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, 2022

☐ 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, 2022 was approximately $18,300,000 based upon the closing price of the registrant's common stock of $2.60 on The Nasdaq Capital Market as of that date.

Number of common shares outstanding as of March 17, 2023 was 13,898,822 shares.

Documents Incorporated by Reference: Portions of the registrant's definitive proxy statement (the "2023 Proxy Statement") relating to its 2023 annual meeting of stockholders (the "2023 Annual Meeting of Stockholders") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2023 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 ultimate impact of the COVID-19 pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole;
- the 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. has the following two business units:

ImmixBio. ImmixBio is focused on developing Tissue Specific Therapeutics targeting solid tumors and immune-dysregulated diseases. As of February 2023, 19 patients with advanced solid tumors were treated with IMX-110, ImmixBio's lead candidate.

Nexcella. Our majority-owned subsidiary, Nexcella, Inc. (formerly known as Immix Biopharma Cell Therapy, Inc.), is engaged in the discovery and development of novel cell therapies for hematologic malignancies (blood cancers) and other indications. As of February 2023, 42 patients with relapsed/refractory multiple myeloma (90% overall response rate at therapeutic dose) and 5 relapsed/refractory light chain (AL) amyloidosis patients (100% organ response, 100% complete response rate) have been treated with next-generation CAR-T NXC-201.

IMMIXBIO – TISSUE SPECIFIC THERAPEUTICS FOR SOLID TUMORS

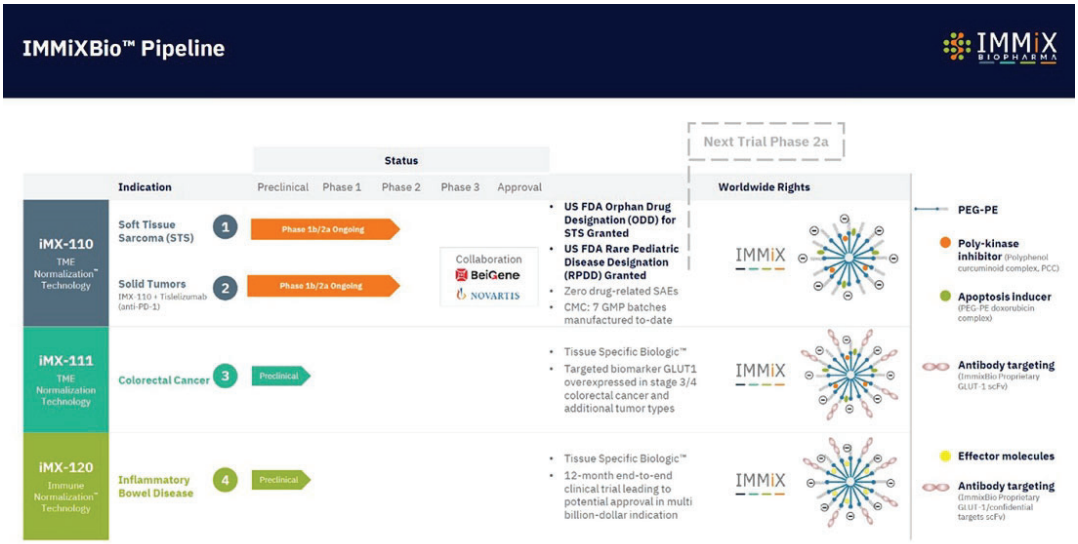
Overview of ImmixBio

We are a clinical-stage biopharmaceutical company developing a novel class of Tissue-Specific Therapeutics ("TSTx")^{TM} in oncology and inflammation. Our lead asset, IMX-110, is currently in Phase 1b/2a clinical trials for solid tumors in the United States and Australia. IMX-110 is a negatively-charged TSTx that simultaneously disables resistance pathways with a poly-kinase inhibitor (which inhibits multiple kinases simultaneously) and induces tumor cell death with an apoptosis inducer (which activates apoptosis, a non-inflammatory programmed cell death pathway), leveraging our TME Normalization^{TM} Technology, delivered deep into the tumor micro-environment ("TME"). Our proprietary System Multi-Action RegulaTors SMAR$_x$T Tissue-Specific^{TM} Platform produces drugs that accumulate at intended therapeutic sites at 3-5 times the rate of conventional medicines. Our TME Normalization™ Technology allows our drug candidates to circulate in the bloodstream, exit through tumor blood vessels and simultaneously attack all components of the TME. To date, we have not generated any revenues. 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.

Pipeline

Our SMAR$_x$T Tissue-Specific^{TM} Platform has produced 3 drug candidates which we believe derisks the clinical development of each subsequent candidate due to shared design elements across tolerability, chemistry, manufacturing and controls, regulatory understanding, and multi-target therapeutic approach, the first of which is IMX-110, currently in Phase 1b/2a oncology clinical trials.

Figure 1: ImmixBio SMAR$_x$T Tissue-Specific^{TM} Platform – Pipeline



Our Lead Product Candidate

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 soft tissue sarcoma ("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.

As of February 2023, we have treated the first 2 patients in our ongoing Phase 1b/2a clinical trial of IMX-110 + Novartis/BeiGene anti-PD-1 Tislelizumab.

As of February 2023, we have treated 17 patients in our ongoing Phase 1b/2a clinical trial in the United States and Australia. 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. In our trial, we observed radiological progression-free-survival of 6 months in 50% of our STS patients, with a 4-month median progression free survival ("mPFS") across all STS patients. mPFS is the time that patients live without their cancer progressing. The trial includes patients with leiomyosarcoma, carcinosarcoma, poorly differentiated soft tissue sarcoma, cholangiocarcinoma, colorectal cancer, prostate cancer, pancreatic cancer, esophageal cancer, breast cancer, and nasopharyngeal cancer.

In August 2021, we 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). In genetic mouse models of pancreatic cancer, IMX-110 has demonstrated an immunomodulation effect, turning "cold" tumors "hot," and, in combination with murine anti-PD-1, IMX-110 produced extended survival versus multi-drug combinations. The goal of this study is to demonstrate the potential for TSTx to be an integral component of combination therapies for a wide range of advanced solid tumors. Pursuant to the terms of the agreement, we and BeiGene shall form a committee made up of an equal number of individuals, but not more than two representatives of each of our Company and BeiGene, which shall, among other things, coordinate activities with respect to the trial; provided, however, we shall be entitled to receive, review or approve any budgets or other costs relating to the trial. Pursuant to the terms of the agreement, we shall be responsible for all costs associated with the manufacturing and supply of IMX-110 for the trial as well as all costs associated with conducting the trial and BeiGene shall be responsible for costs associated with supplying Tislelizumab for the trial. Notwithstanding the foregoing, if the Tislelizumab supplied by BeiGene is lost, damaged or destroyed or becomes unable to comply with applicable specifications while under our control, BeiGene shall not be required to replace such Tislelizumab and in the event BeiGene replaces such Tislelizumab, it may charge us a reasonable replacement cost. The agreement shall continue until the earlier of (i) the one year anniversary of the date upon which we provide BeiGene with the trial's final clinical study report and (ii) the date of termination of the trial. In addition, either party may terminate the agreement (i) upon 30 days prior written notice to the other party if, in the case of our Company, we cease the development of IMX-110 or, in the case of BeiGene, it ceases the development, marketing and sale of Tislelizumab, (ii) upon written notice to the other party if there have been one or more serious adverse events indicating a patient safety issue with continuing the trial, (iii) upon written notice to the other party if a regulatory authority withdraws approval of IMX-110 or Tislelizumab, as applicable, and/or the trial, (iv) upon 60 days' notice to the other party with or without reason, (v) immediately upon written notice to the other party if such other party consummates a Change of Control Transaction (as defined in the agreement) and/or (vi) upon written notice to the other party in the event such other party is in material breach of the agreement and has not cured such breach within 60 days after receipt of notice from the non-breaching party. As of the date hereof, we have not paid any amounts to BeiGene.

In September 2021, the United States Food and Drug Administration ("FDA") granted Orphan Drug Designation ("ODD") to IMX-110 for the treatment of soft tissue sarcoma. 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).

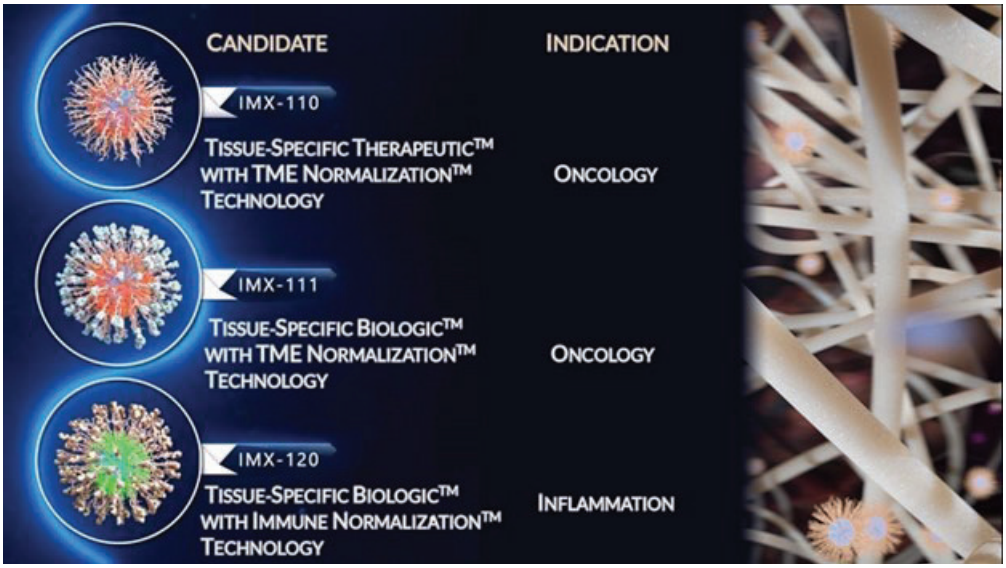
In January 2022, the FDA granted Rare Pediatric Disease Designation ("RPDD") to IMX-110 for the treatment of rhabdomyosarcoma, a life-threatening pediatric cancer in children. RPDD qualifies us to receive fast track review and a priority review voucher ("PRV") at the time of marketing approval of IMX-110.

Our Other Product Candidates

IMX-111 is a Tissue-Specific Biologic™ built on our TME Normalization™ Technology with proprietary GLUT1 antibody biomarker targeting coupled with our poly-kinase inhibitor / apoptosis inducer. IMX-111 takes advantage of the fact that GLUT1 is an essential cancer biomarker that is overexpressed on 92% of colorectal cancer cells and other tumor types. Furthermore, the degree of its overexpression correlates with more advanced stages of tumor progression. Building on the well-tolerated profile of our lead candidate from our ongoing clinical trial, we believe IMX-111 is the first cancer therapeutic to be developed that takes advantage of GLUT1 overexpression in cancer.

IMX-120 is a Tissue-Specific Biologic™ built on our Immune Normalization Technology™ for inflammatory bowel disease with proprietary GLUT1 antibody biomarker targeting coupled with polyphenol poly-kinase inhibitors. IMX-120 takes advantage of the fact that overexpression and activation of GLUT1 on overactive immune cells has been shown to be widely present in patients with inflammatory bowel diseases ("IBD"). Similar to tumor growth, the inflammatory processes active in IBD are caused by recurring waves of activation of multiple kinases that upregulate NF-κB, STAT3 and other key transcriptional factors. IMX-120's polyphenol poly-kinase inhibitors block upstream kinase signal transduction systems that activate NF-κB and STAT3. GLUT1 presents an ideal targeting moiety (component of a drug) for these overactive immune cells, allowing for tissue-specific delivery of IMX-120.

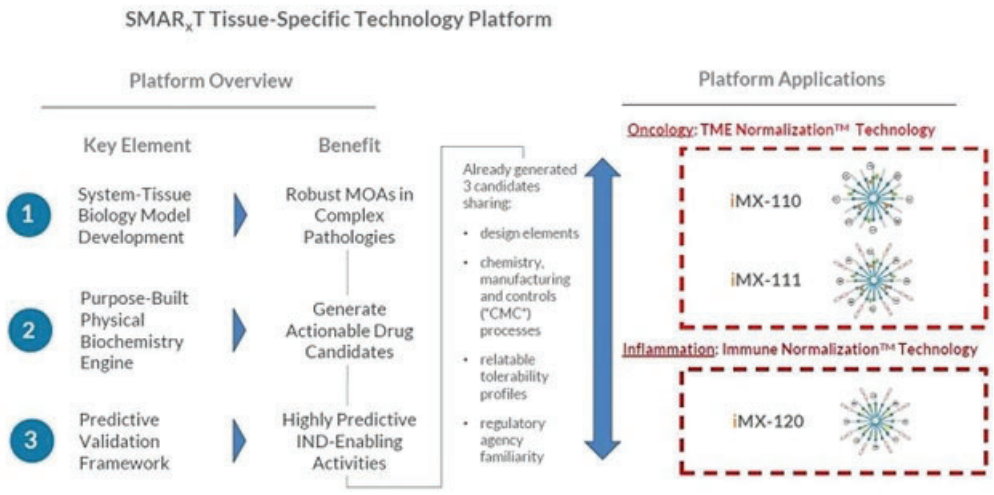
Figure 2: ImmixBio SMAR$_x$T Tissue-Specific™ Platform – Summary Rendering



Our Platform and Technologies

Our SMAR$_x$T Tissue-Specific Platform consists of 3 pillars: first, System-Tissue Biology Model Development, which allows us to develop robust mechanisms of action in complex pathologies; second, Purpose-Built Physical Biochemistry Engine, which allows us to generate actionable drug candidates; and third, Predictive Valuation Framework, which allows us to conduct highly predictive IND-enabling activities.

Figure 3: SMARxT Tissue-Specific™ Platform Overview



Specifically, the 3 pillars of our platform are:

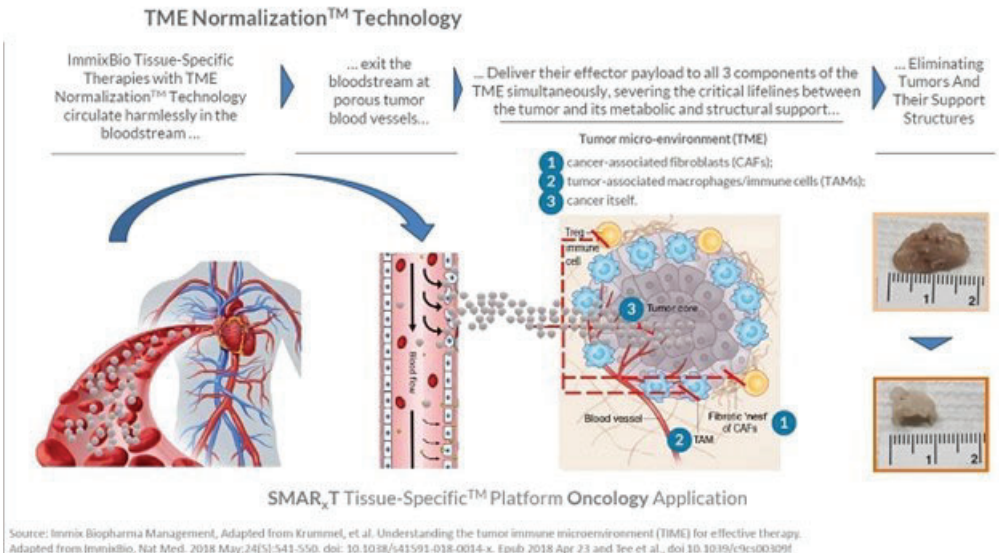
1) System-Tissue Biology Model Development: Interplay of cellular elements define and drive disease states. Based on transcriptional and epigenetic factors operating in key cell types, we have built a proprietary model of network motifs driving human pathologies such as cancer and auto-immune/inflammatory diseases. We believe this model represents the most complete view of biologic interrelationships on an organismal and tissue level. We apply this model in the early stages of our drug development to overcome systemic factors that have prevented traditional "targeted" therapies' effectiveness in complex pathologies such as cancer and inflammatory bowel disease.

2) Purpose-Built Physical Biochemistry Engine: Traditional drug development focuses on "one drug, one target" approach. In contrast, our proprietary physical biochemistry engine is designed to incorporate wide-ranging elements into our drug design, encompassing a diverse target profile, allowing our drugs to operate simultaneously in time and space to jointly combat disease at the tissue and organismal level.

3) Predictive Validation Framework: Using our unique relationships and our internal expertise, we have developed a proprietary framework of high-efficiency, rapid development *in vitro* and *in vivo* animal models that have high relatability to human disease, minimizing the traditional poor predictive value of animal models.

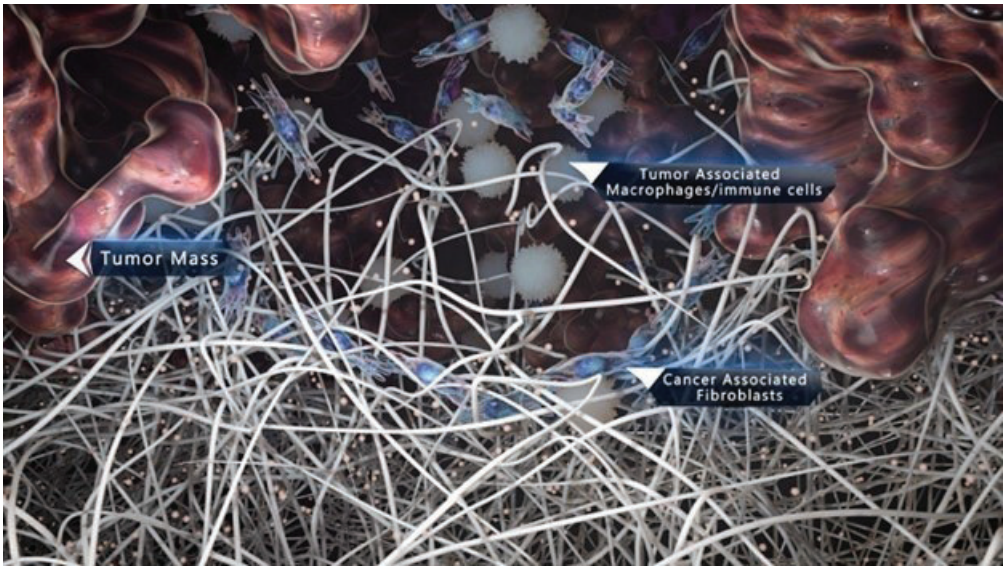
The application of the SMARxT Tissue-Specific Platform in oncology is TME Normalization™ Technology, and in inflammation is Immune Normalization™ Technology.

Figure 4: TME Normalization™ Technology



The TME is made up of a tightly packed mass of: 1) cancer associated fibroblasts ("CAFs"), 2) tumor-associated macrophages/immune cells ("TAMs"), and 3) cancer itself. The TME's unique biophysical properties include regions of varying degrees of hypoxia, acidosis and an immunosuppressive milieu. As cancer cells outgrow their blood supply, the resulting hypoxia and acidosis shift their metabolism towards glycolysis, lactate and lipids. This, in turn, shapes the responses of proximal fibroblasts and resident immune cells. Fibroblasts begin to secrete lactate that is taken up by nearby cancer cells and consumed as fuel. Lactate in the TME reprograms the macrophages toward the M2 "tolerant" pro-inflammatory phenotype that drives immunosuppression. At the same time, the TME hypoxia produces increased levels of reactive oxygen species that enhance tumorigenicity (tendency to form tumors) and immunosuppressive functions of Treg T-cells, as well as resistance to immune drugs such as PD-1/PD-L1 inhibitors. Our TME Normalization™ Technology reverses the hypoxia- and acidosis-activated genetic programs in every cellular component of the TME, "normalizing" the TME, and reactivating apoptosis cell death pathways. This technology offers an attractive opportunity to reshape the pathological niche that is the TME and overcome the critical factors that have hampered available treatments to date.

Figure 5: Representation of the TME Composed of CAFs, TAMs, and Cancer Cells



Our TME Normalization™ Technology causes tumor apoptosis, a non-inflammatory tumor-cell death (instead of necroptosis, which results in repeat reignition of the inflammatory cascade leading to tumor progression). Thus, when the inflammatory cascade is inhibited, tumor resistance can be suppressed, enabling tumor cell apoptosis by ImmixBio therapies.

We believe that our TME Normalization™ Technology is a promising direction of research that may enable a new generation of high-therapeutic index drugs (drugs that have high relative safety as defined by the ratio of toxic to effective dose), unlocking additional therapeutic benefit without adding toxicity.

IMX-110 - Tissue-Specific Therapeutic™ with TME Normalization™ Technology

IMX-110 Market Opportunity

The first potential indication we intend to pursue for IMX-110 is STS. STSs are cancers that arise from muscle, fat, nerves, fibrous tissues, blood vessels or deep skin tissues. Globally, there are roughly 116,000 new cases of soft tissue sarcomas each year, of which 21,500 are in the European Union and 40,500 are in China. 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.

The global soft tissue sarcoma market is estimated to reach approximately $6.5 billion by 2030 from the estimated $2.9 billion in 2019. 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).

$844 million is the total publicly disclosed combined annual sales of eribulin (Halaven®), pazopanib (Votrient®), and trabectedin (Yondelis®) according to the most recent available annual reports.

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 in which 50% of patients received three or more lines of previous chemotherapy prior to eribulin. Eribulin produced a mPFS in STS patients of 2.6 months according to Schöffski et al., 2016.

Pazopanib (Votrient®), was trialed in a study in which 21% of patients received three or more lines of treatment prior to pazopanib. Pazopanib produced a mPFS in STS patients of 4.6 months according to van der Graaf et al., 2012.

Trabectedin (Yondelis®) was trialed in a study in which 12% of patients received three or more lines of chemotherapy prior to trabectedin. Trabectedin produced a mPFS in STS patients of 4.2 months according to Demetri et al., 2016.

IMX-110 Clinical Data

As of March 2023, we have treated 17 patients in our ongoing Phase 1b/2a clinical trial in the United States and Australia, of which 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.

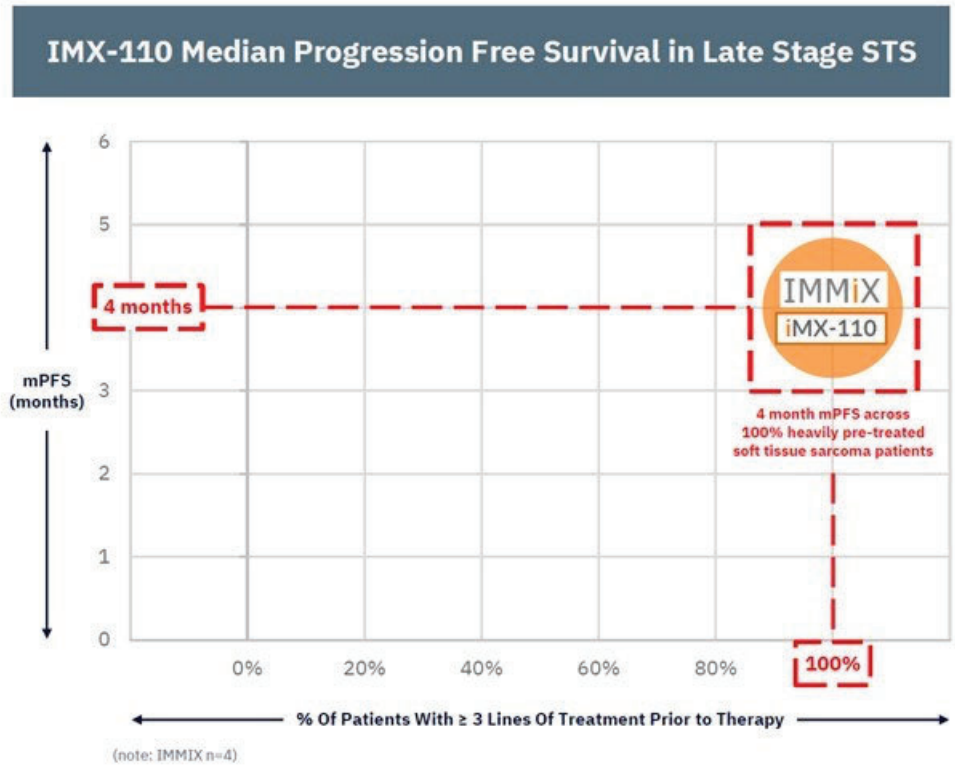
4 months was the mPFS observed in STS patients treated with IMX-110 in the United States in our ongoing Phase 1b/2a clinical trial.

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.

Figure 6: IMX-110 Soft Tissue Sarcoma Median Progression Free Survival and Level of Pre-treatment

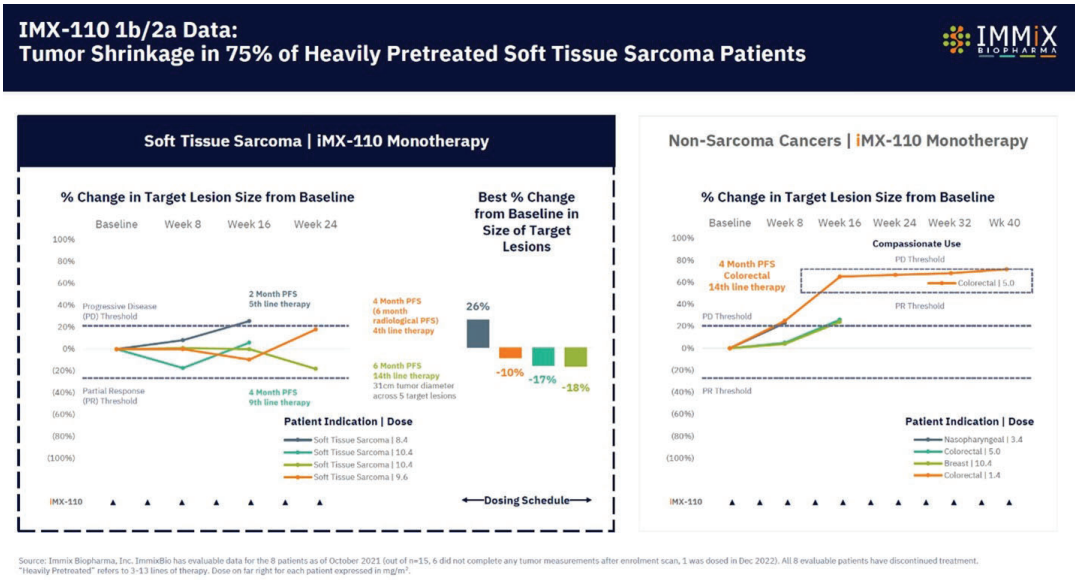


In our ongoing IMX-110 clinical trial:

- 100% of STS patients had controlled disease at 2 months.
- 75% of STS patients experienced tumor shrinkage. The range of the best percentage change from baseline in size of target lesions was between -10% and -18%.
- A 59 year old male STS patient experienced 6 month PFS, despite having 13 prior lines of therapy and the largest tumor burden at the time of enrollment (312mm diameter across 5 target lesions).
- A 77 year old male STS patient with 8 lines of prior therapy experienced 4 month PFS.
- A 27 year old female STS patient with 3 lines of prior therapy experienced 4 month clinical PFS and 6 month radiological PFS.

Figure 7: IMX-110 Phase 1b/2a Clinical Trial Interim Patient Data:
75% of Heavily Pretreated Soft Tissue Sarcoma Patients Experienced Tumor Shrinkage

Soft Tissue Sarcoma % Change in Target Lesion Size from Baseline (Left)
Soft Tissue Sarcoma Best % Change from Baseline in Size of Target Lesions (Center)
Non-Sarcoma Cancers % Change in Target Lesion Size from Baseline (Right)



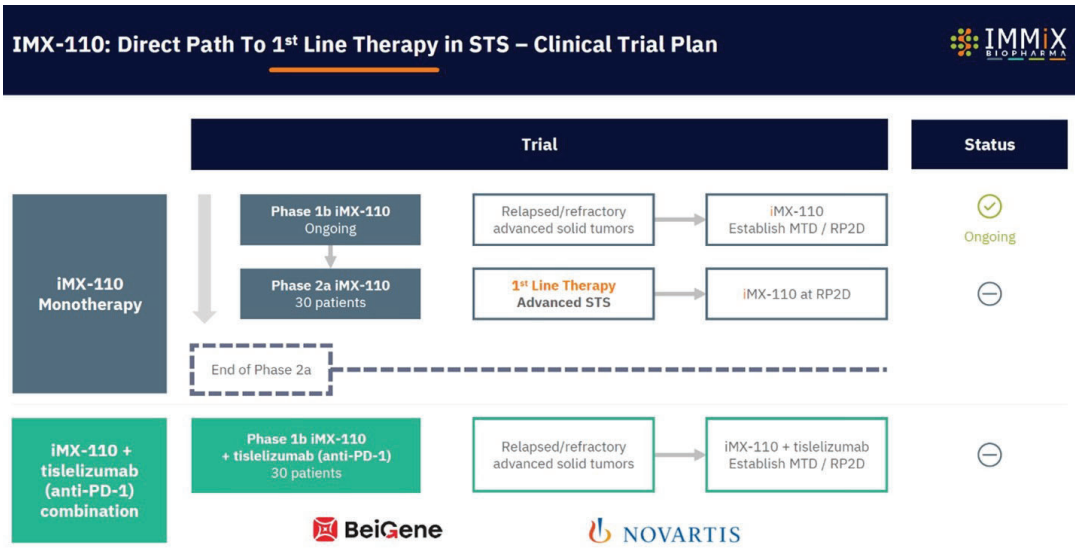
Source: Immix Biopharma, Inc. ImmixBio has evaluable data for the 8 patients as of October 2021 (out of n=15, 6 did not complete any tumor measurements after enrolment scan, 1 was dosed in Dec 2022). All 8 evaluable patients have discontinued treatment. "Heavily Pretreated" refers to 3-13 lines of therapy. Dose on far right for each patient expressed in mg/m^2.

(Source: Immix Biopharma, Inc. ImmixBio has evaluable data for 8 patients as of March 2022 (out of n=17, the remaining 9 did not complete any tumor measurements after enrollment scan, of which 2 due to being dosed in December 2022). All 8 evaluable patients have discontinued treatment. "Heavily Pretreated" refers to 3-13 lines of therapy. Dose expressed in mg/m^2. Our employees were involved in the design of this study and the results are unpublished.)

In addition to IMX-110 STS data, a colorectal cancer patient originally considered for hospice, was subsequently treated with IMX-110 for 10 months with zero serious drug-related adverse events. This patient experienced 4 month PFS on half of what we expect to be IMX-110's recommended Phase 2 therapeutic dose.

IMX-110 Development Strategy

Figure 8: IMX-110: Direct Path To 1st Line Therapy In Soft Tissue Sarcoma – Clinical Trial Plan



We plan to treat an additional 30 STS patients in our Phase 2a trial with IMX-110 as a first-line therapy.

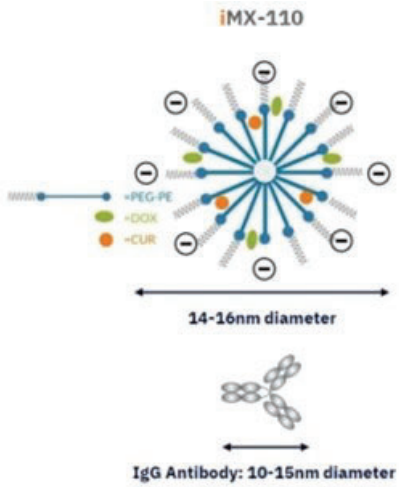
We expect our Phase 2a trial to require around 24 months after the first patient is dosed in 2023. The basis for IMX-110 as a first-line therapy in STS is threefold:

- encouraging clinical trial mPFS (4 month mPFS) data and tolerability data in our IMX-110 Phase 1b dose escalation trial;
- we have identified precedent FDA clinical trial design for a first-line treatment; and
- interest from leading STS PIs.

Subsequently, we plan to initiate an 80 patient Phase 2b/3 clinical trial.

IMX-110 Composition and Mechanism of Action

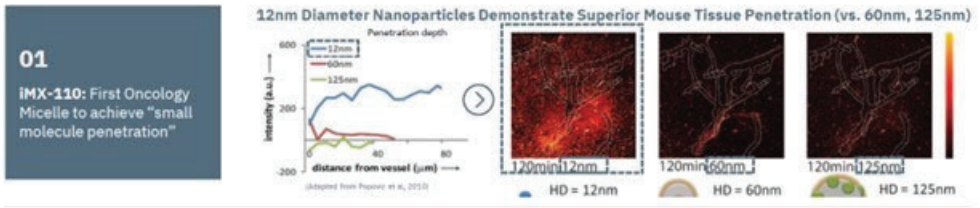
Figure 9: IMX-110 Tissue-Specific Therapeutic™ with TME Normalization™ Technology for Soft Tissue Sarcoma



IMX-110 is a negatively-charged Tissue-Specific Therapeutic™ built on our TME Normalization™ Technology encapsulating a synergistic 5:1 ratio of poly-kinase inhibitor (PCC) and apoptosis inducer (PEG-PE doxorubicin complex) delivered deep into the TME.

IMX-110 is the first clinical-stage drug built on our TME Normalization™ Technology.

Figure 10: IMX-110 – the First Oncology Micelle to Achieve "Small Molecule Penetration"



(Intravital multiphoton imaging of intravenous injection into a mouse bearing an Mu89 melanoma in a dorsal skinfold chamber with a mixture of nanoparticles with diameters of 12 nm, 60 nm, and 125 nm. Adapted from Popovic, et al., 2010. We did not fund or sponsor this study, and we were not involved in this study or its publication.)

IMX-110 is 14-16 nanometers in diameter, and is about the size of an Immunoglobulin G ("IgG") antibody. Tumor blood vessels have perforations of several hundred nanometers in diameter. Once IMX-110 has exited the bloodstream toward the tumor, it must traverse the fibrous extracellular matrix, laid down by CAFs, that encases and scaffolds the tumor. IMX-110's small size enables IMX-110 to exit perforated tumor blood vessels and penetrate the fibrous extracellular matrix.

Figure 11: Representation of IMX-110 in the Bloodstream, Prior to Exiting Perforated Tumor Blood Vessels

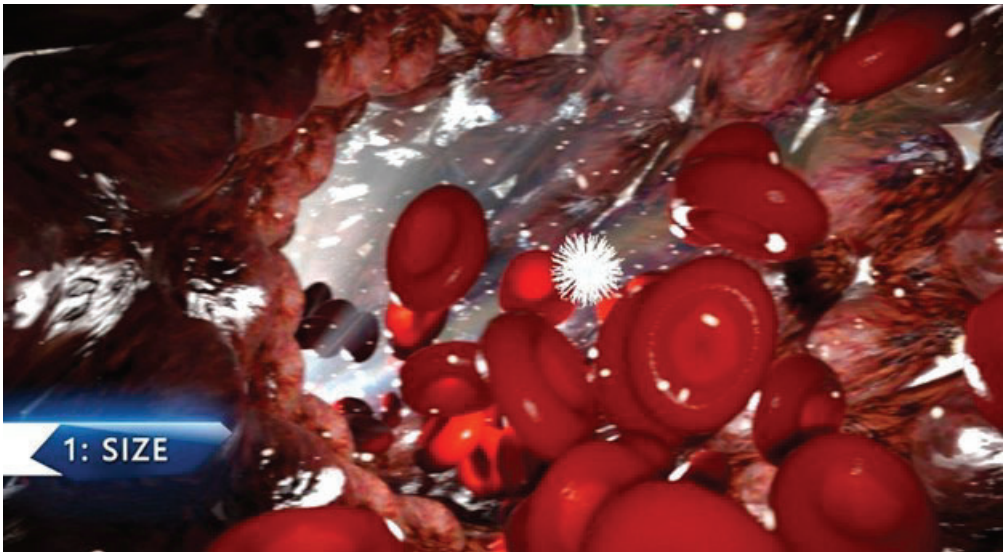


Figure 12: Representation of IMX-110 Traversing the Fibrous Extracellular Matrix Toward the Tumor

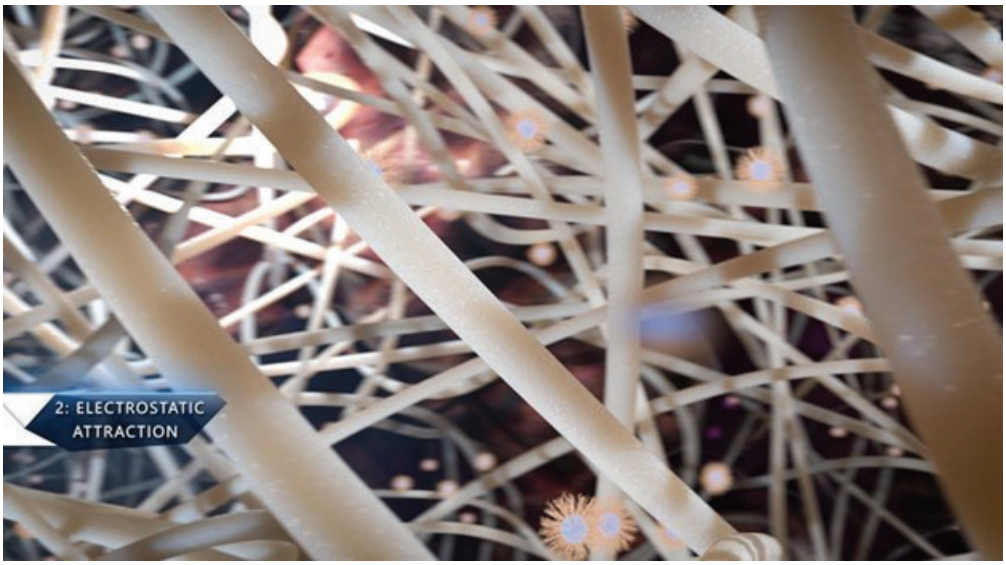
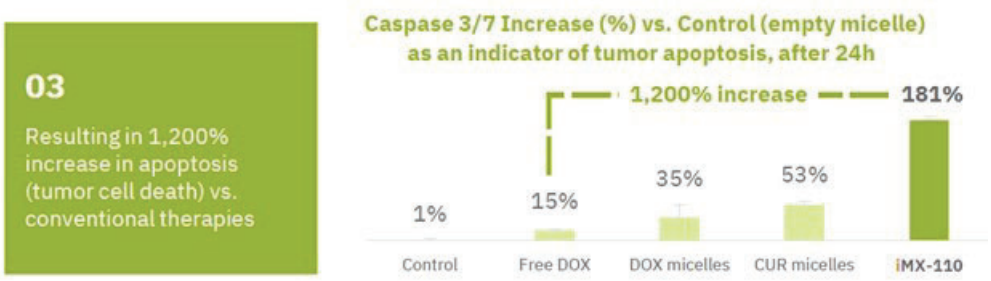


Figure 13: IMX-110 – Negative Charge Facilitates Selective Tumor Accumulation

(Concentration in tumor after IV injection. C-labeled doxorubicin in micellular or free form was injected into the tail veins of C 26-bearing CDF_1 female mice (7 weeks old) at a volume of 0.1 ml/10g body weight. After defined time periods (15 min, 1, 4, 24, and 48 h), mice were anesthetized with diethylether and tumor samples were collected. Adapted from Yokoyama, et al., 1999. We did not fund or sponsor this study, and we were not involved in this study or its publication.)

We believe IMX-110's negative charge enables it to be electrostatically attracted to the tumor, and accumulate at tumor sites at a rate 4-9 times higher than the rate of existing standard of care chemotherapies such as conventional doxorubicin.

Figure 14: IMX-110 – 12x Tumor Killing vs. Conventional Doxorubicin



(See below paragraph for study description. Adapted from Sarisozen, et al., 2016)

We observed that IMX-110 has statistically significantly increased apoptosis in 3D spheroid U87MG glioblastoma model as measured by increase in caspase 3/7 activity after 24 hours versus groups treated with: control group (empty micelles), 0.1 μM free doxorubicin (free DOX), 0.1 μM micellular doxorubicin (DOX micelles), 20 μM micellular curcumin (CUR micelles). The primary endpoint of the study was level of apoptosis as measured by increase in caspase 3/7 activity after 24 hours of treatment. 3D Spheroid U87MG glioblastoma cells were treated with 0.1 μM DOX and 20 μM CUR in micellar formulations for 24 h, followed by the Apo-ONE Homogeneous Caspase-3/7 Assay. Results were normalized against the control group and presented as mean ± SD. Our employees were involved in the design of this study and Ilya Rachman, our Chief Executive Officer and Chairman of our board of directors, was a co-author of the results published in 2016. Results were generated in triplicate using 15 spheroids per treatment.

IMX-110's synergistic combination induces caspase 3/7 activity, a proxy for apoptosis/tumor cell killing, at a rate of 12 times higher than that of conventional doxorubicin, and at a rate 5 times higher than micellular doxorubicin, confirming IMX-110's potent tumor cell killing activity.

Figure 15: Representation of IMX-110 Effector Molecules (Orange and Red) Attacking Multiple Protein Targets Simultaneously

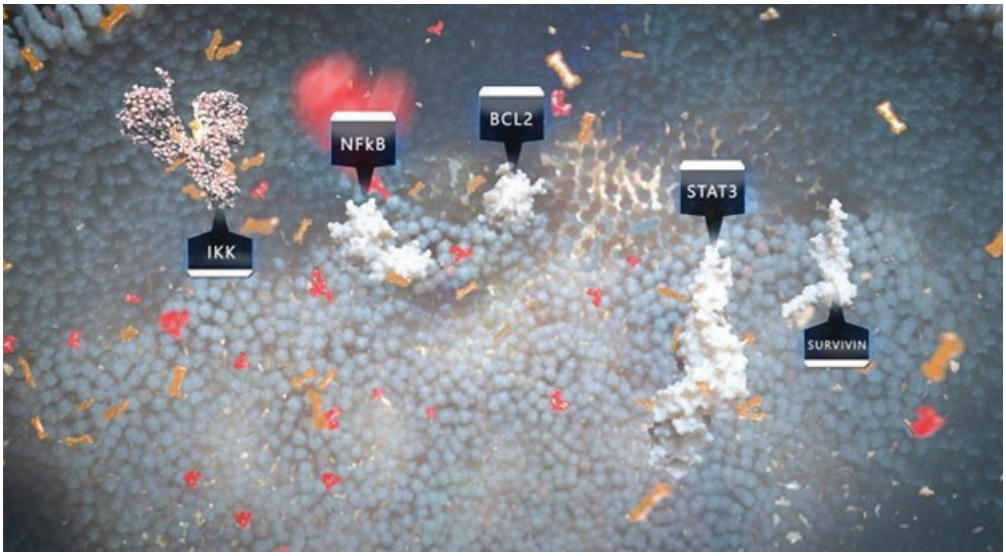
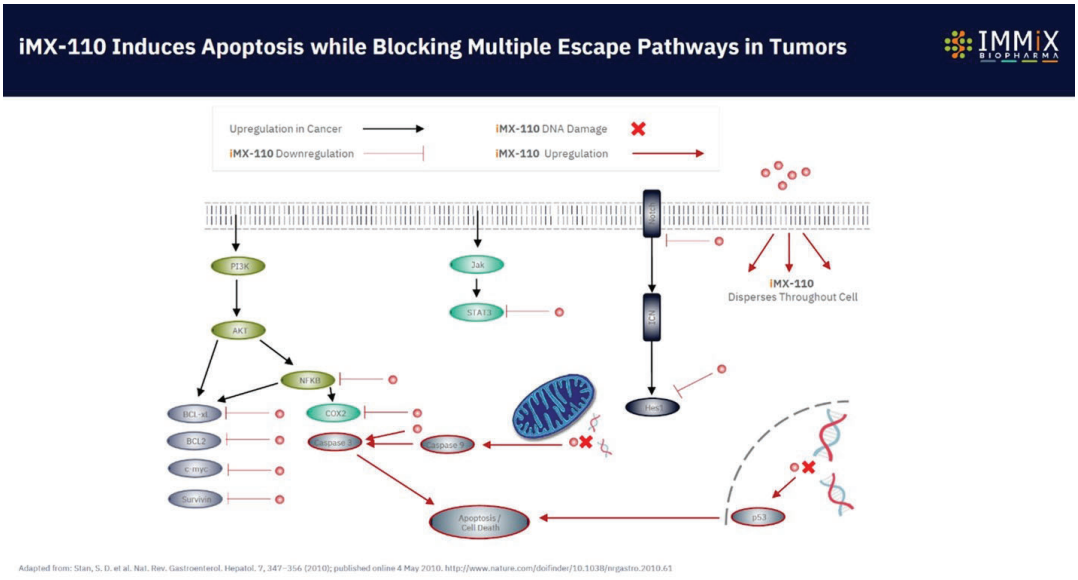


Figure 16: IMX-110 Tissue-Specific Therapeutic™ with TME Normalization™ Technology
Intracellular Mechanism of Action



Specifically, IMX-110 induces potent tumor killing by blocking multiple tumor escape pathways targeted by FDA approved targeted agents and targeted agents in development.

Leveraging its multi-kinase inhibition capabilities, not only does IMX-110 block activation of NF-κB and STAT3, IMX-110 also simultaneously blocks activation of other well-known cancer-related proteins such as COX2, BCL2, BCL-xL, Survivin, c-myc, Notch, and Hes1. With these pathways shut down, IMX-110 is able to activate apoptosis through double-stranded DNA breaks caused by IMX-110's apoptosis inducer (PEG-PE doxorubicin complex).

Table 1: Select Drugs Targeting Same Targets That IMX-110 Targets

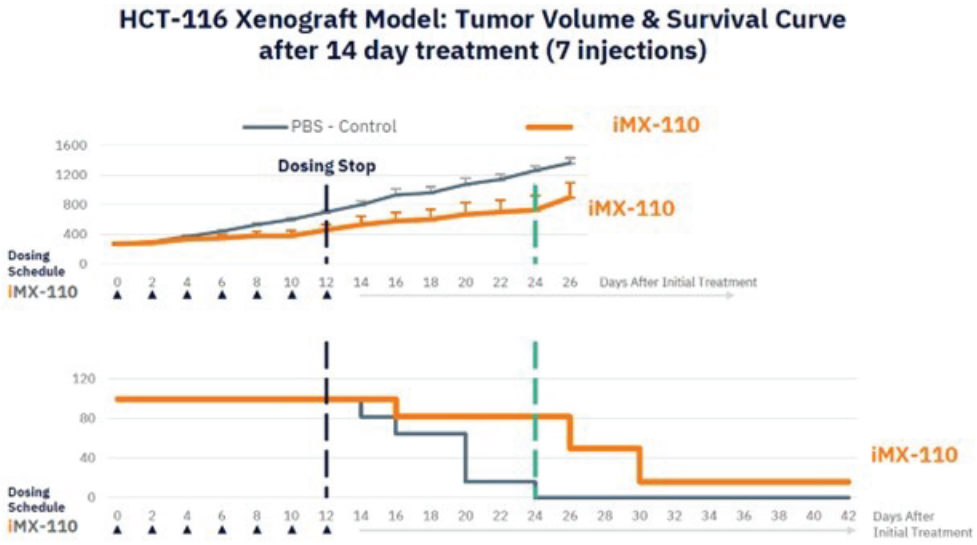
Company	Name	Target	2021 status
 	Venetoclax / Venclexta	BCL2	Approved
	Navitoclax	BCL2, BCL-xL	Phase II
	ZN-d5	BCL2, BCL-xL	Phase I
	Celebrex/celecoxib	COX2	Off patent
	Brontictuzumab	Notch1	Phase I

IMX-110 Pre-clinical Data

We have funded and sponsored pre-clinical experiments to characterize the activity profile of IMX-110 in a range of solid tumor models, including genetic KPC pancreatic mouse model, xenograft mouse models of various cancers, and *in vitro* with various cancer cell lines.

We observed that IMX-110 has statistically significantly inhibited tumor growth in a pre-clinical study that we funded and was conducted on an industry sponsored research basis in a HCT-116 colon cancer xenograft mouse model (which is poorly sensitive to doxorubicin). The primary endpoint of the study was tumor growth inhibition as measured by tumor volume, with the secondary endpoint being overall survival. Female nude (NU/NU) mice bearing 250mm^3 HCT-116 tumors were treated every 2 days starting at day 0 (7 total tail vein injections, arrows correspond to injection days) at a dose of 4 mg/kg CUR and 0.4 mg/kg DOX (six mice per dosing group). Survival was determined when the tumor reached 1000mm^3. Our employees were involved in the design of this study and Ilya Rachman, our Chief Executive Officer and Chairman of our board of directors, was a co-author of the results published in 2013. No adverse side effects of IMX-110 were observed as measured by lack of weight loss.

Figure 17: IMX-110 Tissue-Specific Therapeutic™ with TME Normalization™ Technology Statistically Significantly Inhibited Tumor Growth in HCT-116 Pre-clinical Xenograft Model

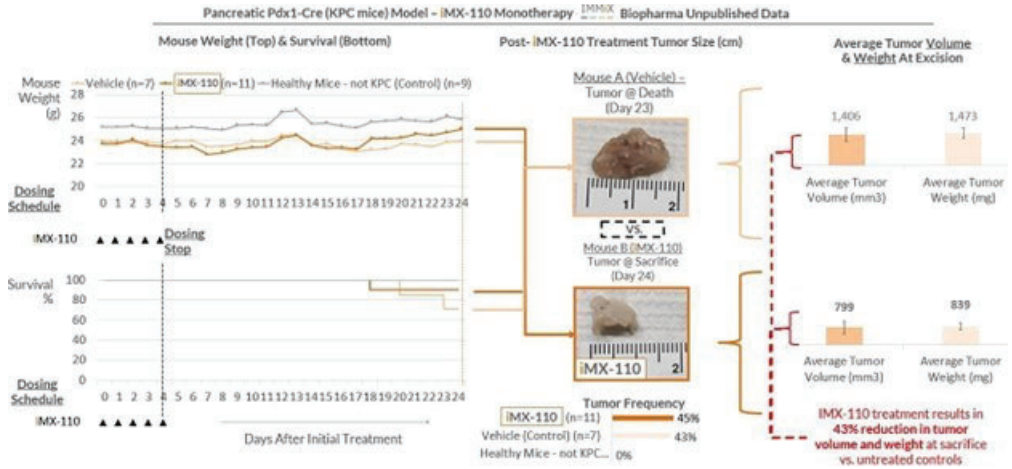


(See above paragraph for study description. Adapted from Abouzeid et al., 2013)

In this pre-clinical study of IMX-110 in the HCT-116 colorectal cancer xenograft mouse model, at day 24, 80% of mice treated with 1 cycle of low-dose IMX-110 were alive while all control animals were dead.

We observed that IMX-110 monotherapy has statistically significantly inhibited tumor growth in a pre-clinical study that we funded and was conducted in a genetic pancreatic cancer (KPC) mouse model. The primary endpoint of the study was tumor growth inhibition as measured by tumor volume and weight. Transgenic mice (Pdx1-Cre) were treated every day starting at day 0 (5 total tail vein injections, arrows correspond to injection days) at a dose of 6 mg/kg CUR and 1.4 mg/kg DOX (at least six mice per dosing group). Survival was determined when the tumor reached 1500mm^3. Surviving animals were euthanized after the last blood collection prior to Day 30, tumors were excised, measured, weighted, photographed and sectioned for histological analysis. Our employees were involved in the design of this study and the results are unpublished. No adverse side effects of IMX-110 were observed as measured by lack of weight loss.

Figure 18: IMX-110 Tissue-Specific Therapeutic™ with TME Normalization™ Technology Monotherapy Statistically Significantly Inhibited Tumor Growth in Genetic (KPC) Pancreatic Cancer Pre-clinical Model



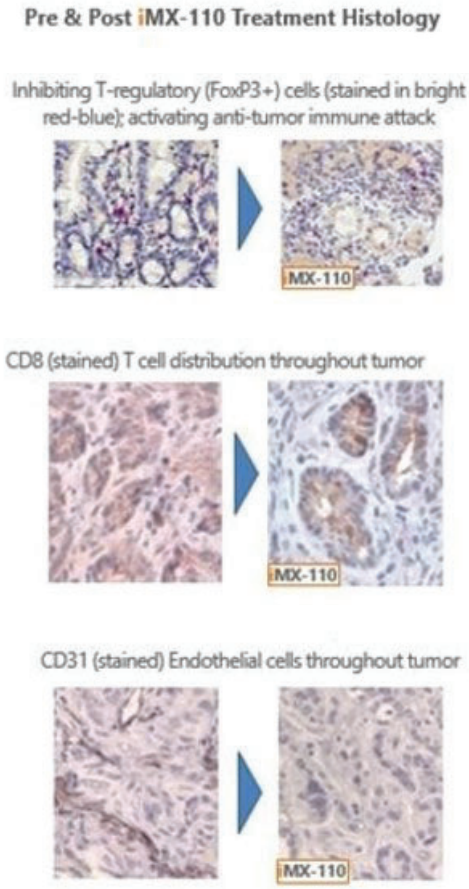
(See above paragraph for study description. ImmixBio unpublished results.)

In this pre-clinical study of IMX-110 monotherapy in the genetic KPC pancreatic cancer mouse model, one cycle of low-dose IMX-110 produced an average 43% reduction in tumor volume and weight at sacrifice vs. tumor volume and weight in untreated controls.

IMX-110 Immunomodulation Effects

In this pre-clinical study of IMX-110 monotherapy in the genetic 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 19: IMX-110 Tissue-Specific Therapeutic™ with TME Normalization™ Technology Monotherapy Turns "Cold" Tumors "Hot" in Genetic (KPC) Pancreatic Cancer Pre-clinical Model



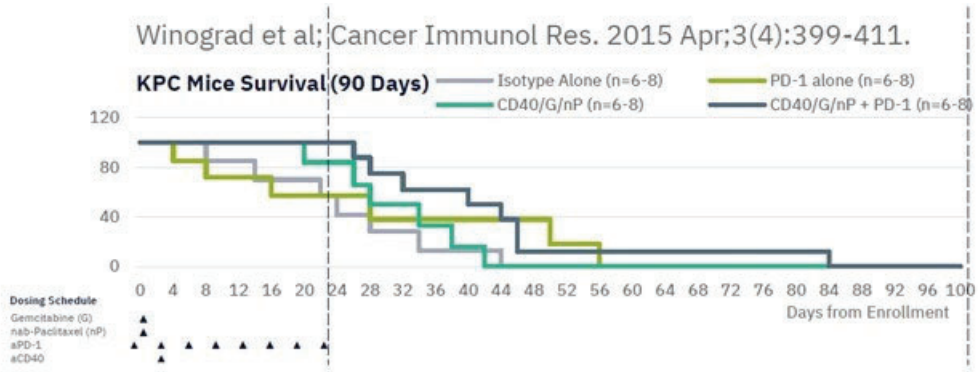
(See above paragraph for study description. ImmixBio unpublished results.)

IMX-110 + Anti-PD-1

In published literature, the effect of a combination of murine anti-PD-1, gemcitabine, nab-paclitaxel, and murine anti-CD40 was studied in a genetically engineered mouse model of pancreatic ductal adenocarcinoma (KPC), and produced median survival of 42 days.

The primary endpoint of the study was tumor growth inhibition as measured by tumor volume and weight. Mice were treated intraperitoneally (i.p.) with murine anti-PD-1 (RMP1-14; BioXcell; 200 mg/dose) on days 0, 3, 6, 9, 12, 15, 18, and 21 (after enrollment), with chemotherapy (gemcitabine + nab-paclitaxel) injected i.p. at 120 mg/kg (for each chemotherapeutic) on day 1, and agonistic anti-CD40 (FGK45; BioXcell; 100 mg injected on day 3. For isotype controls, rat IgG2a (2A3; BioXcell; 100 mg) and rat IgG2b (LTF-2; BioXcell; 200 mg/dose) were used (6-8 mice per group). Duration of survival was studied. We did not fund or sponsor this study, and we were not involved in this study or its publication.

Figure 20: 4 Drug Combination (Anti-PD-1, Anti-CD40, Gemcitabine, Nab-paclitaxel) Produced Median 42 day Survival in Genetic (KPC) Pancreatic Cancer Pre-clinical Model

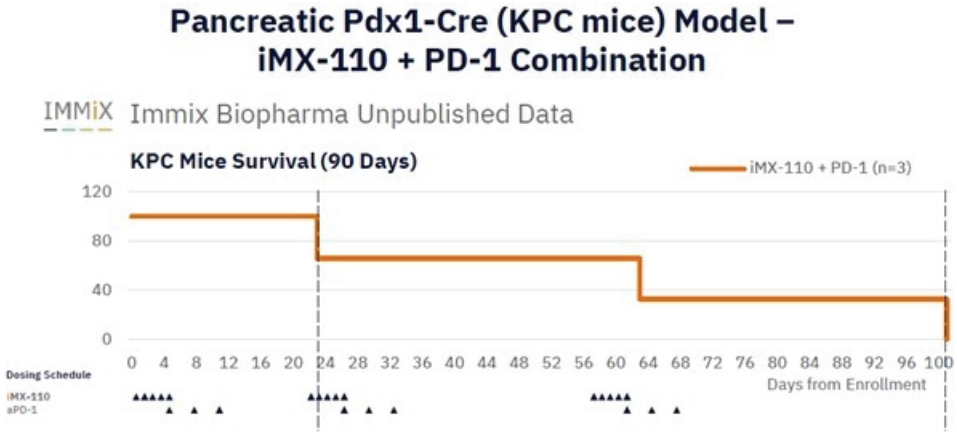


(See above paragraph for study description. Adapted from Winograd et al., 2015)

A combination of IMX-110 + murine anti-PD-1 in a pre-clinical study in a genetic pancreatic cancer (KPC) mouse model that we funded produced extended median survival of 63 days.

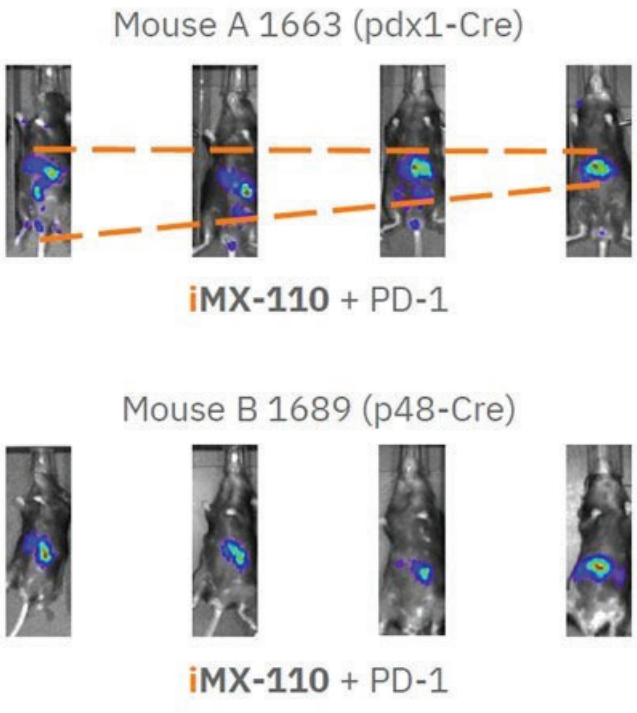
The primary endpoint of the study was tumor growth inhibition as measured by tumor volume and weight. Transgenic mice (Pdx1-Cre) were treated every day starting at day 0 (5 total tail vein injections) at a dose of 6 mg/kg CUR and 1.5 mg/kg DOX, and treated on days 5, 8, and 11 with murine anti-PD-1 (RMP1-14; BioXcell) 100µg/dose (three mice). This treatment was repeated started on day 21 and day 25. Duration of survival was studied. Tumors were periodically visualized using an *in vivo* luciferase assay. Our employees were involved in the design of this study and the results are unpublished. No adverse side effects of IMX-110 were observed as measured by lack of weight loss.

Figure 21: IMX-110 + Murine Anti-PD-1 Produced Extended Survival Produced Median 63 Day Survival in Genetic (KPC) Pancreatic Cancer Pre-clinical Model



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

In our genetic pancreatic cancer (KPC) mouse model study, luciferase assay visually demonstrated tumor shrinkage in the IMX-110 + anti-PD-1 combination group throughout the study.



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

We believe there exists significant potential for TSTx IMX-110 to be an integral component of combination therapies for a wide range of advanced solid tumors.

IMX-111 Tissue-Specific Biologic™ with TME Normalization™ Technology

IMX-111 Market Opportunity

The first potential indication we intend to pursue for IMX-111 is colorectal cancer ("CRC"). CRCs are cancers that arise from the colon, rectum and anus. According to American Cancer Society, there were roughly 153,020 new cases of colorectal cancer in the United States in 2023. Globally, there are roughly 1,930,000 new cases of colorectal cancer each year, of which 519,500 are in Europe, 148,500 are in Japan, 20,500 are in Australia and New Zealand, and 555,000 are in China. 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.

The colorectal cancer market is estimated to reach approximately $31.2 billion by 2025 from the estimated $26.3 billion in 2019. 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), and ramucirumab (marketed as Cyramza®, by Eli Lilly).

$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 the most recent available annual reports.

However, these therapies are either approved in combination with chemotherapies, or in a small subset of colorectal cancer patients.

Table 2: Select Drugs Used To Treat Advanced Colorectal Cancer

Drug	Comments
bevacizumab (Avastin®, Roche)	Approved in combination with 5-FU or 5-FY/LV chemotherapy
ramucirumab (Cyramza®, Eli Lilly)	Approved in combination with FOLFIRI chemotherapy
pembrolizumab (Keytruda®, Merck & Co.)	Unresectable/metastatic MSI-H or mismatch repair deficient metastatic CRC that have progressed following prior treatment and have no alternative options / MSI-H or dMMR CRC (<10% of metastatic CRC)
nivolumab (Opdivo®, Bristol Meyers Squibb)	Advanced MSI-H/dMMR CRC who have progressed following treatment with fluoropyrimidine, oxaliplatin and irinotecan (<10% of metastatic CRC)

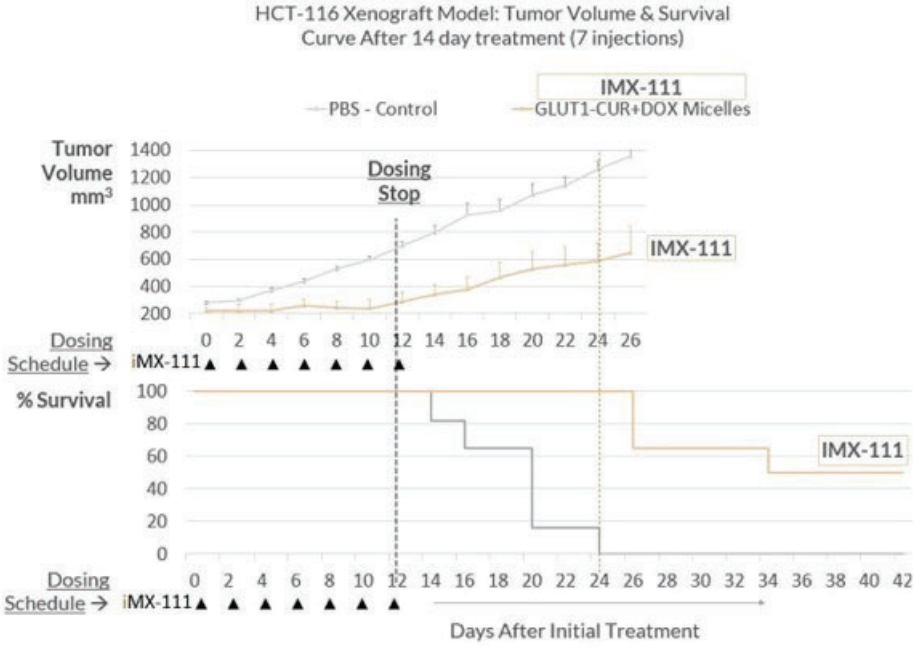
We intend to pursue IMX-111 for treatment of advanced colorectal cancer ("aCRC"), which includes all CRC diagnosed with regional, distant, and other staging, and includes approximately 63% of all patients newly diagnosed with CRC annually. Treatment of aCRC typically involves removal of sections of the colon (colectomy) or rerouting of the intestine by colostomy. Radiotherapy and chemotherapy, including the above drugs, are also used to treat aCRC patients.

IMX-111 Pre-clinical Data

We have funded and sponsored pre-clinical experiments to characterize the activity profile of IMX-111 in a range of solid tumor models, xenograft mouse models of various cancers, and *in vitro* with various cancer cell lines.

We observed that IMX-111 has statistically significantly inhibited tumor growth in a pre-clinical study that we funded and was conducted on an industry sponsored research basis in a HCT-116 colon cancer xenograft mouse model (which is poorly sensitive to doxorubicin). The primary endpoint of the study was tumor growth inhibition as measured by tumor volume, with the secondary endpoint being overall survival. Female nude (NU/NU) mice bearing 250mm^3 HCT-116 tumors were treated every 2 days starting at day 0 (7 total tail vein injections, arrows correspond to injection days) at a dose of 4 mg/kg CUR and 0.4 mg/kg DOX (six mice per dosing group). Survival was determined when the tumor reached 1000mm^3. Our employees were involved in the design of this study and Ilya Rachman, our Chief Executive Officer and Chairman of our board of directors, was a co-author of the results published in 2013. No adverse side effects of IMX-111 were observed as measured by lack of weight loss.

Figure 22: IMX-111 Tissue-Specific Biologic™ with TME Normalization™ Technology Statistically Significantly Inhibited Tumor Growth in HCT-116 Colorectal Cancer Pre-clinical Xenograft Model

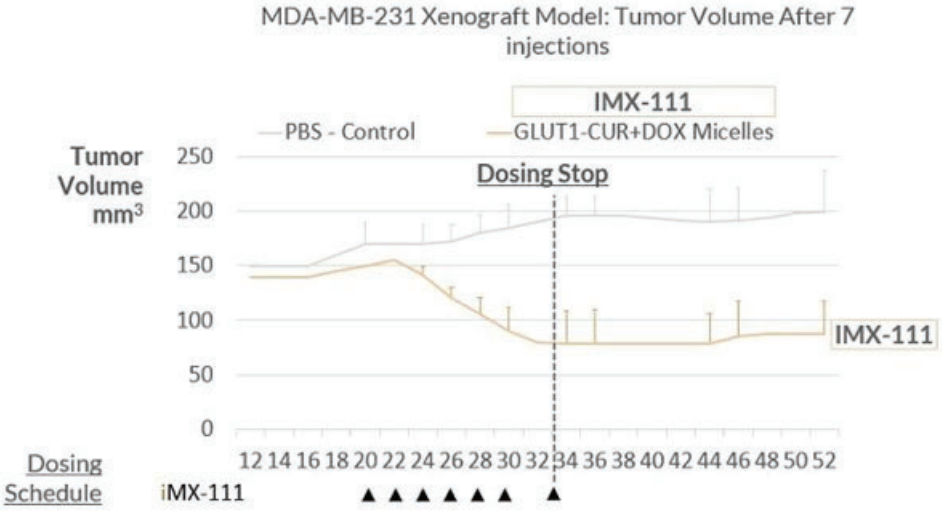


(See above paragraph for study description. Adapted from Abouzeid et al., 2013)

In this pre-clinical study of IMX-111 in the HCT-116 colorectal cancer xenograft mouse model, at day 24, 100% of mice treated with 1 cycle of low-dose IMX-111 were alive while all control animals were dead.

We observed that IMX-111 has statistically significantly inhibited tumor growth in a pre-clinical study that we funded and was conducted on an industry sponsored research basis in a MDA-MB-231 triple-negative breast cancer xenograft mouse model (which is poorly sensitive to doxorubicin). The primary endpoint of the study was tumor growth inhibition as measured by tumor volume, with the secondary endpoint being overall survival. Female nude (NU/NU) mice bearing 150mm^3 MDA-MB-231 tumors were treated every 2 days starting at day 20 except last injection administered at day 33 (7 total IV injections) at a dose of 6 mg/kg CUR and 1 mg/kg DOX (at least six mice per dosing group). Survival was determined when the tumor reached 1000mm^3. Our employees were involved in the design of this study and Ilya Rachman, our Chief Executive Officer and Chairman of our board of directors, was a co-author of the results published in 2014. No adverse side effects of IMX-111 were observed as measured by lack of weight loss.

Figure 23: IMX-111 Tissue-Specific Biologic™ with TME Normalization™ Technology Statistically Significantly Inhibited Tumor Growth in MDA-MB-231 Triple-Negative Breast Cancer Xenograft Model

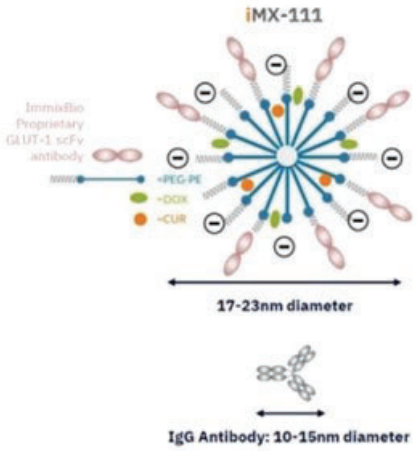


(See above paragraph for study description. Adapted from Abouzeid et al., 2014)

In this pre-clinical study of IMX-111 in the MDA-MB-231 triple-negative breast cancer xenograft mouse model, treatment with one cycle of low-dose IMX-111 resulted in 50% reduction in tumor mass, versus 33% growth in controls. The IMX-111 treatment effect lasted throughout the 52 day experiment duration.

IMX-111 Composition and Mechanism of Action

Figure 24: IMX-111 Tissue-Specific Biologic™ with TME Normalization™ Technology for CRC



IMX-111 is a Tissue-Specific Biologic™ built on our TME Normalization™ Technology with proprietary GLUT1 antibody biomarker targeting facilitating preferential accumulation in glucose-consuming cancer cells such as CRC. IMX-111 takes advantage of the fact that GLUT1 is an essential cancer biomarker that is overexpressed on 92% of colorectal cancer tumor cells and other tumor types. Furthermore, the degree of its overexpression correlates with more advanced stage of tumor progression. IMX-111 is the first cancer therapeutic to take advantage of this fact by coupling anti-GLUT1 antibody to our poly-kinase inhibitor / apoptosis inducer.

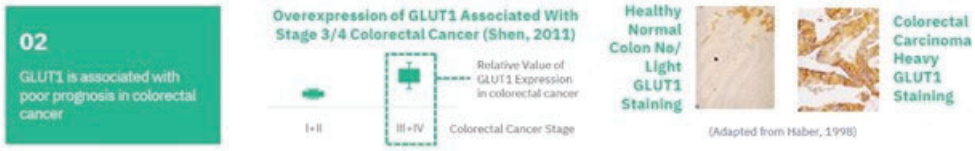
IMX-111 is 17-23 nanometers in diameter, which is just larger than the size of an IgG antibody.

Figure 25: IMX-111's Target GLUT1 is Overexpressed on Colorectal and Other Cancers

(Adapted from a review paper by Amann, et al., 2009. We did not fund or sponsor this study, and we were not involved in this study or its publication.)

GLUT1 is a glucose transporter which is overexpressed on 92% of CRC, making GLUT1 a prime biomarker for IMX-111 targeting in CRC.

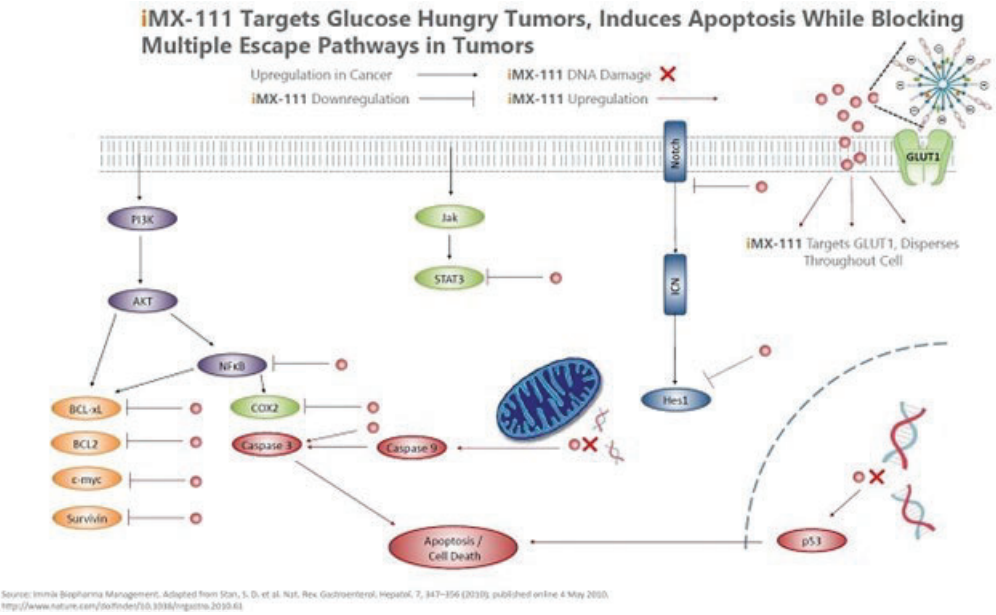
Figure 26: IMX-111's Target GLUT1 Overexpression is Associated with a Poor Prognosis



(Adapted from Shen, et al., 2011 and Haber, et al., 1998. Shen, et al.: Expression of GLUT1 in 163 primary patient colorectal cancer tumors was examined using real-time PCR. Haber, et al.: GLUT1 glucose transporter immunostaining was studied in normal colon and benign colon adenomas and in 112 colorectal carcinomas from patients with known clinical outcomes. We did not fund or sponsor these studies, and we were not involved in these studies or their publication.)

GLUT1 overexpression in CRC correlates with advanced, later stage (stage III-IV) disease. Heavy GLUT1 staining is observed in cancerous colorectal tissue versus healthy normal colon.

Figure 27: IMX-111 Tissue-Specific Biologic™ with TME Normalization™ Technology
Intracellular Mechanism of Action



Source: Immix Biopharma Management. Adapted from Stan, S. D. et al. Nat. Rev. Gastroenterol. Hepatol. 7, 347–356 (2010); published online 4 May 2010. http://www.nature.com/doifinder/10.1038/nrgastro.2010.61

Once IMX-111 enters the TME, consisting of: 1) CAFs, 2) TAMs/immune cells, and 3) cancer itself, it binds to its GLUT1 biomarker target and empties its poly-kinase inhibitor / apoptosis inducer payload into these cells, causing tumor apoptosis. Specifically, IMX-111 induces potent tumor killing by blocking multiple tumor escape pathways targeted by FDA approved targeted agents and targeted agents in development (see Table 1).

IMX-111 Development Strategy

We plan to conduct IND-enabling studies for IMX-111 in 2023 (completing in in the first half 2024), pursuing advanced colorectal cancer as the initial indication. We anticipate filing an IND for IMX-111 in in the first half 2024. We plan to initiate a Phase 1b/2a study with IMX-111 in solid tumors in the United States and Australia, with the first patient anticipated to be dosed in 2024. We plan for IMX-111 to pursue advanced colorectal cancer as its initial indication.

IMX-120 Tissue-Specific Biologic™ with Immune Normalization Technology™ for inflammatory bowel disease

IMX-120 Market Opportunity

The first potential indications we intend to pursue for IMX-120 are ulcerative colitis ("UC") and severe Crohn's disease ("CD"), which are both forms of inflammatory bowel disease ("IBD"). IBD is estimated to affect over 2,000,000 people in the United States and over 5,000,000 people globally. IBD is a complex gastrointestinal disease caused primarily by a dysregulated immune system.

Drugs used to treat IBD include adalimumab (marketed as Humira®, by Abbvie), ustekinumab (marketed as Stelara®, by Janssen/Johnson& Johnson), and vedolizumab (marketed as Entyvio®, by Takeda).

$36.27 billion is the total publicly disclosed combined annual sales of adalimumab (Humira®), ustekinumab (Stelara®), and vedolizumab (Entyvio®, Takeda) according to the most recent available annual reports.

Endpoints for clinical trials in IBD are measured in terms of remission rates at 4-8 weeks post treatment.

For adalimumab (Humira®), in a study of moderate-to-severe UC who received concurrent treatment with oral corticosteroids or immunosuppressants, overall rates of clinical remission at week 8 were 16.5% on adalimumab and 9.3% on placebo, according to Sandborn et al., 2012.

For ustekinumab (Stelara®), in a study of moderate-to-severe UC, overall rates of clinical remission at week 8 were 15.6% on 130mg intravenous ustekinumab and 5.3% on placebo, according to Sands et al., 2019.

For vedolizumab (Entyvio®), in a study of moderately to severely active UC, overall rates of clinical remission at week 6 were 17% on vedolizumab and 5% on placebo, according to the FDA Entyvio® Prescribing Label.

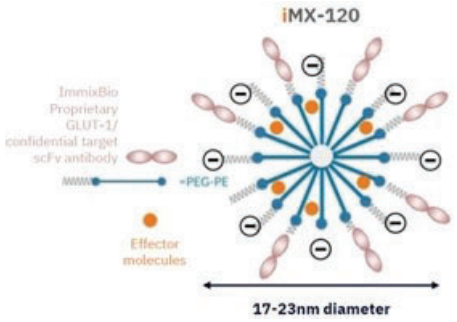
UC and CD are two of the most common forms of IBD. Both UC and CD are chronic, relapsing, remitting, inflammatory conditions of the gastrointestinal tract that begin most commonly during adolescence and young adulthood. UC involves the innermost lining of the large intestine, and symptoms include abdominal pain and diarrhea, frequently with blood and mucus. CD can affect the entire thickness of the bowel wall and all parts of the gastrointestinal tract from mouth to anus. CD symptoms include abdominal pain, diarrhea, and other more systemic symptoms such as weight loss, nutritional deficiencies, and fever.

The current standard of care for the treatment of patients with moderate-to-severe IBD is typically anti-inflammatory agents. The majority of IBD patients do not respond to first-line anti-tumor necrosis factor agents. The approvals of the first anti-tumor necrosis factor agent for the treatment of CD in 1998 and newer biological agents, including anti-integrin and anti-IL12/23, have improved the care of moderate-to-severe IBD.

However, these subsequently approved therapies in UC have generally failed to demonstrate a clinical remission effect size of more than 15% relative to placebo. Moreover, among those patients who do respond to therapy, up to 50% will lose response over time. Additionally, the markets for UC and CD represent a high unmet need patient population. Only 2 out of 5 UC patients are on advanced therapy.

IMX-120 Composition and Mechanism of Action

Figure 28: IMX-120 Tissue-Specific Biologic™ with Immune Normalization Technology™ for Inflammatory Bowel Disease



IMX-120, built on our SMAR$_x$T Tissue-Specific™ Platform with shared CMC and design elements with our other drug candidates, is a Tissue-Specific Biologic™ with proprietary GLUT1/confidential target antibody encapsulating polyphenol poly-kinase inhibitors selectively silencing disease-causing inflammatory bowel immune cells.

Driving inflammatory bowel disease are the interactions between 3 components of the immune synapse: 1) gut-lining enterocytes, 2) gut microbes, and 3) gut-resident immune cells. Cellular contacts and signaling molecules exchanged between these components activate abnormal inflammatory responses in immune cells driving a self-sustaining feed-forward loop of pathological inflammation in gastrointestinal tissues. Through simultaneous repression of pathological inflammatory signaling in all of these components at the same time, Immune Normalization™ Technology halts this self-sustaining feed-forward loop propagated among these 3 components, addressing the root cause of inflammatory pathologies.

IBD is caused by a dysregulated, chronic, pathological immune response by bowel immune cells to the microbiome and other components of the gastrointestinal cellular environment. In the process of becoming dysregulated, cytotoxic T-cells and macrophages secrete signaling cytokines, resulting in a self-sustaining feed-forward loop of inflammation. Similar to tumor growth, these inflammatory processes active in IBD are caused by recurring waves of activation of multiple kinases that upregulate NF-κB, STAT3 and other key transcriptional factors.

IMX-120 takes advantage of the fact that overexpression and activation of GLUT1 on overactive immune cells has been shown to be widely present in patients with IBD. IMX-120's polyphenol poly-kinase inhibitors block upstream kinase signal transduction systems that activate NF-κB and STAT3, thus shutting down the self-sustaining feed-forward loop of inflammation. GLUT1 presents an ideal targeting moiety for these overactive immune cells, allowing for tissue-specific delivery of IMX-120.

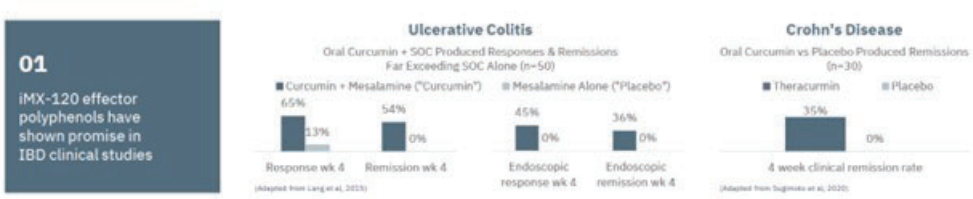
Curcuminoid polyphenols have been generally well-tolerated in multiple clinical trials, two of which are summarized below.

In a randomized, multi-center placebo-controlled, double-blind study of 50 mesalamine-treated patients with active mild-to-moderate ulcerative colitis (UC) (defined by the Simple Clinical Colitis Activity Index, or SCCAI) who did not respond to an additional 2 weeks of the maximum dose of mesalamine oral and topical therapy, patients were randomly assigned to groups who were given curcumin capsules (3 g/day, n = 26) or an identical placebo (n = 24) for 1 month, with continued mesalamine. The primary endpoint was the rate of clinical remission (SCCAI <=2) at week 4. Clinical and endoscopic responses were also recorded. The incidence of adverse effects was not significantly different between the 2 arms. The primary results of the trial at 4 weeks are outlined in the figure below (left hand side).

In a randomized, double-blinded study performed at 5 independent medical centers in Japan, curcuminoid Theracurmin (360 mg/day, 20 patients) or placebo (10 patients) was administered to patients with active mild-to-moderate Crohn's disease (CD) for 12 weeks. The agent's clinical activity was assessed by evaluating clinical and endoscopic remission, healing of anal lesions, and blood levels of inflammatory markers. The primary endpoint was the difference in Crohn's disease activity index, or CDAI, improvement between the Theracurmin and placebo groups when comparing week 12 to week 0. No serious adverse events were observed in either group throughout the study. The primary results of the trial at 4 weeks are outlined in the figure below (right hand side).

For both studies, because of the lack of previous data on the subject, a formal power analysis calculation of sample size was not performed. Also for both studies, $P < 0.05$ was considered statistically significant. For all results below, p values of differences between placebo and treatment group was < 0.05. We did not fund or sponsor these studies, and we were not involved in these studies or their publications.

Figure 29: Polyphenols have Shown Promise in Both Ulcerative Colitis and Crohn's

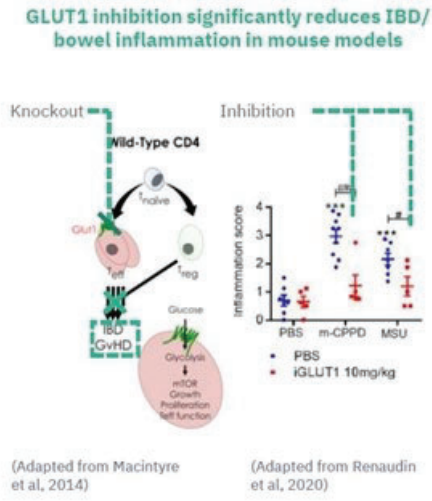


(Adapted from Lang, et al., 2015 and Sugimoto et al., 2020. See above paragraphs for study descriptions)

Despite an almost complete lack of bioavailability in oral form, a polyphenol (curcumin) showed signs of clinical activity in a 50 patient UC study, with >50% remission rate in the treatment arm at week 4 compared to a 0-13% remission rate in a control group at week 4. In a 30 patient CD study, a polyphenol (theracurmin) produced a 35% clinical remission rate in the treatment arm at week 4 compared to 0% in a control group at week 4.

With IMX-120's proprietary GLUT1 targeting, we believe the potential for IMX-120 in IBD is favorable.

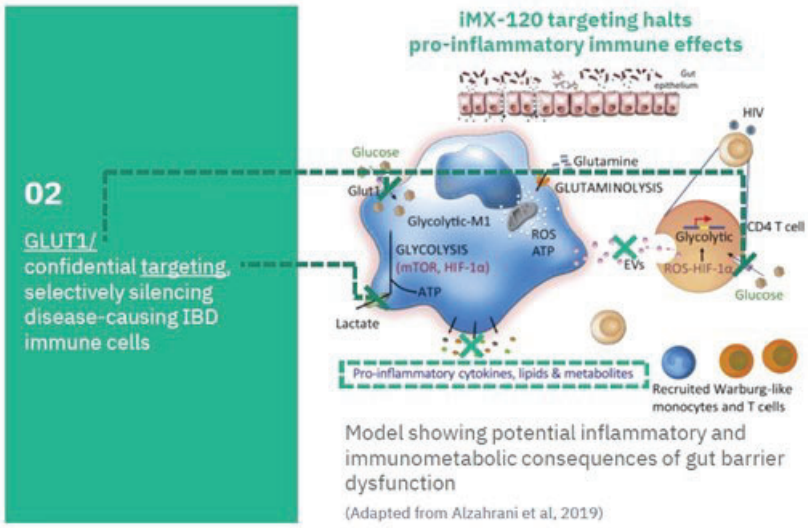
Figure 30: GLUT1 Targeting Significantly Reduces IBD Inflammation in *in vitro* Models



(Adapted from Macintyre et al., 2014 and Renaudin et al., 2020. See below paragraph for study descriptions. We did not fund or sponsor these studies, and we were not involved in these studies or their publications.)

In inflammatory bowel disease in mice, GLUT1 appears to be required for metabolic reprogramming of CD4 T cells into T effector cells that are critical for induction of disease-causing inflammation (above figure left hand side graphical abstract). In mice, GLUT1 inhibition results in the reduction of global tissue inflammatory score observed by hematoxylin and eosin (HE) staining (above figure right hand side).

Figure 31: IMX-120 Silences Disease Causing Inflammatory Bowel Immune Cells



(Illustrative figure adapted from Alzahrani, et al., 2019. We did not fund or sponsor this study, and we were not involved in this study or its publication.)

IMX-120 targets GLUT1 and a second proprietary target that were described in the literature as key activators of overactive immune response, that are expected to allow IMX-120 to selectively silence disease-causing, overactive inflammatory bowel immune cells with its polyphenol poly-kinase inhibitors.

IMX-120 Development Strategy

We plan to conduct IND-enabling studies for IMX-120 in 2023 (completing in the first half of 2024), pursuing ulcerative colitis and severe Crohn's disease indications. We anticipate filing an IND for IMX-120 in the first half of 2024. We plan to initiate a Phase 1b/2a study with IMX-120 in IBD in the United States and Australia with the first patient anticipated to be dosed in 2024. We plan for IMX-120 to pursue UC and severe CD indications.

NEXCELLA – CELL THERAPIES FOR HEMATOLOGIC MALIGNANCIES

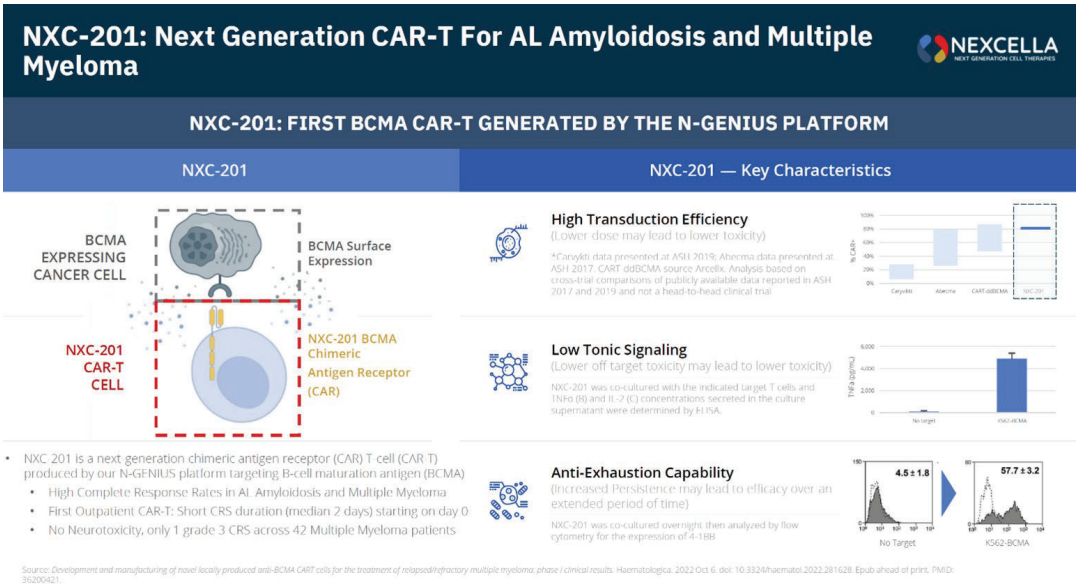
Overview of Nexcella

Nexcella, Inc, our majority-owned subsidiary, is a clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications. We believe cell therapies are one of the forward pillars of medicine, and our mission is to harness the power of cell therapies to rapidly engineer safe, effective, accessible treatments to improve patient outcomes in oncology and other indications. Our N-GENIUS cell engineering platform with EXPAND technology has already produced clinical-stage NXC-201, which we believe is the first outpatient autologous chimeric antigen receptor T-cell therapy ("CAR-T"). Autologous cells refer to the patient's own cells (versus allogeneic, which refers to another person's cells). NXC-201 targets B-cell maturation antigen ("BCMA") for multiple myeloma ("MM") and AL amyloidosis ("ALA"). Though CAR-T cell therapies have shown benefits to date, they have historically faced barriers to adoption due to prolonged hospitalization with frequent intensive care unit ("ICU") stays due to unpredictable onset and duration of immune effector cell-associated neurotoxicity syndrome ("ICANS") neurotoxicity and grade 3 and 4 cytokine release syndrome ("CRS"), leading to a 15-day median hospital stay for CAR-T treatments today. NXC-201 has already demonstrated class-leading 90% overall response rates, 59% complete response rates, and favorable tolerability in MM (exemplified by no ICANS neurotoxicity over 42 multiple myeloma patients). According to the National Cancer Institute, "overall response" refers to "the percentage of patients whose cancer shrinks or disappears after treatment" and "complete response" refers to "the disappearance of all signs of cancer in response to treatment." Additionally, 8 ALA patients have also been treated by NXC-201 to-date with a 100% hematologic complete response rate, of which 5 published patients demonstrated 100% hematologic complete response rate and 100% cardiac, liver, and renal organ system response rate. Based on NXC-201 short (median onset day 1, median duration 2 day) low-grade CRS, we believe NXC-201 could require only a 2-3 day hospital stay, potentially reducing hospital stay costs by 80-87% and make NXC-201 the first and only potential outpatient CAR-T in development. Additionally, outpatient treatment could create a much larger accessible market/wider access for NXC-201 (99% of CAR-T today is administered in large academic medical centers, which account for only 5% of medical centers by count today in the US).

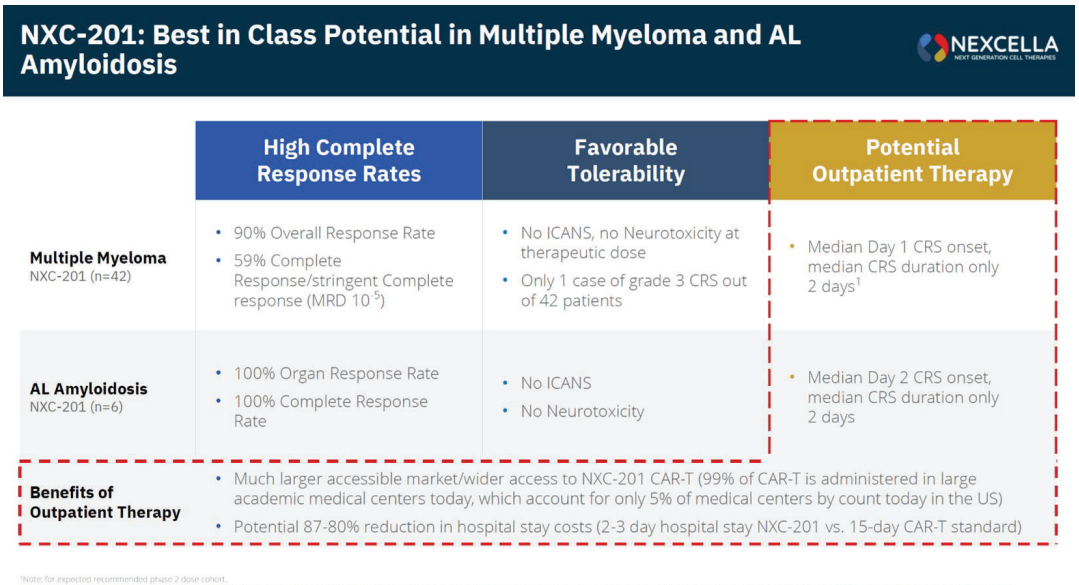
We estimate the current market size for multiple myeloma therapies is $18 billion, expected to reach $29 billion in 2027, according to Wilcock, et al. *Nature Reviews*. The Amyloidosis market was $3.6 billion in 2017, expected to reach $6 billion in 2025.

We believe our N-GENIUS platform with EXPAND technology will allow us to treat additional BCMA-positive indications such as chronic lymphocytic leukemia ("CLL"), follicular lymphoma ("FL"), Waldenstrom's macroglobulinemia, and B-cell lymphoma with NXC-201. We believe our platform will also accelerate the development of CAR-T NXC-301 for acute lymphoblastic leukemia ("ALL"), large B-Cell lymphoma ("LBCL") and mantle cell lymphoma ("MCL"), as well as NXC-401 for Acute myeloid leukemia ("AML"). We plan to treat oncology and other indications.

Our Lead Product Candidate (Nexcella)

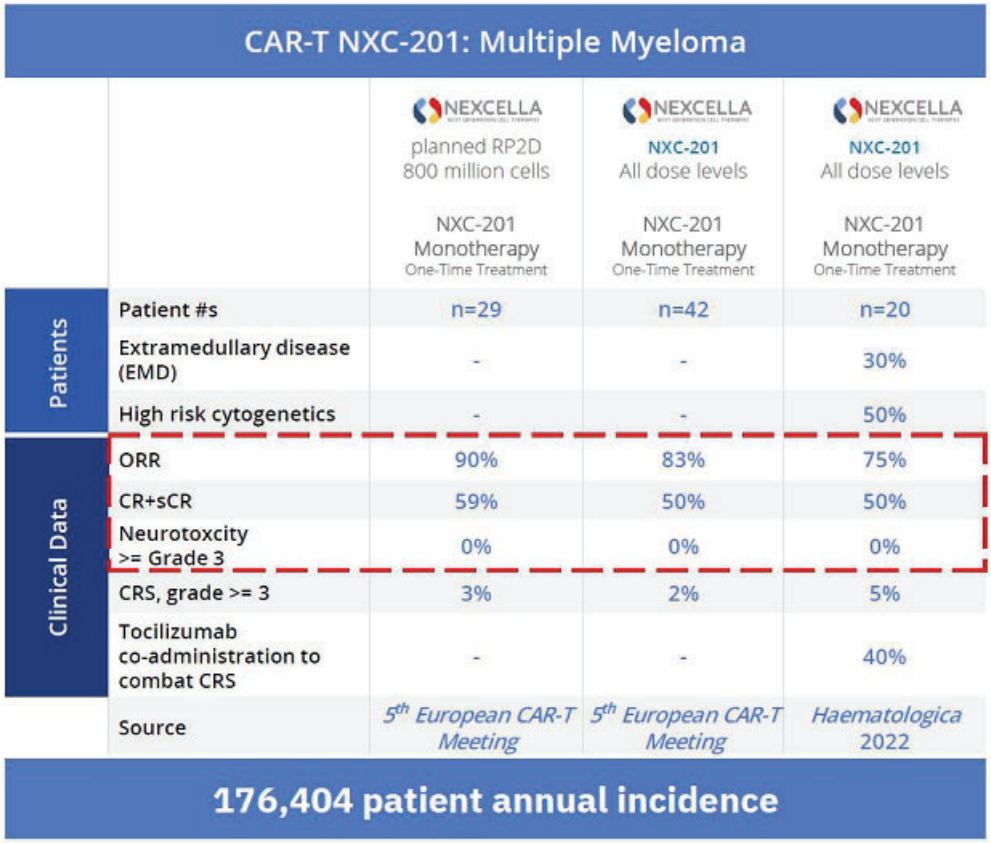


NXC-201, currently in Phase 1b/2a clinical trials for relapsed or refractory ("r/r") MM and relapsed or refractory (r/r) ALA, is a next generation autologous CAR-T targeting BCMA. BCMA is a highly expressed protein in a number of hematologic malignancies including MM. When an antigen such as BCMA is expressed on cancer cells, NXC-201 is able to target and kill those cancer cells, sparing healthy tissue. BCMA has been shown to be over-expressed on MM, LBCL, CLL, ALA and other plasma cell dyscrasia diseased cells.



NXC-201 Multiple Myeloma Clinical Data To-Date

Published in *Haematologica* in 2022 and presented at the 5th European CAR T-cell Meeting, we recently announced positive interim results for the 42 patients enrolled in our ongoing NEXTIVATE-1 (NCT04720313) Phase 1b/2a clinical trial of NXC-201, our lead product candidate, for the treatment of patients with relapsed or refractory (r/r) MM. As of the October 23, 2022 data cutoff date, based on median follow-up of 146 days (range, 18-314), clinical data is presented below. These data comprised the dose escalation cohorts for the first dose level (DL1) (150 million CAR+ T cells, n=6), the second dose level (DL2) (450 million CAR+ T cells, n=7), and the third, therapeutic dose level (DL3) (800 million CAR+ T cells, n=29).

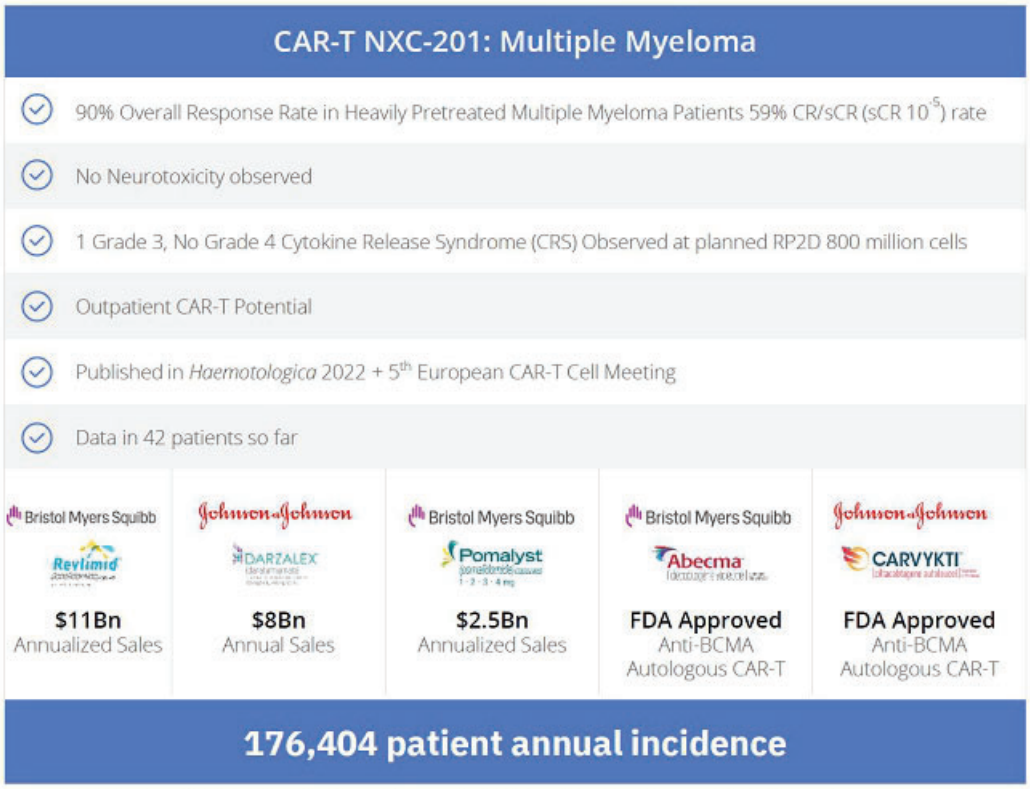


Source: *Development and manufacturing of novel locally produced anti-BCMA CART cells for the treatment of relapsed/refractory multiple myeloma: phase I clinical results.* Haematologica. 2022 Oct 6. doi: 10.3324/haematol.2022.281628. Epub ahead of print. PMID: 36200421. *Point-of-care CART manufacture and delivery: Expanding access to CART therapy via local institutions, Hadassah Medical Center experience.* Poster Presentation, European Society for Blood and Marrow Transplantation and European Hematology Association 5th European CAR T-cell Meeting. 2023 Feb 9-11.

Key highlights from the MM data presented are as follows:

- 90% overall response rate ("ORR") was observed in 29 multiple myeloma patients receiving the therapeutic dose of NXC-201
- 17 of 29 (59%) of patients receiving the therapeutic dose reached complete response ("CR") or stringent complete response ("sCR")
- CRS was manageable and no neurotoxicity was observed
- The therapeutic dose of NXC-201 (800 million CAR+T cells) has been established as the recommended Phase 2 dose ("RP2D")
- Data supports investigating NXC-201 as the first potential outpatient CAR-T cell therapy
- No patients in the clinical trial experienced Grade 4 CRS
- Just 1 patient in the clinical trial experienced Grade 3 CRS
- The longest response in the clinical trial so far was over 11 months

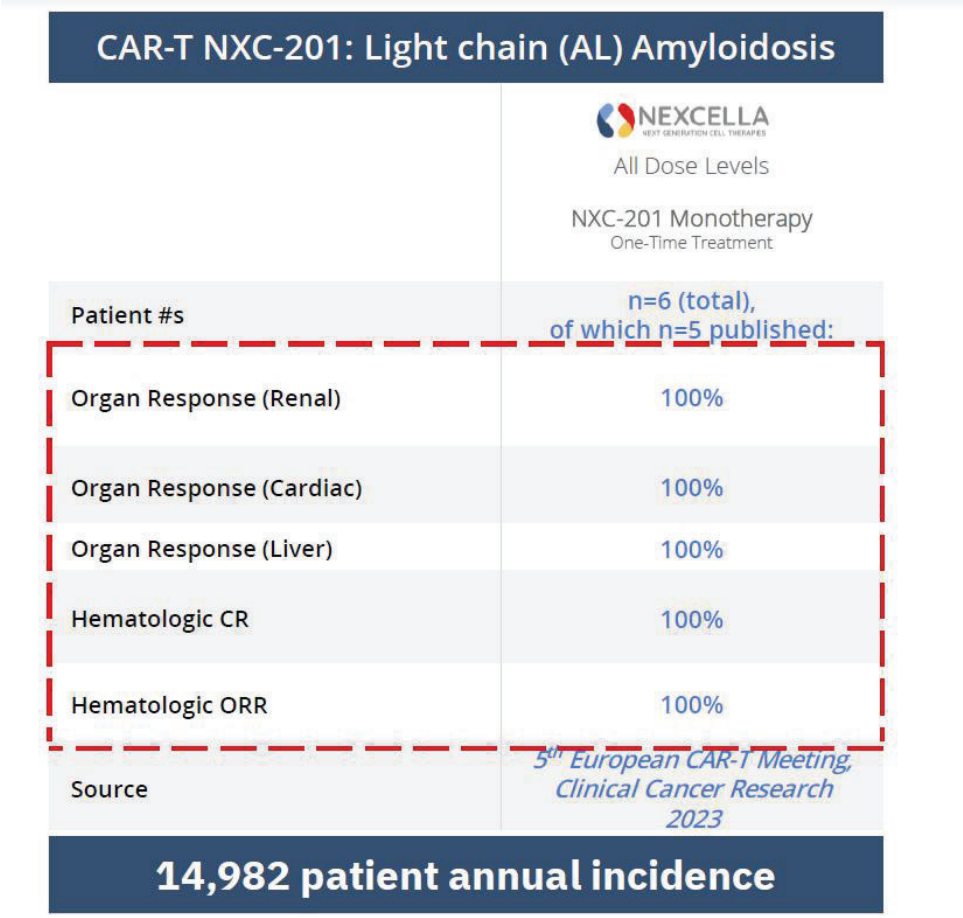
All 42 patients treated as of the October 23, 2022 were triple-class refractory (to at least 1 immunomodulatory drug, 1 proteasome inhibitor and 1 anti-CD38 antibody).



Source: BMS First Quarter 2022 financial results; 'Genmab Improves Its 2022 Financial Guidance' November 3 2022, Celgene Second Quarter 2019 Operating and Financial Results., *Development and manufacturing of novel locally produced anti-BCMA CART cells for the treatment of relapsed/refractory multiple myeloma: phase I clinical results.* Haematologica. 2022 Oct 6. doi: 10.3324/haematol.2022.281628. Epub ahead of print. PMID: 36200421, Point-of-care CART manufacture and delivery: Expanding access to CART therapy via local institutions, Hadassah Medical Center experience. Poster Presentation, European Society for Blood and Marrow Transplantation and European Hematology Association 5th European CAR T-cell Meeting. 2023 Feb 9-11.

NXC-201 AL Amyloidosis Clinical Data To-Date

8 ALA patients have been treated by NXC-201 to-date with a 100% hematologic complete response rate, of which, 4 were Published in Clinical Cancer Research in 2022 and presented at the 5th European CAR T-cell Meeting. We recently published positive interim results for the first 5 patients enrolled in our ongoing clinical trial of NXC-201, our lead product candidate, for the treatment of patients with ALA.



Source: *Development and manufacturing of novel locally produced anti-BCMA CART cells for the treatment of relapsed/refractory multiple myeloma: phase I clinical results.* Haematologica. 2022 Oct 6. doi: 10.3324/haematol.2022.281628. Epub ahead of print. PMID: 36200421., *Point-of-care CART manufacture and delivery: Expanding access to CART therapy via local institutions, Hadassah Medical Center experience.* Poster Presentation, European Society for Blood and Marrow Transplantation and European Hematology Association 5th European CAR T-cell Meeting. 2023 Feb 9-11.

As of the October 23, 2022 cutoff for 5 patients treated with NXC-201 with r/r ALA:

- 100% organ response rate:
  - 100% organ response rate (cardiac)
  - 100% organ response rate (renal)
  - 100% organ response rate (kidney)
- 100% complete responses (MRD negativity 10^{-5}) were produced by NXC-201.

These data comprised the dose escalation cohorts for the first dose level (DL1) (150 million CAR+ T cells, n=1), the second dose level (DL2) (450 million CAR+ T cells, n=2), and the third, therapeutic dose level (DL3) (800 million CAR+ T cells, n=2).

Detailed information is available in our *Clinical Cancer Research* publication for the first 4 ALA patients treated with NXC-201. As of the February 26, 2022 publication date, based on median follow-up of 5.2 months, key highlights are as follows:

- 100% organ response rate:
  - 100% organ response rate (cardiac)
  - 100% organ response rate (renal)
  - 100% organ response rate (kidney)
- 100% achieved CR (MRD negativity 10^{-5})
- 2-stage improvement in New York Heart Association (“NYHA”) Heart Failure Stage was observed with NXC-201
- Mean 65% reduction (2,656pg/mL) in NT-proBNP from baseline

- No patients experienced ICANS neurotoxicity
- No patients experienced Grade 4 CRS

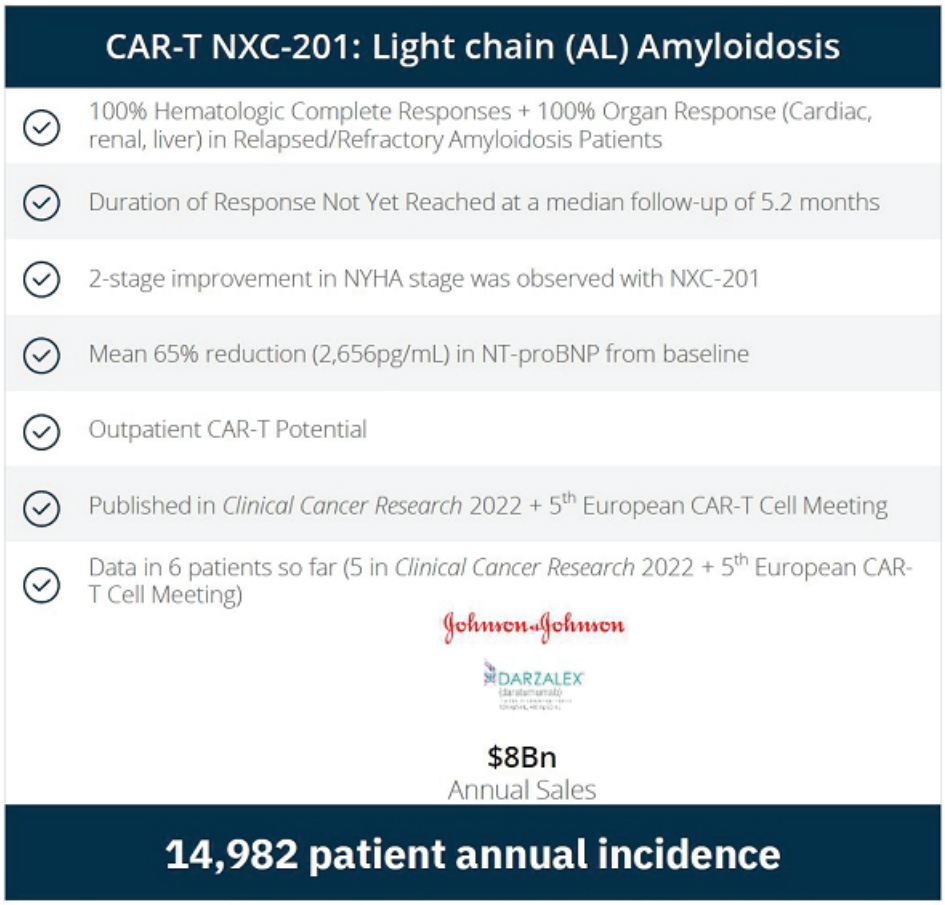
Of the 4 patients in the ongoing AL amyloidosis clinical trial as of the February 26, 2022 publication date, of the patients with NYHA stage> 2, 1 was stage 4, and 2 were stage 3. After treatment with NXC-201, the stage 4 patient improved to stage 2, and both of the stage 3 patients also improved to stage 2.

	Dose Level	Patient 1 $150x10^6$	Patient 2 $450x10^6$	Patient 3 $800x10^6$	Patient 4 $450x10^6$
Pre-treatment	NYHA Stage	3	4	1	3
Post-treatment	NYHA Stage	2	2	1	2
NXC-201 Treatment Effect	**NYHA Stage Reduction**	**-1**	**-2**	**-**	**-1**

In the ongoing AL amyloidosis clinical trial, N-terminal (NT)-pro hormone BNP (NT proBNP) (pg/mL) levels were reported. According to the Cleveland Clinic, for patients above 50 years of age, >900 NT proBNP (pg/mL) could mean heart function is unstable. Of the 4 patients in the ongoing AL amyloidosis ALA clinical trial as of the February 26, 2022 publication date, 3 had pre-treatment NT proBNP levels of 7,500, 2,800 and 2,773, respectively, which were reduced to 2,700 (4,800 point reduction), 1,505 (1,295 point reduction) and 901 (1,872 point reduction) (units: pg/mL), respectively, after treatment with NXC-201.

	Dose Level	Patient 1 $150x10^6$	Patient 2 $450x10^6$	Patient 3 $800x10^6$	Patient 4 $450x10^66$	**Mean**
	Age	64	58	82	63	-
Pre-treatment	NT ProBNP (pg/mL)	7,500	2,800	119	2,773	-
Post-treatment	NT ProBNP (pg/mL)	2,700	1,505	-	901	-
NXC-201 Treatment Effect	**NT ProBNP absolute reduction (pg/mL)**	**-4,800**	**-1,295**	**-**	**-1,872**	**-2,656**
NXC-201 Treatment Effect	**NT ProBNP percentage reduction (pg/mL)**	**-64%**	**-46%**	**-**	**-68%**	**-65%**

In our ongoing AL amyloidosis clinical trial, N-terminal (NT)-pro hormone BNP (NT proBNP) (pg/mL) levels were reported. According to the Cleveland Clinic, for patients above 50 years of age, NT proBNP >900 (pg/mL) could mean heart function is unstable. Of the 4 patients in the ongoing AL amyloidosis clinical trial as of the February 26, 2022 publication date, 3 had pre-treatment NT proBNP levels of 7,500, 2,800 and 2,773, respectively, which were reduced to 2,700 (4,800 point reduction), 1,505 (1,295 point reduction) and 901 (1,872 point reduction) (units: pg/mL), respectively, after treatment with NXC-201.



Source:; "Genmab Improves Its 2022 Financial Guidance' November 3 2022, Celgene Second Quarter 2019 Operating and Financial Results, Feasibility of a Novel Academic BCMA-CART (HBI0101) for the Treatment of Relapsed and Refractory AL Amyloidosis. Clin Cancer Res. 2022 Dec 1;28(23):5156-5166. doi: 10.1158/1078-0432.CCR-22-0637. PMID: 36107221., Point-of-care CART manufacture and delivery: Expanding access to CART therapy via local institutions, Hadassah Medical Center experience. Poster Presentation, European Society for Blood and Marrow Transplantation and European Hematology Association 5th European CAR T-cell Meeting. 2023 Feb 9-11.

NXC-201: Potentially The First Outpatient CAR-T

We believe NXC-201 is the first and only potential next-generation CAR-T treatment that could be delivered as an outpatient treatment.

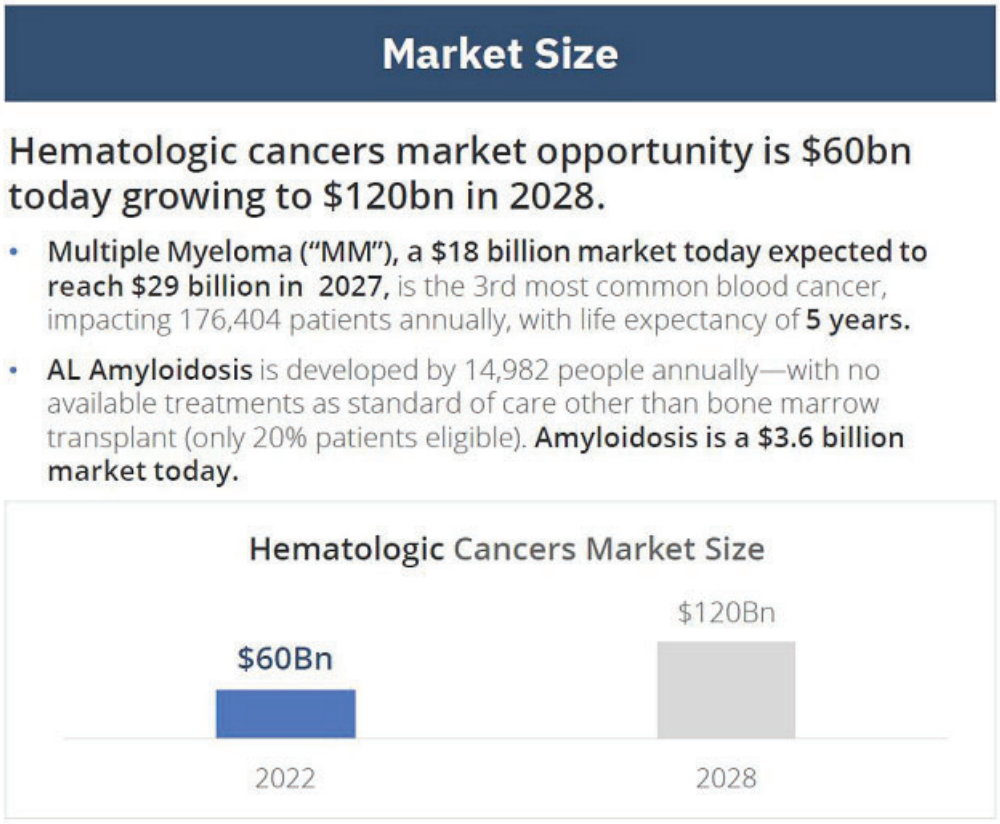
Outpatient therapy may enable NXC-201 to address a much larger accessible market/wider access to NXC-201 CAR-T therapy (99% of CAR-T today is administered in large academic medical centers, which account for only 5% of medical centers by count today in the US). Additionally, NXC-201 treatment may result in an 80-87% reduction in hospital stay costs (2-3 day hospital stay NXC-201 vs. 15-day CAR-T standard).

In multiple myeloma, as of the October 23, 2022 data cutoff, low-grade CRS duration of median 2 days at therapeutic dose (range: 1-7 days) (n=42) points to NXC-201 potentially becoming the first and only out-patient CAR-T for Multiple Myeloma and other BCMA-positive malignancies.

In AL amyloidosis, as of the October 23, 2022 publication date, no grade 4 CRS was observed, and CRS duration of median 4 days at therapeutic dose (range: 1-5 days) (n=5) points to NXC-201 potentially becoming the first and only out-patient CAR-T for AL Amyloidosis.

Our Market Opportunity (Nexcella)

The hematologic cancer market size is $60 billion today, growing to $120 billion in 2028.



Sources: Multiple Myeloma life expectancy source - Arcellx July 2022 Investor presentation (NADSAQ:ACLX). Multiple myeloma annual incidence source: GLOBOCAN 2020. Hematologic cancers market size source: reportsanddata.com. AL Amyloidosis annual incidence source: Global epidemiology of amyloid light-chain amyloidosis https://doi.org/10.1186/s13023-022-02414-6. AL Amyloydosis transplant eligibility source: Bone Marrow Transplant. 2013 Oct;48(10):1302-7. doi: 10.1038/bmt.2013.53
Wilcock, et al. *Nature Reviews*, Grand View Research.

NXC-201 – Multiple Myeloma

We estimate the current market size for multiple myeloma therapies is $18 billion, expected to reach $29 billion in 2027, according to Wilcock, et al. *Nature Reviews*.

Multiple myeloma ("MM") is an incurable blood cancer of plasma cells that starts in the bone marrow and is characterized by an excessive proliferation of these cells. Despite initial remission, unfortunately, most patients are likely to relapse. There are 34,470 patients in the United States diagnosed with MM each year. Prognosis for patients who do not respond to or relapse after treatment with standard therapies, including protease inhibitors and immunomodulatory agents remains poor.

MM is the third most common hematological malignancy in the United States and Europe, representing approximately 10% of all hematological cancer cases, 20% of deaths due to hematological malignancies and impacting over 100,000 patients globally each year. The Surveillance, Epidemiology, and End Results ("SEER") Program database projects that approximately 35,000 new cases of MM in the United States and over 35,000 new cases in six select markets within Europe and Asia.

In 2021, the FDA approved idecabtagene vicleucel (marketed as ABECMA® by Bristol Myers Squibb), at the time the only BCMA-targeted CAR-T for multiple myeloma. ABECMA® was approved based on a 100-patient, open-label MM study which resulted in a complete response rate of 28% and >= Grade 3 neurotoxicity of 8% at the therapeutic dose, according to the ABECMA® FDA approval label.

In December 2022, Gilead paid $225 million upfront and invested $100 million in Arcellx, Inc. in exchange to equally share profits of CART-ddBCMA, a BCMA-targeted CAR-T for multiple myeloma. CART-ddBCMA was evaluated in a clinical trial in which 19 patients were treated at the therapeutic dose, which resulted in a complete response rate of 71%, and >= Grade 3 neurotoxicity of 4%, according to Arcellx, Inc.

NXC-201 – AL amyloidosis

We estimate the current market size for amyloidosis therapies is $3.6 billion, expected to reach $6 billion in 2027.

ALA is a rare systemic disorder caused by an abnormality of plasma cells in the bone marrow. Misfolded amyloid proteins produced by plasma cells cause buildup in and around tissues, nerves and organs, gradually affecting their function. This can cause progressive and widespread organ damage, and high mortality rates.

ALA affects roughly 30,000 – 40,000 patients in total throughout the U.S. and Europe, and it is estimated that there are approximately 3,000 – 4,000 new cases of AL amyloidosis annually in the U.S., though actual incidence is likely higher as a result of under-diagnosis. Amyloidosis has a one-year mortality rate of 47 percent, 76 percent of which is caused by cardiac amyloidosis.

ALA remains a high unmet need disease with just one FDA approved therapy in the last two decades - daratumumab.

In 2021, the FDA approved daratumumab (marketed as DARZALEX® by Janssen/Johnson & Johnson), which is the only FDA approved therapy for AL amyloidosis. Daratumumab (DARZALEX®) was trialed in an ALA study where daratumumab was combined with cyclophosphamide + bortezomib + dexamethasone in a 4-drug combination, which produced a 53% hematologic complete response rate with a 42% organ response rate (cardiac) according to Kastritis, et al., 2021.

Why Now?

- We are leveraging market CAR-T experience so far—manufacturing consistency, automation technology, efficacy, tolerability.
- Demand for MM CAR-Ts continues to exceed supply – there are currently only 2 MM CAR-Ts on the market.
- Still common with approved CAR-Ts: High grade Cytokine Release Syndrome (> grade 3) and neurotoxicity side-effects.
- Bi-specifics/Allogeneic CAR-Ts still work in progress.

Why Now

1. Leveraging market CAR-T experience so far—manufacturing consistency, automation technology , efficacy, safety.

2. Demand for MM CAR-Ts continues to exceed supply - only 2 MM CAR-Ts on the market:

"Patients With Multiple Myeloma May Face CAR T-Cell Shortages"
The ASCO Post Sep 25, 2022

"Gilead lands new cell therapy for Kite in $225M Arcellx deal, providing global scale for future J&J-Legend showdown"
Dec 9, 2022
FIERCE Biotech

Bristol Myers Squibb Abecma CARVYKTI

3. Still common with approved CAR-Ts: High grade Cytokine Release Syndrome (> grade 3) and neurotoxicity side-effects.

4. Bispecifics/Allogeneic CAR-Ts still work in progress.

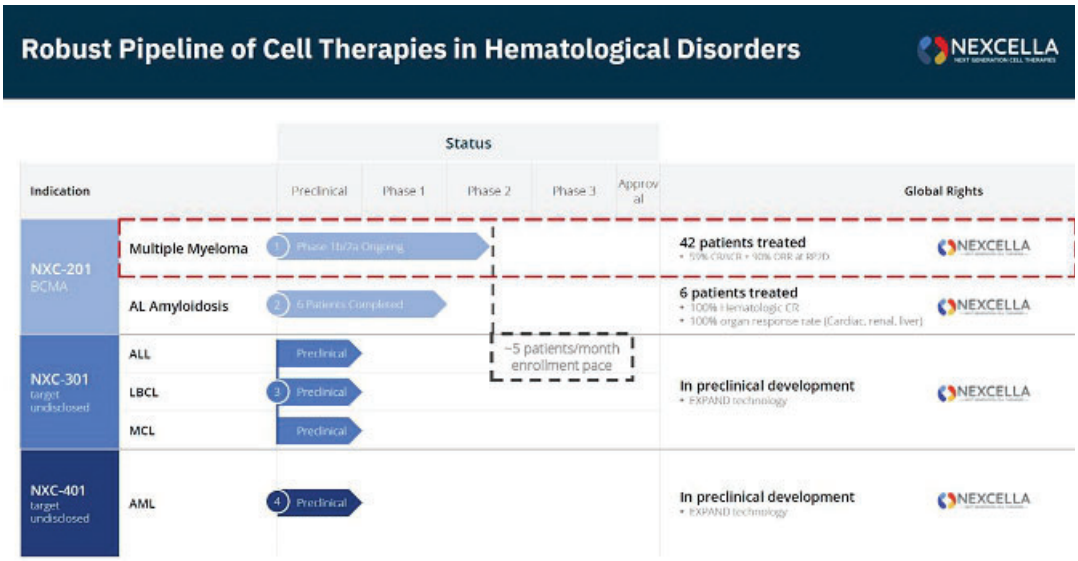
	NXC-201 800 x 10^6 cells (n=29)	Allogeneic BCMA-CAR-T	BCMA bispecific engagers
Best ORR	90%	71%	75%
CR/sCR	**59%**	25%	43%

Sources: Note: Allo BCMA CAR- T scope includes ALLO-715 (Allogene); CYAD-211 (Celyad). BCMA Bispecific Engagers scope includes Teclistamab (Janssen); Elranatamab (Pfizer); ABBV-383 (AbbVie); REGN5458 (Regeneron); CC-93269 (Bristol Myers);HPN217 (Harpoon) as of March 1 2022.

Our Pipeline (Nexcella)

We are building a broad and scalable pipeline that has positioned us to capitalize on the potential of our proprietary platform technologies and achieve long-term growth and sustainability within the field of cell therapy. We believe our N-GENIUS platform and EXPAND technology will enable us to target a range of hematologic malignancies.

We have worldwide rights to all of our programs and have summarized our preclinical and clinical programs in the pipeline chart below:



We are in the process of extending our ongoing NEXICART-I (NCT04720313) Phase 1b/2a clinical trial to the United States, which could cause NEXICART-I to be a registrational clinical trial, generating clinical data that could be included in a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA). Based on our current regulatory pathway, we believe that results from our NEXICART-I trial, if positive, together with clinical results from our United States studies could be sufficient to support the filing of a BLA.

Our Platform and Technologies (Nexcella)

Our N-GENIUS platform has broad potential utility in hematologic and autoimmune disease.

Our N-GENIUS platform, which has produced NXC-201, consists three key elements: (1) Purpose-Built Cell Therapy Evidence Capture Engine + Relational Database, which relates Nexcella 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, to potentially increase efficacy and tolerability; and (3) Atomized, Novel Binding Scaffold Generation Engine, which allows us to make the correct binding for every molecule. 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 (lower dose may lead to lower toxicity), (b) low tonic signaling (lower off-target toxicity may lead to lower toxicity), and (c) anti-exhaustion capability (increased persistence may lead to efficacy over an extended period of time).

N-GENIUS Platform: Robust Pipeline of Clinical & Preclinical CAR-Ts

NEXCELLA
NEXT GENERATION CELL THERAPIES

N-GENIUS PLATFORM

3 Key Elements

Purpose-Built Cell Therapy Evidence Capture Engine + Relational Database
Relating Nexcella internal data to external to accelerate therapy design, manufacture, and preclinical

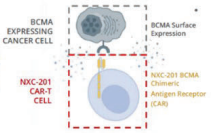
Proprietary EXPAND technology
Applied to multiple cell therapy indications, already utilized to create NXC-201, to potentially increase efficacy and tolerability

Atomized, Novel Binding Scaffold Generation Engine
Allows us to make the correct binding for every molecule

Source: *Development and manufacturing of novel locally produced anti-BCMA CART cells for the treatment of relapsed/refractory multiple myeloma: phase I clinical results.* Haematologica. 2022 Oct 6. doi: 10.3324/haematol.2022.281628. Epub ahead of print. PMID: 36200421.

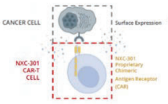
Produced NXC-201, NXC-301, NXC-401

NXC-201 CAR-T CELL



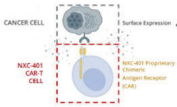
- NXC-201 is a next-generation chimeric antigen receptor (CAR) T-cell (CAR-T) targeting B-cell maturation antigen (BCMA)
  - High Complete Response Rates in AL Amyloidosis and Multiple Myeloma
  - First Outpatient CAR-T: Short CRS duration (median 2 days) starting on day 0
  - No Neurotoxicity, only 1 grade 3 CRS across 42 Multiple Myeloma patients

NXC-301 CAR-T CELL



- NXC-301 is a next-generation CAR-T with a proprietary target.
  Indications:
  - Acute lymphocytic leukemia (ALL)
  - Large B-Cell Lymphoma (LBCL)
  - Mantle cell lymphoma (MCL)

NXC-401 CAR-T CELL



- NXC-401 is a next-generation CAR-T with a proprietary target.
  Indications:
  - Acute Myeloid Leukemia (AML)

Our Clinical Development Plan and Milestones (Nexcella)

We are in the process of extending our ongoing NEXICART-I (NCT04720313) Phase 1b/2a clinical trial to the United States, which could cause NEXICART-I to be a registrational clinical trial, generating clinical data that could be included in a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA). We also intend to rapidly pursue clinical development of NXC-201 in AL Amyloidosis, in earlier lines of multiple myeloma therapy, and other BCMA-positive hematologic malignancies on an outpatient basis.

In MM, we plan to enroll approximately 100 patients in our ongoing open-label study at the recommended phase 2 dose, then submit a BLA for approval to the FDA.

In ALA, we plan to enroll approximately 30-40 patients in an open-label study at the recommended phase 2 dose, then submit a BLA for approval to the FDA.

In 2023, we plan to continue to report interim data results from our ongoing phase 1b/2a NXC-201 clinical trial, complete a pre-IND meeting with the FDA, file an IND for US phase 2 trial for NXC-201, and open a US clinical trial for NXC-201.

We plan to submit our first NXC-201 BLA to the FDA in the first half of 2025.

We believe that the foundation of our competitive advantage is our proprietary technology, clinical evidence, track record of execution, manufacturing success, and assembly of a proven management team. We believe these advantages may position us to achieve significant market share in a large and attractive market and to ultimately transform the cell therapy market, contributing to a significant advancement in medicine.

Manufacturing

We have already established a track record of producing 7 batches of our TSTx according to current Good Manufacturing Practice ("cGMP"), and have treated 17 patients so-far in our ongoing Phase 1b/2a clinical trial as of February 2023.

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 TSTx^{TM} moving forward.

We currently do not own or operate any manufacturing facilities. 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. While we believe we have significant competitive advantages with our years of expertise in systems biology drug design, pharmacology and drug delivery, and clinical depth, trials and expertise, and intellectual property position, 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 both oncology and inflammation include, but are not limited to, Kymera Therapeutics Inc., Morphic Holding Inc., and RAPT Therapeutics Inc. Companies developing therapies for IBD (including UC and CD) include, but are not limited to, Arena Pharmaceuticals Inc., Landos Biopharma Inc., and Seres Therapeutics Inc.

Companies developing CAR-Ts targeting multiple myeloma include, but are not limited to, Janssen/Johnson & Johnson, Bristol Myers Squibb, and Arcellx, Inc. Companies developing therapies for AL amyloidosis include, but are not limited to, Prothena Corp, Caelum Biosciences (Now Alexion/AstraZeneca), and Janssen/Johnson & Johnson.

IMX-110 – Soft Tissue Sarcoma

Drugs in trials to treat STS include nivolumab (marketed as Opdivo®, by Bristol Meyers Squibb), ipilimumab (marketed as Yervoy®, by Merck & Co), and pembrolizumab (marketed as Keytruda®, by Merck & Co).

Nivolumab (Opdivo®), was trialed in a study in which 61% of patients had received at least three previous lines of chemotherapy prior to nivolumab. Nivolumab monotherapy produced a mPFS in sarcoma of 1.7 months, according to D'Angelo et al., 2018.

Nivolumab (Opdivo®) and ipilimumab (Yervoy®), were trialed in a study in which 61% of patients had received at least three previous lines of chemotherapy prior to a combination of nivolumab + ipilimumab. Nivolumab + ipilimumab combination therapy produced a mPFS in sarcoma of 4.1 months, according to D'Angelo et al., 2018.

Pembrolizumab (Keytruda®, Merck & Co), was trialed in a study in which 42% of patients had received at least three previous lines of chemotherapy prior to pembrolizumab. Pembrolizumab monotherapy produced a mPFS in sarcoma of 4.2 months, according to Tawbi et al., 2017.

In addition to the above, companies with approved therapies and that are developing therapies for soft tissue sarcoma include, but are not limited to, BioAtla Inc., Epizyme Inc., Nanobiotix SA, C4 Therapeutics, Inc., Adaptimmune Therapeutics plc, Eisai, Novartis, Mirati Therapeutics, Inc., and Janssen/Johnson & Johnson.

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 17, 2023, our patent portfolio includes 11 U.S. and foreign granted patents, 3 pending U.S. and foreign patent applications, 2 pending international (PCT) patent applications, and 1 pending U.S. provisional patent application related to our technology platform and our product candidates. Of those, 1 patent 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. One non-provisional patent application is currently pending in the U.S. and 2 foreign patent applications are currently pending before the European Patent Office and Hong Kong. Certain platform patents are expected to remain in force until 2033. Other patents directed to platform technology 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	Patent	9,833,508	Cancer therapeutics	03/15/2033	Methods of treatment
United States	Pending	16/789,401	Methods and related compositions for the treatment of cancer	03/15/2033	Compositions and methods of treatment
United States	Provisional	63/357,536	Nanoparticles for the treatment of inflammatory diseases	06/30/2023	Compositions and methods of treatment
PCT	Pending	PCT/US2022/036419	Nanoparticles for cancer treatment	1/7/2024	Compositions and methods of treatment
PCT	Pending	PCT/US22/44948	Nanoparticles for cancer treatment	3/27/2024	Compositions and methods of treatment
France	Patent	13760370.0	Micelles ciblant le Glut-1 et comprenant de la curcumine (Glut-1 targeted and curcumin loaded micelles)	03/15/2033	Compositions
Germany	Patent	13760370.0	Glut-1 zielgerichtete und mit Kurkumin beladene Mizellen (Glut-1 targeted and curcumin loaded micelles)	03/15/2033	Compositions
Ireland	Patent	13760370.0	Glut-1 targeted and curcumin loaded micelles	03/15/2033	Compositions
Switzerland	Patent	13760370.0	Glut-1 zielgerichtete und mit Kurkumin beladene Mizellen (Glut-1 targeted and curcumin loaded micelles)	03/15/2033	Compositions
United Kingdom	Patent	13760370.0	Glut-1 targeted and curcumin loaded micelles	03/15/2033	Compositions
European Patent Office	Pending	20196191.9	Micelle comprising an inhibitor of NF-KB	03/15/2033	Compositions
Hong Kong	Pending	42021037058.1	Micelle comprising an inhibitor of NF-kB	03/15/2033	Compositions
France	Patent	16858309.4	Méthodes et compositions associées pour le traitement du cancer (methods and related compositions for the treatment of cancer)	10/21/2036	Compositions
Germany	Patent	16858309.4	Verfahren und verwandte zusammensetzungen zur behandlung von krebs (methods and related compositions for the treatment of cancer)	10/21/2036	Compositions
Ireland	Patent	16858309.4	Methods and related compositions for the treatment of cancer	10/21/2036	Compositions
Switzerland	Patent	16858309.4	Verfahren und verwandte zusammensetzungen zur behandlung von krebs (methods and related compositions for the treatment of cancer)	10/21/2036	Compositions
United Kingdom	Patent	16858309.4		10/21/2036	Compositions

	Methods and related compositions for the treatment of cancer

Additionally, as of March 17, 2022, Nexcella, Inc. has global exclusive rights to patents #63/308,277, #63/368,002, PCT/IL2023/050142 which are directed to our N-GENIUS platform, EXPAND technology, and to our product candidates, including NXC-201. The patents include one pending PCT application (PCT Application No. PCT/IL2023/050142), filed in 2023. 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, 2022, 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, 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 shall 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 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 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.

Restricted Stock Awards

On December 8, 2022, we issued an aggregate of 350,000 shares of Nexcella restricted common stock to our officers for services to be performed, which shares vest in 48 equal monthly installments.

Recent Developments

On January 12, 2023, Nexcella entered into share purchase agreements with certain accredited investors for their purchase of an aggregate 100,152 shares of Nexcella's common stock at a purchase price of $6.49 per share, for gross proceeds of approximately $650,000. In addition, our Chief Executive Officer and Chief Financial Officer collectively purchased 23,112 shares of Nexcella's common stock for an aggregate purchase price of $150,000. As a result of the foregoing offering, as of January 12, 2023, we owned 98% of Nexcella.

On March 22, 2023, we entered into an ATM Sales Agreement (the "Sales Agreement") with ThinkEquity LLC (the "Sales Agent"), pursuant to which we may offer and sell, from time to time, through the Sales Agent, shares of our common stock having an aggregate offering price of up to $5,000,000, subject to the terms and conditions set forth in the Sales Agreement. We will pay the Sales Agent a fixed commission rate of 3.75% of the aggregate gross proceeds from the sale of the shares of our common stock pursuant to the Sales Agreement. We have paid an expense deposit of $15,000 to the Sales Agent, which will be applied against the actual out-of-pocket accountable expenses. We have 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 offering pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all of the shares of common stock subject to the Sales Agreement, and (ii) termination of the Sales Agreement as permitted therein. We may terminate the Sales Agreement in our sole discretion at any time by giving ten days' prior notice to the Sales Agent. The Sales Agent may terminate the Sales Agreement under the circumstances specified in the Sales Agreement and in its sole discretion at any time by giving ten days' prior notice to us. In addition, the Sales Agreement may be terminated upon mutual agreement by us and the Sales Agent.

Government Regulations

United States Regulation of Drugs and Biologics

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 that IMX-111 and IMX-120 will be regulated by the FDA as a biological product, or biologic, by submitting a Biologics License Application ("BLA") to the FDA. 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 17, 2023, we had 11 employees, 9 of which are full-time employees. Of such employees, 7 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 98% 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, 2022 and 2021, we reported net losses of $8,229,713 and $24,383,879, respectively. As of December 31, 2022, we had an accumulated deficit of $37,985,247.

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 balance of $13,436,714 as of December 31, 2022, and funds available to be raised pursuant to the Sales Agreement, will be sufficient to meet our cash, operational and liquidity requirements for at least 12 months from March 27, 2023, 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, 2022, we had federal net operating loss ("NOLs") carryforwards of approximately $5,800,000. 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 2027. 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.

We do not own or operate any 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 both oncology and inflammation some of which include Kymera Therapeutics Inc., Morphic Holding Inc., and RAPT Therapeutics Inc. In addition, we face competition from companies developing therapies for IBD (including UC and CD) some of which include Arena Pharmaceuticals Inc., Landos Biopharma Inc., and Seres Therapeutics Inc. Moreover, companies with approved therapies and that are developing therapies for soft tissue sarcoma include, but are not limited to, BioAtla Inc., Epizyme Inc., Nanobiotix SA, C4 Therapeutics, Inc., Adaptimmune Therapeutics plc, Eisai, Novartis, and Janssen/Johnson & Johnson, and a company developing multi-kinase inhibitors is Mirati Therapeutics, Inc. We also face competition from companies developing CAR-Ts targeting multiple myeloma, some of which include Janssen/Johnson & Johnson, Bristol Myers Squibb, and Arcellx, Inc. and companies developing therapies for AL amyloidosis some of which include Prothena Corp, Caelum Biosciences (Now Alexion/AstraZeneca), 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.

The outbreak of COVID-19, or a similar pandemic, epidemic or outbreak of an infectious disease in the United States or elsewhere, could have a material adverse impact on our business, financial condition and results of operations, including the execution of our pre-clinical studies and clinical trials and the use and sufficiency of our existing cash.

The outbreak of COVID-19 evolved into a global pandemic and spread to many regions of the world. The extent to which COVID-19 impacts our business and operating results may continue to depend on future developments that are uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, including various variants, and the actions to contain the virus or treat its impact, among others.

The spread of an infectious disease, such as COVID-19, may also result in the inability of our suppliers to deliver supplies to us on a timely basis. We currently utilize third parties to, among other things, manufacture components of our product candidates and, in the future, intend to utilize third parties to conduct our pre-clinical studies and clinical trials. If either we or any third-party parties in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from a health epidemic such as COVID-19, which, among other things, resulted in quarantines and restrictions on travel, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our pre-clinical studies and clinical trials.

Infections and deaths related to a health epidemic may also disrupt the United States' healthcare and healthcare regulatory systems as well as other healthcare systems which could divert healthcare resources away from, or materially delay review and/or approval of our product candidates by the FDA and other regulatory agencies. Furthermore, a health epidemic may also slow potential enrollment of current and planned clinical trials, reduce the number of eligible patients for our current and planned clinical trials, create difficulties in recruiting clinical site investigators and staff, divert healthcare resources away from the conduct of clinical trials, delay receiving approval from local authorities to initiate our current and planned clinical trials, delay necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees, interrupt key clinical trial activities (like site monitoring) and create difficulties in data collection and analysis, among other things.

The spread of COVID-19, which caused a broad impact globally may have a material economic effect on our business. While the potential economic impact brought by the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from COVID-19 could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our pre-clinical studies and clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations.

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.

Because Immix Biopharma and certain of its affiliates control a significant number of securities of Nexcella, it may have effective control over actions requiring Nexcella stockholder approval.

As of March 20, 2023, Immix Biopharma and certain of its affiliates (Ilya Rachman, our Chief Executive Officer and Chairman and Gabriel Morris, our Chief Financial Officer and director) collectively own 5,044,988 shares of Nexcella's common stock, or 98.50% of Nexcella's outstanding common stock, 1,000,000 shares of Nexcella's Class A common stock, or 100% of Nexcella's outstanding Class A common stock and 250,000 shares of Nexcella's Class A preferred stock, or 100% of Nexcella's outstanding Class A preferred stock. Therefore, Immix Biopharma would have the ability to control the outcome of matters submitted to Nexcella's stockholders for approval.

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 other regulatory authorities, even if granted for any of our product candidates developed for therapeutic 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 17, 2023, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 64.73% 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 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, 2022 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 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.

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

On December 16, 2021, our common stock began trading on The Nasdaq Capital Market under the symbol "IMMX." Prior to that time, there was no public market for our common stock.

Stockholders

As of March 17, 2023, there were 13 stockholders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

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

The following table provides information about our purchases of equity securities during the quarter ended December 31, 2022. During the quarter ended December 31, 2022, we repurchased 34,945 shares of our common stock at a cost of $43,910. We have used available cash to finance these repurchases.

Period	Total Number of Shares Purchased	Average Price Paid per Share (1)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (2)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
				(in thousands)
10/1/2022 – 10/31/2022	-	$ -	-	$ 944
11/1/2022 – 11/30/2022	34,945	$ 1.26	34,945	$ 900
12/1/2022 – 12/31/2022	-	$ -	-	$ -(3)
Total	**34,945**	**$ 1.26**	**34,945**	**-**

(1) The average price paid per share and approximate dollar value of shares that may yet be purchased under the share repurchase program exclude fees, commissions, and other charges for the related transactions.

(2) On April 29, 2022, our board of directors authorized the repurchase of up to $1,000,000 shares of our common stock. Under this program, we could repurchase shares of our common stock in the open market or through privately-negotiated transactions.

(3) The share repurchase plan became effective on April 29, 2022 and expired on December 31, 2022. As such, as of December 31, 2022, we did not have any amount authorized for repurchase under the share repurchase plan.

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

We have the following two business units:

ImmixBio. ImmixBio is focused on developing Tissue Specific Therapeutics targeting solid tumors and immune-dysregulated diseases. As of February 2023, 19 patients with advanced solid tumors were treated with IMX-110, ImmixBio's lead candidate.

Nexcella. Our majority-owned subsidiary, Nexcella, Inc., is engaged in the discovery and development of novel cell therapies for hematologic malignancies (blood cancers) and other indications. As of February 2023, 42 patients with relapsed/refractory multiple myeloma (90% overall response rate at therapeutic dose) and 5 relapsed/refractory light chain (AL) amyloidosis patients (100% organ response, 100% complete response rate) have been treated with next-generation CAR-T NXC-201.

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

On January 12, 2023, Nexcella entered into share purchase agreements with certain accredited investors for their purchase of an aggregate 100,152 shares of Nexcella's common stock at a purchase price of $6.49 per share, for gross proceeds of approximately $650,000. In addition, our Chief Executive Officer and Chief Financial Officer collectively purchased 23,112 shares of Nexcella's common stock for an aggregate purchase price of $150,000. As a result of the foregoing offering, as of January 12, 2023, we owned 98% of Nexcella.

On March 22, 2023, we entered into the Sales Agreement with the Sales Agent pursuant to which we may offer and sell, from time to time, through the Sales Agent, shares of our common stock having an aggregate offering price of up to $5,000,000, subject to the terms and conditions set forth in the Sales Agreement. We will pay the Sales Agent a fixed commission rate of 3.75% of the aggregate gross proceeds from the sale of the shares of our common stock pursuant to the Sales Agreement. We have paid an expense deposit of $15,000 to the Sales Agent, which will be applied against the actual out-of-pocket accountable expenses. We have 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 offering pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all of the shares of common stock subject to the Sales Agreement, and (ii) termination of the Sales Agreement as permitted therein. We may terminate the Sales Agreement in our sole discretion at any time by giving ten days' prior notice to the Sales Agent. The Sales Agent may terminate the Sales Agreement under the circumstances specified in the Sales Agreement and in its sole discretion at any time by giving ten days' prior notice to us. In addition, the Sales Agreement may be terminated upon mutual agreement by us and the Sales Agent.

The COVID-19 Pandemic and its Impacts on Our Business

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. This pandemic could result in difficulty securing clinical trial site locations, CROs, and/or trial monitors and other critical vendors and consultants supporting our trial. These situations, or others associated with COVID-19, could cause delays in our clinical trial plans and could increase expected costs, all of which could have a material adverse effect on our business and financial condition. At the current time, we are unable to quantify the potential effects of this pandemic on our future consolidated financial statements.

Results of Operations

Year Ended December 31, 2022 compared to the Year Ended December 31, 2021

General and Administrative Expenses

General and administrative expenses were $4,023,170 for the year ended December 31, 2022 compared to $1,225,487 for the year ended December 31, 2021.

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, 2022 due to the Company becoming a fully reporting public company.

Research and Development Expenses

Research and development expenses were $4,195,778 for the year ended December 31, 2022 compared to $126,527 for the year ended December 31, 2021.

The increased research and development expenses during the year ended December 31, 2022, as compared to the year ended December 30, 2021, were related 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 as a result of closing the IPO in December 2021, and we expect to incur increased research and development costs in the future as our product development activities expand. In addition, the Company paid $1,500,000 for an upfront license fee in connection with the Agreement.

Change in Fair Value of Derivative Liability

The change in fair value of derivative liability was $0 for the year ended December 31, 2022 compared to $22,759,829 for the year ended December 31, 2021. The derivative liability related to the probability of a "Qualified Financing" (as defined in our convertible notes), was reclassified to equity in connection with the automatic conversion of the convertible notes to shares of our common stock in connection with our initial public offering ("IPO") in December 2021.

Loss on Debt Extinguishment

In December 2021, in connection with our IPO, our convertible notes along with the corresponding accrued interest, were automatically converted into an aggregate of 5,633,689 shares of our common stock. As a result of the conversion, we recorded a loss on debt extinguishment of $86,170.

Interest Expense

Interest expense was $497 for the year ended December 31, 2022 compared to $179,853 for the year ended December 31, 2021. Interest expense in the prior period was related to interest accrued on our convertible notes payable bearing interest at rates from the applicable federal rate to 6% per annum, all of which were converted to shares of our common stock in connection with our IPO in December 2021.

Provision for Income Taxes

Provision for income taxes for the year ended December 31, 2022 was $10,268 compared to $6,013 for the year ended December 31, 2021, due to withholding taxes relating to our Australian subsidiary.

Funding Requirements

Our primary use of cash is to fund operating expenses, which consist of research and development expenditures and various general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of discovery, pre-clinical development, laboratory testing and clinical trials for our product candidates;
- the costs of manufacturing our product candidates for clinical trials and in preparation for regulatory approval and commercialization;
- the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;
- expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs required to scale up our clinical, regulatory and manufacturing capabilities;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for any of our product candidates for which we receive regulatory approval; and
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive regulatory approval.

We will need additional funds to meet our operational needs and capital requirements for clinical trials, other research and development expenditures, and general and administrative expenses. We currently have no credit facility or committed sources of capital.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. 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.

Cash used in operating activities

Net cash used in operating activities was $7,408,303 for the year ended December 31, 2022 and $1,589,307 for the year ended December 31, 2021 and primarily included CRO, clinical site costs and related logistics.

Cash used in investing activities

Net cash used by investing activities was $0 for the year ended December 31, 2022 and $802 for the year ended December 31, 2021. We purchased equipment during the year ended December 31, 2021.

Cash provided by financing activities

Net cash provided by financing activities was $3,232,063 for the year ended December 31, 2022 and $18,848,934 for the year ended December 31, 2021. Net cash provided by financing activities in 2022 was primarily related to $2,913,750 in net proceeds from the issuance of shares of our common stock pursuant to the exercise of the underwriter's overallotment option to purchase additional shares of our common stock in connection with our IPO completed in December 2021 and funds of $475,000 received by our subsidiary, Nexcella, in connection with a private placement offering. We received $18,648,934 in net proceeds from the issuance of our shares of common stock pursuant to our initial public offering during the year ended December 31, 2021, along with $200,000 in proceeds from convertible notes payable.

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. As of December 31, 2022, we have incurred an accumulated deficit of $37,985,247 and have not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand will be sufficient to fund its planned operations for at least 12 months from the filing date of this Annual Report on Form 10-K.

We will have additional capital requirements going forward and may need to seek additional financing, which may not be available to us on acceptable terms, if at all.

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.

Derivative Instruments - We evaluated our convertible notes to determine if those contracts or embedded components of those contracts qualified as derivatives to be separately accounted for in accordance with Accounting Standards Codification ("ASC") 815, *Derivatives and Hedging*. The result of this accounting treatment is that the fair value of the embedded derivative is marked to market each balance sheet date and recorded as a liability. In the event that the fair value is recorded as a liability, the change in fair value is recorded in the statements of operations and comprehensive loss as other income or expense. Upon conversion or exercise of a derivative instrument, the instrument is marked to fair value at the conversion date and then that fair value is reclassified to equity.

In circumstances where the embedded conversion option in a convertible instrument is required to be bifurcated and there are also other embedded derivative instruments in the convertible instrument that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument.

We determined that the convertible notes contain embedded features that provide the noteholders with multiple settlement alternatives. Certain of these settlement features provide the noteholders the right to receive cash or a variable number of shares upon the completion of a capital raising transaction, change of control or default by us, which are referred to as "redemption features."

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, 2022 and 2021:

	2022	2021
Volatility	117-124%	117-128%
Expected life (years)	5.27-10.0	10.0
Risk-free interest rate	1.70-3.06%	1.37-1.74%
Dividend rate	—%	—%

Before establishing a public market for the trading of our common stock and due to a lack of company-specific historical and implied volatility data, we based the estimate of expected stock price volatility on the historical volatility of a representative group of publicly traded companies for which historical information was available. The historical volatility was generally calculated based on a period of time commensurate with the expected term assumption. We used the simplified method to calculate the expected term for options granted to employees and directors. We did not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term and used the contractual term since the stock options were not issued at-the-money. For options granted to non-employees, we utilized the contractual term. The risk-free interest rate was based on a U.S. treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield was assumed to be zero, as we had never paid dividends and do not have current plans to pay any dividends on our common stock.

Fair Value of Common Stock

Prior to establishing a public market for our common stock, the estimated fair value of our common stock had been determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant.

Third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common stock valuations were prepared using a hybrid method that incorporated elements of both a probability-weighted expected return method ("PWERM") and an option pricing method ("OPM").

The OPM is based on the Black-Scholes option pricing model, which allows for the identification of a range of possible future outcomes. The OPM treats common stock and convertible instruments as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. A discount for lack of marketability of the common stock is applied to arrive at an indication of value for the common stock.

PWERM involves a forward-looking analysis of the possible future outcomes of the enterprise. This method is particularly useful when discrete future outcomes can be predicted at a relatively high confidence level with a probability distribution. Discrete future outcomes considered under the PWERM include an initial public offering, as well as non-initial public offering market-based outcomes. Determining the fair value of the enterprise using the PWERM requires the Company to develop assumptions and estimates for both the probability of an initial public offering liquidity event and stay private outcomes, as well as the values the Company expects those outcomes could yield.

Prior to establishing a public trading market of our capital stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine its estimate of the fair value of our common stock, including changes in the following factors between the date of the March 31, 2021 valuation and the grant date:

- our business, financial condition and results of operations, including related industry trends affecting our operations;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company, given prevailing market conditions;
- the lack of marketability of our common stock;
- the market performance of comparable publicly traded companies; and
- U.S. and global economic and capital market conditions and outlook.

The assumptions underlying our board of directors' valuations represented our board's best estimates, which involved inherent uncertainties and the application of our board's judgment. As a result, if factors or expected outcomes had changed or our board of directors had used significantly different assumptions or estimates, our equity-based compensation expense could have been materially different.

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.

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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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.

/s/ KMJ Corbin & Company LLP

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

Irvine, California
March 27, 2023

Immix Biopharma, Inc.
Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash	$ 13,436,714	$ 17,644,478
Tax receivable	255,705	25,722
Prepaid expenses and other current assets	1,205,398	516,193
Total current assets	14,897,817	18,186,393
Other assets	6,724	-
Equipment, net	3,560	5,695
Total assets	$ 14,908,101	$ 18,192,088
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,273,296	$ 142,940
Accrued interest	-	9,099
Note payable	-	50,000
Total current liabilities	1,273,296	202,039
Funds held for subsidiary private offering	475,000	-
Total liabilities	1,748,296	202,039
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; 13,964,485 shares issued and 13,892,122 shares outstanding at December 31, 2022, and 13,228,689 shares issued and outstanding at December 31, 2021	1,397	1,323
Additional paid-in capital	51,156,597	47,618,852
Accumulated other comprehensive income	87,021	125,408
Accumulated deficit	(37,985,247)	(29,755,534)
Treasury stock at cost, 72,363 and no shares as of December 31, 2022 and 2021, respectively	(99,963)	-
Total stockholders' equity	13,159,805	17,990,049
Total liabilities and stockholders' equity	$ 14,908,101	$ 18,192,088

See accompanying notes to the consolidated financial statements.

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

	For the Years Ended December 31,	
	2022	2021
Operating expenses:		
General and administrative expenses	$ 4,023,170	$ 1,225,487
Research and development	4,195,778	126,527
Total operating expenses	8,218,948	1,352,014
Loss from operations	(8,218,948)	(1,352,014)
Other expense:		
Change in fair value of derivative liability	-	(22,759,829)
Loss on debt extinguishment	-	(86,170)
Interest expense	(497)	(179,853)
Total other expense	(497)	(23,025,852)
Loss before provision for income taxes	(8,219,445)	(24,377,866)
Provision for income taxes	10,268	6,013
Net loss	(8,229,713)	(24,383,879)
Other comprehensive loss:		
Foreign currency translation	(38,387)	(6,453)
Total other comprehensive loss	(38,387)	(6,453)
Comprehensive loss	$ (8,268,100)	$ (24,390,332)
Loss per common share - basic and diluted	$ (0.59)	$ (6.64)
Weighted average shares outstanding – basic and diluted	13,887,309	3,672,611

See accompanying notes to the consolidated financial statements.

Immix Biopharma, Inc.
Consolidated Statements of Stockholders' Equity
For the Years Ended December 31, 2022 and 2021

	Common Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Shares	Treasury Stock Amount	Total Stockholders' Equity
Balance December 31, 2020	3,375,000	$ 338	$ 508,872	$ 131,861	$ (5,371,655)	-	$ -	$ (4,730,584)
Shares issued for cash proceeds, net of offering costs	4,200,000	420	18,648,514	-	-	-	-	18,648,934
Shares issued for conversion of convertible notes payable, related accrued interest and settlement of derivative liability	5,633,689	563	28,167,882	-	-	-	-	28,168,445
Relative fair value of warrants issued in connection with debt	-	-	74,603	-	-	-	-	74,603
Stock-based compensation	20,000	2	218,981	-	-	-	-	218,983
Net loss	-	-	-	-	(24,383,879)	-	-	(24,383,879)
Foreign currency translation adjustment	-	-	-	(6,453)	-	-	-	(6,453)
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
Stock-based compensation	-	-	524,069	-	-	-	-	524,069
Repurchase of common shares	-	-	-	-	-	(72,363)	(99,963)	(99,963)
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

See accompanying notes to the consolidated financial statements.

Immix Biopharma, Inc.
Consolidated Statements of Cash Flows

	For the Years Ended December 31,	
	2022	2021
Operating Activities:		
Net loss	$ (8,229,713)	$ (24,383,879)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	524,069	218,983
Shares issued for services	100,000	-
Convertible note issued in exchange for services	-	60,000
Change in fair value of derivative liability	-	22,759,829
Loss on debt extinguishment	-	86,170
Amortization of debt discount	-	58,157
Depreciation	2,135	2,468
Changes in operating assets and liabilities:		
Tax receivable	(236,384)	97,667
Prepaid expenses and other current assets	(691,047)	(502,795)
Accounts payable and accrued expenses	1,131,736	(106,061)
Accrued interest	(9,099)	120,154
Net cash used in operating activities	(7,408,303)	(1,589,307)
Investing Activities:		
Purchase of equipment	-	(802)
Net cash used in investing activities	-	(802)
Financing Activities:		
Payments of deferred offering costs	(6,724)	-
Proceeds from convertible notes payable	-	200,000
Payments on note payable	(50,000)	-
Proceeds from sale of common stock, net of offering costs	2,913,750	18,648,934
Funds received for subsidiary private offering	475,000	-
Repurchase of common stock	(99,963)	-
Net cash provided by financing activities	3,232,063	18,848,934
Effect of foreign currency on cash	(31,524)	(5,433)
Net change in cash	(4,207,764)	17,253,392
Cash - beginning of year	17,644,478	391,086
Cash - end of year	$ 13,436,714	$ 17,644,478
Supplemental Disclosures of Cash Flow Information:		
Interest paid	$ 9,596	$ 1,542
Income taxes paid	$ -	$ -
Supplemental Disclosures of Noncash Financing Information:		
Relative fair value of warrants issued in connection with convertible debt	$ -	$ 74,603
Debt discount related to derivative liabilities	$ -	$ 80,000
Common stock issued upon conversion of notes payable, related accrued interest and settlement of derivative liability	$ -	$ 28,178,721
Cashless exercise of stock options	$ 6	$ -

See accompanying notes to the consolidated financial statements.

Note 1 – Nature of Business

Immix Biopharma, Inc. (the "Company") is a clinical-stage pharmaceutical company organized as a Delaware corporation on January 7, 2014 to focus on the development of therapies for patients with cancer and inflammatory 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. (formerly known as Immix Biopharma Cell Therapy, Inc.) ("Nexcella") in order to conduct various preclinical and clinical activities for its development candidates.

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.

Beginning in late 2019, the outbreak of a novel strain of virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease 2019, or COVID-19, has evolved into a global pandemic. The extent of the impact of the coronavirus outbreak on the Company's business will depend on certain developments, including the duration and spread of the outbreak and the extent and severity of the impact on the Company's clinical trial activities, research activities and suppliers, all of which are uncertain and cannot be predicted. At this point, the extent to which the coronavirus outbreak may materially impact the Company's financial condition, liquidity or results of operations is uncertain. 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, the valuation of derivative financial instruments, and stock-based compensation. Actual results could differ from those estimates.

Forward Stock Split – On October 4, 2021, the Company effected a 3-for-1 forward stock split of its issued and outstanding common stock. Accordingly, all share and per-share amounts relating to the common stock, stock options and warrants for all periods presented in the accompanying consolidated financial statements have been retroactively adjusted, where applicable, to reflect the forward stock split.

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 (see Note 6). 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 (See Note 6). On March 22, 2023, the Company entered into an ATM Sales Agreement (the "Sales Agreement") with ThinkEquity LLC (the "Sales Agent"), pursuant to an "at the Market" offering program (the "ATM Facility"), under which the Company, may, from time to time, issue and sell through the Sales Agent, up to $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 (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 on hand at December 31, 2022, and funds available to be raised from the ATM Facility, will be sufficient to meet the Company's working capital requirements through at least March 27, 2024.

Concentration of Credit Risk - Periodically, the Company may carry cash balances at financial institutions in excess of the federally insured limit of $250,000, or the Australian insured limit of AUD 250,000. As of December 31, 2022, the Company had $13,975,090 in excess of the FDIC insurance limit and no amounts in excess of the Australian insured limit. The Company has not experienced losses on these accounts and management believes, based upon the quality of the financial institutions, that the credit risk with regard to these deposits is not significant.

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, tax receivable, accounts payable and accrued expenses, and notes payable 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.

Prior to the conversion of the convertible notes payable in December 2021, the Company was required to measure and record its derivative instruments at fair value on a recurring basis (see Notes 4 and 5).

Derivative Instruments – Prior to the conversion of the convertible notes payable in December 2021, the Company evaluated its convertible notes to determine if those contracts or embedded components of those contracts qualified as derivatives to be separately accounted for in accordance with Accounting Standards Codification ("ASC") 815, *Derivatives and Hedging*. The result of this accounting treatment was that the fair value of the embedded derivative was marked to market at each balance sheet date and recorded as a liability. The change in fair value was recorded in the consolidated statements of operations and comprehensive loss as other income or expense. Upon conversion of the derivative instrument, the instrument was marked to fair value at the conversion date and then that fair value was reclassified to equity.

The Company determined that the convertible notes contained embedded features that provided the noteholders with multiple settlement alternatives. Certain of these settlement features provided the noteholders the right to receive cash or a variable number of shares upon the completion of a capital raising transaction, change of control or default by the Company, which are referred to as "redemption features."

The redemption features of the convertible notes met the requirements for separate accounting and were accounted for as a single derivative instrument. The derivative instrument was recorded at fair value at inception and was subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in the statements of operations and comprehensive loss (see Notes 4 and 5).

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 $236,376 and $79,978 for the years ended December 31, 2022 and 2021, respectively.

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, 2022 and 2021.

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 $2,245 and $(6,093) for the years ended December 31, 2022 and 2021, respectively, and are included in general and administrative expenses in the accompanying statements of operations and comprehensive loss.

Loss Per Common Share – Basic loss per common share is computed by dividing net loss available 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. As of December 31, 2022 and 2021, 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 2,168,742 and 1,686,984 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.

Recent Accounting Pronouncements - In August 2020, the FASB issued Accounting Standards Update ("ASU") 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity).* ASU 2020-06 reduces the number of accounting models for convertible debt instruments and convertible preferred stock, which results in fewer embedded conversion features being separately recognized from the host contract as compared with current U.S. GAAP. Additionally, ASU 2020-06 affects the diluted earnings per share calculation for instruments that may be settled in cash or shares and for convertible instruments and requires enhanced disclosures about the terms of convertible instruments and contracts in an entity's own equity. ASU 2020-06 allows entities to use a modified or full retrospective transition method and is effective for smaller reporting companies for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years, with early adoption permitted. The Company has chosen to early adopt the ASU as of January 1, 2022. Upon adoption, no retrospective changes were required in the Company's consolidated financial statements.

Note 3 – Agreements with Nexcella Subsidiary

Founders Agreement

Effective December 8, 2022, the Company entered 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 and 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 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 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 the Nexcella COI") or Qualified Change in Control (as defined in the Nexcella COI), the shares 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 in 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 shall be 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 shall be 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 shall 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 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 the Company in performing the Services shall be reimbursed to the Company 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 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 – Notes Payable

Convertible Notes

On September 1, 2016, the Company entered into a secured convertible promissory note, as amended, with an entity affiliated with a stockholder of the Company for aggregate borrowings of $3,000,000 (as amended, "2016 Note"). The 2016 Note was scheduled to mature on March 31, 2022, and bore interest at the applicable federal rate per annum. The 2016 Note was secured by (i) all of the Company's purchased equipment (to the extent not already encumbered) and (ii) any amounts received as a tax rebate or incentive during the term of the 2016 Note. On December 20, 2021, the outstanding principal and accrued interest were converted into shares of the Company's common stock in connection with the Company's IPO (see below).

On October 30, 2018, the Company entered into an unsecured convertible promissory note in the principal amount of $250,000 (as amended, "2018 Note"). The 2018 Note was scheduled to mature on March 31, 2022, and bore interest at 4% per annum. On December 20, 2021, the outstanding principal and accrued interest were converted into shares of the Company's common stock in connection with the Company's IPO (see below).

On October 30, 2019, the Company entered into a series of unsecured convertible promissory notes (as amended, "2019 Notes") in the aggregate principal amount of $800,000. The 2019 Notes were scheduled to mature on March 31, 2022 and bore interest at 6% per annum. On December 20, 2021, the outstanding principal and accrued interest was converted into shares of the Company's common stock in connection with the Company's IPO (see below).

In March and April 2021, the Company issued a series of unsecured convertible promissory notes ("2021A Notes") in the aggregate principal amount of $260,000 to the Company's Chief Financial Officer and Alwaysraise LLC, an entity in which the Company's Chief Financial Officer is the sole member. Of the $260,000 principal amount, the Company received $200,000 in cash proceeds and issued a $60,000 note in exchange for services. The 2021A Notes were scheduled to mature on March 1, 2023, and bore interest at 6% per annum. In connection with the issuance of the 2021A Notes, the Company issued ten-year warrants to purchase 156,000 shares of the Company's common stock at an exercise price of $0.80 per share. The warrants were valued using the Black-Scholes option pricing model with the following inputs: an expected and contractual life of 10 years, an assumed volatility of 117%, a zero dividend rate, and a risk free rate of 1.70%. The relative fair value of the warrants amounting to $74,603 was recorded to debt discount and was amortized to interest expense through the date of the Company's IPO, at which time the outstanding principal and accrued interest was converted into shares of the Company's common stock (see below).

The 2016 Note, 2018 Note, 2019 Notes and 2021A Notes are collectively referred to as the "Notes." In the event that the Company issued and sold shares of its equity securities ("Equity Securities") to investors (the "Investors") prior to the maturity dates of the Notes in an equity financing with total proceeds to the Company of not less than $10,000,000 (including the conversion of the Notes, other indebtedness or other convertible securities issued for capital raising purposes (e.g., Simple Agreements for Future Equity)) (a " Qualified Financing"), then the outstanding principal amount of the Notes and any unpaid accrued interest would automatically convert in whole without any further action by the holders into Equity Securities sold in the Qualified Financing at a conversion price equal to the lesser of (i) the price paid per share for Equity Securities by the Investors in the Qualified Financing multiplied by 0.80, and (ii) the quotient resulting from dividing $10,000,000 by the number of pre-split outstanding shares of the common stock of the Company immediately prior to the Qualified Financing (assuming conversion of all securities convertible into common stock and exercise of all outstanding options and warrants, including all shares of common stock reserved and available for future grant under any equity incentive or similar plan of the Company, and/or any equity incentive or similar plan created or increased in connection with Qualified Financing, and including the shares of equity securities of the Company issued for capital raising purposes (e.g., Simple Agreements for Future Equity)). The issuance of Equity Securities pursuant to the conversion of the Notes were subject to the same terms and conditions applicable to Equity Securities sold in the Qualified Financing.

Upon the occurrence of a change of control prior to a Qualified Financing or maturity, the 2019 Notes and the 2021A Notes would upon the election of the holders either (i) become due and payable upon closing of such change of control in cash in an amount equal to (a) the outstanding principal amount plus any unpaid accrued interest, plus (b) a repayment premium equal to 200% of the outstanding principal amount, or (ii) be converted such that the outstanding principal balance and any unpaid accrued interest would convert into shares of the Company's common stock at a conversion price equal to the quotient resulting from dividing $10,000,000 by the number of outstanding shares of common stock of the Company immediately prior to the change of control (assuming conversion of all securities convertible into common stock and exercise of all outstanding options and warrants, and including the shares of equity securities of the Company issuable upon the conversion of notes, other indebtedness or other convertible securities issued for capital raising purposes).

On December 20, 2021, in connection with the Company's IPO, which was deemed a Qualified Financing, the Notes along with the corresponding accrued interest, were automatically converted into an aggregate of 5,633,689 shares of the Company's common stock. As a result of the conversion, the Company recorded a loss on debt extinguishment of $86,170.

The Notes contained embedded derivative instruments, including automatic conversion into equity securities upon completion of a Qualified Financing, that were required to be bifurcated and accounted for separately as a single derivative instrument initially and subsequently measured at fair value with the change in fair value recorded in other income (expense) in the accompanying consolidated statements of operations and comprehensive loss. The Company determined that the issuance date fair values of the derivative instruments for the 2016 Note, 2018 Note, and 2019 Notes, was nominal based on its assumptions of probabilities of a Qualified Financing or change of control transaction. For the 2021A Notes issued during March and April 2021, the Company recorded the fair value of the derivative instruments of $80,000, as a debt discount on the issuance dates which was amortized to interest expense through the date of the Company's IPO, at which time the 2021A Notes were converted into shares of the Company's common stock. During the year ended December 31, 2021, the Company recognized expense of $22,759,829 related to the change in fair value of the derivative instruments. Upon the conversion of the Notes, the Company reclassified the estimated fair value of the derivative liability of $23,414,829 to additional paid-in capital.

Interest expense related to the Notes was $118,904 for the year ended December 31, 2021. Amortization of the debt discounts related to the 2021A Notes was $58,157 for the year ended December 31, 2021.

Note Payable – Related Party

On September 14, 2014, the Company issued an unsecured promissory note in the principal amount of $50,000 to a stockholder of the Company. The note matured on September 14, 2017 and bore interest at 2.5% per annum. On June 9, 2021, the note was amended to extend the maturity date to September 14, 2022. On May 26, 2022, the Company repaid the outstanding principal balance and accrued interest in full. As of December 31, 2022 and 2021, the outstanding principal balance on this note was $0 and $50,000, respectively.

Interest expense related to the note was $497 and $1,250 for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, accrued interest on the note was $0 and $9,099, respectively.

Note 5 – Fair Value Measurements

As of December 31, 2022 and 2021, the Company had no assets or liabilities required to be measured at fair value on a recurring basis.

The fair value of the embedded derivative instrument identified in the Notes was estimated using a two-step approach to valuation, employing a probability-weighted scenario valuation method and then comparing the instrument's value with-and-without the derivative features in order to estimate their combined fair value, using unobservable inputs, which are classified as Level 3 within the fair value hierarchy. In order to estimate the fair value of the Notes, the Company estimated the future payoff in each scenario, discounted them to a present value and then probability weighted them based upon the Company's best likelihood of each event occurring. The primary inputs for the valuation approach included the probability of achieving various settlement scenarios that provide the noteholders the rights or the obligations to receive cash or a variable number of shares upon the completion of a Qualified Financing. At December 31, 2020, the Company estimated a 5% probability of a Qualified Financing occurring, a de minimis probability of a change of control occurring and a 20% probability of bankruptcy or dissolution of the Company. As of December 31, 2020, the embedded derivative was remeasured to $575,000. Immediately prior to the conversion of the Notes in connection with the Company's IPO, the Company estimated a 100% probability of a Qualified Financing occurring, a de minimis probability of a change of control occurring and a 0% probability of bankruptcy or dissolution of the Company. Accordingly, the estimated fair value of the embedded derivative was remeasured at $23,414,829. A loss of $22,759,829 related to the change in fair value of the derivative liability was recorded during the year ended December 31, 2021. There were no transfers among Level 1, Level 2 or Level 3 categories in the years ended December 31, 2022 and 2021.

The following table provides a summary of changes in fair value of the Company's Level 3 financial liabilities for the year ended December 31, 2021:

	Debt Derivative
Balance, January 1, 2021	$ 575,000
Additions – initial issuance of 2021A Notes recognized as debt discount	80,000
Loss from change in fair value included in earnings	22,759,829
Reclassification to additional paid-in capital upon conversion of convertible notes payable	(23,414,829)
Balance, December 31, 2021	$ -

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.

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.

On December 20, 2021, the Company closed on its IPO of 4,200,000 shares offered at a price of $5.00 for gross proceeds of $21,000,000. In connection with the offering the Company paid $2,351,066 in offering costs resulting in net proceeds of $18,648,934.

On December 20, 2021, in connection with the IPO, the Notes along with the related accrued interest, were automatically converted into an aggregate of 5,633,689 shares of the Company's common stock.

On December 20, 2021, the Company issued 20,000 shares of restricted common stock to an unrelated third party for entering into an investor relations contract. The stock was valued at a share price of $2.95, the closing price of the Company's common stock on date of issuance, for a total value of $59,000 related to services which is included in general and administrative expenses.

Fair Value of Common Stock – prior to establishing a public market

Prior to establishing a public market for the Company's common stock, the estimated fair value of the Company's common stock was determined by the Company's Board of Directors as of the date of each option grant, with input from management, considering the Company's most recently available third-party valuations of common stock, and the Board of Directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant.

Third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The Company's common stock valuations were prepared using a hybrid method that incorporated elements of both a probability-weighted expected return method ("PWERM") and an option pricing method ("OPM").

The OPM was based on the Black-Scholes option pricing model, which allows for the identification of a range of possible future outcomes. The OPM treats common stock and convertible instruments as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. A discount for lack of marketability of the common stock was applied to arrive at an indication of value for the common stock.

PWERM involves a forward-looking analysis of the possible future outcomes of the enterprise. This method is particularly useful when discrete future outcomes can be predicted at a relatively high confidence level with a probability distribution. Discrete future outcomes considered under the PWERM included an initial public offering, as well as non-initial public offering market-based outcomes. Determining the fair value of the enterprise using the PWERM required the Company to develop assumptions and estimates for both the probability of an initial public offering liquidity event and stay private outcomes, as well as the values the Company expected those outcomes could yield.

Prior to establishing a public trading market of the Company's capital stock, the Company's Board of Directors exercised reasonable judgment and considered a number of objective and subjective factors to determine its estimate of the fair value of the Company's common stock, including changes in the following factors between the date of the valuation and the grant date:

- the Company's business, financial condition and results of operations, including related industry trends affecting the Company's operations;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of the Company, given prevailing market conditions;
- the lack of marketability of the Company's common stock;
- the market performance of comparable publicly traded companies; and
- U.S. and global economic and capital market conditions and outlook.

The assumptions underlying the Company's Board of Directors' valuations represented the Board's best estimates, which involved inherent uncertainties and the application of the Board's judgment. As a result, if factors or expected outcomes had changed or the Company's Board of Directors had used significantly different assumptions or estimates, the Company's equity-based compensation expense could have been materially different. Following the completion of our IPO, the Company's Board of Directors began determining the fair value of the Company's common stock based on the quoted market prices of its common stock.

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 (the "2021 Plan") which reserves and makes 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) shall not count against such share limit. Subsequent to September 10, 2021, no further awards shall 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. As of December 31, 2022, there are 748,886 awards remaining to be issued under the 2021 Plan.

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.

During the year ended December 31, 2021, the Company granted options to purchase 736,500 shares of the Company's common stock to officers of the Company, and granted options to purchase 292,500 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 $0.80-$1.86 and the options expire ten years following grant. These options vest in equal monthly installments beginning on the grant date ranging from 24 to 48 months.

The Company estimated the fair value of the stock options using the Black-Scholes option pricing model. The fair value of stock options is being amortized on a straight-line basis over the requisite vesting period of the awards. The fair value of stock options was estimated using the following assumptions for the year ended December 31, 2022: an expected and contractual life of 5.27-10 years, an assumed volatility of 117%-124%, a zero dividend rate, a risk free rate of 1.70%-3.06%, and fair value of common stock of $2.21-$5.50. The fair value of stock options was estimated using the following assumptions for the year ended December 31, 2021: an expected and contractual life of 10 years, an assumed volatility of 117%-128%, a zero dividend rate, a risk free rate of 1.37%-1.74%, and fair value of common stock of $0.83. The Company recognized stock-based compensation of $476,746 and $159,983 related to stock options for the years ended December 31, 2022 and 2021, respectively, which is included in general and administrative expenses.

As of December 31, 2022, the Company had unrecognized stock-based compensation expense of $1,554,372, related to unvested stock options, which is expected to be recognized over the weighted-average vesting period of 1.65 years.

The following table summarizes the stock option activity under the 2021 Plan for the years ended December 31, 2022 and 2021:

	Options		Weighted-Average Exercise Price Per Share
Outstanding and exercisable, January 1, 2021	291,984	$	1.33
Granted	1,029,000	$	1.60
Exercised	-	$	-
Forfeited	-	$	-
Expired	-	$	-
Outstanding, December 31, 2021	1,320,984	$	1.54
Granted	591,250	$	2.70
Exercised	(140,992)	$	1.33
Forfeited	-	$	-
Expired	-	$	-
Outstanding and expected to vest, December 31, 2022	1,771,242	$	1.94

The following table discloses information regarding outstanding and exercisable options at December 31, 2022:

	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	8.20	224,438	$ 0.80
$1.33	150,992	$ 1.33	2.67	150,992	$ 1.33
$1.86	772,500	$ 1.86	8.47	289,377	$ 1.86
$2.64	580,000	$ 2.64	9.54	85,419	$ 2.64
$5.83	11,250	$ 5.83	9.04	2,578	$ 5.83
	1,771,242	$ 1.94	8.29	752,804	$ 1.54

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, 2022, the intrinsic value for the options vested and outstanding was $603,294 and $858,809, respectively.

The total intrinsic value of stock options exercised during the year ended December 31, 2022 was $148,982.

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.

In March and April 2021, in connection with the issuance of the 2021A Notes as discussed in Note 4, the Company issued warrants for the purchase of 156,000 shares of the Company's common stock, with a term of 10 years and an exercise price of $0.80 per share which vested immediately.

In December 2021, in connection with the IPO discussed above, the Company issued warrants for the purchase of 210,000 shares of the Company's common stock, with a term of 5 years and an exercise price of $6.25 per share which vested six months after the date of issuance.

The following table summarizes the stock warrant activity for the years ended December 31, 2022 and 2021:

	Warrants	Weighted-Average Exercise Price Per Share
Outstanding and exercisable, January 1, 2021	-	$ -
Granted	366,000	$ 3.93
Exercised	-	$ -
Forfeited	-	$ -
Expired	-	$ -
Outstanding and exercisable, December 31, 2021	366,000	$ 3.93
Granted	31,500	$ 6.25
Exercised	-	$ -
Forfeited	-	$ -
Expired	-	$ -
Outstanding and exercisable, December 31, 2022	397,500	$ 4.11

The following table discloses information regarding outstanding and exercisable warrants at December 31, 2022:

	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	156,000	$ 0.80	8.23	156,000	$ 0.80
$6.25	241,500	$ 6.25	3.96	241,500	$ 6.25
	397,500	$ 4.11	5.64	397,500	$ 4.11

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, 2022, the intrinsic value for the warrants vested and outstanding was $232,440.

Nexcella Equity Transactions

The Nexcella 2022 Plan allows for the Board of Directors to grant various forms of incentive awards covering i) up to 375,000 shares of common stock and ii) up to 1,125,000 options to purchase shares of common stock. As of December 31, 2022, there were 25,000 shares of common stock available for issuance under the Nexcella 2022 Plan. No incentive stock options have been issued pursuant to the Nexcella 2022 Plan as of December 31, 2022.

During the year ended December 31, 2022, Nexcella entered into subscription agreements for the sale of 73,188 common shares of Nexcella, 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 has recorded the proceeds of $475,000 in funds held for subsidiary private offering in the accompanying consolidated balance sheet at December 31, 2022 (see Note 10).

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, of which $47,323 was included in general and administrative expenses for the year ended December 31, 2022.

As of December 31, 2022, the Company had unrecognized stock-based compensation expense of $2,224,177, related to unvested restricted common stock, which is expected to be recognized over the remaining vesting period of 3.9 years.

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.

Note 8 – Income Taxes

The Company is subject to taxation in the United States, California and Australia. At December 31, 2022, the Company had federal, state, and foreign net operating loss ("NOL") carryforwards of approximately $5,800,000, $5,800,000 and $1,500,000, respectively. The federal loss carryforwards generated after 2017 of approximately $5,800,000 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 do not expire. The Company also has federal and California research and development credit carryforwards totaling approximately $110,000 and $106,000, respectively, at December 31, 2022. 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 $67,000 at December 31, 2022. 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, 2022 and 2021 is as follows:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Expected income tax benefit computed at the statutory rate	$ (1,736,301)	$ (5,119,352)
State income tax benefit, net of federal benefit, net of valuation allowance	-	-
Foreign rate differential	14,228	(6,232)
Foreign losses not benefited	119,362	32,407
Tax effect of:		
Change in valuation allowance	1,692,278	299,385
Change in fair value of derivative liability	-	4,779,564
Other permanent items and tax credits	(180,713)	(2,491)
Other non-deductible expenses	91,196	22,732
Provision for income taxes	$ 10,268	$ 6,013

Net deferred tax assets are comprised of the following as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Net operating losses	$ 1,920,819	$ 739,168
Foreign tax credits	73,326	63,058
Federal & state research credit carryforwards	216,418	32,602
Stock-based compensation	1,167,687	105,750
Valuation allowance	(3,378,250)	(940,578)
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, 2022 and 2021, domestic and foreign pre-tax loss were:

	December 31, 2022	December 31, 2021
Loss before income taxes - Domestic	$ 7,741,995	$ 24,253,224
Loss before income taxes – Foreign	477,450	124,642
Loss before income taxes - Consolidated	$ 8,219,445	$ 24,377,866

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, 2022 and 2021.

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, 2022, no amounts have been paid or accrued under the MSA. As of December 31, 2022, 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. 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 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. The Morris MSA contains provisions for the protection of the Company's intellectual property and confidential information.

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

Nexcella Private Placement Offering

On January 12, 2023, the Company, through its majority-owned subsidiary, Nexcella, closed on a private placement offering in which it sold an aggregate of 100,152 shares of Nexcella's common stock at a purchase price of $6.49, for gross proceeds of approximately $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.

Common Stock Issuance – Marketing Services Agreement

On March 16, 2023, the Company, issued 6,700 shares of the Company's common stock valued at $12,730, pursuant to a marketing services agreement for future services to be provided to the Company.

ATM Sales Agreement

On March 22, 2023, the Company entered into an ATM Sales Agreement (the "Sales Agreement") with ThinkEquity LLC (the "Sales Agent"), pursuant to which the Company may offer and sell, from time to time, through the Sales Agent, shares (the "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 Sales Agreement. The Shares will be offered and sold pursuant to the Company's prospectus supplement, dated March 22, 2023, filed by the Company with the Securities and Exchange Commission (the "SEC"), to the prospectus forming a part of the Company's shelf Registration Statement on Form S-3 (File No. 333-269100) filed by the Company with the SEC (the "Registration Statement") on January 3, 2023 and declared effective by the SEC on January 11, 2023. The aggregate market value of Shares eligible for sale under the Sales Agreement will be subject to the limitations of General Instruction I.B.6 of Form S-3.

Under the Sales Agreement, the Sales Agent may sell the 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 or any other existing trading market for the 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 Shares if the sales cannot be effected at or above the price designated by the Company from time to time.

Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, the Sales Agent will use commercially reasonable efforts, consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations, and the rules of The Nasdaq Capital Market, to sell the Shares from time to time based upon the Company's instructions, including any price, time or size limits specified by the Company.

The offering pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all of the Shares subject to the Sales Agreement, and (ii) termination of the Sales Agreement as permitted therein. The Company may terminate the Sales Agreement in its sole discretion at any time by giving ten days' prior notice to the Sales Agent. The Sales Agent may terminate the Sales Agreement under the circumstances specified in the Sales Agreement and in its sole discretion at any time by giving ten days' prior notice to the Company. In addition, the Sales Agreement may be terminated upon mutual agreement of the Company and the Sales Agent.

The Company will pay the Sales Agent a fixed commission rate of 3.75% of the aggregate gross proceeds from the sale of the 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.

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, 2022, 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, 2022, 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, 2022. 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 implemented remediation steps in 2021 including addition of accounting 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

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the rules of the SEC for new public companies. In addition, this Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting as an attestation is not required pursuant to the exemption provided to issuers that are not "large accelerated filers" nor "accelerated filers" under the Dodd-Frank Wall Street Reform and Consumer Protection Act.

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 2023 Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our 2023 Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

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 2023 Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

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

The information required by this item is incorporated by reference to our 2023 Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our 2023 Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022.

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 4.1 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
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)
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
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 28, 2022)
21.1*	Subsidiaries
23.1*	Consent of KMJ Corbin & Company LLP, independent registered public accounting firm
24.1*	Power of Attorney (included on signature page hereto)

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
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, 2022 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 27th day of March, 2023.

IMMIX BIOPHARMA, INC.

/s/ Ilya Rachman
Ilya Rachman
Chief Executive Officer (Principal Executive Officer) and Chairman of the Board of Directors

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Ilya Rachman as his or her attorney-in-fact, with full power of substitution and resubstitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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 27, 2023
/s/ Gabriel Morris Gabriel Morris	Chief Financial Officer and Director (Principal Financial and Accounting Officer)	March 27, 2023
/s/ Jason Hsu Jason Hsu	Director	March 27, 2023
/s/ Magda Marquet Magda Marquet	Director	March 27, 2023
/s/ Helen C. Adams Helen C. Adams	Director	March 27, 2023
/s/ Carey Ng Carey Ng	Director	March 27, 2023
/s/ Jane Buchan Jane Buchan	Director	March 27, 2023