-	-	(38,387)	-	-	-	-	(38,387)
Balance December 31, 2022	13,964,485	1,397	51,156,597	87,021	(37,985,247)	(72,363)	(99,963)	-	13,159,805
Shares issued under ATM facilities for cash proceeds, net of offering costs	2,523,702	252	5,438,718	-	-	-	-	-	5,438,970
Shares and warrants issued under private placement for cash proceeds, net of offering costs	3,241,076	324	9,933,829	-	-	-	-	-	9,934,153
Shares issued for exercise of stock options	1,351	-	2,618	-	-	-	-	-	2,618
Nexcella shares issued for cash proceeds	-	-	650,000	-	-	-	-	-	650,000
Shares issued for services	264,105	27	622,396	-	-	-	-	-	622,423
Stock-based compensation	-	-	1,943,285	-	-	-	-	-	1,943,285
Non-controlling interests in subsidiary	-	-	32,263	-	-	-	-	(32,263)	-
Net loss	-	-	-	-	(15,426,048)	-	-	(169,474)	(15,595,522)
Foreign currency translation adjustment	-	-	-	47,645	-	-	-	-	47,645
Balance December 31, 2023	19,994,719	$ 2,000	$69,779,706	$ 134,666	$(53,411,295)	(72,363)	$(99,963)	$ (201,737)	$ 16,203,377

See accompanying notes to the consolidated financial statements.

Immix Biopharma, Inc.
Consolidated Statements of Cash Flows

	For the Years Ended December 31,	
	2023	2022
Operating Activities:		
Net loss	$ (15,595,522)	$ (8,229,713)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,565,708	624,069
Depreciation	5,468	2,135
Changes in operating assets and liabilities:		
Tax receivable	(893,401)	(236,384)
Prepaid expenses and other current assets	111,842	(691,047)
Accounts payable and accrued expenses	2,434,467	1,131,736
Accrued interest	-	(9,099)
Net cash used in operating activities	(11,371,438)	(7,408,303)
Investing Activities:		
Purchase of equipment	(52,089)	-
Net cash used in investing activities	(52,089)	-
Financing Activities:		
Payments of deferred offering costs	(234,616)	(6,724)
Proceeds from exercise of stock options	2,618	-
Payments on note payable	-	(50,000)
Proceeds from sale of common stock, net of offering costs	15,520,510	2,913,750
Proceeds from sale of Nexcella common stock	175,000	475,000
Repurchase of common stock	-	(99,963)
Net cash provided by financing activities	15,463,512	3,232,063
Effect of foreign currency on cash	33,092	(31,524)
Net change in cash and cash equivalents	4,073,077	(4,207,764)
Cash and cash equivalents - beginning of year	13,436,714	17,644,478
Cash and cash equivalents - end of year	$ 17,509,791	$ 13,436,714
Supplemental Disclosures of Cash Flow Information:		
Interest paid	$ -	$ 9,596
Income taxes paid	$ -	$ -
Supplemental Disclosures of Noncash Financing Information:		
Nexcella shares issued for funds previously received	$ 475,000	$ -
Deferred offering costs charged against proceeds from sale of common stock	$ 147,387	$ -
Cashless exercise of stock options	$ -	$ 6

See accompanying notes to the consolidated financial statements.

Immix Biopharma, Inc.
Notes to the Consolidated Financial Statements

Note 1 – Nature of Business

Immix Biopharma, Inc. (the "Company") is a clinical-stage biopharmaceutical pharmaceutical company organized as a Delaware corporation on January 7, 2014 which is focused on developing a novel class of Tissue-Specific Therapeutics in oncology and immune-dysregulated diseases. In August 2016, the Company established a wholly-owned Australian subsidiary, Immix Biopharma Australia Pty Ltd. ("IBAPL"), in order to conduct various preclinical and clinical activities for its development candidates. In November 2022, the Company established a majority-owned subsidiary, Nexcella, Inc. ("Nexcella"), its cell therapy division.

Note 2 – Summary of Significant Accounting Policies

The accompanying consolidated financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and in accordance with the rules and regulations of the United States Securities and Exchange Commission (the "SEC"). The Company's fiscal year end is December 31.

Risk and Uncertainties - The Company operates in a dynamic and highly competitive industry and is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, contract manufacturer and contract research organizations, compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies and clinical trials and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting. The Company believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows; ability to obtain future financing; advances and trends in new technologies and industry standards; results of clinical trials; regulatory approval and market acceptance of the Company's products; development of sales channels; certain strategic relationships; litigation or claims against the Company based on intellectual property, patent, product, regulatory, or other factors; and the Company's ability to attract and retain employees necessary to support its growth.

Products developed by the Company require approvals from the U.S. Food and Drug Administration ("FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that the products will receive the necessary approvals, or that any approved products will be commercially viable. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval, it could have a material adverse impact on the Company. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from other pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and other third parties.

The Company has expended and will continue to expend substantial funds to complete the research, development and clinical testing of product candidates. The Company also will be required to expend additional funds to establish commercial-scale manufacturing arrangements and to provide for the marketing and distribution of products that receive regulatory approval. The Company may require additional funds to commercialize its products. The Company is unable to entirely fund these efforts with its current financial resources. If adequate funds are unavailable on a timely basis from operations or additional sources of financing, the Company may have to delay, reduce the scope of or eliminate one or more of its research or development programs which may materially and adversely affect its business, financial condition and operations.

Use of Estimates in Financial Statement Presentation - The preparation of these 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 revenues and expenses during the reporting periods. The Company uses significant judgements when making estimates related to the valuation of deferred tax assets and related valuation allowances, accrual and prepayment of research and development expenses, and stock-based compensation. Actual results could differ from those estimates.

Principles of Consolidation – The accompanying consolidated financial statements include the accounts of Immix Biopharma, Inc., the accounts of its 100% owned subsidiary, IBAPL, and the accounts of its majority owned subsidiary, Nexcella. All intercompany transactions and balances have been eliminated in consolidation. For consolidated entities where the Company owns less than 100% of the subsidiary, the Company records net loss attributable to non-controlling interests in its consolidated statements of operations and comprehensive loss equal to the percentage of the economic or ownership interest retained in such entities by the respective non-controlling parties.

Liquidity and Going Concern - These consolidated financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The continuation of the Company as a going concern is dependent upon the ability of the Company to obtain financing to continue operations. In December 2021, the Company received $18,648,934 in net proceeds from the initial public offering ("IPO") of its common stock. In January 2022, the Company raised additional net proceeds of $2,913,750 from the exercise of the underwriter's over-allotment option in connection with the Company's IPO. On March 22, 2023, the Company entered into an ATM Sales Agreement (the "March Sales Agreement") with ThinkEquity LLC (the "Sales Agent"), pursuant to which the Company, issued and sold through the Sales Agent, approximately $5 million of shares of the Company's common stock in sales deemed to be "at-the-market offerings" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "March ATM Facility") (see Note 6). As of June 15, 2023, the Company completed the equity raise pursuant to the March Sales Agreement and received net proceeds of $4,685,576 under the March ATM Facility. On July 14, 2023, the Company entered into an additional ATM Sales Agreement (the "July Sales Agreement") with the Sales Agent, pursuant to which the Company, may, from time to time, issue and sell through the Sales Agent shares of the Company's common stock in sales deemed to be "at-the-market offerings" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "July ATM Facility") (see Note 6). Initially, the Company is eligible to sell up to $4,200,000 worth of shares of its common stock as the aggregate market value of the Company's shares of common stock eligible for sale under the July Sales Agreement is subject to the limitations of General Instruction I.B.6 of Form S-3 until such time that the Company's public float equals or exceeds $75.0 million. In the event the aggregate market value of the Company's outstanding common stock held by non-affiliates equals or exceeds $75.0 million, then the one-third limitation on sales set forth in General Instruction I.B.6 of Form S-3 shall not apply to additional sales made pursuant to the July Sales Agreement.

In August 2023, the Company sold (i) 3,241,076 shares of the Company's common stock, par value $0.0001, and (ii) Pre-Funded warrants to purchase 1,913,661 shares of common stock (the "Pre-Funded Warrants"). The Company received gross proceeds of $10 million from the private placement and net proceeds of approximately $9.93 million, after deducting fees and expenses paid by the Company (the "August 2023 Private Placement") (see Note 6).

From July 14, 2023 through February 5, 2024, the Company has sold 328,136 common shares pursuant to the July ATM Facility for net proceeds of $1,091,887, after offering expenses. On February 5, 2024, the Company suspended, and is not offering any shares of its common stock pursuant to, the prospectus supplement dated July 14, 2023, relating to the July Sales Agreement by and between the Company and ThinkEquity LLC. The Company will not make any sales of common stock pursuant to the July Sales Agreement unless and until a new prospectus supplement is filed with the SEC; however, the Sales Agreement remains in full force and effect.

In February 2024, the Company conducted an underwritten public offering of 5,535,055 shares of its common stock at the public offering price of $2.71 per share, for the net proceeds of $13,566,697, after underwriter discounts and offering expenses (the "Offering"). Pursuant to the underwriting agreement, the Company granted the underwriter a 30-day over-allotment option to purchase up to an additional 783,970 shares of the Company's common stock, which was exercised in full on March 1, 2024 for net proceeds of $1,954,594, after underwriting discounts and offering expenses (see Note 10).

The Company has a history of, and expects to continue to report, negative cash flows from operations and a net loss. While the Company's estimates of its operating expenses and working capital requirements could be incorrect and the Company may use its cash resources faster than it anticipates, management believes that its cash and cash equivalents on hand at December 31, 2023, and funds raised from the July ATM Facility and the Offering (see Note 10), will be sufficient to meet the Company's working capital requirements through at least March 29, 2025.

Concentration of Credit Risk - Periodically, the Company may carry cash and cash equivalents balances at financial institutions in excess of the federally insured limit of $250,000, or the Australian insured limit of AUD 250,000. At times, deposits held with financial institutions may exceed the amount of insurance provided. The Company has not experienced losses on these accounts and management believes that the credit risk with regard to these deposits is not significant.

Cash and Cash Equivalents – The Company's cash equivalents include short-term highly liquid investments with an original maturity of 90 days or less when purchased and are carried at fair value.

Equipment – Equipment is recorded at cost and depreciated over its estimated useful lives using the straight-line depreciation method as follows:

Computer equipment	3 years
Machinery and equipment	5 years
Furniture and office equipment	7 years

Repairs and maintenance costs are expensed as incurred.

Impairment of Long-lived Assets – The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of a long-lived asset is measured by comparison of the carrying amount to the expected future undiscounted cash flows that the asset is expected to generate. Any impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value.

Fair Value of Financial Instruments – The carrying value of short-term instruments, including cash and cash equivalents, tax receivable, accounts payable and accrued expenses approximate fair value due to the relatively short period to maturity for these instruments.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The Company utilizes a three-level valuation hierarchy for disclosures of fair value measurements, defined as follows:

Level 1 – inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 – inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the assets or liability, either directly or indirectly, for substantially the full term of the financial instruments.

Level 3 – inputs to the valuation methodology are unobservable and significant to the fair value.

The following fair value hierarchy table presents information about the Company's asset measured at fair value on a recurring basis:

	Fair Value Measurements at December 31, 2023		
	Level 1	Level 2	Level 3
Assets:			
Cash equivalents (money market funds).....	$ 16,113,006	$ -	$ -

As of December 31, 2023, the Company had no liabilities required to be measured at fair value on a recurring basis.

As of December 31, 2022, the Company had no assets or liabilities required to be measured at fair value on a recurring basis.

Income Taxes – The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of reported assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740-10 which prescribes a recognition threshold and measurement attribute for financial statement disclosure of tax positions taken, or expected to be taken, on its tax return. The Company evaluates and records any uncertain tax positions based on the amount that management deems is more likely than not to be sustained upon examination and ultimate settlement with the tax authorities in the tax jurisdictions in which it operates.

Australian Tax Incentive – IBAPL is eligible to receive a cash refund from the Australian Taxation Office for eligible research and development ("R&D") expenditures under the Australian R&D Tax Incentive Program (the "Australian Tax Incentive"). The Australian Tax Incentive is recognized as a reduction to R&D expense when there is reasonable assurance that the relevant expenditure has been incurred, the amount can be reliably measured and that the Australian Tax Incentive will be received. The Company recognized reductions to R&D expense of $1,064,745 and $236,376 for the years ended December 31, 2023 and 2022, respectively.

Deferred Offering Costs – The Company has capitalized qualified legal, accounting and other direct costs related to its efforts to raise capital through the sale of its common stock under the July ATM Facility. Deferred offering costs will be deferred and amortized ratably upon sales under the July ATM Facility, and upon completion, they will be reclassified to additional paid-in capital as a reduction of the July ATM proceeds. If the Company terminates the July ATM Facility or there is a significant delay, all of the deferred offering costs will be immediately written off to operating expenses. As of December 31, 2023, $87,229 of deferred offering costs were capitalized related to the July ATM Facility.

Stock-Based Compensation – Stock-based compensation expense represents the estimated grant date fair value of the Company's equity awards, consisting of stock options issued under the Company's stock option plan and restricted common stock (see Note 6). The fair value of equity awards is recognized over the requisite service period of such awards (usually the vesting period) on a straight-line basis. The Company estimates the fair value of stock options using the Black-Scholes option pricing model on the date of grant and recognizes forfeitures as they occur. For stock awards for which vesting is subject to performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable, or the performance condition has been achieved.

Patent Costs – Although the Company believes that its patents have continuing value, the amount of future benefits to be derived from the patents is uncertain. Accordingly, patent costs are expensed as incurred.

Advertising Costs – The Company expenses advertising costs as incurred. Advertising costs were not significant during the years ended December 31, 2023 and 2022.

Research and Development Costs – Research and development costs are expensed as incurred. Research and development costs consist primarily of clinical research fees paid to consultants and outside service providers, other expenses relating to design, development and testing of the Company's therapy candidates, and for license and milestone costs related to in-licensed products and technology. Costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. Such licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and has no alternative future use.

Clinical trial costs are a component of research and development expenses. The Company estimates expenses incurred for clinical trials that are in process based on services performed under contractual agreements with clinical research organizations and actual clinical investigators. Included in the estimates are (1) the fee per patient enrolled as specified in the clinical trial contract with each institution participating in the clinical trial and (2) progressive data on patient enrollments obtained from participating clinical trial sites and the actual services performed. Changes in clinical trial assumptions, such as the length of time estimated to enroll all patients, rate of screening failures, patient drop-out rates, number and nature of adverse event reports, and the total number of patients enrolled can impact the average and expected cost per patient and the overall cost of the clinical trial. The Company monitors the progress of the trials and their related activities and adjusts expense accruals, when applicable. Adjustments to accruals are charged to expense in the period in which the facts give rise to the adjustments become known.

Other Comprehensive Income (Loss) – Other comprehensive income (loss) includes foreign currency translation gains and losses. The cumulative amount of translation gains and losses are reflected as a separate component of stockholders' equity in the consolidated balance sheets, as accumulated other comprehensive income.

Foreign Currency Translation and Transaction Gains (Losses) – The Company, and its majority-owned subsidiary Nexcella, maintain their accounting records in U.S. Dollars. The Company's operating wholly-owned subsidiary, IBAPL, is located in Australia and maintains its accounting records in Australian Dollars, which is its functional currency. Assets and liabilities of the subsidiary are translated into U.S. dollars at exchange rates at the balance sheet date, equity accounts are translated at historical exchange rate and revenues and expenses are translated by using the average exchange rates for the period. Translation adjustments are reported as a separate component of other comprehensive income (loss) in the consolidated statements of operations and comprehensive loss. Foreign currency denominated transactions are translated at exchange rates approximating those in effect at the transaction dates. Exchange gains and (losses) are recognized in income and were $(992) and $2,245 for the years ended December 31, 2023 and 2022, respectively, and are included in general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

Loss Per Common Share - Basic loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted loss per common share is determined using the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents. In periods when losses are reported, the weighted-average number of common shares outstanding excludes common stock equivalents because their inclusion would be anti-dilutive. Basic weighted average shares outstanding for the year ended December 31, 2023 include 1,913,661 shares underlying Pre-Funded warrants to purchase common shares. As the shares underlying these Pre-Funded warrants can be issued for little consideration (an exercise price per share equal to $0.0001 per share), these shares are deemed to be issued for purposes of basic loss per common share. As of December 31, 2023 and 2022, the Company's potentially dilutive shares and options, which were not included in the calculation of net loss per share, included stock options and warrants for 2,910,061 and 2,168,742 common shares, respectively.

Emerging Growth Company Status - The Company is an "emerging growth company" ("EGC") as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act and has elected to use the extended transition period for complying with new or revised accounting standards. As a result of this election, the Company's financial statements may not be comparable to companies that comply with public company Financial Accounting Standards Board ("FASB") standards' effective dates. The Company may take advantage of these exemptions up until it is no longer an EGC.

Reclassifications

Certain reclassifications have been made to the prior year financial statements to conform to the current year presentation. These reclassifications had no effect on our previously reported results of operations or accumulated deficit.

Recent Accounting Pronouncements – In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280)*: *Improvements to Reportable Segment Disclosures,* which requires disclosure of incremental segment information on an annual and interim basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. The Company is currently evaluating the effect of this pronouncement on its disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740)*: *Improvements to Income Tax Disclosures,* which expands the disclosures required for income taxes. This ASU is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The amendment should be applied on a prospective basis while retrospective application is permitted. The Company is currently evaluating the effect of this pronouncement on its disclosures.

Note 3 – Agreements with Nexcella Subsidiary

Founders Agreement

Effective December 8, 2022, the Company entered into a Founders Agreement with Nexcella (the "Nexcella Founders Agreement").

The Nexcella Founders Agreement provides that prior to a Qualified IPO (as defined in Nexcella's Amended and Restated Certificate of Incorporation, as amended (the "Nexcella COI")) or Qualified Change in Control (as defined in the Nexcella COI), the Company shall provide funds to Nexcella as requested by Nexcella, in good faith, to be evidenced by a senior unsecured promissory note. In exchange for the time and capital expended in the formation of Nexcella and the identification of specific assets, the acquisition of which benefit Nexcella, on December 21, 2022, the Company loaned Nexcella approximately $2.1 million, evidenced by a senior unsecured promissory note, representing the up-front fee required to acquire Nexcella's license agreement with Hadasit Medica Research Services & Development, Ltd. ("HADASIT") and BIRAD Research and Development Company Ltd. ("BIRAD"), and for use as working capital for its research and development activities. The note, which matures on January 31, 2030, accrues interest at a rate of 7.875% per annum and is convertible into shares of common stock of Nexcella at a conversion price of $2.00 per share, subject to adjustment; provided, however, that such note shall automatically convert into shares of Nexcella common stock immediately prior to certain conversion triggers set forth in the note. Nexcella may not prepay the note without the Company's prior written consent. The Nexcella Founders Agreement has a term of 15 years, which, upon expiration, automatically renews for successive one-year periods unless terminated by the Company upon notice at least six months prior to the end of the term or upon the occurrence of a Change of Control (as defined in the Nexcella Founders Agreement). In connection with the Nexcella Founders Agreement, the Company was issued 250,000 shares of Nexcella's Class A Preferred Stock, 1,000,000 shares of Nexcella's Class A Common Stock, and 5,000,000 shares of Nexcella's common stock. The Class A Preferred Stock is identical to the common stock other than as to conversion rights, the PIK Dividend right (as defined below) and voting rights.

Each share of Class A Preferred Stock is convertible, at the Company's option, into one fully paid and nonassessable share of Nexcella's common stock, subject to certain adjustments. As a holder of Nexcella's Class A Preferred Stock, the Company will receive on each March 13 (each a "PIK Dividend Payment Date") until the date all outstanding Class A Preferred Stock is converted into Nexcella's common stock or redeemed (and the purchase price is paid in full), pro rata per share dividends paid in additional fully paid and nonassessable shares of Nexcella common stock ("PIK Dividends") such that the aggregate number of shares of common stock issued pursuant to such PIK Dividend is equal to 2.5% of Nexcella's fully-diluted outstanding capitalization on the date that is one business day prior to any PIK Dividend Payment Date. In addition, as a holder of Class A Preferred Stock, the Company will be entitled to cast for each share of Class A Preferred Stock held as of the record date for determining stockholders entitled to vote on matters presented to the stockholders of Nexcella, the number of votes that is equal to 1.1 times a fraction, the numerator of which is the sum of (A) the shares of outstanding Nexcella common stock and (B) the whole shares of Nexcella common stock into which the shares of outstanding Nexcella Class A Common Stock and the Class A Preferred Stock are convertible and the denominator of which is the number of shares of outstanding Nexcella Class A Preferred Stock.

Each share of Class A Common Stock is convertible, at the Company's option, into one fully paid and nonassessable share of Nexcella's common stock, subject to certain adjustments. In addition, upon a Qualified IPO (as defined in the Nexcella COI) or Qualified Change in Control (as defined in the Nexcella COI), each share of Class A Common Stock will automatically convert into one fully paid and nonassessable share of Nexcella's common stock; provided however, if at that time, the Class A Common Stock is not then convertible into a number of shares of Nexcella common stock (or such other capital stock or securities at the time issuable upon the conversion of the Class A Common Stock) that have a value of: (a) in the case of a Qualified IPO, at least $5,000,000 based on the initial offering price in such initial public offering, or (b) in the case of a Qualified Change in Control, at least $5,000,000 in cash or at least $5,000,000 of equity based on the implied value of a share of Nexcella common stock resulting from the price paid upon the consummation of such Qualified Change of Control, the Class A Common Stock will automatically convert into such number of shares of Nexcella common stock (or such other capital stock or securities at the time issuable upon the conversion of the Class A Common Stock) that have a value of $5,000,000 based on the initial offering price in such initial public offering or the implied value of a share of Nexcella common stock resulting from the price paid upon the consummation of such Qualified Change of Control (or if such Qualified Change of Control results in the Class A Shares being exchanged solely for cash, then $5,000,000 in cash). The Company is entitled to cast such number of votes equal to the number of whole shares of Nexcella common stock into which the Company's Class A Common Stock is convertible as of the record date for determining stockholders entitled to vote on matters presented to the stockholders of Nexcella.

In addition to the foregoing, the Company is entitled to one vote for each share of Nexcella common stock held by it. Except as provided by law or by the Nexcella COI, holders of Nexcella Class A Common Stock and Class A Preferred Stock shall vote together with the holders of Nexcella common stock, as a single class.

As additional consideration under the Nexcella Founders Agreement, Nexcella will also: (i) pay an equity fee in shares of common stock, payable within five business days of the closing of any equity or debt financing for Nexcella or any of its respective subsidiaries that occurs after the effective date of the Nexcella Founders Agreement and ending on the date when the Company no longer has majority voting control in Nexcella's voting equity, equal to 2.5% of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to 4.5% of Nexcella's annual Net Sales (as defined in the Nexcella Founders Agreement), payable on an annual basis, within 90 days of the end of each calendar year. In the event of a Change of Control, Nexcella will pay a one-time change in control fee equal to five times the product of (A) Net Sales for the 12 months immediately preceding the Change of Control and (B) 4.5%.

Management Services Agreement

Effective as of December 8, 2022, the Company entered into a Management Services Agreement (the "Nexcella MSA") with Nexcella. Pursuant to the terms of the Nexcella MSA, the Company will render management, advisory and consulting services to Nexcella. Services provided under the Nexcella MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Nexcella's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of Nexcella with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). At the request of the Company, Nexcella will utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by the Company, provided those services are offered at market prices. In consideration for the Services, Nexcella will pay the Company an annual base management and consulting fee of $500,000 (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year; provided, however, that such Annual Consulting Fee will be increased to $1.0 million for each calendar year in which Nexcella has Net Assets (as defined in the Nexcella MSA) in excess of $100 million at the beginning of the calendar year. Notwithstanding the foregoing, the first Annual Consulting Fee payment is not due until first business day of the calendar quarter immediately following the completion of the first equity financing for Nexcella that is in excess of $10 million in gross proceeds, which hasn't yet occurred. The first payment will include all amounts in arrears from the effective date of the Nexcella MSA through such payment as well as the amounts in advance for such first quarterly payment. Actual and direct out-of-pocket expenses reasonably incurred by the Company in performing the Services are required to be reimbursed to the Company by Nexcella. The Nexcella MSA continues for a period of five years from the effective date thereof and shall be automatically extended for additional five year periods unless the Company and Nexcella provide written notice to not extend the term at least 90 days prior to the end of the term, unless the Nexcella MSA is terminated earlier by mutual agreement of the Company and Nexcella.

Note 4 – Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following as of December 31, 2023 and 2022:

	December 31, 2023	December 31, 2022
Prepaid research and development expenses	$ 412,773	$ 792,130
Prepaid insurance expense	263,927	323,296
Prepaid investor relations expense	384,494	11,905
Other current assets	44,582	78,067
Total prepaid expenses and other current assets	$ 1,105,776	$ 1,205,398

Note 5 – Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following as of December 31, 2023 and 2022:

	December 31, 2023	December 31, 2022
Accounts payable	$ 1,433,022	$ 143,074
Accrued research and development expenses	1,571,261	57,500
Accrued professional services	38,639	81,691
Accrued compensation and related expenses	577,854	552,835
Other accrued expenses	101,007	438,196
Total accounts payable and accrued expenses	$ 3,721,783	$ 1,273,296

Note 6 – Stockholders' Equity

The Company has authorized 200,000,000 shares of common stock and 10,000,000 shares of preferred stock each with a par value of $0.0001 per share.

March ATM Sales Agreement

On March 22, 2023, the Company entered into the March Sales Agreement with the Sales Agent pursuant to which the Company could offer and sell, from time to time, through the Sales Agent, shares (the "March Shares") of the Company's common stock, par value $0.0001 per share, having an aggregate offering price of up to $5,000,000, subject to the terms and conditions set forth in the March Sales Agreement. The March Shares were offered and sold pursuant to the Company's prospectus supplement, dated March 22, 2023, filed by the Company with the SEC on March 22, 2023, including the accompanying base prospectus forming a part of the Company's Registration Statement on Form S-3 (File No. 333-269100) filed by the Company with the SEC on January 3, 2023 and declared effective by the SEC on January 11, 2023. The aggregate market value of March Shares eligible for sale under the Sales Agreement was subject to the limitations of General Instruction I.B.6 of Form S-3.

Under the March Sales Agreement, the Sales Agent sold the March Shares in sales deemed to be "at-the-market offerings" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on or through The Nasdaq Capital Market, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law. The Company could instruct the Sales Agent not to sell any March Shares if the sales could not be effected at or above the price designated by the Company from time to time.

The Company paid the Sales Agent a fixed commission rate of 3.75% of the aggregate gross proceeds from the sale of the March Shares pursuant to the March Sales Agreement. In addition, the Company paid an expense deposit of $15,000 to the Sales Agent, which was applied against the actual out-of-pocket accountable expenses that were paid by the Company to the Sales Agent in connection with the offering. The Company reimbursed the Sales Agent for all expenses related to the offering including, without limitation, the fees and expenses of the Sales Agent's legal counsel up to $50,000 and reimbursed the Sales Agent, upon request, for such costs, fees and expenses in an amount not to exceed $7,500 on a quarterly basis for the first three fiscal quarters of each year and $10,000 for the fiscal fourth quarter of each year. Furthermore, the Company provided indemnification and contribution to the Sales Agent with respect to certain liabilities, including liabilities under the Securities Act.

During the year ended December 31, 2023, the Company sold 2,263,868 March Shares pursuant to the March ATM Facility for net cash proceeds of $4,811,393, after deducting commissions. In addition, the Company amortized $125,817 of deferred offering costs for fees paid related to the March ATM Facility.

July ATM Sales Agreement

On July 14, 2023, the Company entered into the July Sales Agreement with the Sales Agent pursuant to which the Company may offer and sell, from time to time, through the Sales Agent, shares (the "July Shares") of the Company's common stock, par value $0.0001 per share, subject to the terms and conditions set forth in the Sales Agreement. Initially, the Company is eligible to sell up to $4,200,000 worth of shares of its common stock as the aggregate market value of the Company's shares of common stock eligible for sale under the July Sales Agreement is subject to the limitations of General Instruction I.B.6 of Form S-3 until such time that the Company's public float equals or exceeds $75.0 million. In the event the aggregate market value of the Company's outstanding common stock held by non-affiliates equals or exceeds $75.0 million, then the one-third limitation on sales set forth in General Instruction I.B.6 of Form S-3 shall not apply to additional sales made pursuant to the July Sales Agreement. The July Shares will be offered and sold pursuant to the Company's prospectus supplement, dated July 14, 2023, filed by the Company with the SEC on July 14, 2023, including the accompanying base prospectus forming a part of the Company's Registration Statement on Form S-3 (File No. 333-269100) filed by the Company with the SEC on January 3, 2023 and declared effective by the SEC on January 11, 2023.

Under the July Sales Agreement, the Sales Agent may sell the July Shares in sales deemed to be "at-the-market offerings" as defined in Rule 415(a)(4) promulgated under the Securities Act, including sales made directly on or through The Nasdaq Capital Market or any other existing trading market for the Company's common stock, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law. The Company may instruct the Sales Agent not to sell any July Shares if the sales cannot be effected at or above the price designated by the Company from time to time.

The Company will pay the Sales Agent a fixed commission rate of 3.75% of the aggregate gross proceeds from the sale of the July Shares pursuant to the Sales Agreement. The Company has paid an expense deposit of $15,000 to the Sales Agent, which will be applied against the actual out-of-pocket accountable expenses that will be paid by the Company to the Sales Agent in connection with the offering. The Company has agreed to reimburse the Sales Agent for all expenses related to the offering including, without limitation, the fees and expenses of the Sales Agent's legal counsel up to $50,000, and shall reimburse the Sales Agent, upon request, for such costs, fees and expenses in an amount not to exceed $7,500 on a quarterly basis for the first three fiscal quarters of each year and $10,000 for the fiscal fourth quarter of each year. The Company has also agreed to provide indemnification and contribution to the Sales Agent with respect to certain liabilities, including liabilities under the Securities Act.

During the year ended December 31, 2023, the Company sold 259,834 July Shares pursuant to the July ATM Facility for net cash proceeds of $801,442, after deducting commissions. In addition, the Company recorded offering expenses of $26,478 and amortized $21,570 of deferred offering costs for fees paid related to the July ATM Facility.

August 2023 Private Placement

On August 21, 2023, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with a certain accredited investor (the "Purchaser"), pursuant to which the Company sold and issued to the Purchaser in a private placement transaction (the "Private Placement") (i) 3,241,076 shares (the "Shares") of the Company's common stock, par value $0.0001, and (ii) Pre-Funded warrants to purchase 1,913,661 shares of common stock (the "Pre-Funded Warrants"). The purchase price per share of common stock was $1.94 per share (the "Purchase Price") and the purchase price for the Pre-Funded Warrants was the Purchase Price minus $0.0001 per Pre-Funded Warrant. The Company received gross proceeds of $10 million from the Private Placement and net proceeds of $9,934,153, after deducting fees and expenses paid by the Company. The Company intends to use the proceeds of the August 2023 Private Placement for working capital and general corporate purposes.

The Pre-Funded Warrants have a per share exercise price of $0.0001, subject to proportional adjustments in the event of stock splits or combinations or similar events. The Pre-Funded Warrants will not expire until exercised in full. The Pre-Funded Warrants contain a "blocker" provision providing that a holder (together with its affiliates) may not exercise any portion of a warrant to the extent that the holder would own more than 19.99% of the outstanding shares of common stock of the Company. The Securities Purchase Agreement contains customary representations and warranties and agreements of the Company and the Purchaser and customary indemnification rights and obligations of the parties.

The Shares and Pre-Funded Warrants, and the common stock issuable upon the exercise of the Pre-Funded Warrants, have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), and were offered pursuant to the exemption from registration provided in Section 4(a)(2) under the Securities Act.

Pursuant to the Securities Purchase Agreement, the Company filed with the SEC a Registration Statement on Form S-3 (File No. 333-274684) on September 25, 2023 and declared effective by the SEC on September 28, 2023, to register the resale of the Shares and Pre-Funded Warrants.

None of the Pre-Funded Warrants have been exercised to date.

Other Common Stock Issuances

During the year ended December 31, 2023, the Company entered into various marketing services agreements, whereby the Company agreed to issue 122,300 shares of its common stock, valued at $247,500, in exchange for future services. As of December 31, 2023, the Company has issued 122,300 shares of the Company's common stock pursuant to the marketing services agreements. During the year ended December 31, 2023, the Company recorded stock-based compensation expense of $232,624 related to the fair value of the shares of common stock. As of December 31, 2023, the Company has $14,876 of unamortized stock-based compensation which will be amortized over the remaining service period.

During the year ended December 31, 2023, the Company entered into various marketing services agreements, whereby the Company issued 123,396 shares of its common stock valued at $322,299 for services received, which was recorded as stock-based compensation during the year ended December 31, 2023.

During the year ended December 31, 2023, the Company entered into a marketing services agreement, whereby the Company agreed to issue shares of restricted common stock for services performed on a monthly basis valued at $22,500 based on the average closing price for the prior 10 trading days. During the year ended December 31, 2023, the Company has issued 18,409 shares of its common stock for an aggregate value of $67,500 pursuant to the agreement.

During the year ended December 31, 2023, the Company issued 1,351 shares of its common stock upon the exercise of stock options for cash proceeds of $2,618.

On January 5, 2022, the Company sold 630,000 shares of its common stock pursuant to the full exercise of the over-allotment option in connection with the Company's IPO. The shares were sold at the IPO price of $5.00 per share, resulting in gross proceeds of $3,150,000 and bringing the total gross proceeds of the IPO to $24,150,000. In connection with the exercise of the over-allotment, the Company paid $243,275 in offering costs resulting in net proceeds of $2,913,750 and bringing total net proceeds to $21,562,684.

During the year ended December 31, 2022, the Company issued 43,264 shares of its common stock with a fair value of $100,000 for services.

During the year ended December 31, 2022, the Company purchased 72,363 shares of its common stock at a cost of $99,963 pursuant to its share repurchase program. The shares are being held in treasury. The share repurchase plan was approved by the Company's board of directors ("Board of Directors" or "Board") on May 9, 2022 and authorized the repurchase of up to $1,000,000 of the Company's common stock. The share repurchase plan expired on December 31, 2022.

During the year ended December 31, 2022, the Company issued 62,532 shares of its common stock upon the cashless exercise of 140,992 stock options.

Stock Options

In 2016, the Board of Directors of the Company approved the Immix Biopharma, Inc. 2016 Equity Incentive Plan (the "2016 Plan"). The 2016 Plan allows for the Board of Directors to grant various forms of incentive awards covering up to 417,120 shares of common stock. During the year ended December 31, 2021, the Board of Directors amended the 2016 Plan to increase the aggregate number of shares available for issuance under the 2016 Plan to 1,761,120 shares of common stock. On September 10, 2021, the Board of Directors approved the 2021 Equity Incentive Plan (as amended and restated, the "2021 Plan") pursuant to which it initially reserved and made available for future issuance under the 2021 Plan (i) 900,000 shares of common stock, plus (ii) the number of shares of common stock reserved, but unissued under the 2016 Plan, and (iii) the number of shares of common stock underlying forfeited awards under the 2016 Plan, provided that shares of common stock issued under the 2021 Plan with respect to an Exempt Award (as defined in the 2021 Plan) would not count against such share limit. Subsequent to September 10, 2021, no further awards are to be issued under the 2016 Plan, but all awards under the 2016 Plan which were outstanding as of September 10, 2021 (including any Grandfathered Arrangement (as defined in the 2021 Plan)) shall continue to be governed by the terms, conditions and procedures set forth in the 2016 Plan and any applicable award agreement.

On April 24, 2023, the Company's Board of Directors adopted the Immix Biopharma, Inc. Amended and Restated 2021 Omnibus Equity Incentive Plan (the "Amended 2021 Plan") which, among other things, increased the number of shares of common stock that may be issued under such plan by 1,034,561 shares, subject to stockholder approval. On June 7, 2023, stockholders of the Company approved the Amended 2021 Plan. As of December 31, 2023, there were 1,040,777 shares of the Company's common stock remaining to be issued under the Amended 2021 Plan.

During the year ended December 31, 2023, the Compensation Committee of the Board of Directors approved the issuance of options to purchase 136,670 shares of the Company's common stock to non-employee members of the Board of Directors of the Company and 586,000 shares of the Company's common stock to management of the Company. The options have a term of 10 years, exercise prices ranging from $1.82 to $1.95 per share and vest over periods of 10 to 48 equal monthly installments.

During the year ended December 31, 2023, the Board of Directors approved the issuance of options to purchase 20,000 shares of the Company's common stock to a consultant of the Company with a term of 10 years and an exercise price of $1.95 per share, which options vest in 48 equal monthly installments.

During the year ended December 31, 2022, the Company granted options to purchase 500,000 shares of the Company's common stock to officers of the Company, and granted options to purchase 91,250 shares of the Company's common stock to non-employee members of the Board of Directors and scientific advisors of the Company. The exercise price of the options is $2.64-$5.83 and the options expire ten years following grant. These options vest in equal monthly installments beginning on the grant date ranging from 12 to 48 months.

The following table reflects the weighted average assumptions used to estimate the fair value of stock options granted during the years ended December 31, 2023 and 2022:

	2023	2022
Volatility	114-120%	117-124%
Expected life (years)	5.27-10	5.27-10.0
Risk-free interest rate	4.12-4.38%	1.70-3.06%
Dividend rate	—%	—%

The Company recognized stock-based compensation of $731,329 and $476,746 related to stock options for the years ended December 31, 2023 and 2022, respectively, which is included in general and administrative expenses.

As of December 31, 2023, the Company had unrecognized stock-based compensation expense of $1,990,396, related to unvested stock options, which is expected to be recognized over the weighted-average vesting period of 2.73 years.

The following table summarizes the stock option activity for the years ended December 31, 2023 and 2022:

	Options	Weighted-Average Exercise Price Per Share
Outstanding and exercisable, January 1, 2022	1,320,984	$ 1.54
Granted	591,250	$ 2.70
Exercised	(140,992)	$ 1.33
Forfeited	-	$ -
Expired	-	$ -
Outstanding, December 31, 2022	1,771,242	$ 1.94
Granted	742,670	$ 1.86
Exercised	(1,351)	$ 1.94
Forfeited	-	$ -
Expired	-	$ -
Outstanding and expected to vest, December 31, 2023	2,512,561	$ 1.92

The following table discloses information regarding outstanding and exercisable options at December 31, 2023:

	Outstanding			Exercisable	
Exercise Price	Number of Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Number of Option Shares	Weighted Average Exercise Price
$ 0.80	256,500	$ 0.80	7.20	256,500	$ 0.80
$ 1.33	150,892	$ 1.33	1.67	150,892	$ 1.33
$ 1.80	36,670	$ 1.80	9.64	8,890	$ 1.80
$ 1.86	1,458,500	$ 1.86	8.48	564,671	$ 1.86
$ 1.99	18,749	$ 1.99	9.67	416	$ 1.99
$ 2.64	580,000	$ 2.64	8.54	257,084	$ 2.64
$ 5.83	11,250	$ 5.83	8.04	5,391	$ 5.83
	2,512,561	$ 1.92	7.98	1,243,844	$ 1.76

Aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option and the fair value of the Company's common stock for stock options that were in-the-money at period end. As of December 31, 2023, the intrinsic value for the options vested and outstanding was $6,423,762 and $12,567,619, respectively.

The total intrinsic value of stock options exercised during the year ended December 31, 2023 was $2,827.

Stock Warrants

On January 5, 2022, in connection with the issuance of shares of the Company's common stock pursuant to the exercise of the over-allotment discussed above, the Company issued warrants for the purchase of 31,500 shares of the Company's common stock with a term of 5 years and an exercise price of $6.25 per share, which warrants vested six months after the date of issuance.

The following table summarizes the stock warrant activity for the years ended December 31, 2023 and 2022:

	Warrants		Weighted-Average Exercise Price Per Share
Outstanding and exercisable, January 1, 2022	366,000	$	3.93
Granted	31,500	$	6.25
Exercised	-	$	-
Forfeited	-	$	-
Expired	-	$	-
Outstanding and exercisable, December 31, 2022	397,500	$	4.11
Granted	1,913,661	$	0.0001
Exercised	-	$	-
Forfeited	-	$	-
Expired	-	$	-
Outstanding and exercisable, December 31, 2023	2,311,161	$	0.71

The following table discloses information regarding outstanding and exercisable warrants at December 31, 2023:

	Outstanding			Exercisable	
Exercise Price	Number of Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Number of Option Shares	Weighted Average Exercise Price
$ 0.0001	1,913,661	$ 0.0001	-	1,913,661	$ 0.0001
$ 0.80	156,000	$ 0.80	7.23	156,000	$ 0.80
$ 6.25	241,500	$ 6.25	2.96	241,500	$ 6.25
	2,311,161	$ 4.11	0.80	2,311,161	$ 0.71

Aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock warrant and the fair value of the Company's common stock for stock warrants that were in-the-money at period end. As of December 31, 2023, the intrinsic value for the warrants vested and outstanding was $14,358,868.

Nexcella Equity Transactions

As of December 31, 2023, the Company's controlling interest, on a fully dilutive basis, of Nexcella represents 91.6% of Nexcella's total common stock equivalents outstanding.

The Nexcella 2022 Equity Incentive Plan (the "2022 Plan") allows for Nexcella's Board of Directors to grant various forms of incentive awards initially covering up to 375,000 shares of common stock. On May 29, 2023, Nexcella's Board of Directors approved the Second Amended and Restated Nexcella 2022 Equity Incentive Plan, which submitted an increase to the number of shares of Nexcella common stock issuable under the plan from 375,000 shares to 607,640 shares. On August 11, 2023, Nexcella's Board of Directors requested the Third Amended and Restated 2022 Equity Incentive Plan, which increased the number of shares of Nexcella common stock issuable under the plan from 607,640 to 800,000 shares. The Nexcella shareholders subsequently approved the increase in Nexcella common stock issuable under the plan to 800,000. As of December 31, 2023, there were 83,688 shares of common stock available for issuance under the Nexcella 2022 Plan.

Common Stock

During the year ended December 31, 2023, Nexcella closed on its private offering for the sale of 100,152 common shares of Nexcella at a purchase price of $6.49 per share for total proceeds of $650,000. The Company's Chief Executive Officer purchased 7,704 shares of Nexcella's common stock for a purchase price of $50,000 in the private placement offering. In addition, the Company's Chief Financial Officer through Alwaysraise, LLC and Alwaysraise Ventures I, L.P., entities affiliated with the Company's Chief Financial Officer, purchased an aggregate of 15,408 shares of Nexcella's common stock in the private placement offering for $100,000. As of December 31, 2022, Nexcella entered into subscription agreements for the sale of 73,188 shares of Nexcella's common stock, at a purchase price of $6.49 per share for total proceeds of $475,000. As of December 31, 2022, the offering had not yet closed, and the shares were not issued by Nexcella as of December 31, 2022, and accordingly, the Company recorded the proceeds of $475,000 in funds held for subsidiary private offering at December 31, 2022.

On March 13, 2023, pursuant to the terms of the Founders Agreement, Nexcella issued 167,566 shares of common stock to the Company as a PIK Dividend based on the total dilutive shares of Nexcella outstanding as of March 12, 2023.

Restricted Stock Awards

On December 8, 2022, Nexcella issued 350,000 shares of Nexcella restricted common stock to the officers of the Company for services to be performed, which vest in 48 equal monthly installments. The stock was valued at a share price of $6.49 on the date of issuance, which represents the most recent cash sales price of Nexcella's common stock, for a total value of $2,271,500 related to services.

During the year ended December 31, 2023, the Board of Directors of Nexcella, granted 179,784 shares of restricted common stock to the non-employee members of the Board of Directors for services to be performed, which vest in 24 equal monthly installments. The stock was valued at a share price of $6.49 on the date of issuance, which represents the most recent cash sales price of Nexcella's common stock, for a total value of $1,166,798 related to services.

During the years ended December 31, 2023 and 2022, the Company recorded stock-based compensation expense of $950,672 and $47,323, respectively, related to the total value, which was included in general and administrative expenses. The unrecognized stock-based compensation expense of $2,440,303 related to unvested restricted common stock is expected to be recognized over the remaining vesting period of 2.42 years. As of December 31, 2023, 144,628 shares of restricted common stock have vested with the remaining 385,156 restricted shares to vest over the vesting period of 2.42 years.

Stock Options

During the year ended December 31, 2023, the Board of Directors of Nexcella, granted 114,028 options to purchase shares of common stock to the non-employee members of the Board of Directors for services to be performed, with a term of 10 years and an exercise price of $6.49 per share, which options vest in 24 equal monthly installments.

During the year ended December 31, 2023, the Board of Directors of Nexcella granted 72,500 options to purchase shares of common stock to three consultants for services to be performed, with a term of 10 years and an exercise price of $6.49 per share, which options vest in 48 equal monthly installments.

The Company recognized stock-based compensation of $261,284 related to stock options for the year ended December 31, 2023, which is included in general and administrative expenses. As of December 31, 2023, Nexcella had unrecognized stock-based compensation expense of $813,378, related to unvested stock options, which is expected to be recognized over the weighted-average vesting period of 2.41 years.

The following table summarizes the stock option activity for the year ended December 31, 2023 for Nexcella:

	Options	Weighted-Average Exercise Price Per Share
Outstanding and exercisable, January 1, 2023	-	$ -
Granted	186,528	$ 6.49
Exercised	-	$ -
Forfeited	-	$ -
Expired	-	$ -
Outstanding and expected to vest, December 31, 2023	186,528	$ 6.49

The following table discloses information regarding outstanding and exercisable options at December 31, 2023:

	Outstanding			Exercisable	
Exercise Price	Number of Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Number of Option Shares	Weighted Average Exercise Price
$ 6.49	186,528	$ 6.49	9.74	43,023	$ 6.49
	186,528	$ 6.49	9.74	43,023	$ 6.49

Note 7 – Licenses Acquired

On December 8, 2022, Nexcella entered into a Research and License agreement with HADASIT and BIRAD (collectively, the "Licensors") to acquire intellectual property rights pertaining to CAR-T (the "H&B License"). Pursuant to the H&B License, Nexcella paid the Licensors an upfront license fee of $1.5 million in December 2022 (included in research and development expenses on the consolidated statements of operations and comprehensive loss). Additional quarterly payments totaling approximately $13.0 million are due through September 2026 along with an annual license fee of $50,000. Future royalty payments of 5% are due on net sales of licensed products, combined with sales milestone payments in the aggregate amount of up to $20 million when annual net sales reach certain thresholds for each licensed product. The royalties for each licensed product on a country-to-country basis are to be paid through the latter of (a) the expiration of the last-to-expire valid claim under a licensed patent (if any) in such country; (b) the date of expiration of any other Exclusivity Right (as defined in the H&B License) or data protection period granted by a regulatory or other governmental authority with respect to a licensed product that provides exclusivity in the relevant country; or (c) the end of a period of 15 years from the date of the First Commercial Sale (as defined in the H&B License) of the applicable Licensed Product (as defined in the H&B License) in such country.

During the year ended December 31, 2023 and 2022, the Company recorded R&D expenses of $2,793,712 and $1,500,000, respectively, related to the license agreement.

Note 8 – Income Taxes

The Company is subject to taxation in the United States, California and Australia. At December 31, 2023, the Company had federal, state, and foreign net operating loss ("NOL") carryforwards of approximately $11,800,000, $11,800,000 and $3,100,000, respectively. The federal loss carryforwards generated after 2017 of approximately $11,200,000 will carryforward indefinitely and can be used to offset up to 80% of future annual taxable income, while those loss carryforwards generated prior to 2018 begin expiring in 2034, unless previously utilized. State loss carryforwards also begin expiring in 2034, unless previously utilized, while the Company's foreign loss carryforward does not expire. The Company also has federal and California research and development credit carryforwards totaling approximately $241,000 and $219,000, respectively, at December 31, 2023. The Federal credits begin to expire in 2034, unless previously utilized, while the State credits do not expire. The Company also has foreign withholding tax carryforwards totaling $100,000 at December 31, 2023. The foreign withholding tax carryforward credit begins to expire in 2028, unless previously utilized.

The Company's NOL and credit carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of ownership changes that could occur in the future pursuant to Internal Revenue Code Sections 382 and 383. These ownership changes may limit the amount of NOL and credit carryforwards that can be utilized to offset future taxable income and income tax, respectively. In general, an "ownership change" as defined by the tax code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percent of the outstanding stock of a company by certain stockholders or public groups.

The Company's federal income tax returns from 2019 forward, state income tax returns from 2018 forward, and its Australian tax returns beginning in 2020 are subject to examination by tax authorities.

A reconciliation of the provision for income taxes to the amount computed by applying the statutory federal income tax rate to the loss from operations for the years ended December 31, 2023 and 2022 is as follows:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Expected income tax benefit computed at the statutory rate	$ (4,308,817)	$ (1,736,301)
State income tax benefit, net of federal benefit, net of valuation allowance	-	-
Foreign rate differential	43,337	14,228
Foreign losses not benefited	404,260	119,362
Tax effect of:		
Change in valuation allowance	3,849,451	1,692,278
Change in fair value of derivative liability	-	-
Other permanent items and tax credits	(298,179)	(180,713)
Other non-deductible expenses	336,363	91,196
Provision for income taxes	$ 26,415	$ 10,268

Net deferred tax assets are comprised of the following as of December 31, 2023 and 2022:

	December 31, 2023	December 31, 2022
Net operating losses	$ 4,081,830	$ 1,920,819
Foreign tax credits	99,741	73,326
Federal & state research credit carryforwards	461,098	216,418
Stock-based compensation	109,859	149,599
Amortization of capitalized research and development	2,879,433	1,018,128
Valuation allowance	(7,631,961)	(3,378,250)
Net deferred tax assets	$ -	$ -

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use existing deferred tax assets. Based on the weight of available evidence, including the Company's history of operating losses, management has determined that it is more likely than not that the Company's net deferred tax assets will not be realized. Accordingly, a valuation allowance has been established by the Company to fully offset these net deferred tax assets.

For the years ended December 31, 2023 and 2022, domestic and foreign pre-tax losses were as follow:

	December 31, 2023	December 31, 2022
Loss before income taxes – Domestic	$ 13,952,065	$ 7,741,995
Loss before income taxes – Foreign	1,617,042	477,450
Loss before income taxes - Consolidated	$ 15,569,107	$ 8,219,445

Note 9 – Commitments and Contingencies

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and may provide for indemnification of the counterparty. The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future but have not yet been made. To date, the Company has not been subject to any claims or been required to defend any action related to its indemnification obligations.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as the director or officer may be subject to any proceeding arising out of acts or omissions of such individual in such capacity. The maximum amount of potential future indemnification is unlimited. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations as of December 31, 2023 and 2022.

Royalty Agreement

On December 22, 2014, the Company entered into a Master Service Agreement ("MSA") with AxioMx, Inc. ("AxioMx"). AxioMx is in the business of developing and supplying custom affinity reagents. AxioMx and the Company entered into the MSA to serve as a master agreement governing multiple sets of projects as may be agreed upon by them from time to time. Pursuant to the MSA, AxioMx is entitled to royalties on the sale of any Deliverable (as defined in the MSA) that is used for diagnostic, prognostic or therapeutic purposes, in humans or animals, or for microbiology testing, including food safety testing or environmental monitoring. Specifically, the Company shall pay AxioMx a royalty of 3.5% of Net Sales (as defined in the MSA) of assigned products for each Deliverable used in licensed products for therapeutic purposes. In addition, the Company shall pay AxioMx a royalty of 1.5% of Net Sales of assigned products for each Deliverable used in licensed products for diagnostic or prognostic purposes; provided, however, if three Deliverables are used in an assigned product for diagnostic or prognostic purposes, the royalty shall be 4.5%. Through December 31, 2023, no amounts have been paid or accrued under the MSA. As of December 31, 2023, the MSA has expired and the Company does not intend to extend the MSA; however, the royalty obligations shall survive the termination of the MSA.

Legal Proceedings

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

Employment Agreements

On June 18, 2021, the Company entered into an Employment Agreement with Ilya Rachman (as amended, the "Rachman Employment Agreement"), effective for a three-year term. Pursuant to the Rachman Employment Agreement, the Company employs Dr. Rachman as Chief Executive Officer and Dr. Rachman was entitled to a base salary of $360,000 annually. Dr. Rachman was also entitled to a performance-based bonus of 100% of the base salary (subject to, and determined by, the Board in its sole discretion) plus additional performance bonuses to be determined by the Board. On July 14, 2022, the Compensation Committee of the Board of Directors approved a new compensation package for Dr. Rachman, and on November 9, 2022, the Company entered into an amendment to the Rachman Employment Agreement dated as of June 18, 2021 pursuant to which (i) Dr. Rachman's annual base salary was increased to $425,000, retroactive as of January 1, 2022 and (ii) entitling Dr. Rachman to a performance-based bonus of up to 50% of his base salary (subject to, and determined by, the Board in its sole discretion) plus additional performance bonuses to be determined by the Board. In addition, on July 14, 2022, the Company issued Dr. Rachman options to purchase up to 250,000 shares of the Company's common stock at an exercise price of $2.64 per share. Unless terminated by the Company without "cause" or by Dr. Rachman with "good reason" (as such terms are defined in the Rachman Employment Agreement), upon termination, Dr. Rachman will be entitled only to his base salary through the date of termination, valid expense reimbursements and unused vacation pay. If terminated by the Company without "cause" or by Dr. Rachman with "good reason," he is entitled to be paid his base salary through the end of the term at the rate of 150%, valid expense reimbursements and accrued but unused vacation pay. On March 7, 2023, the Compensation Committee of the Board of Directors approved an increase in the annual base salary and on May 12, 2023, the Company entered into an amendment to the Rachman Employment Agreement pursuant to which Dr. Rachman's annual base salary was increased to $446,000, effective January 1, 2023. Dr. Rachman's employment agreement contains provisions for the protection of the Company's intellectual property and contains non-compete restrictions in the event of his termination other than by the Company without "cause" or by Dr. Rachman with "good reason" (generally imposing restrictions on (i) employment or consultation with competing companies or customers, (ii) recruiting or hiring employees for a competing company and (iii) soliciting or accepting business from our customers for a period of six months following termination). Pursuant to the Rachman Employment Agreement, Dr. Rachman may serve as a consultant to, or on boards of directors of, or in any other capacity to, other companies provided that they will not interfere with the performance of his duties to the Company. On February 6, 2024, the Compensation Committee of the Board of Directors approved an increase in the annual base salary for Dr. Rachman to $475,000, effective January 1, 2024.

On March 18, 2021, the Company entered into a Management Services Agreement with Alwaysraise LLC, an entity which Gabriel Morris, the Company's Chief Financial Officer and a member of the Board, is sole member, effective for a three-year term, which was amended effective June 18, 2021 (as amended, the "Morris MSA"). Pursuant to the Morris MSA, the Company employs Mr. Morris as Chief Financial Officer and Mr. Morris was entitled to a base salary of $240,000 annually beginning in December 2021 ($120,000 annually prior). Mr. Morris was also entitled to a performance-based bonus of 100% of the base salary (subject to, and determined by, the Board in its sole discretion) plus additional performance bonuses to be determined by the Board. On July 14, 2022, the Compensation Committee of the Board of Directors approved a new compensation package for Mr. Morris, and on November 9, 2022, the Company entered into an amendment to the Morris MSA dated as of March 24, 2021 pursuant to which (i) Mr. Morris' annual base salary was increased to $425,000, retroactive as of January 1, 2022 and (ii) entitling Mr. Morris to a performance-based bonus of up to 50% of his base salary (subject to, and determined by, the Board in its sole discretion) plus additional performance bonuses to be determined by the Board. In addition, on July 14, 2022, the company issued Mr. Morris options to purchase up to 250,000 shares of the Company's common stock at an exercise price of $2.64 per share. Unless terminated by the Company without "cause" or by Alwaysraise LLC (as such terms are defined in the Morris MSA), upon termination, Mr. Morris will be entitled only to his base salary through the date of termination, valid expense reimbursements and unused vacation pay. If terminated by the Company without "cause," he is entitled to be paid his base salary through the end of the term at the rate of 150%, valid expense reimbursements and accrued but unused vacation pay. On March 7, 2023, the Compensation Committee of the Board of Directors approved an increase in annual base salary, and on May 12, 2023, the Company entered into an amendment to the Morris MSA pursuant to which the Mr. Morris' annual base salary was increased to $446,000, effective January 1, 2023. The Morris MSA contains provisions for the protection of the Company's intellectual property and confidential information. On February 6, 2024, the Compensation Committee of the Board of Directors approved an increase in the annual base salary for Mr. Morris to $475,000, effective January 1, 2024.

On June 24, 2021, the Company issued an offer letter to Graham Ross Oncology Consulting Services Ltd., a United Kingdom company, of which Graham Ross, the Company's consulting Acting Chief Medical Officer and Head of Clinical Development is the sole member, regarding Dr. Ross' provision of consultative services to the Company (the "Offer Letter"). Pursuant to the Offer Letter (signed by Dr. Ross on June 24, 2021), Dr. Ross is entitled to an hourly rate for his consulting services and an option grant. On June 24, 2021, the Company also signed a mutual confidentiality and non-disclosure agreement with Graham Ross Oncology Consulting Services Ltd.

Collaboration Agreement

In August 2021, the Company entered into a Clinical Collaboration and Supply Agreement with BeiGene Ltd. ("BeiGene") for a combination Phase 1b clinical trial in solid tumors of IMX-110 and anti-PD-1 Tislelizumab (the subject of a collaboration and license agreement among BeiGene and Novartis). Under the terms of the agreement, the Company will conduct the combination trial. The cost of Tislelizumab manufacture and supply (including shipping, taxes and duty if applicable and any third-party license payments that may be due) will be solely borne by BeiGene. To date, no amounts have been paid to BeiGene.

Note 10 – Subsequent Events

Common Stock Issuance – Marketing Services Agreements

Subsequent to December 31, 2023, the Company issued 15,486 shares of restricted common stock valued at $67,500 for investor relations services based on the average closing price for the prior 10 trading days pursuant to a marketing services agreement entered into on July 25, 2023.

Subsequent to December 31, 2023, the Company issued 70,000 shares of restricted common stock valued at $245,000 for investor relations services based on the closing price pursuant to the extension of a marketing services agreement entered into on February 29, 2024.

Common Stock Issuance – July ATM Facility

Subsequent to December 31, 2023, the Company sold a total of 68,302 shares of its common stock under the July ATM Facility for aggregate net proceeds of $425,728 after deducting commissions and SEC fees. On February 5, 2024, the Company suspended, and is not offering any shares of its common stock pursuant to, the prospectus supplement dated July 14, 2023, relating to the July Sales Agreement by and between the Company and ThinkEquity LLC. The Company will not make any sales of common stock pursuant to the July Sales Agreement unless and until a new prospectus supplement is filed with the SEC; however, the Sales Agreement remains in full force and effect.

Common Stock Issuance – Public Offering

On February 5, 2024, the Company entered into an Underwriting Agreement (the "Agreement") with Titan Partners Group LLC, a division of American Capital Partners, LLC (the "Underwriter"), relating to an underwritten offering (the "Offering") of 5,535,055 shares of common stock of the Company. The public offering price is $2.71 per share of Common Stock and the Underwriter has agreed to purchase the Common Stock pursuant to the Underwriting Agreement at a price of $2.5203 per share. On February 8, 2024, the Company closed the offering and received net proceeds of $13,566,697, after deducting underwriting discounts and commissions and estimated offering expenses. Pursuant to the Agreement, the Company granted the Underwriter a 30-day over-allotment option to purchase up to an additional 783,970 shares of Common Stock which was exercised in full on March 1, 2024 for net proceeds of $1,954,594, after deducting underwriting discounts and offering expenses.

Common Stock Issuances – Option exercises

Subsequent to December 31, 2023, the Company issued 834 shares of common stock upon the exercise of certain common stock options for cash proceeds of $1,660.

Lease

In January 2024, the Company entered into a long-term operating lease agreement for 14,000 square feet of biopharmaceutical manufacturing space in California under a non-cancelable operating lease that expires in December 2033. Under the terms of the lease, the Company is required to pay monthly base rents ranging from $11,900 to $16,218, and pay its proportionate share of property taxes, insurance and normal maintenance costs. The lease agreement includes two options to extend the lease for a term of five years each.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our "disclosure controls and procedures" as of December 31, 2023, the end of the period covered by this Annual Report on Form 10-K. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is accumulated and communicated to a company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our management, with the participation of our principal executive officer and principal financial officer has concluded that, based on such evaluation, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were not effective due to the material weakness described below. However, our management, including our principal executive officer and principal financial officer, has concluded that, notwithstanding the identified material weakness in our internal control over financial reporting, the financial statements in this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Material Weakness in Internal Controls Over Financial Reporting

We identified a material weakness in our internal control over financial reporting that exists as of December 31, 2023. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We determined that we had a material weakness because, due to our small size, and our limited number of personnel, we did not have in place an effective internal control environment with formal processes and procedures, including journal entry processing and review, to allow for a detailed review of accounting transactions that would identify errors in a timely manner.

Notwithstanding the material weaknesses in our internal control over financial reporting, we have concluded that the consolidated financial statements included in this Annual Report on Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States of America.

Management's Plan to Remediate the Material Weakness

With the oversight of senior management, we have implemented remediation steps in 2024, including addition of employees and consultants and continue to evaluate and implement procedures that will strengthen our internal controls. We believe these measures will remediate the material weakness identified and strengthen our internal control over financial reporting. We are committed to continuing to improve our internal control processes and will continue to diligently review our financial reporting controls and procedures.

Management's Annual Report on Internal Control Over Financial Reporting and Auditor Attestation

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting, as defined under Rule 13a-15(f) under the Exchange Act. Our management has assessed the effectiveness of our internal controls over financial reporting as of December 31, 2023 based on the framework established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) ("COSO"). Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. An internal control material weakness is a significant deficiency, or aggregation of deficiencies, that does not reduce to a relatively low level the risk that material misstatements in financial statements will be prevented or detected on a timely basis by employees in the normal course of their work. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023, and based on that evaluation, management concluded that our internal control over financial reporting was not effective as of December 31, 2023. We determined that we had a material weakness because, due to our small size, and our limited number of personnel, we did not have in place an effective internal control environment with formal processes and procedures, including journal entry processing and review, to allow for a detailed review of accounting transactions that would identify errors in a timely manner.

This report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the rules of the Securities and Exchange Commission that permit us to provide only management's report in this Annual Report.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our 2024 Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our 2024 Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our 2024 Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our 2024 Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our 2024 Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) Financial Statements:

(b) Exhibits

The following documents are included as exhibits to this report.

Exhibit No.	Title of Document
3.1	Third Amended and Restated Certificate of Incorporation of Immix Biopharma, Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on December 20, 2021)
3.2	Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on December 20, 2021)
4.1	Specimen Stock Certificate Evidencing the Shares of Common Stock (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 6, 2021)
4.2	Form of Representative's Warrant (Incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 28, 2021)
4.3*	Description of the Registrant's Securities (Incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K filed with the SEC on March 27, 2023)
4.4	Form of Senior Indenture (Incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-3 filed with the SEC on January 3, 2023)
4.5	Form of Subordinated Indenture (Incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-3 filed with the SEC on January 3, 2023)
10.1+	2021 Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 6, 2021)
10.2+	Form of Indemnification Agreement with Directors and Executive Officers (Incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 6, 2021)
10.3#	IP License Agreement by and between the Company and Immix Biopharma Australia Pty Ltd dated January 23, 2017 (Incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 6, 2021)

Exhibit No.	Title of Document
10.4+	Employment Agreement by and between the Company and Ilya Rachman dated June 18, 2021 (Incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 6, 2021)
10.5+	Management Services Agreement by and between the Company and Alwaysraise LLC, dated March 18, 2021 (Incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 6, 2021)
10.6	Master Service Agreement by and between the Company and AxioMx, Inc. dated December 22, 2014 (Incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 6, 2021)
10.7#	Clinical Collaboration and Supply Agreement by and between the Company and BeiGene Switzerland GmbH dated August 20, 2021 (Incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 15, 2021)
10.8+	Amendment to Employment Agreement by and between the Company and Ilya Rachman dated as of November 9, 2022 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2022)
10.9+	Amendment to Master Services Agreement by and between the Company and Alwaysraise, LLC dated as of November 9, 2022 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2022)
10.10#	Research and License Agreement entered into on December 8, 2022 by and between Nexcella, Inc. (formerly Immix Biopharma Cell Therapy, Inc.), Hadasit Medical Research Services & Development, Ltd. and BIRAD Research and Development Company Ltd. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 14, 2022)
10.11	Form of Share Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 18, 2023)
10.12*	Senior Unsecured Promissory Note issued by Nexcella, Inc. to Immix Biopharma, Inc. on December 21, 2022 (Incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K filed with the SEC on March 27, 2023.
10.13+	2016 Equity Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1/A filed with the SEC on October 6, 2021)
14.1*	Code of Business Conduct and Ethics (Incorporated by reference to Exhibit 14.1 to the Company's Annual Report on Form 10-K filed with the SEC on March 29, 2022)
21.1*	Subsidiaries
23.1*	Consent of KMJ Corbin & Company LLP, independent registered public accounting firm
31.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002

Exhibit No.	Title of Document
99.7	Immix Biopharma, Inc. Executive Clawback Policy (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2023)
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
104*	Cover Page Interactive Data File – the cover page of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023 is formatted in Inline XBRL

* Filed herewith.
** Furnished herewith.
+ Management contract or compensatory plan or arrangement.
# Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the Company customarily and actually treats such information as private or confidential and such omitted information is not material.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on this 29th day of March, 2024.

/s/ Ilya Rachman
Ilya Rachman
Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Ilya Rachman Ilya Rachman	Chief Executive Officer (Principal Executive Officer) and Chairman of the Board of Directors	March 29, 2024
/s/ Gabriel Morris Gabriel Morris	Chief Financial Officer and Director (Principal Financial and Accounting Officer)	March 29, 2024
/s/ Jason Hsu Jason Hsu	Director	March 29, 2024
/s/ Magda Marquet Magda Marquet	Director	March 29, 2024
/s/ Helen C. Adams Helen C. Adams	Director	March 29, 2024
/s/ Carey Ng Carey Ng	Director	March 29, 2024
/s/ Jane Buchan Jane Buchan	Director	March 29, 2024
/s/ Yekaterina Chudnovsky Yekaterina Chudnovsky	Director	March 29, 2024

Exhibit 21.1

List of Subsidiaries of Immix Biopharma, Inc.

Name	State/Country of Organization or Incorporation	Ownership Interest
Immix Biopharma Australia Pty Ltd.	Australia	100%
Nexcella, Inc.	Delaware	95%*

*Prior to December 9, 2022, Nexcella, Inc. was a wholly-owned subsidiary of the Company. As of March 2024, Nexcella, Inc. is 95% owned by the Company.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements (File No. 333-269100 and 333-274684) on Form S-3 and in Registration Statements (File No. 333-262336, 333-272625 and 333-277163) on Form S-8 of our report dated March 29, 2024, relating to the consolidated financial statements of Immix Biopharma, Inc. and its subsidiaries, appearing in this Annual Report on Form 10-K of Immix Biopharma, Inc. for the year ended December 31, 2023.

/s/ KMJ Corbin & Company LLP

Irvine, California
March 29, 2024

Exhibit 31.1

Certification of Chief Executive Officer of Immix Biopharma, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Ilya Rachman, certify that:

1. I have reviewed this Annual Report on Form 10-K of Immix Biopharma, 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 consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-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 consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2024

/s/ Ilya Rachman
Ilya Rachman
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer of Immix Biopharma, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Gabriel Morris, certify that:

1. I have reviewed this Annual Report on Form 10-K of Immix Biopharma, 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 consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-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 consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2024

/s/ Gabriel Morris
Gabriel Morris
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Statement of Chief Executive Officer and Chief Financial Officer
Pursuant to Section 1350 of Title 18 of the United States Code

Pursuant to Section 1350 of Title 18 of the United States Code as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Ilya Rachman and Gabriel Morris, the Chief Executive Officer and Chief Financial Officer, respectively, of Immix Biopharma, Inc. (the "Company"), hereby certify that based on the undersigned's knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2023 (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 29, 2024

/s/ Ilya Rachman
Ilya Rachman
Chief Executive Officer
(Principal Executive Officer)

Date: March 29, 2024

/s/ Gabriel Morris
Gabriel Morris
Chief Financial Officer
(Principal Financial and Accounting Officer)