2022 Annual Report

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InVivo Therapeutics

1500 District Avenue

Burlington, MA 01803

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 001-37350

INVIVO THERAPEUTICS HOLDINGS CORP.

(Exact name of registrant as specified in its charter)

Nevada (State or other jurisdiction of incorporation or organization)	**36-4528166** (I.R.S. Employer Identification No.)
One Kendall Square, Building 1400 West, 4th Floor, Suite B14402, Cambridge, Massachusetts (Address of principal executive offices)	**02139** (Zip Code)

(617) 863-5500
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 exchange on which registered
Common Stock, $0.00001 par value	NVIV	The Nasdaq Capital Market

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

Emerging growth company ☐

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was $5,632,327 based on a per share price of $4.05, which was the closing price of the registrant's Common Stock on the Nasdaq Capital Market on June 30, 2022.

As of February 24, 2023, the number of shares outstanding of the registrant's Common Stock, $0.00001 par value per share, was 2,860,446.

DOCUMENTS INCORPORATED BY REFERENCE

None.

INVIVO THERAPEUTICS HOLDINGS CORP.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2022

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PART I
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements include statements made regarding our commercialization strategy, future operations, cash requirements and liquidity, capital requirements, and other statements on our business plans and strategy, financial position, and market trends. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "should," "believe," "plan," "intend," "anticipate," "target," "estimate," "expect," and other similar expressions. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this Form 10-K, including factors such as our ability to raise substantial additional capital to finance our planned operations and to continue as a going concern; our ability to execute our strategy and business plan; our ability to obtain regulatory approvals for our products, including the *Neuro-Spinal Scaffold*™; if approved, our ability to successfully commercialize our current and future product candidates, including the *Neuro-Spinal Scaffold*; the progress and timing of our development programs; market acceptance of our products; our ability to retain management and other key personnel; our ability to promote, manufacture, and sell our products, either directly or through collaborative and other arrangements with third parties; and other factors detailed under "Risk Factors" in Part I, Item 1A of this Form 10-K. These forward looking statements are only predictions, are uncertain, and involve substantial known and unknown risks, uncertainties, and other factors which may cause our actual results, levels of activity, or performance to be materially different from any future results, levels of activity, or performance expressed or implied by these forward looking statements. Such factors include, among others, the following:

- our limited operating history and history of net losses;
- our ability to raise substantial additional capital to finance our planned operations and to continue as a going concern;
- our ability to execute our strategy and business plan;
- our ability to obtain regulatory approvals for our current and future product candidates, including our *Neuro-Spinal Scaffold* implant;
- our ability to successfully commercialize our current and future product candidates, including our *Neuro-Spinal Scaffold* implant, if approved;
- the progress and timing of our current and future development programs;
- our ability to successfully open, enroll and complete clinical trials and obtain and maintain regulatory approval of our current and future product candidates;
- the length and impact of the COVID-19 pandemic or similar public health crisis;
- our ability to protect and maintain our intellectual property and licensing arrangements;
- our reliance on third parties to conduct testing and clinical trials;
- market acceptance and adoption of our current and future technology and products;
- our ability to promote, manufacture and sell our current and future products, either directly or through collaborative and other arrangements with third parties; and
- our ability to attract and retain key personnel.

We cannot guarantee future results, levels of activity, or performance. You should not place undue reliance on these forward looking statements, which speak only as of the date of this Annual Report on Form 10-K. These cautionary statements should be considered with any written or oral forward looking statements that we may issue in the

future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward looking statements to conform these statements to reflect actual results, later events or circumstances, or to reflect the occurrence of unanticipated events.

As used herein, "we," "us," "our," or the "Company" means InVivo Therapeutics Holdings Corp., together with our wholly owned subsidiary InVivo Therapeutics Corporation, unless otherwise noted.

Risk Factor Summary

Our business is subject to a number of risks of which you should be aware before making an investment decision. 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.

- We are wholly dependent on the success of one product candidate, the *Neuro-Spinal Scaffold* implant, for which we completed enrollment into the INSPIRE 2.0 Study in June 2022, and for which we expect top-line clinical results late in the first quarter of 2023. We cannot be certain that we will be able to obtain favorable clinical results in our clinical trials, including in the INSPIRE 2.0 Study, and further, we cannot be certain that regulatory authorities will accept the results of our clinical trials or interpret them the way that we do. Further, even if we are able to obtain favorable clinical results, including in the INSPIRE 2.0 Study, we may not be able to obtain regulatory approval for, or successfully commercialize, our *Neuro-Spinal Scaffold* implant.

- We will need additional funding before achieving potential profitability. 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, engage in one or more potential transactions, or cease our operations entirely.

- There is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail or cease our operations.

- We anticipate that we will continue to incur substantial losses for the foreseeable future and may never achieve or maintain profitability.

- The COVID-19 pandemic may continue to have adverse effects on our business and operations, including, for example, the disruption of regulatory activities. In addition, this pandemic has caused substantial disruption in economies worldwide, and may cause disruption in the financial markets, both of which could result in adverse effects on our business and operations.

- If we cannot protect, maintain and, if necessary, enforce our intellectual property rights, our ability to develop and commercialize products will be adversely impacted.

- We will depend upon strategic relationships to develop and manufacture our products. If these relationships are not successful, we may not be able to capitalize on the market potential of these products.

- Our success depends on our ability to retain our management and other key personnel.

- We may face, and in the past have faced, lawsuits, which could divert management's attention and harm our business.

- The price of our common stock has been and may continue to be volatile, which could lead to losses by investors and costly securities litigation.

Item 1. BUSINESS

Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries, or SCIs. Our mission is to redefine the life of the SCI patient, and we seek to develop treatment options intended to provide meaningful improvement in patient outcomes following SCI. Our approach to treating acute SCIs is based on our investigational *Neuro-Spinal Scaffold* implant, a bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord and is intended to treat acute SCI. The *Neuro-Spinal Scaffold* implant incorporates intellectual property licensed under an exclusive, worldwide license from Boston Children's Hospital (BCH) and the Massachusetts Institute of Technology (MIT). We also plan to evaluate other technologies and therapeutics that may be complementary to our development of the *Neuro-Spinal Scaffold* implant or offer the potential to bring us closer to our goal of redefining the life of the SCI patient.

The current standard of care for acute management of spinal cord injuries focuses on preventing further injury to the spinal cord. However, the current standard of care does not address repair of the spinal cord.

Market Opportunity

Our clinical program is intended to address the lack of successful treatments for SCIs, which can lead to permanent paralysis, sensory impairment, and autonomic (bowel, bladder, and sexual) dysfunction. The current management of acute SCI is a surgical approach consisting of spine stabilization and an external decompression procedure of uncertain value. We believe the market opportunity for our *Neuro-Spinal Scaffold* implant is significant. It is estimated that approximately 285,000 people are currently living in the United States with paralysis due to SCI (chronic SCI), and approximately 17,000 individuals in the United States will become fully or partially paralyzed each year (acute SCI). We are pursuing regulatory approval from the U.S. Food and Drug Administration, or FDA, through the Humanitarian Device Exemption, or HDE, pathway. When this pathway was initiated for the *Neuro-Spinal Scaffold* implant, it was limited to populations of 4,000 or less patients per year. We were granted a Humanitarian Use Device, or HUD, designation for the *Neuro-Spinal Scaffold* implant, which includes thoracic and cervical patients afflicted with complete (no motor or sensory function in the lowest sacral segments) SCI, such as paraplegia or tetraplegia, and excludes gunshot or other penetrating wounds. The 21st Century Cures Act increased the upper population limit for an HDE from 4,000 to 8,000, which allows us to potentially request an expansion of our current HUD to include additional SCI patients, i.e., incomplete (partial sensory or sensory/motor function below the injury site, including the lowest sacral segments) SCI patients. Future products, which may include use of stem cells or drug ingredients, may enable the treatment of a broader population such as patients with chronic paralysis and would require separate regulatory approval.

Since 1973, the National Spinal Cord Injury Statistical Center, or NSCISC, at the University of Alabama has been commissioned by the U.S. government to maintain a national database of SCI statistics. The financial impact of SCIs, as reported by the NSCISC, is substantial. Direct costs, which include hospital and medical expenses, modification of the home, and personal assistance, are highest in the first year after injury. According to the fact sheet published in 2017 by NSCISC titled "Spinal Cord Injury—Facts and Figures at a Glance", (i) during the first year, average cost of care ranges from $352,279 to $1,079,412, depending on the severity of the injury, (ii) the net present value, or NPV, to maintain a quadriplegic injured at age 25 for life is $4,789,384, and (iii) the NPV to maintain a paraplegic injured at age 25 for life is $2,341,988. These costs place a tremendous financial burden on families, insurance providers, and government agencies. Moreover, despite such a significant financial investment, the patient often remains disabled for life because current medical interventions address only the symptoms of SCI rather than the underlying neurological cause. We believe our approach could represent an important advance in the treatment of SCIs.

The American Spinal Injury Association, or ASIA, in collaboration with the International Spinal Cord Society, or ISCoS, has developed a neurologic examination tool for assessing SCI known as the International Standards for Neurological Classification of Spinal Cord Injury, or ISNCSCI. Results of the ISNCSCI examination are used to determine the ASIA Impairment Scale, or AIS, classification.

Patients with complete SCI are classified as AIS A. Patients with incomplete SCI, who have partial sensory and/or motor function below the level of injury, including the lowest sacral segments, are classified as AIS B (partial sensory function), AIS C (partial sensory and motor function), or AIS D (partial sensory and increased motor function,

i.e., can move at least half of the muscles against gravity). Patients who have a complete return of sensory and motor function are classified as AIS E.

These classifications are based upon the ISNCSCI examination in which an examiner performs a neurologic examination to assess sensory function of the entire body and motor function of the upper and lower extremities.

Our Clinical Program

We currently have one clinical development program for the treatment of acute SCI.

Neuro-Spinal Scaffold Implant for acute SCI

Our *Neuro-Spinal Scaffold* implant is an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord. The *Neuro-Spinal Scaffold* implant is intended to promote appositional, or side-by-side, healing by supporting the surrounding tissue after injury, minimizing expansion of areas of necrosis, and providing a biomaterial substrate for the body's own healing/repair processes following injury. We believe this form of appositional healing may spare white matter, increase neural sprouting, and diminish post-traumatic cyst formation.

The *Neuro-Spinal Scaffold* implant is composed of two biocompatible and bioresorbable polymers that are cast to form a highly porous investigational product:

- Poly lactic-co-glycolic acid, a polymer that is widely used in resorbable sutures and provides the biocompatible support for *Neuro-Spinal Scaffold* implant; and

- Poly-L-Lysine, a positively charged polymer commonly used to coat surfaces in order to promote cellular attachment.

Because of the complexity of SCIs, it is likely that multi-modal therapies will be required to maximize positive outcomes in SCI patients. In the future, we may attempt to further enhance the performance of our *Neuro-Spinal Scaffold* implant through multiple combination strategies involving electrostimulation devices, additional biomaterials, drugs approved by the FDA, or growth factors. We expect the *Neuro-Spinal Scaffold* implant to be regulated by the FDA as a Class III medical device.

INSPIRE 2.0 Study

Our *Neuro-Spinal Scaffold* implant has been approved to be studied under our approved Investigational Device Exemption, or IDE in the INSPIRE 2.0 Study, which is titled the "Randomized, Controlled, Single-blind Study of Probable Benefit of the *Neuro-Spinal Scaffold*™ for Safety and Neurologic Recovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury as Compared to Standard of Care." The purpose of the INSPIRE 2.0 Study is to assess the overall safety and probable benefit of the *Neuro-Spinal Scaffold* for the treatment of neurologically complete thoracic traumatic acute SCI. The INSPIRE 2.0 Study is designed to enroll 10 subjects into each of the two study arms, which we refer to as the Scaffold Arm and the Comparator Arm. Patients in the Comparator Arm will receive the standard of care, which is spinal stabilization without dural opening or myelotomy. The INSPIRE 2.0 Study is a single blind study, meaning that the patients and assessors are blinded to treatment assignments. The FDA approved the enrollment of up to 35 patients in this study so that there would be at least 20 evaluable patients (10 in each study arm) at the primary endpoint analysis, accounting for events such as randomization, screen failures or deaths that would prevent a patient from reaching the primary endpoint visit. On June 2, 2022, the Company announced that it had completed enrollment in the INSPIRE 2.0 Study. Top-line data from the INSPIRE 2.0 Study is expected late in the first quarter of 2023.

The primary endpoint is defined as the proportion of patients achieving an improvement of at least one AIS grade at six months post-implantation. Assessments of AIS grade are at hospital discharge, three months, six months, 12 months and 24 months. The definition of study success for INSPIRE 2.0 is that the difference in the proportion of subjects who demonstrate an improvement of at least one grade on AIS assessment at the six-month primary endpoint follow-up visit between the Scaffold Arm and the Comparator Arm must be equal to or greater than 20%. In one example, if 50% of subjects in the Scaffold Arm have an improvement of AIS grade at the six-month primary endpoint

and 30% of subjects in the Comparator Arm have an improvement, then the difference in the proportion of subjects who demonstrated an improvement is equal to 20% (50% minus 30% equals 20%) and the definition of study success would be met. In another example, if 40% of subjects in the Scaffold Arm have an improvement of AIS grade at the six-month primary endpoint and 30% of subjects in the Comparator Arm have an improvement, then the difference in the proportion of subjects who demonstrated an improvement is equal to 10% (40% minus 30% equals 10%) and the definition of study success would not be met. Additional endpoints include measurements of changes in NLI, sensory levels and motor scores, bladder, bowel and sexual function, pain, Spinal Cord Independence Measure, and quality of life.

Our *Neuro-Spinal Scaffold* was previously studied in The INSPIRE Study: the "InVivo Study of Probable Benefit of the Neuro- Spinal Scaffold for Safety and Neurologic Recovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury," under an IDE application for the treatment of neurologically complete thoracic traumatic acute SCI. Although The INSPIRE Study was structured with an Objective Performance Criterion, or OPC, as the primary component for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing a future HDE application. Similarly, while our INSPIRE 2.0 Study is structured with a definition of study success requiring a minimum difference between study arms in the proportion of subjects achieving improvement, that success definition is not the only factor that the FDA would evaluate in the future HDE application. Approval is not guaranteed if the OPC is met for The INSPIRE Study or the definition of study success is met for the INSPIRE 2.0 Study, and even if the OPC or definition of study success are not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor's body of evidence. We cannot be certain what additional information or studies will be required by the FDA to approve our HDE submission.

In 2016, the FDA accepted our proposed HDE modular shell submission and review process for the *Neuro-Spinal Scaffold* implant. The HDE modular shell is comprised of 3 modules: a preclinical studies module, a manufacturing module, and a clinical data module. As part of its review process, the FDA reviews each module, which are individual sections of the HDE submission, on a rolling basis. Following the submission of each module, the FDA reviews and provides feedback, typically within 90 days, allowing the applicant to receive feedback and potentially resolve any deficiencies during the review process. Upon receipt of all 3 modules, which constitutes the complete HDE submission, the FDA makes a filing decision that may trigger the review clock for an approval decision. We submitted the first module (the preclinical module) in March 2017 and have received feedback and provided additional updates to the FDA since that time, including our latest update which was submitted to the FDA in April 2021. In July 2021, the FDA informed us that our preclinical module was accepted. In December 2021, we submitted the second module (the manufacturing module) to the FDA. In June 2022, we received feedback from the FDA on the second module (the manufacturing module) and we are actively assessing the FDA's responses and potential timelines for submitting a response for the second module.

Intellectual Property

We rely on a combination of patents, licenses, trade secrets, and non-disclosure agreements to develop, protect, and maintain our intellectual property. Our patent portfolio includes patents and patent applications. We seek to develop or obtain intellectual property that we believe might be useful or complementary with our products and technologies, including by way of licenses or acquisitions of other companies or intellectual property from third parties.

We hold an exclusive worldwide license to a broad suite of patents co-owned by BCH and MIT covering the use of a wide range of polymers to treat SCI, and to promote the survival and proliferation of human stem cells in the spinal cord, or the BCH License. Issued patents and pending patent applications licensed under the BCH License cover the technology underlying our *Neuro- Spinal Scaffold* implant and the use of a wide range of biomaterial scaffolding for treating SCI by itself or in combination with drugs, growth factors, or human stem cells. The BCH License covers 6 issued United States patents and 19 issued international patents expiring between 2022 and 2027.

The BCH License has a term of 15 years from the effective date of July 2, 2007, or as long as the life of the last expiring patent right under the license, whichever is longer, unless terminated earlier by BCH. The last expiring patent under the BCH License currently expires in 2027. In connection with our acquisition of the BCH License, we submitted to a 5-year development plan to BCH and MIT that includes certain targets and projections related to the timing of product development and regulatory approvals. We are required to either meet the stated targets and projections in the plan or notify BCH and revise the plan. BCH has the right to terminate the BCH License for failure by us to either meet

the targets and projections in the plan or our failure to submit an acceptable revision to the plan within a 60-day cure period after notification by BCH that we are not in compliance with the plan. We are currently in compliance with the development plan.

We have the right to sublicense the patents covered by the BCH License and have full control and authority over the development and commercialization of any products that use the licensed technology, including clinical trial design, manufacturing, marketing, and regulatory filings. We also own the rights to the data generated pursuant to the BCH License, whether generated by us or a sublicensee. We have the first right of negotiation with BCH and MIT for a 30 day period to any improvements to the intellectual property covered by the BCH License.

We are required to pay certain fees and royalties under the BCH License. We paid an initial fee upon execution of the BCH License and are required to pay an amendment fee if we expand the field of use under the BCH License. We are also required to make milestone payments upon completing various phases of product development, including upon (i) filing with the FDA of the first investigational new drug application and IDE application for a product that uses the licensed technology; (ii) enrollment of the first patient in Phase II testing for a product that uses the licensed technology; (iii) enrollment of the first patient in Phase III testing for a product that uses the licensed technology; (iv) filing with the FDA each new drug application or related application for a product that uses the licensed technology; (v) FDA approval of the first new drug application or related application for a product that uses the licensed technology; and (vi) first market approval in any country outside the United States for a product that uses the licensed technology. As of December 2022, we had paid fees associated with the achievement of milestones (i), (ii) and (iii) described above. Each year prior to the release of a licensed product, we are also required to pay a maintenance fee for the BCH License. Further, we are required to make ongoing payments based on any sublicenses we grant to manufacturers and distributors. Following commercialization, we are required to make ongoing royalty payments equal to a percentage in the low single digits of net sales of any product that uses the licensed technology.

In addition to the rights we license under the BCH License, we have additional rights relating to the *Neuro-Spinal Scaffold* implant. Together with MIT, we co-own U.S. patent No. 10,131,786 (“Poly((lactic-co-glycolic acid)-b-lysine) and process for synthesizing a block copolymer of PLGA and PLL- (poly-e-cbz-l-lysine)”), which expires in 2033.

Government Regulation

The testing, manufacturing, and potential labeling, advertising, promotion, distribution, import, and marketing of our products are and would be subject to extensive regulation by governmental authorities in the United States and in other countries. In the United States, the FDA, under the Public Health Service Act, the Federal Food, Drug and Cosmetic Act (FDCA), the FDA regulates, among other things, medical device products. In particular, the FDA regulates medical devices to ensure that when distributed domestically and/or abroad, they are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition, our products under development are subject to extensive regulation by other U.S. federal and state regulatory bodies and comparable authorities in other countries. To ensure that medical products distributed domestically are safe and effective for their intended use, the FDA and comparable authorities in other countries have imposed regulations that govern, among other things, the following activities that we or our partners perform or will perform:

- product design and development;
- product testing;
- product manufacturing;
- product labeling;
- product storage;
- premarket clearance, approval, or Conformité Européenne (“CE”) marking of products;
- advertising and promotion;

- product marketing, sales, and distribution; and
- post-market surveillance reporting, including reporting of death or serious injuries.

The labeling, advertising, promotion, marketing, and distribution of biopharmaceuticals, or biologics, and medical devices also must be in compliance with the FDA requirements which include, among others, standards and regulations for off-label promotion, industry-sponsored scientific and educational activities, promotional activities involving the internet, and direct-to-consumer advertising. In addition, the Federal Trade Commission, or FTC, also regulates the advertising of many medical devices. The FDA and the FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from regulatory standards and enforcement actions that can include seizures, injunctions, and criminal prosecution. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

The FDA has broad premarket, post-market, and regulatory enforcement powers. As with medical devices, manufacturers of biologics and combination products are subject to unannounced inspections by the FDA to determine compliance with applicable regulations, and these inspections may include the manufacturing facilities of some of our subcontractors. Failure by manufacturers or their suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities. Potential FDA enforcement actions, discussed in more detail further below, include:

- warning letters, fines, injunctions, consent decrees, and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, or refunds;
- recall, detention, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance on HDE or premarket approval applications, or PMA, of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances on HDE or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

FDA Regulation—Medical Device Products

FDA’s Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires one of the following: (i) grant of a de-novo classification petition; (ii) clearance under a 510(k) premarket notification; (iii) approval under a PMA application; or (iv) approval under an HDE. During public health emergencies, FDA also may grant emergency use authorizations (EUAs) to allow commercial distribution of devices intended to address the public health emergency. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturing and regulatory control needed to ensure its safety and effectiveness.

Class I devices include those with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to the FDA’s “general controls” for medical devices, which include compliance

with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events and malfunctions through the submission of Medical Device Reports, or MDRs, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I or low risk devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are moderate risk devices subject to the FDA's general controls, and any other "special controls" deemed necessary by the FDA to ensure the safety and effectiveness of the device, such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or post-market surveillance. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process, though certain Class II devices are exempt from this premarket review process. When required, the manufacturer must submit to the FDA a premarket notification, or 510(k), submission demonstrating that the device is "substantially equivalent" to a legally marketed predicate device, which in some cases may require submission of clinical data. If the FDA determines that the device, or its intended use, is not substantially equivalent to a legally marketed device, the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill more rigorous premarket approval requirements.

Class III devices include devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices and devices deemed not substantially equivalent to a predicate device following a 510(k) submission. The safety and effectiveness of Class III devices cannot be reasonably assured solely by general or special controls. Submission and FDA approval of a PMA application is required before marketing of a Class III device can proceed. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA application, which is intended to demonstrate that the device is reasonably safe and effective for its intended use and must be supported by extensive data, typically including data from preclinical studies and clinical trials. A Class III device may qualify for FDA approval to be distributed under a HDE rather than a PMA. HDEs are very similar to PMAs but are not required to demonstrate a reasonable assurance of effectiveness. Rather, HDE applications require demonstration of "probable benefit." Devices marketed under an HDE must also first be designated as a HUD. Our *Neuro-Spinal Scaffold* implant is a Class III device, and we are initially seeking HDE approval. Following our receipt of HDE approval, we intend to pursue a PMA for our *Neuro-Spinal Scaffold* for use in a broader patient population.

Premarket Approval Pathway

Class III devices that do not qualify as HUDs require a PMA before they can be marketed, although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. In addition, HDE approved Class III devices require a PMA if the manufacturer desires to expand indications for use or patient populations, or to otherwise treat more than 8,000 patients per year and avoid the other limitations imposed on HDE approved devices. The PMA process is more demanding than the HDE and 510(k) processes. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. In some cases, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR. PMA devices are also subject to the payment of user fees.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of

those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which may affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

Humanitarian Device Exemption (HDE)

Alternatively, a Class III device may qualify for FDA approval to be distributed under an HDE rather than a PMA. For a device to be eligible for an HDE, it must be first designated by the FDA as a HUD intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 8,000 individuals in the United States per year (increased by the 21st Century Cures Act from 4,000 to 8,000). The HDE pathway also requires that there must be no other comparable device available to provide therapy for this condition. An HDE application is similar in form and content to a PMA and, although exempt from the effectiveness requirements of a PMA, an HDE does require sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. In addition, a HUD may only be used in facilities that have established a local institutional review board, or IRB, to supervise clinical testing of devices, and after an IRB has approved the use of the device to treat or diagnose the specific disease.

In addition, except in certain circumstances, products approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit). Currently, a product is only eligible to be sold for profit after receiving HDE approval if the device (1) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or (2) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe. If an HDE-approved device does not meet either of the eligibility criteria, the device cannot be sold for profit. We expect our *Neuro-Spinal Scaffold* implant may meet the eligibility criteria to be sold for a profit.

Clinical Trials

Clinical trials are almost always required to support a PMA or HDE application. If the device presents a "significant risk" to human health as defined by the FDA, the FDA requires the device sponsor to submit an IDE to the FDA and obtain IDE approval prior to commencing the human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. The IDE must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a "non-significant risk" device, in which case an IDE approval from the FDA would not be required, although the clinical trial would need to meet other requirements including Institutional Review Board (IRB) approval. The IRB is responsible for the initial and continuing review of the IDE study, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Clinical trials for a significant risk device may begin once an IDE is approved by the FDA and the appropriate IRB at each clinical trial site. Future clinical trials may require that we obtain an IDE from the FDA prior to commencing any such clinical trial and that the trial be

conducted with the oversight of an IRB at the clinical trial site.

Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

Our clinical trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human subject protection, including informed consent and healthcare privacy. A clinical trial may be suspended by the FDA or at a specific site by the relevant IRB at any time for various reasons, including a belief that the risks to the trial participants outweigh the benefits of participation in the clinical trial. Even if a clinical trial is completed, the results of our clinical testing may not demonstrate the safety and efficacy of the device, or may be equivocal or otherwise not be sufficient for us to obtain approval of our product.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Pervasive and Continuing FDA Regulation (Post-market Regulation)

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared or unapproved indications or other off-label uses;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- approval of product modifications that affect the safety or effectiveness of one of our approved devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;

- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

Class III devices that obtain HDE approval are subject to the additional restrictions discussed above, including:

- the treatment of no more than 8,000 individuals in the United States per year;
- a HUD may only be used if approved by an IRB to supervise clinical testing of devices, and after an IRB has approved the use of the device to treat or diagnose the specific disease; and
- limitations on whether the device may be sold for a profit, subject to certain exceptions.

We, and any third party manufacturers that we use, must register with the FDA as medical device manufacturers and must obtain all necessary state permits or licenses to operate our business. As manufacturers, we, and any third party manufacturers that we use, are subject to announced and unannounced inspections by the FDA to determine our compliance with quality system regulation and other regulations. We have not yet been inspected by the FDA. We believe that we are in substantial compliance with quality system regulation and other regulations.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, or refunds;
- recall, detention, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance on HDE or PMA of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances on HDE or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Regulatory Pathway for the Neuro-Spinal Scaffold Implant

The *Neuro-Spinal Scaffold* implant will be regulated by the FDA as a Class III medical device. The FDA granted HUD designation for our *Neuro-Spinal Scaffold* implant in 2013 for use in complete SCI (defined as less than 4,000 patients per year at the time), thus allowing us to qualify for FDA approval under an HDE. In 2015, we received conditional approval from the FDA to convert our ongoing pilot study into a pivotal probable benefit study (The INSPIRE Study). Full approval of such conversion was subsequently granted in January 2016. In early March 2018, we received FDA approval for a randomized controlled trial (the INSPIRE 2.0 Study) to supplement the existing clinical evidence for the *Neuro-Spinal Scaffold* implant that we obtained from The INSPIRE Study.

In 2016, the FDA accepted our proposed HDE modular shell submission and review process for the *Neuro-Spinal Scaffold* implant. The HDE modular shell is comprised of 3 modules: a preclinical studies module, a manufacturing module, and a clinical data module. As part of its review process, the FDA reviews each module, which

are individual sections of the HDE submission, on a rolling basis. Following the submission of each module, the FDA reviews and provides feedback, typically within 90 days, allowing the applicant to receive feedback and potentially resolve any deficiencies during the review process. Upon receipt of all 3 modules, which constitutes the complete HDE submission, the FDA makes a filing decision that may trigger the review clock for an approval decision. We submitted the first module (the preclinical module) in March 2017 and have received feedback and provided additional updates to the FDA since that time, including our latest update which was submitted to the FDA in April 2021. In July 2021, the FDA informed us that our preclinical module was accepted. In December 2021, we submitted the second module (the manufacturing module) to the FDA. The HDE submission will not be complete until the clinical data module is also submitted. In June 2022, we received feedback from the FDA on the second module (the manufacturing module) and we are actively assessing the FDA's responses and potential timelines for submitting a response for the second module.

In the future, if our *Neuro-Spinal Scaffold* implant is approved via either the PMA or HDE pathway, modifications or enhancements that could significantly affect the safety or effectiveness of the device or that constitute a major change to the intended use of the device will require new PMA or HDE application and approval.

Other changes may require a supplement or other change notification that must be reviewed and approved by the FDA. Modified devices for which a new PMA or HDE application, supplement, or notification is required cannot be distributed until the application is approved by the FDA. An adverse determination or a request for additional information could delay the market introduction of new products, which could have a material adverse effect on our business, financial condition, and results of operations. We may not be able to obtain PMA or HDE approval in a timely manner, if at all, for the *Neuro-Spinal Scaffold* implant or any future devices or modifications to *Neuro-Spinal Scaffold* implant or such devices for which we may submit a PMA or HDE application.

European Economic Area or the EEA

Sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our products outside the United States, we must obtain regulatory approvals or CE Certificates of Conformity and comply with extensive safety and quality regulations. The time required to obtain approval by a foreign country or to obtain a CE Certificate of Conformity may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. In the EEA, we are required to obtain Certificates of Conformity before drawing up a European Commission, or EC, Declaration of Conformity and affixing the CE mark to our medical devices. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE Certificates of Conformity or FDA clearance or approval although others, such as Brazil, Canada and Japan, require separate regulatory filings. We have not yet applied for a CE mark for the *Neuro-Spinal Scaffold* implant.

If any of our products has been CE marked and placed on the market in the EEA, we would need to comply with a number of regulatory requirements relating to:

- registration/notification of medical devices in individual EEA countries;
- pricing and reimbursement of medical devices;
- establishment of post-marketing surveillance and adverse event reporting procedures;
- Field Safety Corrective Actions, including product recalls and withdrawals;
- marketing and promotion of medical devices; and
- interactions with physicians.

Failure to comply with these requirements at such time could result in enforcement measures being taken against us by the competent authorities of the EEA countries. These measures can include fines, administrative penalties, compulsory product withdraws, injunctions, and criminal prosecution. Such enforcement measures would have an

adverse effect on our capacity to market our products in the EEA and, consequently, on our business and financial position. Such failures could also lead to cancelation, suspension, or variation of our CE Certificates of Conformity by the relevant Notified Body, which is an organization designated by the competent authorities of an EEA country to conduct conformity assessments.

Further, the advertising and promotion of our products in the EEA is subject to regulatory directives concerning misleading and comparative advertising, and unfair commercial practices, as well as other national legislation in the individual EEA countries governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

Financial Information and Research and Development Expenditures

We have incurred net losses each year since our inception, including net losses of $10.5 million for the year ended December 31, 2022 and $9.9 million for the year ended December 31, 2021. To date, we have not commercialized any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities related to our *Neuro Spinal Scaffold* implant. Our research and development expenditures, which include research and development related to our product candidates, were $5.2 million and $4.4 million in 2022 and 2021, respectively.

Competition

We have many potential competitors, including major drug companies, specialized biotechnology firms, academic institutions, government agencies, and private and public research institutions. Many of these competitors have significantly greater financial and technical resources than us, and superior experience and expertise in research and development, preclinical testing, design and implementation of clinical trials, regulatory processes and obtaining regulatory approval for products, production and manufacturing, and sales and marketing of approved products. Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly if they have collaborative arrangements with larger and more established biotechnology companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, and registering subjects for clinical trials.

In order to compete effectively, we will have to make substantial investments in development, clinical testing, manufacturing, and sales and marketing, or partner with one or more established companies. There is no assurance that we will be successful in having any of our products approved or gaining significant market share for any of our products. Our technologies and products also may be rendered obsolete or noncompetitive as a result of products introduced by our competitors.

Manufacturing

We have developed a proprietary manufacturing process to build our *Neuro-Spinal Scaffold* implant. We manufacture our implants following FDA regulations for design controls using 2 fully operational manufacturing cleanrooms located at our facility in Cambridge, Massachusetts. These 2 cleanrooms are validated to ISO 14644 1 Class ISO 7 (Class 10-K) and Class ISO 8 (Class 100k) cleanroom standards, respectively. In addition, the manufacturing process contains numerous quality control steps including in process and final inspection. Currently, we are working with 2 vendors for our critical raw materials; however, these materials are also available from other vendors. We are currently manufacturing our *Neuro-Spinal Scaffold* implant to support the INSPIRE 2.0 Study. If we are able to move toward preparing for commercialization, we intend to be compliant with all applicable regulations on a country specific basis.

Sales and Marketing

If we obtain approval from the FDA, or another foreign regulatory body, to commercialize our products, we plan to establish a direct sales force to sell our products to major markets in the United States, and we may sell direct or through distributors in major foreign markets. We anticipate the direct sales force, once and if established, would focus its efforts on maximizing revenue through product training, placement, and support. We would also seek to establish

strong relationships with neurosurgeons, orthopedic spine surgeons, and trauma surgeons, and would expect to provide a high level of service for any of our approved products including providing on-site assistance and service during procedures. In addition, we expect to implement medical education programs intended for outreach to practitioners in physical medicine and rehabilitation centers and patient advocacy groups. We may also seek corporate partners with expertise in commercialization.

Compliance with Environmental, Health and Safety Laws

In addition to the FDA regulations discussed above, we are also subject to evolving federal, state, and local environmental, health, and safety laws and regulations. In the past, compliance with environmental, health, and safety laws and regulations has not had a material effect on our capital expenditures. We believe that we comply in all material respects with existing environmental, health, and safety laws and regulations applicable to us.

Employees and Human Capital

As of December 31, 2022, we had six full-time employees. None of our employees are represented by a labor union and we consider our employee relations to be good. We also utilize a number of consultants to assist with financial, research and development, human resources, clinical and regulatory activities. We believe that our future success will depend in part on our continued ability to attract, hire, and retain qualified personnel.

Corporate Information

We were incorporated on April 2, 2003, under the name of Design Source, Inc. as a Nevada corporation. On October 26, 2010, we acquired the business of InVivo Therapeutics Corporation, which was founded in 2005 as a Delaware corporation, and we are continuing the existing business operations of InVivo Therapeutics Corporation as our wholly-owned subsidiary.

Our principal executive offices are located in leased premises at One Kendall Square, Building 1400 West, 4th Floor, Suite B14402, Cambridge, Massachusetts 02139. Our telephone number is (617) 863-5500. We maintain a website at www.invivotherapeutics.com. Information contained on, or accessible through, our website is not a part of, and is not incorporated by reference into this Annual Report on Form 10-K.

Available Information

We make available free of charge on or through the Investor Relations link on our website, www.invivotherapeutics.com, all materials that we file electronically with the Securities and Exchange Commission, including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports.

Information appearing on the above websites is not a part of, and is not incorporated in, this Annual Report on Form 10-K. Further, our references to the URLs for these websites are intended to be inactive textual reference only.

Item 1A. RISK FACTORS

Certain factors may have a material adverse effect on our business, financial condition, and results of operations. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. 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. If any of the following risks actually occurs, our business, financial condition, results of operations, and future prospects could be materially and adversely affected.

Risks Related to Our Business

We are wholly dependent on the success of one product candidate, the Neuro-Spinal Scaffold implant, for which we completed enrollment into the INSPIRE 2.0 Study in June 2022, and for which we expect top-line clinical results late in the first quarter of 2023. We cannot be certain that we will be able to obtain favorable clinical results in our clinical trials, including in the INSPIRE 2.0 Study, and further, we cannot be certain that regulatory authorities will accept the results of our clinical trials or interpret them the way that we do. Further, even if we are able to obtain favorable clinical results, including in the INSPIRE 2.0 Study, we may not be able to obtain regulatory approval for, or successfully commercialize, our Neuro-Spinal Scaffold implant.

We currently have only one product candidate, the *Neuro-Spinal Scaffold* implant, in clinical development, and our business depends almost entirely on the successful clinical development, regulatory approval, and commercialization of that product candidate, which may never occur. We expect top-line clinical results late in the first quarter of 2023 for the INSPIRE 2.0 Study of the *Neuro-Spinal Scaffold*, and we cannot be certain that these data will be favorable, or even if favorable, whether regulatory authorities such as the FDA will accept the results of the trial.

We currently have no products available for sale, generate no revenues from sales of any products, and we may never be able to develop marketable products. Our *Neuro-Spinal Scaffold* implant will require substantial additional clinical development, testing, manufacturing process development, and regulatory approval before we are permitted to commence its commercialization. Before obtaining regulatory approval via the Humanitarian Device Exemption, or HDE, pathway for the commercial sale of any product candidate, we must demonstrate through extensive preclinical testing and clinical trials that the product candidate does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

Although we have completed enrollment into our INSPIRE 2.0 Study, our clinical trial results may subsequently fail to meet the safety and probable benefit standards required to obtain regulatory approvals. For example, in the INSPIRE Study, two of the 16 evaluable patients were initially assessed to have improved from complete AIS A SCI to incomplete AIS B SCI, but each was later assessed to have reverted to complete AIS A SCI prior to the patient's 6-month examination. Of these two patients, one patient had converted back to AIS B and the other patient remained at AIS A at the six-month examination. There is known and published variability in some of the measures used to assess AIS improvement and these measures can vary over time or depending upon the examiner. While we implemented procedures in The INSPIRE Study and the INSPIRE 2.0 Study to limit such variations and will also implement procedures in any future clinical study to limit such variations, we cannot be certain that regulatory authorities will accept the results of our clinical trials or interpret them the way that we do.

Alternatively, if we were to seek premarket approval, or PMA, for our product candidate, that would require demonstration that the product is safe and effective for use in each target indication. This process can take many years. Of the large number of medical devices in development in the United States, only a small percentage successfully complete the regulatory approval process required by the FDA and are commercialized. Accordingly, even if we are able to obtain the requisite capital to continue to fund our development and clinical programs, we may be unable to successfully develop or commercialize our *Neuro-Spinal Scaffold* implant or any other product candidate.

The clinical trials of any of our current or future product candidates are, and the manufacturing and marketing of any such product candidates will be, subject to extensive and rigorous review and regulation by the FDA and other government authorities in the United States and in other countries where we intend to test and, if approved, market such product candidates.

The COVID-19 pandemic, which began in late 2019 and has had impacts worldwide, previously delayed our potential to enroll patients in our INSPIRE 2.0 clinical trial and may, in the future continue to have other adverse effects on our business and operations, including the disruption of regulatory activities. In addition, the pandemic has caused substantial disruption to economies worldwide and may adversely impact the financial markets, both of which could result in adverse effects on our business and operations.

The COVID-19 pandemic, which began in December 2019, has had impacts worldwide, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations remain uncertain. We and our clinical research organizations, as well as clinical trial sites, have faced disruptions related to the INSPIRE 2.0 clinical trial arising from suspension of activity at numerous clinical trial sites due to hospital staff shortages or state or city ‘‘stay at home’’ or ‘‘shelter in place’’ orders, delays in the ability to obtain necessary institutional review board, or IRB, or other necessary site approvals, as well as other delays at clinical trial sites. Specifically, we are aware that a significant number of our clinical sites had previously temporarily suspended enrollment into the INSPIRE 2.0 Study at their institution due to the coronavirus pandemic. Although we have now completed enrollment into our INSPIRE 2.0 Study, the full impact of the COVID-19 pandemic continues to evolve as of the date of filing this Annual Report on Form 10-K, and we cannot be certain what future impact the COVID-19 pandemic may have on our business and operations. Additionally, the response to the COVID-19 pandemic may redirect resources of regulators in a way that would adversely impact our ability to progress regulatory approvals. Any of these factors could continue to adversely impact our ability to seek potential regulatory approval of our *Neuro-Spinal Scaffold* implant. Additionally, the pandemic could cause significant disruptions in the financial markets, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our stock price and trading in our stock. Moreover, it is possible the pandemic will continue to significantly impact economies worldwide, which could result in adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and it has the potential to adversely affect our business, financial condition, results of operations, and prospects.

Risks Related to Our Financial Position and Need for Additional Capital

We will need additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts, engage in one or more potential transactions, or cease our operations entirely.

We estimate that our existing cash resources will be sufficient to fund our operations into the first quarter of 2024. We currently do not have sufficient cash resources to continue our business operations beyond that time. We expect that our expenses will increase in connection with our ongoing activities, particularly as we conclude our INSPIRE 2.0 Study, and as we seek regulatory approval for our *Neuro-Spinal Scaffold* implant. If we obtain regulatory approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to manufacturing, marketing, sales, and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

If we are unable to raise additional capital, we may seek to engage in one or more potential transactions, such as the sale of our company, a strategic partnership with one or more parties or the licensing, sale or divestiture of some of our assets or proprietary technologies, or we may be forced to cease our operation entirely. There can be no assurance that we will be able to enter into such a transaction or transactions on a timely basis or on terms that are favorable to us. If we are unable to raise capital when needed or on attractive terms, or should we engage in one or more potential strategic transactions, we could be forced to delay, reduce, or eliminate our research and development programs or any future commercialization efforts or to cease operations entirely. If we determine to change our business strategy or to seek to engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. Because of the significant

uncertainty regarding these events, we are not able to accurately predict the impact of any potential changes in our existing business strategy.

Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to:

- the scope, progress, results, and costs of preclinical development, laboratory testing, and clinical trials for our *Neuro-Spinal Scaffold* implant and any other product candidates that we may develop or acquire, including our INSPIRE 2.0 Study;
- future clinical trial results of our *Neuro-Spinal Scaffold* implant;
- the timing of, and the costs involved in, obtaining regulatory approvals for the *Neuro-Spinal Scaffold* implant, and the outcome of regulatory review of the *Neuro-Spinal Scaffold* implant;
- the cost and timing of future commercialization activities for our products if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales, and distribution costs;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the cost of having our product candidates manufactured for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- the cost and delays in product development as a result of any changes in regulatory oversight applicable to our product candidates;
- our ability to establish and maintain strategic collaborations, licensing, or other arrangements and the financial terms of such agreements;
- the cost and timing of establishing sales, marketing, and distribution capabilities;
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing our intellectual property portfolio;
- the efforts and activities of competitors and potential competitors;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products, and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, and if we are not successful in raising additional capital, we may not be able to continue as a going concern.

There is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail or cease our operations.

Our consolidated financial statements as of December 31, 2022 were prepared under the assumption that we will continue as a going concern. At December 31, 2022, we had unrestricted cash and cash equivalents of $16.4 million. We estimate that our existing cash resources will be sufficient to fund our operations into the first quarter of 2024. Our

ability to continue as a going concern will depend on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce or contain expenditures, and, ultimately, to generate revenue. Based on these factors, management determined that there is substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern in its report dated March 1, 2023 included elsewhere in this Form 10-K.

If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or part of their investment. When we seek additional financing to fund our business activities as a result of the substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

We have a limited operating history and have incurred significant losses since our inception.

We have incurred net losses each year since our inception, including net losses of $10.5 million for the year ended December 31, 2022, $9.9 million for the year ended December 31, 2021 and $9.1 million for the year ended December 31, 2020. As of December 31, 2022, we had an accumulated deficit of $248.6 million. We have a limited operating history on which to base an evaluation of our business and investors should consider the risks and difficulties frequently encountered by early-stage companies in new and rapidly evolving markets, particularly companies engaged in the development of medical devices. To date, we have not commercialized any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate revenue or become profitable. Moreover, we may allocate significant amounts of capital towards products and technologies for which market demand is lower than anticipated and, as a result, may not achieve expectations or may elect to abandon such efforts.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities related to our *Neuro-Spinal Scaffold* implant. Overall, we expect our research and development expenses to be substantial and to increase for the foreseeable future as we continue the development and clinical investigation of our current and future products. We expect that it could be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market our *Neuro-Spinal Scaffold* implant or other products, our future revenues will depend upon the size of any markets in which our products have received approval, our ability to achieve sufficient market acceptance, reimbursement from third-party payers, and other factors.

We anticipate that we will continue to incur substantial losses for the foreseeable future and may never achieve or maintain profitability.

We expect to continue to incur significant expenses and increasing net losses for at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- continue clinical development of our *Neuro-Spinal Scaffold* implant;
- initiate or restart the research and development of other product candidates;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, protect, and expand our intellectual property portfolio; and
- continue our research and development efforts for new product opportunities.

To become and remain profitable, we must succeed in developing and commercializing our product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our current and future product candidates, developing additional product candidates, obtaining regulatory approval for these product candidates, and manufacturing, marketing, and

selling any products for which we may obtain regulatory approval. We are only in the initial stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

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

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.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, and other third party funding alternatives including license and collaboration agreements. To raise additional capital or pursue strategic transactions, we may in the future sell additional shares of our common stock, or other securities convertible into or exchangeable for our common stock, which will dilute the ownership interest of our current stockholders, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our current stockholders. 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 product candidates, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us or that may reduce the value of our common stock. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce, or terminate our product development or commercialization efforts for our *Neuro-Spinal Scaffold* implant or any other product candidates that we develop or acquire or to cease operations entirely.

Although we recently increased the number of authorized shares available, future increases in authorized shares may be required for future financings or other strategic transactions. We have previously experienced difficulties obtaining quorum for our annual meetings of stockholders and achieving the number of votes required for increases in authorized shares. If we continue to experience such difficulties, we will be limited in our efforts to raise additional capital, and our operations, financial condition and our ability to continue as a going concern may be materially and adversely affected.

We will need to seek the additional capital necessary to fund our operations through public or private equity offerings, debt financings, and collaborative and licensing arrangements. We have limited capital and in order for us to execute on our business plan and remain viable as a going concern, we must have the flexibility to engage in capital raising transactions until we are able to generate sufficient revenue and cash flow. Investors in prior transactions have purchased our common stock or our derivative securities, such as warrants, for which we must reserve unissued common stock. We therefore may need to increase the number of authorized shares of our common stock in order to issue common stock or securities convertible or exercisable into common stock to investors and other strategic partners, and as a result enable us to engage in capital raising transactions and other strategic transactions involving the issuance of equity securities.

Such increases to our authorized common stock require shareholder approval. Our 2021 Annual Meeting of Stockholders was held in July 2021, and we were able to achieve quorum but we were not able to obtain the number of necessary votes to approve an increase in our authorized common stock. In connection with our 2022 Annual Meeting of Stockholders, which took place on September 9, 2022, our Board adopted and applied a voting rights plan, which allowed certain shareholders exercise additional voting rights with respect to their shares of common stock to which the voting rights are applied or the Voting Rights Plan. The Voting Rights Plan was of limited scope of and purpose and was designed to facilitate the approval of an amendment to the Company's Articles of Incorporation to increase the number of authorized shares of common stock and another amendment to the Company's Articles of Incorporation to authorize shares of "blank-check" preferred stock at the 2022 Annual Meeting. Although the implementation of the Voting Rights Plan allowed us to successfully pass both proposals at the 2022 Annual Meeting, we cannot be sure that we will not experience future difficulties in obtaining quorum for our annual meetings or difficulties in obtaining the necessary votes required to pass proposals such as increases in authorized shares, as we experienced at the 2021 Annual Meeting and prior meetings. In such events, we will be limited in our efforts to raise additional capital, and our operations, financial condition and our ability to continue as a going concern may be materially and adversely affected.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

As part of Congress' response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or the FFCR Act, was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted on March 27, 2020. Both contain numerous tax provisions. Effective for tax years beginning after December 31, 2021, the Tax Cuts and Jobs Act of 2017, or the Tax Act amendments to Internal Revenue Code, or the Section 174 will no longer permit an immediate deduction for R&D expenditures in the tax year that such costs are incurred. For expenses that are incurred for R&D in the U.S., such amounts will be amortized over five years (this is currently approximately 90% of the Company's relevant spend), and expenses that are incurred for R&D expenditures outside the U.S. will be amortized over 15 years.

Regulatory guidance under the Tax Act, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. Congress is also considering and may enact further tax law changes in connection with the COVID-19 pandemic, some of which could have an impact on our company. In addition, state tax legislation or administration guidance conforming to or decoupling from particular provisions of the Tax Act, the FFCR Act and the CARES Act could affect our business or financial condition.

Our ability to use our net operating loss, or NOLs, carryforwards and tax credit carryforwards may be limited.

We have generated significant NOLs and research and development tax credits, or R&D credits, as a result of our incurrence of losses and our conduct of research activities since inception. We generally are able to carry NOLs and R&D credits forward to reduce our tax liability in future years but certain NOL carryforwards could expire unused and be unavailable to offset our future income tax liabilities. As described above in "Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition," the Tax Act, as amended by the CARES Act, includes changes to U.S. federal tax rates and the rules governing NOLs that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. Nor is it clear how various states will respond to the Tax Act, the FFCR Act or the CARES Act. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

In addition, our ability to utilize the NOLs and R&D credits is subject to the rules of Sections 382 and 383, respectively, of the Code. Those sections generally restrict the use of NOLs and R&D credits after an "ownership change." An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation's common stock or are otherwise treated as 5% stockholders under Section 382 of the Code and the United States Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation's stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over the applicable testing period. In the event of an ownership change, Section 382 imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carryforwards and Section 383 imposes an annual limitation on the amount of tax a corporation may offset with business credit (including the R&D credit) carryforwards. Any unused annual limitation may be carried over to later years until the applicable expiration date for the respective NOL or R&D credit carryforwards. We have completed several financings since our inception, which may have resulted in an ownership change as defined by Sections 382 and 383 of the Code, or could result in an ownership change in the future, but we have not completed an analysis of whether a limitation as noted above exists.. As of December 31, 2022, we have not performed a Section 382 study yet, but we will complete an appropriate analysis before our tax attributes are utilized.

Acquisitions of companies, businesses, or technologies may substantially dilute our stockholders and increase our operating losses.

We continue to actively evaluate business partnerships and acquisitions of businesses, technologies, or intellectual property rights that we believe would be necessary, useful, or complementary to our current business. Any such acquisition may require assimilation of the operations, products or product candidates, and personnel of the acquired business and the training and integration of its employees, and could substantially increase our operating costs, without any offsetting increase in revenue. We may also acquire the right to use certain intellectual property through licensing agreements, which could substantially increase our operating costs. Acquisitions and licensing agreements may not provide the intended technological, scientific or business benefits and could disrupt our operations and divert our limited resources and management's attention from our current operations, which could harm our existing product development efforts. While we may use cash or equity to finance a future acquisition or licensing agreement, it is likely we would issue equity securities as a significant portion or all of the consideration in any acquisition. The issuance of equity securities for an acquisition could be substantially dilutive to our stockholders. Any investment made in, or funds advanced to, a potential acquisition target could also significantly, adversely affect our results of operations and could further reduce our limited capital resources. Any acquisition or action taken in anticipation of a potential acquisition or other change in business activities could substantially depress the price of our stock. In addition, our results of operations may suffer because of acquisition related costs, or the post-acquisition costs of funding the development of an acquired technology or product candidates or operations of the acquired business, or due to amortization or impairment costs for acquired goodwill and other intangible assets.

Risks Related to the Development, Regulatory Approval, and Commercialization of Our Product Candidates

We have experienced delays in our clinical development of our* Neuro-Spinal Scaffold implant*. Clinical trials for future product candidates may also experience delays or may not be able to commence.

Before we can obtain regulatory approval for the sale of any of our product candidates, including the *Neuro-Spinal Scaffold* implant, we must complete the clinical studies that are required. We previously experienced delays in our clinical development of the *Neuro-Spinal Scaffold* implant, and we cannot be certain that we won't experience future delays in or not successfully complete the clinical development of other product candidates. For example, in July 2017, the INSPIRE Study of our *Neuro-Spinal Scaffold* implant was placed on hold following the third patient death in the trial. We subsequently closed enrollment in The INSPIRE Study and will follow the active patients until completion. Although we have now completed enrollment into the INSPIRE 2.0 Study, we experienced delays in the enrollment of subjects into the study. Future clinical studies and clinical development may take longer than anticipated because of any number of factors, including potential delays in the enrollment of subjects in the study, the availability of scaffold implants or other investigational products to supply to our clinical sites, failure to demonstrate clinical success, the lack of adequate funding to continue any clinical trials, or unforeseen safety issues. Further, enrolling patients into any clinical trial will continue to require the approval of the institutional review boards, or IRBs, at each clinical site.

In addition, clinical trials can be delayed or aborted for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence future clinical trials;
- reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain IRB approval at each site;
- recruit, enroll, and retain patients through the completion of clinical trials;
- maintain clinical sites in compliance with trial protocols through the completion of clinical trials;
- address patient safety concerns that arise during the course of the trial;
- initiate or add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of our product candidate for use in clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, by the relevant IRB at the sites at which such trials are being conducted, by the Data Safety Monitoring Board for such trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, a problematic inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse events, or changes in laws or regulations. In addition,

regulatory agencies may require an audit with respect to the conduct of a clinical trial, which could cause further delays or increase costs. For example, in December 2017, we and several of our clinical sites and our CRO were subject to an FDA inspection in association with The INSPIRE Study. At the close of the inspection at the Company, the FDA issued a Form 483 with two observations relating to our oversight of clinical trial sites in The INSPIRE Study. We sought input from the FDA regarding the scope and timing of our proposed remediation efforts and the FDA has indicated that our corrective actions appear adequate. We cannot be certain that we will not be subject to additional regulatory action by the FDA. Our remediation efforts have added, and may continue to add, costs to our clinical development plans. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and regulatory review process, and jeopardize our ability to obtain approval and commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier nonclinical studies and clinical trials may not be predictive of future trial results.

The results of preclinical studies and early clinical trials of new medical devices do not necessarily predict the results of later-stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our product candidates, and if those assumptions are incorrect, the trials may not produce results to support regulatory approval. We are currently pursuing marketing approval via the HDE regulatory pathway which requires us to show the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit of health outweighs the risk of injury or illness from its use. Preliminary results may not be confirmed upon full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical development may fail to show safety and probable benefit sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to obtain regulatory approval in the United States or elsewhere. It is also possible that patients enrolled in clinical trials will experience adverse events or unpleasant side effects that are not currently part of the product candidate's profile. Because of the uncertainties associated with clinical development and regulatory approval, we cannot determine if or when we will have an approved product ready for commercialization or achieve sales or profits, including in connection with the results of our INSPIRE 2.0 Study for our *Neuro-Spinal Scaffold* implant.

Risks Related to Government Regulation

Our Products and our operations are subject to extensive government regulation and oversight in the United States and overseas. We must obtain FDA approval before we can sell any of our products in the United States and approval of similar regulatory authorities in countries outside the United States before we can sell our products in such countries. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our products if such approval is denied or delayed. If we fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market these products could suffer.

The development, manufacture, and marketing of our products are subject to government regulation in the United States and other countries. In the United States and most foreign countries, we must complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and effectiveness of a product in order to apply for regulatory approval to market the product. If the FDA grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to its distribution. Expanded or additional indications for approved devices may not be approved, which could limit our potential revenues. Foreign regulatory authorities may apply similar or additional limitations or may refuse to grant any approval. Consequently, even if we believe that preclinical and clinical data are sufficient to support regulatory approval for our products, the FDA and foreign regulatory authorities may not ultimately grant approval for commercial sale in any jurisdiction. If our product candidates are not approved, our ability to generate revenues will be limited and our business will be adversely affected.

We are currently pursuing an HDE regulatory pathway in the United States for our *Neuro-Spinal Scaffold* implant. The HDE requires that there is no other comparable device available to provide therapy for a condition and requires sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. The amended protocol for The INSPIRE Study, which was approved in February 2016, established an Objective Performance Criteria, or OPC, which is a measure of study success used in clinical studies designed to demonstrate safety and

probable benefit in support of an HDE approval. The OPC for The INSPIRE Study is currently defined as 25% or more of the patients in the study demonstrating an improvement of at least one ASIA Impairment Scale, or AIS, grade by six months post-implantation. While we expect The INSPIRE Study to serve as one source of data used to support HDE approval in the future, we did not complete full enrollment of that study. In addition, although The INSPIRE Study is structured with the OPC as the primary component for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing a future HDE application.

The FDA had previously recommended that we include a randomized, concurrent control arm in the study and we have proposed and received approval for the INSPIRE 2.0 Study. The primary endpoint is defined as the proportion of patients achieving an improvement of at least one AIS grade at six months post-implantation. The definition of study success is that the difference in the proportion of subjects who demonstrate an improvement of at least one grade on AIS assessment at the six-month primary endpoint follow-up visit between the Scaffold Arm and the Comparator Arm must be equal to or greater than 20%. While our INSPIRE 2.0 Study is structured with a definition of study success requiring a minimum difference between groups in the percentage of subjects achieving improvement, that success definition is not the only factor that the FDA would evaluate in the future HDE application.

Approval is not guaranteed if the OPC is met for The INSPIRE Study or the definition of study success is met for the INSPIRE 2.0 Study, and even if the OPC or definition of study success are not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor's body of evidence.

In addition, as one source of comparator data, we completed the CONTEMPO Registry Study, utilizing existing databases and registries to develop a historical comparator that, to the extent possible, matches patients to those patients enrolled in The INSPIRE Study. Analysis of data from the CONTEMPO Registry Study may suggest a higher threshold for evidencing probable benefit. For example, AIS conversion rates at approximately six months post-injury across the three registries used in CONTEMPO varied from 16.7% – 23.4%, which are higher than the approximately 15.5% conversion rate from the historical registries that were the basis for the selection of the current OPC for The INSPIRE Study.

Even if we successfully complete the INSPIRE 2.0 Study, we cannot be certain that the FDA will agree that this study, together with the CONTEMPO Registry Study, provides sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use.

In the event our clinical data is not acceptable to the FDA, our ability to obtain approval under the HDE pathway may be delayed or may not be feasible. If the FDA does not approve our product candidates in a timely fashion, or at all, our business and financial condition will be adversely affected.

The 21st Century Cures Act increased the upper population limit for an HDE from 4,000 to 8,000, which allows us to potentially request an expansion of our current Humanitarian Use Device, or HUD to include additional patient populations beyond our current HUD for complete SCI. If we choose to pursue such an expansion, this may cause our application to be delayed or cause the FDA to request additional information. In addition, our current study is not designed to support approval beyond complete SCI. Thus, expansion would require additional studies. We cannot be certain that we will be able to increase the potential population that we might be able to treat based on the HDE pathway. If any of these events occur, our business and financial condition will be adversely affected.

There are risks associated with pursuing FDA approval via an HDE pathway, including the possibility that the approval could be withdrawn in the future if the FDA subsequently approves another device for the same intended use, as well as limitations on the ability to profit from sales of the product.

If the FDA subsequently approves a PMA or clears a 510(k) for the HUD or another comparable device with the same indication, the FDA may withdraw the HDE. Once a comparable device becomes legally marketed through PMA or 510(k) clearance to treat or diagnose the disease or condition in question, there may no longer be a need for the HUD and so the HUD may no longer meet the requirements of section 520(m)(2)(B) of the Food Drug & Cosmetic Act, or the FDCA.

Except in certain circumstances, products approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit). Currently, under section 520(m)(6)(A)(i) of the FDCA, as amended by the Food and Drug Administration Safety and Innovation Act, a HUD is only eligible to be sold for profit after receiving HDE approval if the device (1) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or (2) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe. If an HDE-approved device does not meet either of the eligibility criteria, the device cannot be sold for profit. With enactment of the FDA Reauthorization Act of 2017, Congress provided that the exemption for HUD / HDE profitability is available as long as the request for an exemption was submitted before October 1, 2022. HDE holders who wish to sell their devices for profit and who did not submit the request in the original HDE application may submit a supplement and provide adequate supporting documentation to demonstrate that the HUD meets the eligibility criteria.

Modifications to our products may require new regulatory approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.

Modifications to our products may require new regulatory approvals or clearances, including HDE supplements or PMA Supplements, or require us to recall or cease marketing the modified devices until these approvals are obtained. New HDEs or HDE Supplements are required for modifications that affect the safety and probable benefit of an approved HDE. The type of HDE supplement necessary depends on the evidence needed to demonstrate the safety and probable benefit of the change. Examples of changes include: (i) Use of different manufacturing or sterilization site; (ii) Changes in the manufacturing process; (iii) Changes in performance or design; (iv) Select changes in labeling; (v) Changes to a post-approval study plan/protocol; (vi) Change in the trade name of the device; and (vii) Requests for exemption from the prohibition on profit. Any change seeking a new indication for use of an approved HUD (e.g., for a different disease or condition) requires a new original HDE application and not a supplement.

There is no guarantee that the FDA will grant approval of our future products and failure to obtain necessary approvals for our future products would adversely affect our ability to grow our business. Delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects. Obtaining HDE supplements or new HDEs can be a time-consuming process, and delays in obtaining required future approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Some of our future products may be viewed by the FDA as combination products and the review of combination products is often more complex and more time consuming than the review of other types of products.

Our future products may be regulated by the FDA as combination products. For a combination product, the FDA must determine which center or centers within the FDA will review the product candidate and under what legal authority the product candidate will be reviewed. The process of obtaining FDA marketing clearance or approval is lengthy, expensive, and uncertain, and we cannot be sure that any of our combination products, or any other products, will be cleared or approved in a timely fashion, or at all. In addition, the review of combination products is often more complex and more time consuming than the review of a product candidate under the jurisdiction of only one center within the FDA. We cannot be sure that the FDA will not select to have our combination products reviewed and regulated by only one FDA center and/or different legal authority, in which case the path to regulatory approval would be different and could be lengthier and more costly. If the FDA does not approve or clear our products in a timely fashion, or at all, our business and financial condition will be adversely affected.

We may face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.

In general, the biotechnology industry is subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug companies, specialized biotechnology firms, academic institutions, government agencies, and private and public research institutions. Many of these competitors have significantly greater financial and technical resources than us, and superior experience and expertise in research and

development, preclinical testing, design and implementation of clinical trials, regulatory processes and approval for products, production and manufacturing, and sales and marketing of approved products. Large and established companies compete in the biotechnology market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale, and marketing approved products. Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly if they have collaborative arrangements with larger and more established biotechnology companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, and registering subjects for clinical trials.

In order to effectively compete, we will have to make substantial investments in development, clinical testing, manufacturing, and sales and marketing, or partner with one or more established companies. There is no assurance that we will be successful in having our products approved or gaining significant market share for any of our products. Our technologies and products also may be rendered obsolete or noncompetitive as a result of products introduced by our competitors.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

Our ongoing research and development, preclinical testing, and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. Clinical studies must be conducted in compliance with FDA regulations or the FDA may take enforcement action. The data collected from these clinical studies may ultimately be used to support market clearance for these products. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA will agree with our conclusions regarding them. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and preclinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

If approved, our products will require market acceptance to be successful. Failure to gain market acceptance would impact our revenues and may materially impair our ability to continue our business.

Even if we receive regulatory approvals for the commercial sale of our product candidates, the commercial success of our products will depend on, among other things, their acceptance by physicians, patients, third-party payers such as health insurance companies, and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. Physicians and hospitals will need to establish training and procedures to utilize and implement our *Neuro-Spinal Scaffold* implant, and there can be no assurance that these parties will adopt the use of our device or develop sufficient training and procedures to properly utilize it. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, both within and outside of our control. Payers may view new products or products that have only recently been launched or with limited clinical data available, as investigational, unproven, or experimental, and on that basis may deny coverage of procedures involving use of our products. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business.

If we or our suppliers fail to comply with FDA regulatory requirements, or if we experience unanticipated problems with any approved products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain regulatory approval, and the manufacturing processes, reporting requirements, post-approval clinical data, and promotional activities for such product, will be subject to continued regulatory review and oversight by the FDA. In particular, we and our third-party suppliers will be required to comply with the FDA's Quality System Regulations, or QSRs. These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through

periodic inspections by the FDA. If we, or our manufacturers, fail to adhere to QSR requirements, this could delay production of our product candidates and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition and results of operations.

In addition, we and our suppliers are required to comply with Good Manufacturing Practices and Good Tissue Practices with respect to any human cells and biologic products we may develop, and International Standards Organization regulations for the manufacture of our products, and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of any product for which we obtain clearance or approval. Manufacturing may also be subject to controls by the FDA for parts of the combination products that the FDA may find are controlled by the biologics regulations.

The FDA audits compliance with the QSR and other similar regulatory requirements through periodic announced and unannounced inspections of manufacturing and other facilities. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket approval of new products or modified products;
- withdrawing PMA that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations, and financial condition.

Our products and operations are subject to extensive governmental regulation both in the United States and abroad, and our failure to comply with applicable requirements could cause our business to suffer.

Our medical device and biologic products and operations are subject to extensive regulation by the FDA and various other federal, state, and foreign governmental authorities. Government regulation of medical devices and biologic products is meant to assure their safety and effectiveness, and includes regulation of, among other things:

- design, development, and manufacturing;
- testing, labeling, content, and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales, and distribution;
- regulatory clearances and approvals including premarket clearance and approval;

- conformity assessment procedures;
- product traceability and record keeping procedures;
- advertising and promotion;
- product complaints, complaint reporting, recalls, and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries, and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies; and
- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could impede our ability to carry on or expand our operations and could result in higher than anticipated costs or lower than anticipated sales.

Before we can market or sell a new regulated medical device product in the United States, we must obtain clearance under Section 510(k) of the FDCA, approval of a PMA, or approval of an HDE, unless the device is specifically exempt from premarket review. Our *Neuro-Spinal Scaffold* implant is expected to be regulated by the FDA as a Class III medical device, requiring either PMA or HDE approval. A HUD designation was granted for the *Neuro-Spinal Scaffold* implant in 2013, opening the HDE pathway.

In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing, and labeling data.

Modifications to products that are approved through an HDE or PMA generally need FDA approval. The process of obtaining an HDE or PMA is costly and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained.

An HDE application is similar in form and content to a PMA and, although exempt from the effectiveness requirements of a PMA, an HDE does require sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. Like a PMA, changes to HDE devices generally need FDA approval.

Biological products must satisfy the requirements of the Public Health Services Act and its implementing regulations. In order for a biologic product to be legally marketed in the U.S., the product must have a biologics license applicable approved by the FDA. The testing and approval process requires substantial time, effort, and financial resources, and each may take several years to complete.

The FDA can delay, limit, or deny clearance or approval of a product for many reasons, including:

- we may not be able to demonstrate to the FDA’s satisfaction that our products are safe and effective for their intended uses;
- the data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under

development or impact our ability to modify our currently approved or cleared products on a timely basis.

Further, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA may require us to conduct post-marketing studies. Failure to conduct required studies in a timely manner could result in the revocation of approval for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

Failure to comply with applicable laws and regulations could jeopardize our ability to sell our products and result in enforcement actions such as:

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal of the FDA or other regulators to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and/or
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations, and financial condition.

If our products, or the malfunction of our products, cause or contribute to a death or a serious injury before or after approval, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers with approved products are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. Any such serious adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. In the context of clinical trials, sponsors must report adverse events to the FDA in accordance with IDE regulations and to other relevant regulatory authorities in accordance with applicable national and local regulations. Any corrective action, whether voluntary or involuntary, and either pre- or post-market, needed to address any serious adverse events will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Our products, once approved, may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

If our products are approved for commercialization, the FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the decision to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. A government-mandated or voluntary recall by us or one of our partners could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our commercialized products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations, and financial condition, which could impair our ability to manufacture our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits.

If we obtain approval for our products, we may be subject to enforcement action if we engage in improper marketing or promotion of our products.

We are not permitted to promote or market our investigational products. After approval, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. Surgeons may use our products off-label, as the FDA does not restrict or regulate a surgeon's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our educational and promotional activities or training methods to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. It is also possible that other federal, state or foreign enforcement authorities might take action, including, but not limited to, through a whistleblower action under the False Claims Act, if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil or administrative penalties, treble damages, fines, disgorgement, exclusion from participation in government healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

If we obtain approval for our products, their commercial success will depend in part upon the level of reimbursement we receive from third parties for the cost of our products to users.

The commercial success of any product will depend, in part, on the extent to which reimbursement for the costs of our products and related treatments will be available from third-party payers such as government health administration authorities, private health insurers, managed care programs, and other organizations. Adequate third-party insurance coverage may not be available for us to establish and maintain price levels that are sufficient for us to continue our business or for realization of an appropriate return on investment in product development.

Legislative or regulatory reform of the healthcare systems in which we operate may affect our ability to commercialize our product candidates and could adversely affect our business.

The government and regulatory authorities in the United States, the European Union, and other markets in which we plan to commercialize our product candidates may propose and adopt new legislation and regulatory requirements relating to the approval, Conformité Européenne or European Union marking, manufacturing, promotion, or reimbursement of medical device and biologic products. It is impossible to predict whether legislative changes will be enacted or applicable regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be. Such legislation or regulatory requirements, or the failure to comply with such, could adversely impact our operations and could have a material adverse effect on our business, financial condition, and results of operations.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. Certain policies of current or future administrations may impact our business and industry. It is difficult to predict how any executive actions will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. 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 and we may not achieve or sustain profitability.

We have limited experience manufacturing our* Neuro-Spinal Scaffold *implant for clinical-study scale and no experience for commercial scale.

To date, we have manufactured our *Neuro-Spinal Scaffold* implant on a small scale, including sufficient supply that is needed for our clinical studies. We may encounter unanticipated problems in the scale-up process that will result in delays in the manufacturing of the *Neuro-Spinal Scaffold* implant and therefore delay our clinical studies. During our clinical trials, we are subject to FDA regulations requiring manufacturing of our scaffolds with the FDA requirements for design controls and subject to inspections by regulatory agencies. Our failure to comply with applicable regulations may result in delays and interruptions to our product supply while we seek to secure another supplier that meets all regulatory requirements. If we are unable to scale up our manufacturing to meet requirements for our clinical studies, we may be required to rely on contract manufacturers. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product ourselves, including the possible breach of the manufacturing agreements by the third parties because of factors beyond our control, and the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities.

Risks Related to Our Intellectual Property

We license certain technology underlying the development of our* Neuro-Spinal Scaffold *implant from Boston Children's Hospital, or BCH and the Massachusetts Institute of Technology, or MIT, and the loss of the license would result in a material adverse effect on our business, financial position, and operating results and cause the market value of our common stock to decline.

We license technology from BCH and MIT that is integrated into our *Neuro-Spinal Scaffold* implant under an exclusive license. Under the license agreement, we have agreed to milestone payments and to meet certain reporting obligations. In the event that we were to breach any of the obligations under the agreement and fail to cure timely, BCH and MIT would have the right to terminate the agreement upon notice. In addition, BCH and MIT have the right to terminate our license upon the bankruptcy or receivership of the Company. If we are unable to continue to use or license this technology on reasonable terms, or if this technology fails to operate properly, we may not be able to secure alternatives in a timely manner and our ability to develop our products could be harmed.

If we cannot protect, maintain and, if necessary, enforce our intellectual property rights, our ability to develop and commercialize products will be adversely impacted.

Our success, in large part, depends on our ability to protect and maintain the proprietary nature of our

technology. We and our licensors must prosecute and maintain our existing patents and obtain new patents. Some of our proprietary information may not be patentable, and there can be no assurance that others will not utilize similar or superior solutions to compete with us. We cannot guarantee that we will develop proprietary products that are patentable, and that, if issued, any patent will give a competitive advantage or that such patent will not be challenged by third parties. The process of obtaining patents can be time consuming with no certainty of success, as a patent may not issue or may not have sufficient scope or strength to protect the intellectual property it was intended to protect. We cannot assure you that our means of protecting our proprietary rights will suffice or that others will not independently develop competitive technology or design around patents or other intellectual property rights issued to us. Even if a patent is issued, it does not guarantee that it is valid or enforceable. Any patents that we or our licensors have obtained or obtain in the future may be challenged, invalidated, or unenforceable. If necessary, we may initiate actions to protect our intellectual property, which can be costly and time consuming.

If third parties successfully claim that we infringe their intellectual property rights, our ability to continue to develop and commercialize products could be delayed or prevented.

Third parties may claim that we or our licensors are infringing on or misappropriating their proprietary information. Other organizations are engaged in research and product development efforts that may overlap with our products. Such third parties may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods under development or consideration by us. These rights may prevent us from commercializing products, or may require us to obtain a license from the organizations to use the technology. We may not be able to obtain any such licenses that may be required on reasonable financial terms, if at all, and cannot be sure that the patents underlying any such licenses will be valid or enforceable. There may be rights that we are not aware of, including applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research and development of the product that is the subject of the suit. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our trade secrets or other confidential information could be compromised by disclosure during this type of litigation.

Risks Related to our Dependence on Third Parties

We will depend upon strategic relationships to develop and manufacture our products. If these relationships are not successful, we may not be able to capitalize on the market potential of these products.

The near and long-term viability of our products will depend, in part, on our ability to successfully establish new strategic collaborations with biotechnology companies, hospitals, insurance companies, and government agencies. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory, or intellectual property position. If we fail to establish a sufficient number of collaborations on acceptable terms, we may not be able to commercialize our products or generate sufficient revenue to fund further research and development efforts.

Even if we establish new collaborations, these relationships may never result in the successful development or commercialization of any of our product candidates for reasons both within and outside of our control.

There are a limited number of suppliers that can provide materials to us. Any problems encountered by such suppliers may detrimentally impact us.

We rely on third-party suppliers and vendors for certain of the materials used in the manufacture of our products or other of our product candidates. Any significant problem experienced by one of our suppliers could result in a delay or interruption in the supply of materials to us until such supplier resolves the problem or an alternative source of supply is located. Any delay or interruption could negatively affect our operations.

If the third parties on which we rely to conduct our laboratory testing, animal, and human clinical trials do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

We have been, and will continue to be, dependent on third-party CROs, medical institutions, investigators, and contract laboratories to conduct certain activities related to our laboratory testing and animal and human clinical studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our approved plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on these third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended, or terminated, and we may not be able to obtain regulatory approval or successfully commercialize our products on a timely basis, if at all, and our business, operating results, and prospects may be adversely affected.

Risks Related to Employee Matters and Managing Growth

Our success depends on our ability to retain our management and other key personnel.

We depend on our senior management as well as key scientific personnel. We have implemented restructurings that have significantly reduced our workforce, leaving only key positions filled. The loss of any members of senior management or key scientific personnel could harm our business and significantly delay or prevent the achievement of research, development, or business objectives. Competition for qualified employees is intense among biotechnology companies, and the loss of qualified employees, or an inability to attract, retain, and motivate additional highly skilled employees could hinder our ability to successfully develop marketable products.

Our future success also depends on our ability to identify, attract, hire, train, retain, and motivate other highly skilled scientific, technical, marketing, managerial, and financial personnel. Although we will seek to hire and retain qualified personnel with experience and abilities commensurate with our needs, there is no assurance that we will succeed despite our collective efforts. The loss of the services of any of our senior management or other key personnel could hinder our ability to fulfill our business plan and further develop and commercialize our products and services. Competition for personnel is intense, and any failure to attract and retain the necessary technical, marketing, managerial, and financial personnel would have a material adverse effect on our business, prospects, financial condition, and results of operations.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from collaborators, prospective licensees, and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Litigation and Legal Compliance

We may face, and in the past have faced, lawsuits, which could divert management's attention and harm our business.

We may face, and in the past have faced, lawsuits, including class action or securities derivative lawsuits. The amount of time that is required to resolve these lawsuits is unpredictable and any lawsuits may divert management's attention from the day-to-day operations of our business, which could adversely affect our business, results of operations, and cash flows. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation.

We face potential product liability claims, and, if successful claims are brought against us, we may incur substantial liability and costs.

We will have exposure to claims for product liability. Product liability coverage for the healthcare industry is expensive and sometimes difficult to obtain. We may not be able to maintain such insurance on acceptable terms or be able to secure increased coverage if the commercialization of our products progresses, nor can we be sure that existing or future claims against us will be covered by our product liability insurance. Moreover, the existing coverage of our insurance policy or any rights of indemnification and contribution that we may have may not be sufficient to offset existing or future claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert our management's attention.

We are subject to environmental, health, and safety laws. Failure to comply with such environmental, health, and safety laws could cause us to become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to various environmental, health, and safety laws and regulations, including those relating to safe working conditions, laboratory, and manufacturing practices, the experimental use of animals and humans, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research and development efforts.

Our relationships with customers and third party payers will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, physicians, and third-party payers will play a primary role in the recommendation and use of our products and any other product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians, and third-party payers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

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

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an

obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;

- the federal Health Insurance Portability and Accountability Act of 1996 or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals; and

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

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

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 financial results. 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 significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs.

Our operations and reputation may be impaired if our information technology systems fail to perform adequately or if we are the subject of a data breach or cyber-attack.

Our information technology systems are important to operating our business. We rely on our information technology systems, some of which are or may be managed or hosted by or out-sourced to third party service providers, to manage our business data and other business processes. If we do not allocate and effectively manage the resources necessary to build, sustain, and protect appropriate information technology systems and infrastructure, or we do not effectively implement system upgrades or oversee third party service providers, our business or financial results could be negatively impacted. The failure of our information technology systems to perform as we anticipate could disrupt our business and could result in transaction or reporting errors and processing inefficiencies causing our business and results of operations to suffer.

Furthermore, our information technology systems may be vulnerable to cyber-attacks or other security incidents, service disruptions, or other system or process failures. Such incidents could result in unauthorized access to information including vendor, consumer or other company confidential data as well as disruptions to operations. We have experienced in the past, and expect to continue to experience, cybersecurity threats and incidents. To address the risks to our information technology systems and data, we maintain an information security program that includes updating technology, developing security policies and procedures, implementing and assessing the effectiveness of controls, conducting risk assessments of third-party service providers and designing business processes to mitigate the risk of such breaches. There can be no assurance that these measures will prevent or limit the impact of a future incident. Moreover, the development and maintenance of these measures requires continuous monitoring as technologies change and efforts to overcome security measures evolve. In addition, if a ransomware attack or other cybersecurity incident occurs, either internally or at our vendors or third-party technology service providers, or if we are unable to adequately respond to and resolve a cyber security incident, it may have a material, negative impact on our operations, including the inability to access our data and systems, or our business reputation, and we may experience other adverse consequences such as loss of assets, remediation costs, demands to pay a ransom, litigation, regulatory investigations, and the failure by us to retain or attract customers following such an event. Additionally, we rely on services provided by third-party vendors for certain information technology processes and functions, which makes our operations vulnerable to a failure by any one of these vendors to perform adequately or maintain effective internal controls. If we are unable to prevent or adequately respond to and resolve an incident, it may have a material, negative impact on our operations or business reputation, and we may experience other adverse consequences such as loss of assets, remediation costs, litigation, regulatory investigations, and the failure by us to retain or attract customers following such an event. Additionally, we rely on services provided by third-party vendors for certain information technology processes and functions, which makes our operations vulnerable to a failure by any one of these vendors to perform adequately or maintain effective internal controls.

Risks Related to Investment in Our Securities

The price of our common stock has been and may continue to be volatile, which could lead to losses by investors and costly securities litigation.

The trading price of our common stock is likely to be highly volatile and could fluctuate in response to factors such as:

- the status, completion, and/or results of our clinical trials;

- actual or anticipated variations in our operating results;

- announcement of the commencement or completion of securities offerings by us;

- announcements of developments by us or our competitors;

- regulatory actions regarding our products;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;

- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- sales of our common stock or other securities in the open market; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

In the foreseeable future, we do not intend to pay cash dividends on shares of our common stock so any investor gains 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. Any gains to stockholders will therefore be limited to the increase, if any, in our share price.

In the event that we fail to satisfy any of the listing requirements of the Nasdaq Capital Market, our common stock may be delisted, which could affect our market price and liquidity.

Our common stock is listed on the Nasdaq Capital Market. For continued listing on the Nasdaq Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the corporate governance requirements and the minimum closing bid price requirement, among other requirements. For example, we have received deficiency letters due to the failure to maintain the minimum bid price and the failure to meet stockholder equity requirements, including the deficiency letter from the Listings Qualifications Department of the Nasdaq Stock Market letter we received on May 19, 2021 notifying us of a failure to comply with the minimum bid requirement. To regain compliance, on April 26, 2022, we implemented a 1:25 reverse stock split. Previously, in response to other deficiency letters, we needed to implement reverse stock splits and take other actions including transferring to the Nasdaq Capital Market (from the Nasdaq Global Market) and implementing a warrant amendment.

There can be no assurance that we will maintain compliance with the bid price requirement in the future, or that we will continue to be in compliance with the other continued listing requirements of the Nasdaq Capital Market.

In the event that we fail to regain compliance, or we fail to obtain a second compliance period from Nasdaq, or fail to satisfy any of the listing requirements of the Nasdaq Capital Market, our common stock may be delisted. If our securities are delisted from trading on the Nasdaq Capital Market, and we are not able to list our securities on another exchange our securities could be quoted on the OTC Bulletin Board or on the "pink sheets." As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock," which would require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage
- a limited ability to raise capital to continue to fund our operations by selling shares; and
- a limited ability to acquire other companies or technologies by using our shares as consideration.

Anti-takeover effects of certain provisions of our articles of incorporation and Nevada state law may discourage or prevent a takeover.

Our articles of incorporation divide our Board of Directors into three classes, with three-year staggered terms. The classified board provision could increase the likelihood that, in the event an outside party acquired a controlling block of our stock, incumbent directors nevertheless would retain their positions for a substantial period, which may have the effect of discouraging, delaying, or preventing a change in control. In addition, Nevada has a business combination law, which prohibits certain business combinations between Nevada publicly traded corporations, or Nevada corporations that elect to be subject to the law, and "interested stockholders" for two years after the interested stockholder first becomes an interested stockholder, unless the corporation's board of directors approves the transaction by which the stockholder becomes an interested stockholder in advance, or the proposed combination in advance of the stockholder becoming an interested stockholder.

The proposed combination may be approved after the stockholder becomes an interested stockholder with preapproval by the board of directors and a vote at a special or annual meeting of stockholders holding at least 60% of the voting power not owned by the interested stockholder or his/her/its affiliates or associates. After the two year moratorium period, additional stockholder approvals or fair value requirements must be met by the interested shareholder up to four years after the stockholder became an interested stockholder. In addition, we may become subject to Nevada's control share laws. A corporation is subject to Nevada's control share law if it has more than 200 stockholders, at least 100 of whom are stockholders of record and residents of Nevada, and if the corporation does business in Nevada, including through an affiliated corporation. This control share law may have the effect of discouraging corporate takeovers. Currently, we believe that we have less than 100 stockholders of record who are residents of Nevada, and are therefore not subject to the control share laws.

The provisions of our articles of incorporation and Nevada's business combination and control share laws make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in our stockholders' interest or might result in a premium over the market price for our common stock.

Failure to maintain an effective system of internal controls could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud in which case, our stockholders could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our stock.

We are required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or SOX, and management is required to report annually on our internal control over financial reporting. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of SOX until the date we have a public float of $75 million or greater and $100 million or greater in revenue.

If we fail to maintain effective internal controls and procedures for financial reporting, it could result in material misstatements in the annual or interim financial statements that would not be prevented or detected in a timely manner. We cannot assure you that material weaknesses or significant deficiencies will not occur in the future and that we will be able to remediate such weaknesses or deficiencies in a timely manner, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows.

We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are considered a "smaller reporting company" under Rule 12b-2 of the Exchange Act of 1934 as amended. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our Securities and Exchange Commission filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. 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 common stock prices may be more volatile. We will

remain a smaller reporting company until our public float exceeds $250 million or our annual revenues exceed $100 million with a public float greater than $700 million.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We lease 5,104 square feet of space in Cambridge, Massachusetts, which is used primarily for corporate, manufacturing, and research and development functions. The lease commenced in June 2021, was amended in November 2021, and expires on December 31, 2024.

Item 3. LEGAL PROCEEDINGS

In the ordinary course of business, we may be subject to litigation from time to time. There is no current, pending or, to our knowledge, threatened litigation or administrative action to which we are a party or of which our property is the subject (including litigation or actions involving our officers, directors, affiliates, or other key personnel, or holders of record or beneficially of more than 5% of any class of our voting securities, or any associate of any such party) which in our opinion has, or is expected to have, a material adverse effect upon our business, prospects financial condition or operations.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is currently listed for trading on the Nasdaq Capital Market under the symbol "NVIV."

Dividends

We have never declared or paid cash dividends. We do not intend to pay cash dividends on our common stock for the foreseeable future, but currently intend to retain any future earnings to fund the development and growth of our business. The payment of cash dividends, if any, on our common stock, will rest solely within the discretion of our Board of Directors and will depend, among other things, upon our earnings, capital requirements, financial condition, and other relevant factors.

Holders

As of February 24, 2023, we had approximately 260 stockholders of record. This figure does not reflect persons or entities that hold their stock in nominee or "street" name through various brokerage firms.

Recent Sales of Unregistered Securities

None.

Issuer Repurchases of Equity Securities

None.

Performance Graph

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

Item 6. [Reserved]

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

The following discussion should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by such forward-looking statements as a result of many important factors, including those set forth in Part I of this Annual Report on Form 10-K under the caption "Risk Factors". Please see also the "Special Note Regarding Forward-Looking Statements" in Part I above. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report on Form 10-K.

Introduction

This Management's Discussion and Analysis of our financial condition and results of operations is based on our financial statements, which management has prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that management believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Business Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries, or SCIs. Our approach to treating acute SCIs is based on our investigational *Neuro-Spinal Scaffold*™ implant, a bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord and is intended to treat acute SCI. The *Neuro-Spinal Scaffold* implant incorporates intellectual property licensed under an exclusive, worldwide license from Boston Children's Hospital and the Massachusetts Institute of Technology. We also plan to evaluate other technologies and therapeutics that may be complementary to our development of the *Neuro-Spinal Scaffold* implant or offer the potential to bring us closer to our goal of redefining the life of the SCI patient.

Overall, we expect our research and development expenses to be substantial and to increase for the foreseeable future as we continue the development and clinical investigation of our current and future products. However, expenditures on research and development programs are subject to many uncertainties, including whether we develop our products with a partner or independently, or whether we acquire products from third parties. At this time, due to the uncertainties and inherent risks involved in our business, we cannot estimate in a meaningful way the duration of, or the costs to complete, our research and development programs or whether, when or to what extent we will generate revenues or cash inflows from the commercialization and sale of any of our products. While we are currently focused on advancing our *Neuro-Spinal Scaffold* implant, our future research and development expenses will depend on the determinations we make as to the scientific and clinical prospects of each product candidate, as well as our ongoing assessment of regulatory requirements and each product's commercial potential. In addition, we may make acquisitions of businesses, technologies or intellectual property rights that we believe would be necessary, useful or complementary to our current business. Any investment made in a potential acquisition could affect our results of operations and reduce our limited capital resources, and any issuance of equity securities in connection with a potential acquisition could be substantially dilutive to our stockholders.

There can be no assurance that we will be able to successfully develop or acquire any product, or that we will be able to recover our development or acquisition costs, whether upon commercialization of a developed product or otherwise. We cannot provide assurance that any of our programs under development or any acquired technologies or products will result in products that can be marketed or marketed profitably. If our development-stage programs or any acquired products or technologies do not result in commercially viable products, our results of operations could be materially adversely affected.

We were incorporated on April 2, 2003, under the name Design Source, Inc. On October 26, 2010, we acquired the business of InVivo Therapeutics Corporation, which was founded in 2005, and continued the existing business operations of InVivo Therapeutics Corporation as our wholly-owned subsidiary.

Critical Accounting Policies and Estimates

Our consolidated financial statements, which appear in Item 8 of this Annual Report on Form 10-K, have been prepared in accordance with accounting principles generally accepted in the United States, which require that our management make certain assumptions and estimates and, in connection therewith, adopt certain accounting policies. Our significant accounting policies are set forth in Note 2, "Significant Accounting Policies", in the Notes to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K. Of those policies, we believe that the policies discussed below may involve the highest degree of judgment and may be the most critical to an accurate reflection of our financial condition and results of operations.

Stock-Based Compensation

Our stock options are granted with an exercise price set at the fair market value of our common stock on the date of grant. Our stock options generally expire 10 years from the date of grant and vest upon terms determined by our Board of Directors.

We recognize compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in our statements of operations over the service period based on a measure of fair value for each stock-based award. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option pricing model and the fair value of each restricted stock award or restricted stock unit, which we refer to collectively as restricted securities, is determined based on the fair market value of our common stock on the date of grant. The fair value is amortized as a compensation cost on a straight-line basis over the requisite service period of the award, which is generally the vesting period. The expected term of any options granted under our stock plans is based on the average of the contractual term (generally, 10 years) and the vesting period (generally, 48 months). The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the expected term of the option. The restricted securities generally vest over a three-year period, contingent on the recipient's continued employment. See Note 8, "Share-Based Compensation, Stock Options and Restricted Securities," in the Notes to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K for more information about the assumptions underlying these estimates.

Research and Development Expense

Our research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee related expenses, including salaries, benefits, travel, and stock based compensation expense;
- expenses incurred under agreements with clinical research organization, or CROs, and clinical sites that conduct our clinical studies;
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies;
- costs associated with our research platform and preclinical activities;
- costs associated with our regulatory, quality assurance, and quality control operations; and
- amortization of intangible assets.

Our research and development costs are expensed as incurred. We are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual

costs. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrued expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

New Accounting Pronouncements

In May 2021 the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options, a consensus of the Emerging Issues Task Force, which amends the FASB Accounting Standards Codification, or the ASC, to provide explicit guidance, and, thus, reduce diversity in practice, on accounting by issuers for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after the modification or exchange. This amendment provides that for an entity that presents earnings per share, or EPS, in accordance with Topic 260, the effects of a modification or an exchange of a freestanding equity-classified written call option that is recognized as a dividend should be an adjustment to net income (or net loss) in the basic EPS calculation. We adopted ASU 2021-04 effective January 1, 2022, and it did not have a material impact on our consolidated financial statements.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

Research and Development Expenses

Research and development expenses increased by $0.8 million to $5.2 million for the year ended December 31, 2022 from $4.4 million for the year ended December 31, 2021. The increase in research and development expenses for the year ended December 31, 2022 is primarily due to an increase in clinical consulting costs of $0.4 million associated with the processing of responses to the FDA on comments received on our HDE submission of the second module, an increase in scaffold manufacturing costs of $0.2 million and an increase in compensation related costs of $0.2 million.

General and Administrative Expenses

General and administrative expenses decreased by $0.1 million to $5.4 million for the year ended December 31, 2022 from $5.5 million for year ended December 31, 2021. The decrease in general and administrative expenses for the year ended December 31, 2022 is primarily due to lower compensation related costs of $0.2 million and lower consulting costs of $0.2 million due to the absence of a one time business development initiative expense incurred in 2021. These decreases were partially offset by an increase in legal costs of $0.2 million and an increase of $0.1 million in other miscellaneous general and administrative costs.

Interest Income / (Expense), Net

Interest income increased by $148 thousand to $151 thousand for the year ended December 31, 2022 from $3 thousand for the year ended December 31, 2021. The increase in interest income was primarily due to higher yields in our cash and cash equivalents in 2022.

Other Income

Other income for the years ended December 31, 2022 and 2021 was $9 thousand and $2 thousand, respectively.

Liquidity, Capital Resources and Going Concern

Liquidity is a measure of our ability to meet potential cash requirements, including planned capital expenditures. Since inception, we have devoted substantially all of our efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, and raising capital. We have historically financed our operations primarily through the sale of equity-related securities. We have not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expects to incur additional operating losses.

As of December 31, 2022, we had approximately $15.1 million in working capital, our accumulated deficit was $248.6 million, we had total assets of $18.8 million, total liabilities of $3.1 million, and total stockholders' equity of $15.7 million. During the year ended December 31, 2022, we recorded a net loss of $10.5 million. We believe that our cash and cash equivalents at December 31, 2022 will provide necessary funding to fund operations into the first quarter of 2024. This estimate is based on assumptions that may prove to be wrong; expenses could prove to be significantly higher, leading to a more rapid consumption of our existing resources.

Our consolidated financial statements as of December 31, 2022 were prepared under the assumption that we will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. However, substantial doubt exists about our ability to continue as a going concern exists and we will require additional liquidity to continue operations beyond the next 12 months.

We have limited liquidity and capital resources and must obtain significant additional capital resources in order to fund our operations and sustain our product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, for selling, general and administrative expenses and for other working capital requirements. We will need to raise additional capital through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

We may pursue various other dilutive and non-dilutive funding alternatives depending upon our clinical path forward and the extent to which we require additional capital to proceed with development of some or all of our product candidates on expected timelines. The source, timing and availability of any future financing will depend principally upon market conditions and the status of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us to, among other things, delay, scale back or eliminate some or all of our research and product development programs, planned clinical trials, and capital expenditures or to license our potential products or technologies to third parties. We may alternatively engage in cost-cutting measures in an attempt to extend our cash resources as long as possible. If we are unable to raise additional capital, we may be forced to cease operations entirely.

Our consolidated financial statements as of December 31, 2022, do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if we were unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate its assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or part of their investment.

Financing Transactions

In October 2022, we closed a registered offering of shares of our common stock and associated pre-funded warrants, or the October 2022 Registered Direct Offering, and a concurrent private placement of pre-funded warrants and preferred investment options, or(the October 2022 Private Placement, with an institutional investor together, the October 2022 Financing. In the October 2022 Registered Direct Offering, we issued (i) an aggregate of 154,000 common shares, or the Shares; and (ii) 369,810 pre-funded warrants, or the October 2022 Pre-Funded Warrants. In the concurrent October 2022 Private Placement, we issued (i) additional October 2022 Pre-Funded Warrants to purchase an aggregate of 1,190,476 shares of our common stock, and (ii) Preferred Investment Options to purchase an aggregate of 1,714,286 shares of our common stock, or the Preferred Investment Options. The purchase price of each Share and associated Preferred Investment Option sold in the October 2022 Registered Direct Offering was $5.25 and the purchase price of each Pre-Funded Warrant and associated Preferred Investment Option sold in each of the October 2022 Registered Direct Offering and October 2022 Private Placement was $5.2499. In connection with the October 2022 Financing, we issued, to designees of H.C. Wainwright & Co., LLC, or Wainwright, the placement agent for the October 2022 Financing, Preferred Investment Options to purchase an aggregate of 114,429 shares of our common stock, or the Wainwright Preferred Investment Options. The net proceeds to us, after deducting Wainwright's placement agent fees and other offering expenses payable by us, were approximately $8.0 million. Concurrent with the October 2022 Financing, we modified certain outstanding warrants, consisting of 29,091 Series A Warrants issued in March 2020, 19,048 Series C Warrants issued in April 2020 and 32,000 Series A Warrants issued in October 2020, held by the institutional investor that participated in the October 2022 Financing to lower the exercise price of these warrants to $5.05 and extend the term of the warrants through April 2028. During the year ended December 31, 2022, we issued an aggregate of 884,286 shares of our common stock upon the exercise of certain of the October 2022 - Prefunded Warrants for an immaterial amount, as they were substantially pre-funded.

Cashflows

Net cash used in operating activities for the year ended December 31, 2022, consisted of net loss of $10.5 million, non-cash items of $0.6 million and cash used in working capital of $0.6 million. Adjustments for non-cash items consisted primarily of $0.4 million and $0.2 million in amortization of operating lease right-of-use assets and stock-based compensation expense, respectively. The change in cash from working capital can be attributed primarily to a $0.4 million decrease in the operating lease liability and a $0.2 million decrease in accrued expenses and other liabilities.

Net cash used in operating activities for the year ended December 31, 2021, consisted of net loss of $9.9 million, non-cash items of $0.7 million and cash provided by working capital of $0.4 million. Adjustments for non-cash items consisted primarily of $0.3 million each in amortization of operating lease right-of-use assets and stock-based compensation expense, respectively. The change in cash from working capital included a $0.5 million increase in accrued expenses, and a $0.1 million increase in accounts payable. These increases were offset by a $0.3 million decrease in the operating lease liability and a $0.1 million decrease in prepaid expenses and other assets.

Net cash used in investing activities for the years ended December 31, 2022 and 2021, was $160 thousand and $77 thousand, respectively, attributable to purchases of capital equipment.

Net cash provided by financing activities for the year ended December 31, 2022 was $8.0 million related to proceeds from the October 2022 Financing. This compares to net cash provided by financing activities of $8.5 million for the year ended December 31, 2021 related to proceeds from the exercise of warrants.

Inflation and Changing Prices

We do not believe that inflation has had, or will have, a material impact on our operating costs and earnings.

Material Cash Requirements from Contractual Obligations

Leases

As of December 31, 2022, we reported current and long-term operating lease liabilities of $0.4 million and $0.6 million, respectively. These balances represent our contractual obligation to make future payments on our Cambridge headquarters lease, discounted to reflect our cost of borrowing. In the event that we were to vacate the Cambridge facility, we may be obliged to continue making payments under the Cambridge lease.

Clinical Trial Commitments

We have engaged and executed contracts with CRO's to assist with the administration of our ongoing INSPIRE 1.0 and INSPIRE 2.0 clinical trials. As of December 31, 2022, approximately $3.9 million remains to be paid on these contracts.

See Note 11, "Commitments and Contingencies," in the Notes to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K for information regarding our commitments.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

Item 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

SPECIAL NOTE

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of InVivo Therapeutics Holdings Corp. and Subsidiary

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of InVivo Therapeutics Holdings Corp. and Subsidiary (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, since the Company's inception, the Company has suffered recurring losses and negative cash flows from operations and will need additional funding to complete planned development efforts. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

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

Accruals for Clinical Trials and Other Research and Development Expenses

As discussed in Note 2 to the financial statements, the costs of research and development activities are charged to expense as incurred. Clinical trial research expenses are accrued over the service period based on estimated costs incurred through

the balance sheet date that have not been invoiced by the contract research organizations ("CRO"), clinical study sites, consultants, or other vendors. This process involves reviewing open contracts, communicating with vendors and internal personnel to identify services that have been performed and milestones achieved, and estimating the total expenses that have not yet been invoiced or for which the Company has not yet otherwise been notified of the actual costs incurred. The Company had $1.2 million of prepayments for CRO services and $433 thousand of accruals for clinical trial and clinical study expenses at December 31, 2022 as disclosed in Note 2 and Note 4.

We identified the accruals for clinical trials and other research and development expenses to be a critical audit matter because auditing the Company's accruals required significant audit effort and a high degree of auditor judgment and subjectivity, as the information necessary to make an estimate is accumulated from third parties, in the absence of invoices received, and the Company's assessment of the completeness of the information is subject to uncertainty. In addition, in certain circumstances, the determination of the nature and amount of services that have been received during the reporting period requires judgment, as the timing and pattern of vendor invoicing does not correspond to the level of services provided.

Our audit procedures related to the Company's accruals for clinical trials and other research and development expenses included the following, among others:

- We tested the accuracy and completeness of the underlying data used in the estimates and evaluated the reasonableness of assumptions used by management as follows:
    - We inspected certain contracts with various clinical sites and reviewed information received by the Company to test proper recording of costs incurred to date.
    - We corroborated the progress of research and development activities through discussion with the Company's research and development personnel, specifically those who oversee the projects, and confirmations with the third parties.
    - We performed analytical procedures over fluctuations in accruals on clinical site and patient levels throughout the year and year over year.
    - We tested subsequent invoices received from third parties and cash disbursements to assess completeness of recorded accruals.
    - We performed a retrospective review of disbursements made in the current year and subsequent to the current year to determine if the Company had properly accrued for costs with service periods prior to the fiscal year-end.

/s/ RSM US LLP

We have served as the Company's auditor since 2015.

Boston, Massachusetts
March 1, 2023

InVivo Therapeutics Holdings Corp.

Consolidated Balance Sheets

(In thousands, except share and per-share data)

	December 31, 2022	December 31, 2021
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 16,351	$ 19,031
Prepaid expenses	97	83
Other current assets	1,153	28
Total current assets	17,601	19,142
Property, equipment and leasehold improvements, net	227	127
Restricted cash - non-current	150	150
Operating lease right-of-use assets	844	1,229
Prepaid clinical trial expenses	—	1,122
Total assets	$ 18,822	$ 21,770
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 617	$ 605
Operating lease liabilities	396	361
Accrued expenses	1,455	1,646
Total current liabilities	2,468	2,612
Other liabilities	55	94
Operating lease liabilities - non-current	553	949
Total liabilities	3,076	3,655
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.00001 par value, authorized 1,000,000 and 0 at December 31, 2022 and December 31, 2021. No Preferred stock issued and outstanding at December 31, 2022 and December 31, 2021 respectively.	—	—
Common stock, $0.00001 par value, authorized 250,000,000 and 2,000,000 at December 31, 2022 and December 31, 2021, respectively. 2,429,446 and 1,370,595 shares issued and outstanding including 0 and 254 shares of unvested restricted stock awards, at December 31, 2022 and December 31, 2021, respectively.	3	3
Additional paid-in capital	264,362	256,241
Accumulated deficit	(248,619)	(238,129)
Total stockholders' equity	15,746	18,115
Total liabilities and stockholders' equity	$ 18,822	$ 21,770

See notes to the consolidated financial statements.

InVivo Therapeutics Holdings Corp.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per-share data)

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 5,226	$ 4,381
General and administrative	5,424	5,519
Total operating expenses	10,650	9,900
Operating loss	(10,650)	(9,900)
Other income:		
Interest income (expense), net	151	3
Other income	9	2
Interest and other income, net	160	5
Net loss	$ (10,490)	$ (9,895)
Net loss per share, basic and diluted	$ (6.83)	$ (7.48)
Weighted average number of common shares outstanding, basic and diluted	1,536,474	1,323,659

See notes to the consolidated financial statements.

InVivo Therapeutics Holdings Corp.

Consolidated Statements of Changes in Stockholders' Equity

(In thousands, except share and per-share data)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2020	945,276	3	247,417	(228,234)	$ 19,186
Share-based compensation expense	—	—	315	—	315
Issuance of common stock upon vesting of restricted stock units	2	—	—	—	—
Issuance of common stock upon exercise of warrants	425,317	—	8,509	—	8,509
Net loss	—	—	—	(9,895)	(9,895)
Balance as of December 31, 2021	1,370,595	3	256,241	(238,129)	18,115
Share-based compensation expense	—	—	159	—	159
Forfeiture of restricted stock	(54)	—	—	—	—
Fractional shares issued due to 1 for 25 reverse stock split	20,619	—	—	—	—
Issuance of common stock and warrants in public offering	154,000	—	7,962	—	7,962
Issuance of common stock upon exercise of prefunded warrants	884,286	—	—	—	—
Net loss	—	—	—	(10,490)	(10,490)
Balance as of December 31, 2022	2,429,446	$ 3	$ 264,362	$ (248,619)	$ 15,746

See notes to the consolidated financial statements.

InVivo Therapeutics Holdings Corp.

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (10,490)	$ (9,895)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	60	44
Amortization of operating lease right-of-use assets	385	328
Share-based compensation expense	159	315
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(17)	52
Accounts payable	12	124
Operating lease liability	(360)	(339)
Accrued expenses and other liabilities	(231)	517
Net cash used in operating activities	(10,482)	(8,854)
Cash flows from investing activities:		
Purchases of property and equipment	(160)	(77)
Net cash used in investing activities	(160)	(77)
Cash flows from financing activities:		
Proceeds from exercise of warrants	—	8,509
Proceeds from issuance of common stock and warrants, net of commissions and issuance costs	7,962	—
Net cash provided by financing activities	7,962	8,509
Decrease in cash and cash equivalents and restricted cash	(2,680)	(422)
Cash, cash equivalents and restricted cash at beginning of period	19,181	19,603
Cash, cash equivalents and restricted cash at end of period	$ 16,501	$ 19,181
Supplemental disclosure of cash flow information and non-cash investing and financing activities:		
Fair value of warrants issued in connection with financing activities	$ 5,225	$ —
Increase in operating right-of-use assets and liabilities related to lease modifications	$ —	$ 629
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets		
Cash and cash equivalents	$ 16,351	$ 19,031
Restricted cash included in other non-current assets	150	150
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 16,501	$ 19,181

See notes to the consolidated financial statements.

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements

(In thousands, except share and per-share data)

1. NATURE OF OPERATIONS AND GOING CONCERN

Business

InVivo Therapeutics Holdings Corp., including its subsidiary, (the "Company") is a biomaterials and biotechnology company with a focus on the treatment of spinal cord injuries ("SCIs"). The Company's proprietary technologies incorporate intellectual property that is licensed under an exclusive, worldwide license from Boston Children's Hospital ("BCH") and the Massachusetts Institute of Technology ("MIT"), as well as intellectual property that has been developed internally in collaboration with its advisors and partners.

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, and raising capital. The Company has historically financed its operations primarily through the sale of equity-related securities. The Company has not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. The Company does not expect to be profitable in the next several years, but rather expects to incur additional operating losses. The Company has limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain its product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of its anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, for selling, general and administrative expenses, and other working capital requirements.

Going Concern

The Company's consolidated financial statements as of December 31, 2022 were prepared under the assumption that the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. However, as of December 31, 2022, substantial doubt exists about the Company's ability to continue as a going concern. Since the Company's inception, the Company has suffered recurring losses and negative cash flows from operations and will need additional funding to complete planned development efforts. As of December 31, 2022, the Company had unrestricted cash and cash equivalents of $16.4 million and during the year ended December 31, 2022, the Company recorded a net loss of $10.5 million. At December 31, 2022, the Company had. Given the Company's current plans, the Company estimates cash resources will be sufficient to fund its operations into the first quarter of 2024. The Company will require additional liquidity to continue operations beyond the next 12 months.

The Company is evaluating strategies to obtain the required additional funding for future operations. These strategies may include but are not limited to equity offerings, debt financings, other third-party funding, marketing and distribution arrangements, and other collaborations, strategic alliances, and licensing arrangements. However, given a variety of external factors including the impact of the recent economic downturn in the U.S. and global financial markets, the Company may be unable to access further equity or debt financing when needed. Lack of necessary funds may require the Company to, among other things, delay, scale back or eliminate some or all of its research and product development programs, planned clinical trials, and capital expenditures or to license its potential products or technologies to third parties. The Company may alternatively engage in cost-cutting measures in an attempt to extend its cash resources as long as possible. As such, there can be no assurance that the Company will be able to obtain additional liquidity when needed or under acceptable terms, if at all. The Company believes that it can be successful in obtaining additional capital; however, no assurance can be provided that it will be able to do so. There is no assurance, moreover, that any funds raised will be sufficient to enable the Company to attain profitable operations or continue as a going concern.

The Company's consolidated financial statements as of December 31, 2022, do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern. If the Company is unable to raise additional capital and is therefore unable

to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on its consolidated financial statements, and it is likely that investors will lose all or part of their investment.

Reverse Stock Split

On April 26, 2022, the Company effected a reverse stock split of its common stock, par value $0.00001 per share, at a ratio of 1-for-25 (the "2022 Reverse Stock Split"). As a result of the 2022 Reverse Stock Split, (i) every 25 shares of the issued and outstanding common stock were automatically converted into one newly issued and outstanding share of common stock, without any change in the par value per share; (ii) the number of shares of common stock into which each outstanding warrant or option to purchase common stock is exercisable was proportionally decreased, and (iii) the number of authorized shares of common stock outstanding was proportionally decreased. Shares of common stock underlying outstanding stock options and other equity instruments convertible into common stock were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities.

The 2022 Reverse Stock Split became effective at 5:00 pm New York time on April 26, 2022, with the common stock trading on a post-split basis under the Company's existing trading symbol, "NVIV," at the market open on April 27, 2022. Fractional shares resulting from the 2022 Reverse Stock Split were rounded up to the nearest whole share, and all shares of common stock (including fractions thereof) issuable upon the 2022 Reverse Stock Split to a given stockholder were aggregated for the purpose of determining whether the 2022 Reverse Stock Split would result in the issuance of a fractional share. Pursuant to Section 78.209 of the Nevada Revised Statutes, the Company's Board of Directors was able take action to effect the 2022 Reverse Stock Split by filing a Certificate of Change with the Secretary of State of the State of Nevada without the consent of the Company's stockholders.

All of the Company's historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock in these consolidated financial statements have been adjusted, on a retroactive basis, to reflect the 2022 Reverse Stock Split.

2. SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies followed by the Company in the preparation of the financial statements is as follows:

Use of estimates

The process of preparing financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of assets and liabilities at the date of the financial statements and the reported amounts expensed during the reporting period. Actual results could differ from those estimates and changes in estimates may occur.

Basis of presentation and principles of consolidation

The consolidated financial statements include the accounts of InVivo Therapeutics Holdings Corp. and its wholly-owned subsidiary, InVivo Therapeutics Corporation. All significant intercompany balances and transactions have been eliminated in consolidation. The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP.

Certain reclassifications have been made to the prior year financial statements to conform to the presentation used in the current year. In the current year the Company reclassified other current assets from Prepaid expenses and other current assets and presented them under other current assets on the Consolidated Balance Sheets. These reclassifications did not have an impact on total assets or total liabilities of the Consolidated Balance Sheets or cash flows as previously reported.

Cash and cash equivalents

The Company considers only those investments that are highly liquid, readily convertible to cash, and that mature within 3 months from date of purchase to be cash equivalents. As of each of December 31, 2022 and 2021, the Company has cash balances in a financial institution in excess of insured limits. The Company has not experienced any losses related to these balances. Management believes it is not exposed to significant credit risk. At December 31, 2022 and 2021, cash equivalents were comprised primarily of money market funds.

Cash and cash equivalents consist of the following:

	December 31,	
(In thousands)	**2022**	**2021**
Cash	$ 55	$ 5
Money market funds	16,296	19,026
Total cash and cash equivalents	$ 16,351	$ 19,031

Restricted cash

Restricted cash as each of December 31, 2022 and 2021 was $150 thousand. Restricted cash as of December 31, 2022 and 2021 included a $50 thousand security deposit related to the Company's credit card account and a $100 thousand standby letter of credit in favor of a landlord.

Fair Value of Financial instruments

The carrying amounts reported in the Company's consolidated balance sheets for cash, cash equivalents and accounts payable approximate fair value based on the short-term nature of these instruments.

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 820 Fair Value Measurements and Disclosures ("ASC 820") defines fair value 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. ASC 820 also establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy are described below:

Level 1—Valuation is based on quoted prices in active markets for identical assets or liabilities. Level 1 assets and liabilities generally include debt and equity securities that are traded in an active exchange market. Valuations are obtained from readily available pricing sources for market transactions involving identical assets or liabilities.

Level 2—Valuation is based on observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Valuation is based on unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

Fair value estimates discussed herein are based upon certain market assumptions and pertinent information available to management as of December 31, 2022. The respective carrying value of certain on-balance-sheet financial instruments approximated their fair values due to the short-term nature of these instruments. These financial instruments include accounts payable and accrued expenses.

Property and equipment

Property and equipment of the Company is stated at cost. In accordance with ASC Topic 360 Property, Plant and Equipment, expenditure for fixed assets that substantially increase the useful lives of existing assets are capitalized at cost and depreciated. Routine expenditures for repairs and maintenance are expensed as incurred. Depreciation is provided principally on the straight-line method over the estimated useful lives of the asset. A summary of the estimated useful lives is as follows:

Classification	Estimated Useful Life
Computer hardware	3 - 5 years
Software	3 years
Research and lab equipment	5 years
Leasehold improvements	Remaining life of lease

Research and development expenses

The Company expenses R&D costs as incurred. As part of the process of preparing the Company's financial statements, the Company to estimate certain research and development expenses. This process involves reviewing clinical agreements and open contracts and purchase orders, communicating with its CRO to identify services that have been performed on its behalf and estimating the level of service performed and the associated costs incurred for the services when the Company has not yet been invoiced or otherwise notified of the actual costs. The majority of the Company's service providers invoice the Company in arrears for services performed, on a predetermined schedule or when contractual milestones are met; however, a few require advanced payments. The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known to it at that time. Examples of estimated accrued research and development expenses include fees paid to:

- clinical research organizations, or CROs, in connection with performing research services on its behalf and clinical trials;
- investigative sites or other providers in connection with clinical trials; and
- vendors in connection with clinical development activities

The Company bases its expenses related to clinical trials on its estimates of the services received and efforts expended pursuant to quotes and contracts with CROs that conduct and manage clinical trials on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from its estimate, the Company adjusts the accrual or amount of prepaid expense accordingly. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low in any particular period. To date, the Company has not made any material adjustments to its prior estimates of accrued research and development expenses.

As of December 31, 2022, the Company had $1.2 million in prepayments for CRO services all of which are included in the other current assets balance on the balance sheet. As of December 31, 2021, the Company had $1.2 million in prepayments for CRO services of which $28 thousand is included in prepaid expense and other current assets balance on the balance sheet and the remaining $1.1 million is included within the other long term assets balance on the balance sheet.

Concentrations of credit risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash in commercial banks, which may at times exceed Federally Insured limits. The Company has not experienced any loss in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents.

Segment information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as principally one operating segment, which is developing and commercializing biopolymer scaffolding devices for the treatment of spinal cord injuries. As of December 31, 2022 and 2021, all of the Company's assets were located in one location in the United States.

Income taxes

For federal and state income taxes, deferred tax assets and liabilities are recognized based upon temporary differences between the financial statement and the tax basis of assets and liabilities. Deferred income taxes are based upon prescribed rates and enacted laws applicable to periods in which differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, the Company provides a valuation allowance, if necessary, to reduce deferred tax assets to amounts that are realizable. Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more likely than not" of being sustained by the applicable tax authority.

Tax positions not deemed to meet a more-likely-than-not threshold would be recorded as a tax expense in 2022. There were no material uncertain tax positions that required accrual or disclosure to the financial statements as of December 31, 2022 or 2021. Tax years subsequent to 2019 remain open to examination by U.S. federal and state tax authorities.

Impairment of long-lived assets

The Company continually monitors events and changes in circumstances that could indicate that carrying amounts of long-lived assets may not be recoverable. An impairment loss is recognized when expected cash flows are less than an asset's carrying value. Accordingly, when indicators of impairment are present, the Company evaluates the carrying value of such assets in relation to the operating performance and future undiscounted cash flows of the underlying assets. The Company's policy is to record an impairment loss when it is determined that the carrying value of the asset may not be recoverable.

Share-based payments

The Company accounts for all stock-based payment awards granted to employees and nonemployees using the fair value method. The Company's stock-based payments include stock options and grants of common stock, including common stock subject to vesting. The measurement date for both employee and nonemployee awards is the date of grant, and stock-based compensation costs are recognized as expense over the employees' requisite service period, which is the vesting period, on a straight-line basis. Stock-based compensation costs for nonemployees are recognized as expense over the vesting period on a straight-line basis. Stock-based compensation is classified in the accompanying consolidated statements of operations and comprehensive loss based on the department to which the related services are provided.

Derivative instruments

The Company generally does not use derivative instruments to hedge exposures to cash-flow or market risks. In the past certain of the Company's issued and outstanding warrants to purchase common stock previously contained anti-dilution provisions. These warrants did not meet the requirements for classification as equity and were thus recorded as derivative warrant liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. Such financial instruments are initially recorded at fair value, with subsequent changes in fair value recorded to operations in each reporting period. If these instruments subsequently meet the requirements for classification as equity, the Company reclassifies the fair value to equity.

Net loss per common share

Basic and diluted net loss per share of common stock has been computed by dividing net loss by the weighted average number of shares outstanding during the period as follows:

	Year Ended December 31,	
	2022	2021
Numerator:		
Net loss (in thousands)	$ (10,490)	$ (9,895)
Denominator:		
Weighted average shares used in calculating net loss per share — basic and diluted	1,536,474	1,323,659
Net loss per share — basic and diluted	$ (6.83)	$ (7.48)

In a net loss period, options, warrants, unvested restricted stock units and convertible securities are anti-dilutive and are therefore excluded from diluted loss per share calculations.

For the year ended December 31, 2022 and 2021, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

	December 31,	
	2022	2021
Warrants	3,064,877	563,162
Stock options	136,568	14,582
Unvested RSAs	—	254
Total potentially dilutive securities	3,201,445	577,998

New Accounting Pronouncements

In May 2021 FASB) issued Accounting Standards Update (“ASU”) No. 2021-04, “Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity’s Own Equity (Subtopic 815-40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options, a consensus of the Emerging Issues Task Force”. This ASU amends the ASC to provide explicit guidance, and, thus, reduce diversity in practice, on accounting by issuers for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after the modification or exchange. This amendment provides that for an entity that presents earnings per share (“EPS’) in accordance with Topic 260, the effects of a modification or an exchange of a freestanding equity-classified written call option that is recognized as a dividend should be an adjustment to net income (or net loss) in the basic EPS calculation. The Company adopted ASU 2021-04 effective January 1, 2022, and it did not have a material impact on the Company’s consolidated financial statements.

No other accounting standards known by the Company to be applicable to it that have been issued by the FASB or other standard-setting bodies and that do not require adoption until a future date are expected to have a material impact on the Company’s consolidated financial statements upon adoption.

3. PROPERTY AND EQUIPMENT

Property and equipment, net consisted of the following:

(In thousands)	December 31, 2022	December 31, 2021
Computer hardware	$ 67	$ 52
Computer Software	7	5
Research and lab equipment	723	580
Leasehold improvements	66	66
Property and equipment	863	703
Less accumulated depreciation	(636)	(576)
Property and equipment, net	$ 227	$ 127

Depreciation expense for the years ended December 31, 2022 and 2021, was $60 thousand, and $35 thousand, respectively. Maintenance and repairs are charged to expense as incurred and any additions or improvements are capitalized.

4. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31,	
(In thousands)	2022	2021
Compensation	$ 852	$ 1,287
Clinical	433	218
Other accrued expenses	170	141
Total accrued expenses	$ 1,455	$ 1,646

5. FAIR VALUES OF ASSETS AND LIABILITIES

The Company groups its assets and liabilities generally measured at fair value in 3 levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value. Refer to Note 2, “Significant Accounting Policies,” for additional information on the accounting policies related to fair value.

Assets and liabilities measured at fair value on a recurring basis are summarized below:

	As of December 31, 2022			
(In thousands)	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 16,296	$ —	$ —	$ 16,296

	As of December 31, 2021			
(In thousands)	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 19,026	$ —	$ —	$ 19,026

During the years ended December 31, 2022 and 2021, there were no transfers between levels. The fair value of the Company’s cash equivalents, consisting of a money market fund, is based on quoted market prices in active markets with no valuation adjustment.

The Company believes the carrying amounts of its prepaid expenses and other current assets, restricted cash, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these amounts.

6. INCOME TAXES

No provision or benefit for federal or state income taxes has been recorded as the Company has incurred a net loss for all of the periods presented and the Company has provided a full valuation allowance against its deferred tax assets.

At December 31, 2022, the Company had U.S. federal and Massachusetts net operating loss carryforwards of $164.4 million and $153.9 million, respectively, of which $117.3 million of federal carryforwards will expire in varying amounts beginning in 2026 and $47.0 million carry forward indefinitely. State net operating losses begin to expire in 2029. Utilization of net operating losses and tax credit carryforwards may be subject to substantial annual limitations due to the "change in ownership" provisions of the Internal Revenue Code, and similar state provisions. The annual limitations may result in the expiration of net operating losses before utilization. The Company has completed several financings since its inception, which may have resulted in a change in ownership, or could result in a change in ownership in the future but has not yet completed a Section 382 analysis of whether an ownership change limitation exists. The Company will complete an appropriate analysis before its tax attributes are utilized. The Company also had federal and state research and development tax credits of $1.6 million and $0.2 million respectively, at December 31, 2022, which will begin to expire in 2026 and 2031, respectively, unless previously utilized.

Significant components of the Company's net deferred tax assets are as follows:

	December 31,	
(In thousands)	**2022**	**2021**
Net operating loss carryforward	$ 44,249	$ 42,696
Research and development credit carryforward	1,718	1,663
Stock-based compensation	359	431
Depreciation and amortization	4	17
Capitalized research expenses	1,226	—
Lease liability	252	344
Right of use asset	(224)	(323)
Other deferred tax liabilities	(225)	—
Accruals and other temporary differences	189	—
Subtotal	47,548	44,828
Valuation allowance	(47,548)	(44,828)
Net deferred taxes	$ —	$ —

The Company has maintained a full valuation allowance against its deferred tax assets in all periods presented. A valuation allowance is required to be recorded when it is more likely than not that some portion or all of the net deferred tax assets will not be realized. Since the Company cannot be assured of generating taxable income and thereby realizing the net deferred tax assets, a full valuation allowance has been provided. In the years ended December 31, 2022 and 2021, the valuation allowance increased by $2.7 million and $2.6 million, respectively.

The Company has no uncertain tax positions at December 31, 2022 and 2021 that would affect its effective tax rate. The Company does not anticipate a significant change in the amount of uncertain tax positions over the next 12 months. Since the Company is in a loss carryforward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available.

Income tax benefits computed using the federal statutory income tax rate differ from the same benefits computed using the Company's effective tax rate primarily due to the following:

	December 31,	
	2022	**2021**
Statutory rate	(21.0)%	(21.0)%
State taxes, net of benefit	(5.1)%	(4.7)%
Permanent differences	0.1 %	0.4 %
Research and development tax credit	(0.7)%	(0.9)%
Stock-based compensation	0.9 %	0.2 %
Increase in valuation reserve	25.9 %	26.0 %
Other	(0.1)	— %
Effective tax rate	(0.0)%	0.0 %

The Company is subject to U.S. Federal and Massachusetts state income taxes. The statute of limitations for assessment by the Internal Revenue Service or state tax authority is generally open for the tax years ending December 31, 2019 through December 31, 2022, however federal and state tax attributes that were generated prior to the tax year

ending December 31, 2018 may still be adjusted upon examination by the Internal Revenue Service or stat tax authority if the attributes either have been, or will be, used in a future period.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 ("Tax Act") eliminates the option to deduct research and development expenditures currently and requires taxpayers to amortize them, over five years for domestically incurred expenditures and over fifteen years for foreign incurred expenditures, pursuant to Internal Revenue Code ("IRC") Section 174. As of December 31, 2022, the Company has recorded a deferred tax asset of $1.2 million related to the Capitalized IRC Section 174 expenditures.

7. STOCKHOLDERS EQUITY

Preferred Stock

On September 9, 2022, the Company held its 2022 Annual Meeting of Stockholders (the "2022 Annual Meeting"). At the 2022 Annual Meeting, the Company's stockholders approved an amendment to the Company's Articles of Incorporation to approve the issuance of preferred stock. As of December 31, 2022, the Company had 1,000,000 authorized shares of undesignated preferred stock, $0.00001 par value per share, the rights, preferences and privileges of which may be designated from time to time by our board of directors. No shares of preferred stock have been issued or are outstanding.

Common Stock

At the 2022 Annual Meeting, the Company's stockholders approved an amendment to the Company's Articles of Incorporation to increase the number of shares of authorized common stock from 2,000,000 to 250,000,000. As of December 31, 2022 and 2021, 2,429,446 and 1,370,595 shares were issued and outstanding respectively.

On October 9, 2022, the Company closed a registered offering of shares of its common stock and pre-funded warrants to purchase common stock (the "October 2022 Registered Direct Offering") and a concurrent private placement of pre-funded warrants and preferred investment options (the "October 2022 Private Placement"), with an institutional investor (together, the "October 2022 Financing"). In the October 2022 Registered Direct Offering, the Company issued (i) an aggregate of 154,000 common shares ("Shares"); and (ii) 369,810 pre-funded warrants (the "October 2022 Pre-Funded Warrants"). In the concurrent October 2022 Private Placement, the Company issued additional October 2022 Pre-Funded Warrants to purchase an aggregate of 1,190,476 shares of its common stock, and (ii) Preferred Investment Options to purchase an aggregate of 1,714,286 shares of its common stock (the "October 2022 Preferred Investment Options"). The purchase price of each Share and associated October 2022 Preferred Investment Option sold in the October 2022 Registered Direct Offering was $5.25 and the purchase price of each October 2022 Pre-Funded Warrant and associated October 2022 Preferred Investment Option sold in each of the October 2022 Registered Direct Offering and October 2022 Private Placement was $5.2499.

In connection with the October 2022 Financing, the Company issued to designees of H.C. Wainwright & Co., LLC ("Wainwright"), the placement agent for the October 2022 Financing, Preferred Investment Options to purchase an aggregate of 111,429 shares of its common stock (the "October 2022 Placement Agent Warrants"). The net proceeds to the Company after deducting Wainwright's placement agent fees and other offering expenses payable by the Company, were approximately $8.0 million. The Company assessed whether the October 2022 Pre-Funded Warrants, October 2022 Placement Agent Warrants and the October 2022 Preferred Investment Options required accounting as derivatives and determined that they were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with ASC Topic 815, Derivatives and Hedging. As such, the Company concluded that the October 2022 Pre-Funded Warrants, October 2022 Placement Agent Warrants and the October 2022 Preferred Investment Options meet the scope exception for determining whether the instruments require accounting as derivatives and accordingly are classified in stockholders' equity. The fair value of the October 2022 Placement Agent Warrants was estimated at $0.3 million using a Black-Scholes model with the following assumptions: expected volatility of 129.96%, risk free interest rate of 4.14%, expected life of five years and no dividends. The fair value of the October 2022 Preferred Investment Options was estimated at $4.9 million using a Black-Scholes model with the following assumptions: expected volatility of 128.87%, risk free interest rate of 4.12%, expected life of five and a half years and no dividends. The October 2022 Pre-Funded Warrants had an intrinsic value of approximately $8.2 million. During the year ended December 31, 2022, the Company issued an aggregate of 884,286 shares of common stock upon the exercise of the October 2022 Pre-Funded Warrants for an immaterial amount, as they were substantially pre-funded.

Concurrent with the October 2022 Financing, the Company modified certain outstanding warrants, consisting of 29,091 Series A Warrants issued in March 2020, 19,048 Series C Warrants issued in April 2020 and 32,000 Series A Warrants issued in October 2020 (collectively the "Existing Warrants") held by the institutional investor that participated in the October 2022 Financing to lower the exercise price of these warrants to $5.05 and extend the term through April 2028. The change in the term and exercise price of the Existing Warrants was accounted for as modification of an equity instrument. The Company remeasured the Existing Warrants Fair Value both immediately before and after the modification and the remeasurement resulted in an incremental fair value of $0.1 million. As the modification was executed in an effort to induce the investor to participate in the October 2022 Registered Direct Offering and concurrent October 2022 Private Placement, the incremental fair value was accounted for as an issuance cost.

During the year ended December 31, 2022, as part of the adjustment to reflect the 2022 Reverse Stock Split, the Company issued an aggregate of 20,619 shares of common stock to account for the fractional roundup of shareholders.

During the year ended December 31, 2022, 54 restricted stock shares that were considered issued and outstanding as of December 31, 2021 were forfeited.

During the year ended December 31, 2022, there was no exercise activity related to any warrants that were issued in 2018, 2019 and 2020.

During the year ended December 31, 2021, the Company issued an aggregate of 424,829 and 488 shares of common stock upon the exercise of certain Series A Warrants and placement agent warrants issued in October 2020, respectively, for aggregate proceeds of $8.5 million.

During the year ended December 31, 2021, the Company issued an aggregate of 2 shares of common stock upon vesting of restricted stock units.

Common Stock Reserves

As of December 31, 2022, the Company had the following reserves established for the future issuance of common stock as follows:

	As of December 31, 2022
Reserves for the exercise of warrants	3,064,877
Reserves for the exercise of stock options	136,568
Total reserves	3,201,445

8. SHARE-BASED COMPENSATION, STOCK OPTIONS, AND RESTRICTED SECURITIES

On October 26, 2010, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved, the 2010 Equity Incentive Plan (as subsequently amended, the "2010 Plan"). The 2010 Plan provided for grants of incentive stock options to employees, and nonqualified stock options and restricted common stock to employees, consultants, and non-employee directors of the Company.

In April 2015, the Company's Board of Directors adopted, and the Company' shareholders subsequently approved, the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for grants of incentive stock options to employees, and nonqualified stock, restricted common stock, restricted stock units and stock appreciation rights to employees, consultants, and directors of the Company.

As of December 31, 2022, the total number of shares available to be issued under the 2015 Plan was 788,697.

Options issued under the 2010 Plan, and 2015 Plan (collectively, the "Plans") are exercisable for up to 10 years from the date of issuance.

Share-based compensation

For the years ended December 31, 2022 and 2021, Stock-based compensation recognized was classified in the consolidated statements of operations as follows:

	Year Ended December 31,	
(In thousands)	2022	2021
Research and development	$ (8)	$ 22
General and administrative	167	293
Total	$ 159	$ 315

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model, which uses the assumptions noted in the following table. The Company uses historical data, as well as subsequent events occurring prior to the issuance of the financial statements, to estimate option exercises within the valuation model. The expected term of options granted under the Plans, all of which qualify as "plain vanilla," is based on the average of the contractual term (10 years) and the vesting period (generally, 48 months). For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option. The impact of forfeitures on compensation expense is recorded as they occur.

The assumptions used principally in determining the fair value of options granted during the years ended December 31, 2022 and 2021, were as follows:

	December 31, 2022	December 31, 2021
Risk-free interest rate	3.87%	1.03%
Expected dividend yield	0%	0%
Expected term (employee grants)	5.71	5.70
Expected volatility	126.66%	117.34%

The Company grants restricted stock units ("RSUs"), and restricted stock awards ("RSAs"), collectively referred to as restricted securities under the 2015 Equity Incentive Plan. These restricted securities generally vest over a three-year period, contingent on the recipient's continued employment. Prior to vesting, all RSAs have the right to vote and receive dividends under the 2015 Equity Incentive Plan; however, the Company's form of Restricted Stock Agreement provides that the payment of dividends on unvested RSAs shall be deferred until such time as the shares vest. The grant date fair value of these awards is based on the fair market value of our common stock on the date of grant.

Stock Options

A summary of option activity as of December 31, 2022 and changes for the year then ended are presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding as of December 31, 2021	14,582	$ 437.78	9.18	$ —
Granted	126,600	$ 2.50		
Cancelled/Forfeited	(4,613)	$ 345.06		
Expired	(1)	$ 129,750.00		
Outstanding as of December 31, 2022	136,568	$ 36.46	9.72	$ —
Vested and Exercisable as of December 31, 2022	8,268	$ 547.95	8.15	$ —
Vested and expected to vest as of December 31, 2022	136,568	$ 36.46	9.72	$ —

During the years ended December 31, 2022 and 2021, the Company granted 126,000 and 14,400 stock options respectively. The weighted average grant-date fair value of options granted during the years ended December 31, 2022 and 2021 was $2.21 per share and $23.19 per share, respectively. The total fair value of options that vested in years ended December 31, 2022 and 2021, was $239 thousand and $67 thousand, respectively. For the years ended December 31, 2022 and 2021, the Company recorded stock-based compensation expense of $157 thousand and $219 thousand, respectively, related to stock options. As of December 31, 2022, there was $277 thousand of total unrecognized compensation expense related to non-vested share-based option compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a remaining weighted-average period of 1.42 years at December 31, 2022.

Restricted Securities

A summary of restricted securities activity as of December 31, 2022 and changes for the year then ended are presented below:

Restricted Securities	Number of Grants	Weighted-Average Grant Date Fair Value
Unvested balance as of December 31, 2021	254	$ 387.05
Vested	(200)	$ 387.50
Cancelled/Forfeited	(54)	$ 385.38
Unvested balance as of December 31, 2022	—	$ —

For years ended December 31, 2022 and 2021, the Company recorded stock-based compensation expense of $3 thousand and $96 thousand, respectively, related to the time-based restricted securities.

9. WARRANTS

The following table presents information about warrants to purchase common stock issued and outstanding at December 31, 2022:

Year Issued	Defined Name	Classification	Number of Warrants	Exercise Price as of December 31, 2022	Date of Expiration
2018	2018 Series A Warrants	Equity	8,483	$ 174.53	6/25/2023
2019	2019 Placement Agent Warrants	Equity	610	$ 112.50	11/21/2024
2020	March 2020 Series A Warrants	Equity	72,738	$ 68.75	3/10/2025
2020	Amended March 2020 Series A Warrants	Equity	29,091	5.05	4/11/2028
2020	March 2020 Placement Agent Warrants	Equity	6,620	$ 85.9400	3/5/2025
2020	March 2020 Series B Warrants	Equity	510	$ 0.00025	Until Fully Exercised
2020	April 2020 Series C Warrants	Equity	48,163	$ 40.50	10/17/2025
2020	Amended April 2020 Series C Warrants	Equity	19,048	5.05	4/11/2028
2020	April 2020 Placement Agent Warrants	Equity	4,461	$ 54.6900	4/15/2025
2020	October 2020 Placement Agent Warrants	Equity	48,264	$ 25.00	10/22/2025
2020	October 2020 Series A Warrants	Equity	293,174	$ 20.00	10/27/2025
2020	Amended October 2020 Series A Warrants	Equity	32,000	5.05	4/11/2028
2022	October 2022 Pre-funded Warrants	Equity	676,000	0.00001	Until Fully Exercised
2022	October 2022 Preferred Investment Options	Equity	1,714,286	5.05	4/11/2028
2022	October 2022 Placement Agent Warrants	Equity	111,429	6.56	10/7/2027
Total			3,064,877		
Weighted average exercise price				$ 8.54	
Weighted average life in years					3.69

10. EMPLOYEE BENEFIT PLAN

In November 2006, the Company adopted a 401(k) plan (the "Plan") covering all employees. Employees must be 21 years of age in order to participate in the Plan. Under the Plan, the Company has the option to make matching contributions. During the years ended December 31, 2022 and 2021, the Company contributed $71 thousand and $69 thousand, respectively, in cash matching contributions to employee 401(k) accounts.

11. COMMITMENTS AND CONTINGENCIES

Operating Leases

On May 3, 2018, the Company entered into a sublease for 5,104 square feet of space for its corporate offices and laboratory space in Cambridge Massachusetts (the "Cambridge Sublease"). The Cambridge Lease commenced on May 3, 2018 and was scheduled to expire on October 31, 2023. In May 2021, the Company entered into an agreement to terminate the Cambridge Sublease (the "Sublease Termination"). In connection with the Sublease Termination, the $60 thousand standby letter of credit was cancelled and returned to the Company.

Concurrent with the Sublease Termination, the Company entered into a new lease for the same space with ARE-MA (the "Cambridge Lease"). The Cambridge Lease commenced on June 1, 2021 and was originally scheduled to expire on December 31, 2023. The Cambridge Lease contained rent escalation clauses. In connection with the Cambridge Lease, a new standby letter of credit was established for $100 thousand. Under the Cambridge Lease, the Company will be required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises in excess of new base year amounts. These costs are considered to be variable lease payments and are not included in the determination of the lease's right-of-use asset or lease liability.

The Sublease Termination and concurrent execution of the Cambridge Lease was determined to be a lease modification that qualified as a change of accounting on the existing lease and not a separate contract. As such, the right-of-use assets and operating lease liabilities were remeasured using an incremental borrowing rate at the date of modification of 5.74%, which resulted in an increase of $143 thousand in both the right-of-use asset and operating lease liabilities.

On November 23, 2021, the Company amended the Cambridge Lease to extend the term through December 31, 2024. No other terms within the Cambridge Lease were amended. The amendment of the Cambridge Lease was determined to be a lease modification that qualified as a change of accounting on the existing lease and not a separate contract. As such, the right-of-use assets and operating lease liabilities were remeasured using an incremental borrowing rate at the date of modification of 5.97%, which resulted in an increase of $486 thousand in both the right-of-use asset and operating lease liabilities.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities:

- As the Cambridge Lease does not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments.
- Since the Company elected to account for each lease component and its associated non-lease components as a single combined component, all contract consideration was allocated to the combined lease component.
- The expected lease terms include noncancelable lease periods.

The elements of lease expense are as follows:

	Year Ended December 31,	
Lease cost (In thousands)	**2022**	**2021**
Operating lease cost	$ 452	$ 392
Short-term lease cost	8	3
Variable lease cost	182	95
Total lease cost	$ 642	$ 490
Other information (In thousands)		
Increase in operating right-of-use assets and liabilities related to lease modifications	$ —	$ 629
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from short term leases	$ 8	$ 3
Operating cash flows from operating leases	427	403
Total cash paid for leases	$ 435	$ 406
Weighted-average remaining lease term - operating leases	2 Years	3 Years
Weighted-average discount rate - operating leases	6.0%	6.0%

Maturities of lease liabilities due under the Cambridge Lease as of December 31, 2022 is as follows:

Leases (In thousands)	**As of December 31, 2022**
2023	$ 440
2024	568
Total lease payments	1,008
Less: imputed interest	(59)
Present value of lease liabilities	**$** 949

Leases (In thousands)	**Classification**	**December 31, 2022**	**December 31, 2021**
Assets			
Lease asset, net	Operating	$ 844	$ 1,229
Total lease assets		$ 844	$ 1,229
Liabilities			
Current	Operating	$ 396	$ 361
Non-current	Operating	553	949
Total lease liabilities		$ 949	$ 1,310

Clinical Trial Commitments

The Company has engaged and executed contracts with CROs to assist with the administration of its ongoing INSPIRE 1.0 and INSPIRE 2.0 clinical trials. As of December 31, 2022, approximately $3.9 million remains to be paid on these contracts.

12. RELATED PARTY TRANSACTIONS

During the years ended December 31, 2022 and 2021, the Company did not identify any related party transactions requiring disclosure.

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 its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2022, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of the end of the period covered by this report.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the Company. Our internal control over financial reporting is designed to provide reasonable assurances regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles, or GAAP, and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

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

Our management, with the participation of its Chief Executive Officer and Chief Financial Officer, assessed our internal control over financial reporting as of December 31, 2022, the end of our fiscal year. Management based its assessment on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and concluded that our internal control over financial reporting was effective as of December 31, 2022.

Attestation Report of Registered Public Accounting Firm

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act, and therefore are not required to provide an attestation report of our registered public accounting firm with respect to our internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

There were no changes in our system of internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) during the quarter ended December 31, 2022 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

Information about our Executive Officers and Directors

The following table sets forth the name, age, and position of each of our executive officers and directors as of February 17, 2023.

NAME	AGE	CURRENT POSITION
Executive Officers		
Richard Toselli, M.D.	65	President, Chief Executive Officer, and Director
Richard Christopher	53	Chief Financial Officer
Heather Hamel	33	Chief Legal Officer and General Counsel
Non-Employee Directors		
C. Ann Merrifield (2) (3)	71	Director, Chair of the Board
Daniel R. Marshak, Ph.D. (1) (3)	65	Director
Christina Morrison (1) (2)	56	Director
Richard J. Roberts, Ph.D. (2) (3)	79	Director
Robert J. Rosenthal, Ph.D. (1) (3)	66	Director

(1) Member of audit committee
(2) Member of compensation committee
(3) Member of nominating and corporate governance committee

Biographical and certain other information concerning our executive officers and directors is set forth below.

Executive Officers

Richard Toselli, M.D. 65, has served as our President and Chief Executive Officer and a director since February 2018. Prior to being appointed President and Chief Executive Officer and a director, Dr. Toselli served as our Acting Chief Executive Officer from December 2017 to February 2018. Since July 2017, Dr. Toselli has also served as our Chief Medical Officer. Before joining our company, Dr. Toselli served as the Chief Medical Officer for Cochlear Limited, a medical device company, from June 2016 until March 2017. Prior to that, Dr. Toselli served at Sanofi, a pharmaceutical company, from July 2012 to June 2016 in various levels of increasing responsibility, including Vice President of Global Medical Affairs — Immunology and Inflammation, Biologics Division; Vice President of Global Medical Affairs and Head of the Biosurgery Discovery Performance Unit; and Vice President of Global Medical Affairs, Biosurgery. Before his time at Sanofi, he served as Chief Medical/Technology Officer for Covidien Public Limited Company (now Medtronic Public Limited Company), a medical device company, and earlier held the position of Vice President of Evidence-Based Medicine for the device sector at Johnson & Johnson, a medical device, pharmaceutical and consumer packaged goods manufacturing company. Prior to that, Dr. Toselli held various roles at DePuy Synthes Spine, Inc., a medical device company, including Director of Medical Affairs, Worldwide Vice President of Research and Development, and Worldwide Vice President of Clinical Evidence and External Relations. Dr. Toselli also serves on the Board of SpineX, a privately held medical device company focused on neuromodulation. Dr. Toselli holds a Bachelor of Arts from Providence College, his medical degree from Brown University, and a Master of Business Administration from the University of North Carolina's Kenan-Flagler Business School. Dr. Toselli is a board-certified neurological surgeon.

Richard Christopher, 53, was appointed as our Chief Financial Officer in January 2019. Previously, Mr. Christopher was the Chief Financial Officer of iCAD, Inc. from December 2016 through January 2019. iCAD, Inc. is a Nasdaq-listed company with a focus on therapies and solutions for the early identification and treatment of cancer. Prior to iCAD, Inc., Mr. Christopher was Chief Financial Officer from March 2014 through December 2016 and Chief Operating Officer from October 2015 through December 2016 of Caliber Imaging & Diagnostics, Inc., a medical technology company focused on cancer detection imaging solutions, with primary applications in dermatology. Prior to Caliber and starting in 2000, Mr. Christopher held various positions of increasing responsibility at DUSA Pharmaceuticals, Inc., a Nasdaq-listed dermatology company focused on the treatment of precancerous skin lesions, where he ultimately served as Chief Financial Officer from January 2005 through its acquisition and integration into Sun Pharmaceuticals Industries Ltd in April 2013. Mr. Christopher holds a Master of Science in Accounting from Suffolk University and a Bachelor of Science in Finance from Bentley University.

Heather Hamel, 33, was appointed as our Chief Legal Officer and General Counsel in July 2022. Prior to this appointment, Ms. Hamel served as our Vice President of Legal Affairs and Business Development from August 2020 through July 2022. Prior to this position, Ms. Hamel served as our Director of Legal Affairs and Business Development from July 2017 through August 2020. Before joining our Company, Ms. Hamel worked at Ecolab, Inc., where she oversaw a variety of legal matters including intellectual property strategy, patent prosecution and litigation management and PLR IP, Inc., where she was responsible for global intellectual property licensing and partnering across a range of assets. Ms. Hamel has also served as an external legal advisor to several early-stage pharmaceutical companies. Ms. Hamel holds B.S. degrees in biochemistry and chemistry from the University of Wisconsin at Stevens Point, a J.D from William Mitchell College of Law, and a Master of Liberal Arts degree in general management, extension studies from Harvard University.

Non-Employee Directors

C. Ann Merrifield, 71, has been a director of our company since November 2014. She currently serves as a board director for a number of public and private companies which include Lyra Therapeutics, a public biotechnology company; and MassMutual Premier, Select, MML and MMLII Funds, a portfolio of mutual funds. Ms. Merrifield also serves as trustee and director on several other boards including Partners Continuing Care, the post-acute care services division of Partners HealthCare; Huntington Theatre Company, a non-profit organization; and the YMCA of Greater Boston. She also served on the Board of Directors of Flexion Therapeutics, a public biotechnology company, from 2014 through 2021 when it was acquired by Pacira Biosciences; and the Board of Directors of Juniper Pharmaceuticals, a specialty pharmaceuticals company, from 2015 to 2018 when it was acquired by Catalent Pharma Solutions Inc., a biologics manufacturer, and Ms. Merrifield served on the Board of Veritas Genetics, a private genomics company, from 2015 through 2018. Previously, Ms. Merrifield served as President, Chief Executive Officer and a director of PathoGenetix, a genomics company focused on developing an automated system for rapid bacterial identification from 2012 until July 2014 when the company filed for Chapter 7 bankruptcy. Prior to then, she spent 18 years at Genzyme Corporation, serving in a number of leadership roles including President of Genzyme Biosurgery, President of Genzyme Genetics and Senior Vice President Business Excellence. She holds a B.A. in zoology and a Master of Education from the University of Maine and an M.B.A. from the Tuck School of Business at Dartmouth College. Ms. Merrifield brings to our Board an invaluable amount of experience and expertise over her long career in the life sciences industry.

Daniel R. Marshak, Ph.D., 65, has been a director of our company since September 2014. He has served as part-time Chief Technology Officer to Phase Scientific International Ltd., a medical device and clinical diagnostics company, since 2017, and an Advisory Board member of Catalent Pharma Solutions Inc., a biologics manufacturer, since 2015. He most recently served in a full-time role as Senior Vice President and Chief Scientific Officer for PerkinElmer, Inc., a human and environmental health company, until September 2014. Prior to joining PerkinElmer in 2006, Dr. Marshak was Vice President and Chief Technology Officer, Biotechnology, for Cambrex Corporation and earlier, Chief Scientific Officer at Osiris Therapeutics Inc. Dr. Marshak has received numerous awards for scientific and academic achievements and is named as inventor on six issued U.S. patents. Dr. Marshak has served on the Board of Directors of Tecan Group, a leading global provider of laboratory instruments and solutions in biopharmaceuticals, forensics and clinical diagnostics, since 2018. He also serves on the Board of Directors LifeVault Bio in Massachusetts, USA, as well as Elevian, Inc., a private biotechnology company located in Massachusetts, USA, and RareCyte, Inc., a private biotechnology company located in Washington, USA. Dr. Marshak is the author of more than 100 scientific publications, including one textbook, and has been the editor of five monographs. He held an appointment as Adjunct Associate Professor at the Johns Hopkins University School of Medicine, served as Senior Staff Investigator at Cold Spring Harbor Laboratory, and previously taught graduate biochemistry as an Assistant Professor at the State University of New York, now Stony Brook University. Dr. Marshak received his B.A. degree in biochemistry and molecular biology from Harvard University, and he holds a Ph.D. in biochemistry and cell biology from the Rockefeller University. Dr. Marshak brings to our Board extensive industry experience and a deep understanding of the science and technology behind our business.

Christina Morrison, 56, has served as a director of our company since June 2016. Ms. Morrison has served as Chief Financial Officer of Physicians Endoscopy, an ambulatory surgical center management company since April 2018. Prior to that Ms. Morrison served as the Senior Vice President of Finance of Aramark, a publicly traded foodservice, facilities and uniform services provider, from June 2013 until July 2016. Prior to joining Aramark, Ms. Morrison was

Senior Vice President of Business and Financial Planning at Merck & Co., Inc., a publicly traded pharmaceutical company, from November 2009 to June 2013. Before that, Ms. Morrison spent five years at Wyeth Pharmaceuticals, a publicly traded pharmaceutical company, serving in a number of leadership roles including Senior Vice President and Chief Financial Officer of the pharmaceutical division. Ms. Morrison holds an M.B.A. from the Tuck School of Business at Dartmouth College and a B.S. in Economics from the Wharton School at the University of Pennsylvania. Ms. Morrison brings to our Board significant financial experience and a decade of experience in the pharmaceutical industry.

Richard J. Roberts, Ph.D., 79, has been a director of our company since October 2010 and a director of InVivo Therapeutics Corporation, our wholly-owned subsidiary, since November 2008. Dr. Roberts initially joined InVivo Therapeutics Corporation's Scientific Advisory Board in June 2007 and has continued as a member of our Scientific Advisory Board. He has served as Chief Scientific Officer at New England Biolabs, a life sciences company, since February 2007. Dr. Roberts was awarded the 1993 Nobel Prize in Physiology of Medicine along with Phillip Allen Sharp for the discovery of introns in eukaryotic DNA and the mechanism of gene-splicing. He holds a B.Sc. in Chemistry and a Ph.D. in Organic Chemistry from the University of Sheffield, U.K. Dr. Roberts brings the Board his significant experience and understanding of the science and technology involved in our business.

Robert J. Rosenthal, Ph.D., 66, has been a director of our company since November 2019. Dr. Rosenthal currently serves as Chairman of the Board of Directors of Taconic Biosciences, Inc., a privately-held provider of research models for the pharmaceutical and biotech industry, where from 2014 to 2019 he also served as Chief Executive Officer. Dr. Rosenthal has served as a director of the Bruker Corporation, a publicly traded manufacturer of analytic instruments, since 2015. Dr. Rosenthal has served since 2007 as a director of Safeguard Scientifics, Inc., a publicly-traded provider of capital for early- and growth-stage companies, and as Chairman of its Board of Directors since May 2016. Since 2013, he has also served as a director of Galvanic Applied Sciences, Inc., a privately-held Canadian company. Since 1995, Dr. Rosenthal previously served in a variety of senior management positions with companies involved in the development of diagnostics, therapeutics, medical devices, and life sciences tools, most recently including from 2010 through 2012 as President and Chief Executive Officer of IMI Intelligent Medical Implants, AG, a medical technology company, and from 2005 through 2009 as President and Chief Executive Officer of Magellan Biosciences, Inc., a provider of clinical diagnostics and life sciences research tools. Earlier in his career, Dr. Rosenthal served in senior management positions at Perkin Elmer Inc. and Thermo Fisher Scientific, Inc. Dr. Rosenthal holds a Ph.D. from Emory University and a Master of Science degree from the State University of New York. Dr. Rosenthal brings to our Board an extensive understanding of and experience in strategic planning and positioning; corporate, business and product development; operations management; capital markets transactions; debt and equity financings; fund-raising; merger and acquisition transactions; corporate finance; and corporate governance.

Family Relationships

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

Delinquent Section 16 Reports

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers and persons who own more than 10% of a registered class of our equity securities to file reports of beneficial ownership and changes in beneficial ownership with the Securities and Exchange Commission.

To our knowledge, based solely on a review of copies of such reports furnished to us by our officers and directors, we believe that, during the fiscal year ended December 31, 2022, no person required to file reports under Section 16(a) of the Exchange Act failed to file such reports on a timely basis.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics, as amended, that applies to all employees, officers, and directors of our company, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. Our Code of Business Conduct and Ethics is available on the "Corporate Governance" page of the "Investor Relations" section of our website at www.invivotherapeutics.com. A copy of our Code of Business Conduct and Ethics can also be obtained free of charge by contacting our Secretary, c/o InVivo Therapeutics Holdings Corp., One Kendall Square, Suite B14402, Cambridge, MA 02139. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on our website at www.invivotherapeutics.com.

Process for Stockholder Nominations

There have been no material changes to the procedures by which security holders may recommend nominees to our Board since we last provided disclosure of such procedures.

Audit Committee

The Board has designated our Audit Committee as a principal standing committee. The members of our Audit Committee are Ms. Morrison, Dr. Marshak and Dr. Rosenthal. Dr. Rosenthal is the chair of our Audit Committee. Our Board has determined that each of Ms. Morrison, Dr. Marshak and Dr Rosenthal is independent as defined under Rule 5605(a)(2) of the Nasdaq Listing Rules. The Board has determined that Dr. Rosenthal is an "audit committee financial expert," as defined in Item 407(d)(5) of Regulation S-K. See "Non-Employee Directors – Robert Rosenthal" above for a description of Dr. Rosenthal's relevant experience.

ITEM 11. EXECUTIVE COMPENSATION

EXECUTIVE COMPENSATION

Set forth below is information regarding the compensation of (i) our Chief Executive Officer, (ii) our Chief Financial Officer and (iii) our Chief Legal Officer. Such officers are collectively referred to as our "named executive officers."

2022 Summary Compensation Table

The following table sets forth information regarding the compensation awarded to, earned by, or paid to our named executive officers.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)(2)	All Other Compensation ($)	Total ($)
Richard Toselli	2022	537,339	268,669	134,799 (3)	19,196 (5)	960,003
President and Chief Executive Officer	2021	516,672	409,032	139,266 (4)	14,566 (6)	1,079,536
Richard Christopher	2022	369,420	147,768	45,964 (7)	20,628 (9)	583,780
Chief Financial Officer	2021	355,212	254,569	69,633 (8)	18,422 (10)	697,836
Heather Hamel	2022	307,327	124,250	29,612 (11)	15,380 (12)	476,569
Chief Legal Officer and General Counsel						

1. See below, "Narrative to Summary Compensation Table – Bonuses" for a description of the bonuses paid to Dr. Toselli, Mr. Christopher and Ms. Hamel in 2022.
2. The amounts shown in this column represent the aggregate grant date fair value of the option awards computed in accordance with ASC 718, not the actual amounts paid to or realized by the individual. The assumptions used in determining grant date fair value of these awards are set forth in Note 8 to our Consolidated Financial Statements appearing in this Annual Report on Form 10-K.
3. Dr. Toselli received an option to purchase an aggregate of 61,000 shares with an exercise price of $2.50 per share.
4. Dr. Toselli received an option to purchase an aggregate of 6,000 shares with an exercise price of $27.50 per share.
5. Represents (i) $399 in proceeds from vested restricted stock, (ii) $15,250 in 401(k) cash matching contributions under our 401(k) profit sharing plan, and (iii) $3,547 in commuting and accommodation expenses.
6. Represents (i) $66 in proceeds from vested restricted stock and (ii) $14,500 in 401(k) cash matching contributions under our 401(k) profit sharing plan.
7. Mr. Christopher received an option to purchase an aggregate of 20,800 shares with an exercise price of $2.50 per share.

8. Mr. Christopher received an option to purchase an aggregate of 3,000 shares with an exercise price of $27.50 per share.
9. Represents (i) $278 in proceeds from vested restricted stock, (ii) $5,100 in parking expenses and (iii) $15,250 in 401(k) cash matching contributions under our 401(k) profit sharing plan.
10. Represents (i) $14,500 in 401(k) cash matching contributions under our 401(k) profit sharing plan and (ii) $3,922 in commuting expenses.
11. Ms. Hamel received options to purchase an aggregate of 13,400 shares with an exercise price of $2.50 per share.
12. Represents (i) $130 in proceeds from vested restricted stock and (ii) $15,250 in 401(k) cash matching contributions under our 401(k) profit sharing plan.

Narrative to Summary Compensation Table

Base Salary. We paid Dr. Toselli an annualized base salary of $537,339 and $516,672 in 2022 and 2021, respectively. We paid Mr. Christopher an annualized base salary of $369,420 and $355,212 in 2022 and 2021, respectively. We paid Ms. Hamel an annualized base salary of $307,327 in 2022, consisting of a base salary of $269,100 in the first six months of 2022, which was increased to $355,000 in July 2022 in connection with her promotion to Chief Legal Officer and General Counsel. We use base salaries to recognize the experience, skills, knowledge, and responsibilities required of all our employees, including our named executive officers. Dr. Toselli's employment agreement provides that his salary will be reviewed by the Board and adjusted upward no less frequently than annually. Neither Mr. Christopher nor Ms. Hamel are party to an employment agreement or other arrangement that provides for automatic or scheduled increases in base salary.

Bonuses. Our Board may, in its discretion, award bonuses to our named executive officers from time to time. We typically establish annual bonus targets based around a set of specified corporate goals for our named executive officers and conduct an annual performance review to determine the attainment of such goals. Our management may propose bonus awards to our Board primarily based on such review process. Our Board makes the final determination of the eligibility requirements for and the amount of such bonus awards. Under the terms of their respective employment agreements, each of our named executive officers is eligible to receive an annual performance-based bonus, as determined by our Board in its sole discretion, with a target of a specified percentage of such officer's annual base salary earned in such particular calendar year, which percentage shall be subject to adjustment from time to time by our Board in its sole discretion. Our Board determines the amount of the bonus, if any, based on its assessment of the named executive officer's performance and that of the company against appropriate goals established annually by our Board. The current target annual bonus percentage for each of our named executive officers is 50%, 40% and 35% for Dr. Toselli, Mr. Christopher and Ms. Hamel, respectively.

With respect to 2022, we awarded Dr. Toselli a performance bonus of $268,669 based on our achievement of certain company goals. In 2022, we awarded Mr. Christopher a performance bonus of $147,768 based on our achievement of certain company goals. With respect to 2022, we awarded Ms. Hamel a performance bonus of $124,250 based on our achievement of certain company goals.

With respect to 2021, we awarded Dr. Toselli a performance bonus of $193,752 based on our achievement of certain company goals. In 2021, we also awarded Dr. Toselli a special bonus of $215,280, which was contingent upon his continued service as an active employee of the Company through December 31, 2021. In 2021, we awarded Mr. Christopher a performance bonus of $106,564 based on our achievement of certain company goals. In 2021, we also awarded Mr. Christopher a special bonus of $148,005, which was contingent upon his continued service as an active employee of the Company through December 31, 2021.

On August 11, 2021, our Board adopted a Transaction Incentive Plan (the "Transaction Incentive Plan") under which certain employees, including each of Dr. Toselli, Mr. Christopher and Ms. Hamel, is eligible to receive a predefined percentage of the transaction consideration (as defined in the Transaction Incentive Plan) paid in connection with a company acquisition (as defined in the Transaction Incentive Plan), minus the value of vested equity held by such participant. Payments under the Transaction Incentive Plan are payable each participant on the date that is six months following the closing of the applicable company acquisition (the "Payment Date"), subject to the participant's continued employment with the Company, a related entity or the acquiring entity on such date; provided that, in the event that the participant's employment with the Company, a related entity or the acquiring entity is terminated without cause or by the participant for good reason, in either case following the company acquisition but prior to the Payment Date, then the amount payable shall be paid to the participant within ten days following the participant's termination of employment. Under the original terms of the Transaction Incentive Plan, it automatically terminated twelve months from effectiveness, or on August 11, 2022, subject to the right of the Company's Board of Directors to extend the effectiveness of the Transaction Incentive Plan at its sole discretion. On July 7, 2022, our Board extended the term of the Transaction Incentive Plan by one (1) year through August 11, 2023, subject to the right of the Board to extend the effectiveness of the Amended Plan at its sole discretion.

Equity Incentives. Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executives with a strong link to our long term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. Accordingly, our Board periodically reviews the equity incentive compensation of our named executive officers and from time to time may grant equity incentive awards to them in the form of stock options or restricted stock units.

In 2022, we granted options to purchase an aggregate of 61,000 shares, 20,800 shares and 13,400 shares of Common Stock to Dr. Toselli, Mr. Christopher and Ms. Hamel, respectively.

We award our stock options on the date our Board approves the grant. We set the option exercise price equal to the fair market value of shares of our Common Stock on the date of grant, which is determined by reference to the closing market price of our Common Stock on the date of grant. For grants in connection with initial employment, vesting typically begins on the initial date of employment. Time vested equity grants to our executives and other employees typically vest either (i) 25% on the first anniversary of grant or, if earlier, the initial employment date and in equal monthly installments thereafter, through the fourth anniversary of the vesting commencement date or (ii) 33.33% on the first anniversary of the grant date, 33.33% on the second anniversary of the grant date and the remaining 33.33% on the third anniversary of the grant date, and have a term of ten years from the grant date.

Outstanding Equity Awards at Fiscal Year End

The following table summarizes the option and stock awards made to our named executive officers that were outstanding on December 31, 2022.

	Option Awards				
Name	Award Grant Date	No. of Securities Underlying Unexercised Options (#) Exercisable	No. of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Richard Toselli	7/5/2017	18	—	47,812.50	7/5/2027
	3/18/2021	3,000	3,000 (1)	27.50	3/17/2031
	11/17/2022	—	61,000 (1)	2.50	11/16/2032
Richard Christopher	1/14/2019	120	—	1,147.50	1/13/2029
	3/18/2021	1,500	1,500 (1)	27.50	3/17/2031
	11/17/2022	—	20,800 (1)	2.50	11/16/2032
Heather Hamel	8/25/2014	1	—	49,500.00	8/25/2024
	12/10/2014	1	—	78,750.00	12/10/2024
	12/10/2015	1	—	138,187.50	12/10/2025
	1/18/2017	1	—	81,562.50	1/18/2027
	3/18/2021	480	480 (1)	27.50	3/17/2031
	11/17/2022	—	13,400 (1)	2.50	11/16/2032

(1) 50% of the shares underlying the option vest on the first anniversary of the grant date, and the remaining shares vest on the second anniversary of the grant date, subject to continued service.

Pension Benefits

We do not offer to our executive officers or employees any pension plan or similar plan that provides for payments or other benefits at, following or in connection with retirement.

Non-Qualified Deferred Compensation

We do not offer to our executive officers or employees any defined contribution or similar plan that provides for the deferral of compensation on a basis that is not tax-qualified. We offer a 401(k) profit sharing plan to all of our employees eligible to participate. We make matching contributions on behalf of participating employees, in the form of cash-based matching, up to a maximum of 5% of the employee's annual compensation. Our matching contributions become 50% vested after the employee has been employed by us for one year, and 100% vested after the employee has been employed by us for two years. Any company matching contributions made to our named executive officers are reflected in the "All Other Compensation" column of the Summary Compensation Table above.

Agreements with our Executive Officers

Richard Toselli, M.D., President and Chief Executive Officer. In connection with his appointment as acting Chief Executive Officer in December 2017, we entered into an employment agreement with Dr. Toselli. Under the employment agreement, Dr. Toselli receives an annual base salary, subject to adjustment from time to time, and is eligible to receive an annual cash bonus equal to 50% of his annual salary, subject to his performance of specified objectives to be established by the Board (or a designated Board committee) each year. Dr. Toselli is eligible to receive all medical, dental and other benefits to the same extent as provided to our other senior management employees. Dr. Toselli's annual bonus target is 50% of his base salary. In connection with becoming the company's Chief Executive Officer rather than Acting Chief Executive Officer, Dr. Toselli became eligible for certain severance benefits under his employment agreement.

Under our employment agreement with Dr. Toselli, if his employment is terminated by us without cause, or by Dr. Toselli for "good reason," in the absence of a "change in control" (as defined in our 2015 Equity Incentive Plan) then (i) we are obligated to pay severance (consisting of base salary in effect at the time of termination) to Dr. Toselli for a period of 18 months, plus continued health insurance benefits for a period of 18 months and (ii) the unvested portion of any stock options held by him will vest as with respect to an additional 12 months. If Dr. Toselli' s employment is terminated by us without cause, or by Dr. Toselli for "good reason" within 12 months following of a "change in control," then (a) we are obligated to pay severance (consisting of two times base salary in effect at the time of termination and 100% of his target annual bonus) to Dr. Toselli, plus continued health insurance benefits for a period of 18 months, (b) pay a pro rata portion of the annual bonus for the year in which the termination occurs based on a good faith determination of the attainment of the applicable goals and (c) the unvested portion of any stock options held by him will vest fully. The severance payments and the accelerated vesting of options are contingent on execution of a general release of claims against our company and are in addition to any accrued obligations to Dr. Toselli unpaid by us prior to the time of termination.

The employment agreement also contains various restrictive covenants, including covenants relating to non-solicitation, confidentiality and assignment of inventions.

Richard Christopher, Chief Financial Officer. In connection with his employment with the Company and pursuant to the terms of an employment agreement dated December 24, 2018, Mr. Christopher receives an annual base salary as set by the board of directors. Mr. Christopher is also eligible for an annual bonus that targets forty percent (40%) of his annualized base salary based upon achievement of certain performance goals.

Mr. Christopher is also entitled to severance payments under his employment agreement. If we terminate Mr. Christopher's employment without Cause (as defined in the employment agreement) or if he terminates his employment for Good Reason (as defined in the employment agreement), in each case prior to, or more than 12 months following, a change in control, then he is entitled (A) to continue to be paid his base salary as in effect on the termination date for a period of 12 months and (B) to continue to receive his benefits under the company's employee group health insurance plan until the earlier of (i) 12 months following the termination date or (ii) the date he becomes eligible for coverage under a new employer's group health plan.

If we terminate Mr. Christopher's employment without Cause or he terminates his employment for Good Reason, in each case within 12 months following a Change in Control (as defined in the employment agreement), then he is entitled (A) to an amount equal to 1.5 times his base salary as in effect on the termination date, plus 100% of his target annual bonus, in each case at the salary and target annual bonus level in effect on the termination date or, if higher, at any time within the six month period preceding the Change in Control, (B) to acceleration in full of the vesting on all outstanding, unvested equity awards held by him and (C) to continue to receive his benefits under the company's employee group health insurance plan until the earlier of (i) 12 months following the termination date or (ii) the date he becomes eligible for coverage under a new employer's group health plan. The severance payments are contingent upon Mr. Christopher executing a general release of claims.

The employment agreement also contains various restrictive covenants, including covenants relating to non-solicitation, confidentiality and assignment of inventions. In addition, under the terms of the employment agreement, Mr. Christopher will also be eligible for medical, dental and other fringe benefits available to our other senior management members or any benefit plans established or adopted by us.

Heather Hamel, Chief Legal Officer and General Counsel. In connection with her employment with the Company and pursuant to the terms of an employment agreement dated July 11, 2022, Ms. Hamel receives an annual base salary as set by the board of directors. Ms. Hamel is also eligible for an annual bonus that targets thirty-five percent (35%) of her annualized base salary based upon achievement of certain performance goals.

Ms. Hamel is also entitled to severance payments under her employment agreement. If we terminate Ms. Hamel's employment without Cause or if she terminates her employment for Good Reason, in each case prior to, or more than 12 months following, a change in control, then she is entitled (A) to continue to be paid her base salary as in effect on the termination date for a period of 12 months and (B) to continue to receive his benefits under the company's employee group health insurance plan until the earlier of (i) twelve months following the termination date or (ii) the date she becomes eligible for coverage under a new employer's group health plan.

If we terminate Ms. Hamel's employment without Cause or she terminates her employment for Good Reason, in each case within 12 months following a Change in Control (as defined in the employment agreement), then she is entitled (A) to an amount equal to 1.5 times her base salary as in effect on the termination date, plus 100% of her target annual bonus, in each case at the salary and target annual bonus level in effect on the termination date or, if higher, at any time within the six month period preceding the Change in Control, (B) to acceleration in full of the vesting on all outstanding, unvested equity awards held by her and (C) to continue to receive her benefits under the company's employee group health insurance plan until the earlier of (i) 12 months following the termination date or (ii) the date she becomes eligible for coverage under a new employer's group health plan. The severance payments are contingent upon Ms. Hamel executing a general release of claims.

The employment agreement also contains various restrictive covenants, including covenants relating to non-solicitation, confidentiality and assignment of inventions. In addition, under the terms of the employment agreement, Ms. Hamel will also be eligible for medical, dental and other fringe benefits available to our other senior management members or any benefit plans established or adopted by us.

Potential Payments Upon Termination or Change in Control

Certain of our named executive officers are entitled to payments upon a termination of employment or a change in control.

Richard Toselli, M.D., President, Chief Executive Officer, and Director. Under our employment agreement with Dr. Toselli, if his employment is terminated by us without cause, or by Dr. Toselli for "good reason," in the absence of a "change in control" (as defined in the 2015 Plan) then (i) we are obligated to pay severance (consisting of base salary in effect at the time of termination) to Dr. Toselli for a period of 18 months, plus continued health insurance benefits for a period of 18 months and (ii) the unvested portion of any stock options held by him will vest as with respect to an additional 12 months. If Dr. Toselli's employment is terminated by us without cause, or by Dr. Toselli for "good reason" within 12 months following of a "change in control," then (a) we are obligated to pay severance (consisting of two times base salary in effect at the time of termination and 100% of his target annual bonus) to Dr. Toselli, plus continued health insurance benefits for a period of 18 months, (b) pay a pro rata portion of the annual bonus for the year in which the termination occurs based on a good faith determination of the attainment of the applicable goals and (c) the unvested portion of any stock options held by him will vest fully. The severance payments and the accelerated vesting of options are contingent on execution of a general release of claims against our company and are in addition to any accrued obligations to Dr. Toselli unpaid by us prior to the time of termination. Had his employment been terminated on December 31, 2017, Dr. Toselli would not have been entitled to any payment.

Richard Christopher, Chief Financial Officer. Under our employment agreement with Mr. Christopher, if we terminate Mr. Christopher's employment without Cause or if he terminates his employment for Good Reason, in each case prior to, or more than 12 months following, a change in control, then he is entitled (A) to continue to be paid his base salary as in effect on the termination date for a period of 12 months and (B) to continue to receive his benefits under the company's employee group health insurance plan until the earlier of (i) 12 months following the termination date or (ii) the date he becomes eligible for coverage under a new employer's group health plan. If we terminate Mr. Christopher's employment without Cause or he terminates his employment for Good Reason, in each case within 12 months following a Change in Control (as defined in the employment agreement), then he is entitled (A) to an amount equal to 1.5 times his base salary as in effect on the termination date, plus 100% of his target annual bonus, in each case at the salary and target annual bonus level in effect on the termination date or, if higher, at any time within the six month period preceding the Change in Control, (B) to acceleration in full of the vesting on all outstanding, unvested equity awards held by him and (C) to continue to receive his benefits under the company's employee group health insurance plan until the earlier of (i) 12 months following the termination date or (ii) the date he becomes eligible for coverage under a new employer's group health plan. The severance payments are contingent upon Mr. Christopher executing a general release of claims.

Heather Hamel, General Counsel and Chief Legal Officer. Under our employment agreement with Ms. Hamel, if we terminate Ms. Hamel's employment without Cause or if she terminates her employment for Good Reason, in each case prior to, or more than 12 months following, a change in control, then she is entitled (A) to continue to be paid her base salary as in effect on the termination date for a period of 12 months and (B) to continue to receive her benefits under the company's employee group health insurance plan until the earlier of (i) 12 months following the termination date or (ii) the date she becomes eligible for coverage under a new employer's group health plan. If we terminate

Ms. Hamel's employment without Cause or she terminates her employment for Good Reason, in each case within 12 months following a Change in Control (as defined in the employment agreement), then she is entitled (A) to an amount equal to 1.5 times her base salary as in effect on the termination date, plus 100% of her target annual bonus, in each case at the salary and target annual bonus level in effect on the termination date or, if higher, at any time within the six month period preceding the Change in Control, (B) to acceleration in full of the vesting on all outstanding, unvested equity awards held by her and (C) to continue to receive her benefits under the company's employee group health insurance plan until the earlier of (i) 12 months following the termination date or (ii) the date she becomes eligible for coverage under a new employer's group health plan. The severance payments are contingent upon Ms. Hamel executing a general release of claims.

Our Board adopted the Transaction Incentive Plan (the "Transaction Incentive Transaction Incentive Plan") under which certain employees, including each of Dr. Toselli, Mr. Christopher and Ms. Hamel, is eligible. Under the Transaction Incentive Plan, eligible participants are entitled to receive a predefined percentage of the transaction consideration (as defined in the Transaction Incentive Plan) paid in connection with a company acquisition (as defined in the Transaction Incentive Plan), minus the value of vested equity held by such participant. Payments under the Transaction Incentive Plan are payable each participant on the date that is six months following the closing of the applicable company acquisition (the "Payment Date"), subject to the participant's continued employment with the Company, a related entity or the acquiring entity on such date; provided that, in the event that the participant's employment with the Company, a related entity or the acquiring entity is terminated without cause or by the participant for good reason, in either case following the company acquisition but prior to the Payment Date, then the amount payable shall be paid to the participant within ten days following the participant's termination of employment.

2022 Director Compensation

The following table sets forth the compensation of our non-employee directors for 2022. For information on the compensation of Dr. Toselli, our current President and Chief Executive Officer, see "Executive Compensation" above.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Daniel R. Marshak, Ph.D.	51,250	9,256	60,506
C. Ann Merrifield	78,125	9,256	87,381
Richard J. Roberts, Ph.D.	48,750	9,256	58,006
Christina Morrison	57,500	9,256	66,756
Robert J. Rosenthal, Ph.D.	58,750	9,256	68,006

(1) As of December 31, 2022, the aggregate number of options to purchase shares of our common stock outstanding for each director listed above, including both vested and unvested shares, was as follows: Dr. Marshak, 4,805 shares; Ms. Merrifield, 4,805 shares; Dr. Roberts, 4,806 shares; Ms. Morrison, 4,804 shares; and Dr. Rosenthal, 4,800 shares.

Our director compensation policy provides for the following compensation to our non-employee directors:

- an annual retainer of $40,000 per year, paid quarterly, to each non-employee director;
- an annual retainer of $15,000, paid quarterly, to the Audit Committee chairperson, and an annual retainer of $7,500, paid quarterly, to each member of the Audit Committee of the Board;
- an annual retainer of $10,000, paid quarterly, to the Compensation Committee chairperson, and an annual retainer of $5,000, paid quarterly, to each member of the Compensation Committee of the Board;
- an annual retainer of $7,500, paid quarterly, to the Nominating and Corporate Governance Committee chairperson, and an annual retainer of $3,750, paid quarterly, to each member of the Nominating and Corporate Governance Committee of the Board;
- an annual retainer of $30,000, paid quarterly, to the Chair of the Board; and

- when applicable, an annual retainer of $15,000, paid quarterly, to any Lead Director of the Board.

Non-employee directors are reimbursed for reasonable travel expenses in connection with attendance at meetings of the Board or any of its committees that are conducted in person and other activities directly related to the service to the company.

At the Board's discretion, each non-employee director may also receive an annual grant of a stock option to purchase shares of our common stock at an exercise price equal to the closing price of our common stock on the date of grant. Alternatively, the Board may elect to grant restricted stock units or restricted stock awards. In 2022 the Company granted an option to purchase an aggregate of 4,200 shares of Common Stock shares at an exercise price of $2.50 per share to each of the non-employee directors. These options shall vest in full on the first anniversary of the date of grant, subject to continued service.

Pay Ratio

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

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

The following table sets forth certain information as of February 17, 2023 with respect to the beneficial ownership of our common stock by:

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

Unless otherwise indicated in the footnotes to the following table, each person named in the table has sole voting and investment power, and his or her address is c/o InVivo Therapeutics Holdings Corp., One Kendall Square, Suite B14402, Cambridge, MA 02139. Shares of our common stock subject to options or warrants currently exercisable or exercisable within 60 days of February 17, 2023 are deemed outstanding for computing the share ownership and percentage of the person holding such options and warrants, but are not deemed outstanding for computing the percentage of any other person. The percentage ownership of our common stock of each person or entity named in the following table is based on 2,860,446 shares of our common stock outstanding as of February 17, 2023.

Name of Beneficial Owner	Number of Shares of Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned
Directors and Named Executive Officers		
Richard Toselli, M.D. (1)	6,411	* %
Richard Christopher (2)	3,476	*
Heather Hamel (3)	995	*
Daniel R. Marshak, Ph.D. (4)	605	*
C. Ann Merrifield (5)	898	*
Richard J. Roberts, Ph.D. (6)	618	*
Christina Morrison (7)	604	*
Robert J. Rosenthal, Ph.D. (8)	600	*
All current directors and executive officers as a group (7 persons) (9)	14,207	* %

*Percentage of shares beneficially owned does not exceed one percent.

(1) Consists of (a) 247 shares of common stock owned by Dr. Toselli, (b) 6,018 shares of common stock underlying options held by Dr. Toselli that are exercisable as of February 17, 2023 or will become exercisable within 60 days after such date and (c) 146 shares of common stock underlying warrants held by Dr. Toselli that are exercisable as of February 17, 2023.

(2) Consists of (a) 210 shares of common stock owned by Mr. Christopher (b) 3,120 shares of common stock underlying options held by Mr. Christopher that are exercisable as of February 17, 2023 or will become exercisable within 60 days after such date and (c) 146 shares of common stock underlying warrants held by Mr. Christopher that are exercisable as of February 17, 2023.

(3) Consists of (a) 31 shares of common stock owned by Ms. Hamel and (b) 964 shares of common stock underlying options held by Ms. Hamel that are exercisable as of February 17, 2023 or will become exercisable within 60 days after such date.

(4) Consists solely of shares of common stock underlying options held by Dr. Marshak that are exercisable as of February 17, 2023 or will become exercisable within 60 days after such date.

(5) Consists of (a) 147 shares of common stock owned by Ms. Merrifield, (b) 146 shares of common stock underlying warrants held by Ms. Merrifield that are exercisable as of February 17, 2023 and (c) 605 shares of common stock underlying options held by Ms. Merrifield that are exercisable as of February 17, 2023 or will become exercisable within 60 days after such date.

(6) Consists of (a) 12 shares of common stock owned by Dr. Roberts and (b) 606 shares of common stock underlying options held by Dr. Roberts that are exercisable as of February 17, 2023 or will become exercisable within 60 days after such date.

(7) Consists solely of shares of common stock underlying options held by Ms. Morrison that are exercisable as of February 17, 2023 or will become exercisable within 60 days after such date.
(8) Consists solely of shares of common stock underlying options held by Mr. Rosenthal that are exercisable as of February 17, 2023 or will become exercisable within 60 days after such date.
(9) Consists of (a) 647 shares of common stock owned by all current executive officers and directors as a group (b) 13,122 shares of common stock underlying options that are exercisable as of February 17, 2023 or will become exercisable within 60 days after such date and (c) 438 shares of common stock underlying warrants that are exercisable as of February 17, 2023.

Stockholders Known by Us to Own 5% or More of Our Common Stock

Name of Beneficial Owner	Number of Shares of Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned
Armistice Capital, LLC(1)	244,999	8.6 %

(1) The information regarding Armistice Capital, LLC ("Armistice Capital") is based solely on its Schedule 13G filed with the SEC on February 14, 2023, wherein Armistice Capital declared beneficial ownership consisting of 244,999 shares of common stock. Armistice Capital, is the investment manager of Armistice Capital Master Fund Ltd. (the "Master Fund"), the direct holder of the shares, and pursuant to an Investment Management Agreement, Armistice Capital exercises voting and investment power over the shares of common stock held by the Master Fund and thus may be deemed to beneficially own the shares of common stock held by the Master Fund. Steven Boyd, as the managing member of Armistice Capital, may be deemed to beneficially own the shares of common stock held by the Master Fund. The Master Fund specifically disclaims beneficial ownership of the shares of common stock directly held by it by virtue of its inability to vote or dispose of such securities as a result of its Investment Management Agreement with Armistice Capital. The principal business address for Armistice Capital is 510 Madison Avenue, 7th Floor, New York. New York 10022.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides certain information about shares of our common stock that may be issued under our existing equity compensation plan as of December 31, 2022, which consist of our 2010 Equity Incentive Plan, and 2015 Equity Incentive Plan or other equity compensation plans not approved by security holders.

Equity Compensation Plan Information

Plan Category	(a) Number of securities to be issued upon the exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	136,448	$ 34.68	788,697
Equity compensation plans not approved by security holders (1)	120	1,147.50	—
Total	136,568	$ 35.65	788,697

(1) Consists of a stock option award approved by our Board as an inducement material to our Chief Financial Officer's acceptance of employment with us in accordance with Nasdaq Listing Rule 5635(c)(4). The inducement award has an exercise price per share equal to $1,147.50, the closing price of a share of our common stock on the grant date, and vested as to one-third (1/3) of the shares of the underlying stock option on January 14, 2020, one third (1/3) of the shares of the underlying stock option on January 14, 2021 and the remaining one third (1/3) of the shares of the underlying stock option on January 14, 2022.

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

Transactions with Related Persons

Indemnification Agreements

Our articles of incorporation require that we indemnify our officers, directors, employees, and agents to the full extent permitted by the laws of the State of Nevada. Our bylaws include an indemnification provision under which we have the power to indemnify our directors and officers against all costs, charges and expenses actually and reasonably incurred, including an amount paid to settle an action or satisfy a judgment to which a director or officer is made a party by reason of being or having been a director or officer of the company. In addition, we have entered into an indemnification agreement with each of our officers and directors pursuant to which they will be indemnified by us, subject to certain limitations, for any liabilities incurred by them in connection with their role as officers or directors of the company.

Related Party Transaction Policy

Our Board has adopted written policies and procedures for the review of related party transactions. The Audit Committee reviews and oversees all related party transactions on an ongoing basis. A "related party transaction" is a transaction that meets the minimum threshold for disclosure in the proxy statement under applicable SEC rules (generally, transactions involving amounts exceeding $120,000 in which a "related person" or entity has a direct or indirect material interest). "Related persons" include our executive officers, directors, beneficial owners of 5% or more of our common stock, immediate family members of these persons and entities in which one of these persons has a direct or indirect material interest. When a potential related party transaction is identified, management presents it to the Audit Committee to determine whether to approve or ratify it.

The Audit Committee reviews the material facts of any related party transaction and either approves or disapproves of entering into the transaction. In the course of reviewing the related party transaction, the Audit Committee considers whether (i) the transaction is fair and reasonable to our company, (ii) the transaction is in, or not inconsistent with, our company's best interests under all possible circumstances, and (iii) the transaction will be on terms no less favorable to our company than we could have obtained in an arm's-length transaction with an unrelated third party. If advance approval of a related party transaction is not feasible, then the transaction will be considered and, if the Audit Committee determines it to be appropriate, ratified by the Audit Committee. No director may participate in the approval of a transaction for which he or she is a related party. When a related party transaction is ongoing, any amendments or changes are reviewed, and the transaction is reviewed annually for reasonableness and fairness to our company.

Director Independence

Rule 5605 of the Nasdaq Listing Rules requires a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and corporate governance committees be independent, that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and that compensation committee members also satisfy heightened independence requirements contained in the Nasdaq Listing Rules as well as Rule 10C-1 under the Exchange Act. Under Nasdaq Rule 5605(a)(2), a director will only qualify as an "independent director" if, in the opinion of our Board, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the Board, or any other Board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. When determining the independence of the members of our compensation committee under the heightened independence requirements contained in the Nasdaq Listing Rules and Rule 10C-1 under the Exchange Act, our Board is required to consider all factors specifically relevant to determining whether a director has a relationship with us that is material to that director's ability to be independent

from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of that director, including any consulting, advisory, or other compensatory fee paid by us to that director; and (2) whether that director is affiliated with our company, a subsidiary of our company, or an affiliate of a subsidiary of our company.

Our Board has reviewed the composition of our Board and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment, and affiliations, including family relationships, our Board has determined that each of our directors, other than Dr. Toselli, is an "independent director" as defined under Rule 5605(a)(2) of the Nasdaq Listing Rules.

Our Board also determined that Ms. Morrison, Dr. Marshak, and Dr. Rosenthal, who comprise our audit committee, and Ms. Merrifield, Ms. Morrison, and Dr. Roberts, who comprise our compensation committee, satisfy the independence standards for such committees established by the SEC and the Nasdaq Listing Rules, as applicable. In making such determinations, our Board considered the relationships that each such non-employee director has with our company and all other facts and circumstances our Board deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

Related Party Transactions

During the years ended December 31, 2022 and 2021, the Company did not identify any related party transactions requiring disclosure.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Independent Registered Public Accounting Firm Fees.

Audit Fees

Firm	Year	Fees ($)(1)
RSM US LLP	2022	231,828
	2021	220,185

(1) Audit fees in each of 2022 and 2021 consisted of fees incurred for professional services rendered for the audit of consolidated financial statements and for reviews of our interim consolidated financial statements included in our quarterly reports on Form 10-Q.

Audit-Related Fees

Firm	Year	Fees ($)(1)
RSM US LLP	2022	26,250
	2021	7,875

(1) Audit-related fees in 2022 and 2021 paid to RSM US LLP or RSM consisted of fees related to the delivery of comfort letters in conjunction with proposed common stock financings and consents in conjunction with registration statements.

Tax Fees

There were no fees paid to RSM for any tax-related services in 2022 or 2021.

All Other Fees

There were no other fees paid to RSM in 2022 or 2021.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services

Our Audit Committee is responsible for pre-approving all services provided by our independent registered public accounting firm. All of the above services and fees were reviewed and approved by the Audit Committee before the services were rendered. The Audit Committee has considered the nature and amount of fees billed by RSM US LLP and believes that the provision of services for activities unrelated to the audit is compatible with maintaining RSM US LLP's independence.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Financial Statements.

The financial statements listed in the Index to Consolidated Financial Statements appearing in Item 8 are filed as part of this report.

Financial Statement Schedules.

All financial statement schedules have been omitted as they are either not required, not applicable, or the information is otherwise included.

Exhibits.

The following is a list of exhibits filed as part of this Annual Report on 10-K.

Exhibit No.	Description
3.1	Articles of Incorporation of InVivo Therapeutics Holdings Corp., as amended (incorporated by reference from Exhibit 3.1 to the Company's Quarterly Report on Form 10 Q for the quarter ended June 30, 2016, as filed with the SEC on August 4, 2016).
3.2	Certificate of Change Pursuant to NRS 78.209 filed with Nevada Secretary of State, dated April 13, 2018 (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 16, 2018).
3.3	Certificate of Amendment to Articles of Incorporation of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC June 1, 2018.)
3.4	Certificate of Amendment to Articles of Incorporation of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC January 21, 2020)
3.5	Certificate of Change Pursuant to NRS 78.209 filed with Nevada Secretary of State, dated February 10, 2020 (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 11, 2020)
3.6	Certificate of Change Pursuant to NRS 78.209, filed with the Nevada Secretary of State, dated April 25, 2022 (incorporated by reference from the Company's 8-K, as filed with the SEC on April 26, 2022).
3.7	Certificate of Amendment to Articles of Incorporation of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC August 5, 2020).
3.89	Certificate of Amendment to the Articles of Incorporation filed with the Nevada Secretary of State, dated September 12, 2022 (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on September 13, 2022).
3.9	Certificate of Amendment to the Articles of Incorporation filed with the Nevada Secretary of State, dated September 12, 2022 (incorporated by reference from Exhibit 3.2 to the Company's Current Report on Form 8-K, as filed with the SEC on September 13, 2022).
3.10	Amended and Restated Bylaws of InVivo Therapeutics Holdings Corp, as amended (incorporated by reference from Exhibit 3.2 to the Company's Current Report on Form 8-K, as filed with the SEC on June 5, 2020).
4.1+	Description of the Registrant's Securities.
4.2	Specimen Common Stock Certificate (incorporated by reference from Exhibit 4.2 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the SEC on February 20, 2020).
4.3	Form of Series A Warrant (incorporated by reference from Exhibit 4.5 to the Company's Registration Statement on Form S-1/A (File No. 333- 224424) as filed with the SEC on June 14, 2018).

4.4	Amendment to Warrant Agency Agreement, by and between InVivo Therapeutics Holdings Corp. and Continental Stock Transfer & Trust Company, as Warrant Agent, dated September 27, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on September 28, 2018).
4.5	Second Amendment to Warrant Agency Agreement and Warrant, by and between InVivo Therapeutics Holdings Corp. and Continental Stock Transfer & Trust Company, as Warrant Agent, dated November 20, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 21, 2019).
4.6	Form of Series A Warrant, as amended (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on November 21, 2019).
4.7	Form of Placement Agent Warrant of InVivo Therapeutics Holdings Corp. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 24, 2020).
4.8	Form of Series A Warrant (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 11, 2020).
4.9	Form of Series B Pre-Funded Warrant (incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the SEC on March 11, 2020).
4.10	Form of Placement Agent Warrant (incorporated by reference from Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed with the SEC on March 11, 2020).
4.11	Form of Series C Warrant (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 16, 2020).
4.12	Form of Placement Agent Warrant (incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the SEC on April 16, 2020).
4.13	Form of Series A Warrant (incorporated by reference from Exhibit 4.12 to the Company's Amendment No. 1 to Registration Statement on Form S-1/A (File No. 333-249353), as filed with the SEC on October 16, 2020)
4.14	Form of Series B Pre-Funded Warrant (incorporated by reference from Exhibit 4.13 to the Company's Amendment No. 1 to Registration Statement on Form S-1/A (File No. 333-249353), as filed with the SEC on October 16, 2020)
4.15	Form of Placement Agent Warrant (incorporated by reference from Exhibit 4.14 to the Company's Amendment No. 1 to Registration Statement on Form S-1/A (File No. 333-249353), as filed with the SEC on October 16, 2020)
4.16	Form of Registered Pre-Funded Warrant (incorporated by reference from Exhibit 4.1 to the Company's 8-K, as filed with the SEC on October 11, 2022).
4.17	Form of Unregistered Pre-Funded Warrant (incorporated by reference from Exhibit 4.2 to the Company's 8-K, as filed with the SEC on October 11, 2022).
4.18	Form of Preferred Investment Option (incorporated by reference from Exhibit 4.3 to the Company's 8-K, as filed with the SEC on October 11, 2022).
4.19	Form of Placement Agent Preferred Investment Option (incorporated by reference from Exhibit 4.4 to the Company's 8-K, as filed with the SEC on October 11, 2022).
10.1*	InVivo Therapeutics Holdings Corp. 2010 Equity Incentive Plan, as amended (incorporated by reference to Appendix A to the Company's Schedule 14A Proxy Statement, as filed with the SEC on April 19, 2013).
10.2(i)*	Form of Incentive Stock Option Agreement by and between InVivo Therapeutics Holdings Corp. and participants under the 2010 Equity Incentive Plan (incorporated by reference from Exhibit 10.12(i) to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010, as filed with the SEC on March 24, 2011).
10.2(ii)*	Form of Non-Qualified Stock Option Agreement by and between InVivo Therapeutics Holdings Corp. and participants under the 2010 Equity Incentive Plan (incorporated by reference from Exhibit 10.12(ii) to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010, as filed with the SEC on March 24, 2011).
10.3	Exclusive License Agreement dated July 2007 between InVivo Therapeutics Corporation and Children's Medical Center Corporation (incorporated by reference from Exhibit 10.1 to Amendment No. 2 to the Company's Quarterly Report on Form 10-Q/A for the quarter ended March 31, 2011, as filed with the SEC on July 18, 2011).

10.4	Amendment One to the Exclusive License, dated May 12, 2011, by and between Children's Medical Center Corporation and InVivo Therapeutics Corporation (incorporated by reference from Exhibit 10.22 to the Amendment No. 4 to the Company's Registration Statement on Form S-1/A (File No. 333-171998), as filed with the SEC on July 19, 2011).
10.5	Amendment Two to the Exclusive License, dated August 29, 2017, by and between Children's Medical Center Corporation and InVivo Therapeutics Corporation (incorporated by reference from Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q/A for the quarter ended September 30, 2017, as filed with the SEC on January 3, 2018).
10.6	Form of Indemnification Agreement (for directors and officers) (incorporated by reference from Exhibit 10.19 to the Company's Registration Statement on Form S-1 (File No. 333-171998), as filed with the SEC on February 1, 2011).
10.7*	InVivo Therapeutics Holdings Corp. Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on June 16, 2015).
10.8*	InVivo Therapeutics Holdings Corp. 2015 Equity Incentive Plan, as amended (incorporated by reference to Appendix C to the Company's Definitive Proxy Statement, as filed with the SEC on August 18, 2022).
10.9*	Employment Agreement, dated December 18, 2017, by and between Richard Toselli and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.27 to the Company's Registration Statement on Form S-1/A (File No. 333-222738) as filed with the SEC on February 9, 2018).
10.10	Form of Exchange Agreement, dated as of August 10, 2017, between InVivo Therapeutics Holdings Corp. and certain holders of warrants (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 10, 2017).
10.11*	Amendment to Employment Agreement, by and between InVivo Therapeutics Holdings Corp. and Richard Toselli, dated October 1, 2018 (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on October 5, 2018).
10.12*	Employment Agreement, dated December 24, 2018, between the Company and Richard Christopher (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 14, 2019).
10.13*	Amendment to Employment Agreement, by and between InVivo Therapeutics Holdings Corp. and Richard Christopher, dated November 17, 2022 (incorporated by reference from Exhibit 10.1 to the Company's 8-K, as filed with the SEC on November 18, 2022).
10.14*	Nonstatutory Stock Option Agreement, dated January 14, 2019, between the Company and Richard Christopher (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on January 14, 2019).
10.15*	Form of Restricted Stock Agreement under the Company's 2015 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on September 27, 2019).
10.16*	Form of Restricted Stock Unit Agreement under the Company's 2015 Equity Incentive Plan (incorporated by reference from Exhibit 10.25 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the SEC on February 20, 2020).
10.17	Lease Agreement, dated as of May 28, 2021, by and between the Company and ARE-MA Region No. 59, LLC. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on June 1, 2021).
10.18	First Amendment to Lease, dated as of November 23, 2021, by and between the Registrant and ARE-MA Region No. 59, LLC. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 29, 2021).
10.19	InVivo Therapeutics Holding Corp. Transaction Incentive Plan, as amended on July 7, 2022 (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 12, 2022).
10.20*	Employment Agreement between Heather Hamel and InVivo Therapeutics Holdings Corp., dated as of July 13, 2022 (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2022).
10.21	Form of RDO Securities Purchase Agreement, dated as of October 7, 2022, by and between the Company and the purchasers named therein (incorporated by reference from Exhibit 10.1 to the Company's 8-K, as filed with the SEC on October 11, 2022).
10.22	Form of PIPE Securities Purchase Agreement, dated as of October 7, 2022, by and between the Company and the purchasers named therein (incorporated by reference from Exhibit 10.2 to the Company's 8-K, as filed with the SEC on October 11, 2022).
10.23	Form of Registration Rights Agreement, dated as of October 7, 2022, by and between the Company and the purchasers named therein (incorporated by reference from Exhibit 10.3 to the Company's 8-K, as filed with the SEC on October 11, 2022).
21.1	Subsidiaries of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 21.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
23.1+	Consent of RSM US LLP.
31.1+	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
31.2+	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
32.1+	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
32.2+	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.
104+	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Management contract or compensatory plan or arrangement filed in response to Item 15(a)(3) of Form 10-K.

\+ Filed herewith.

Item 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INVIVO THERAPEUTICS HOLDINGS CORP.

Date: March 1, 2023

By: /s/ RICHARD TOSELLI, M.D
Name: Richard Toselli
Title: President, Chief Executive Officer and Director (Principal Executive Officer)

Date: March 1, 2023

By: /s/ RICHARD CHRISTOPHER
Name: Richard Christopher
Title: Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)

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

Signature	Title	Date
/s/ RICHARD TOSELLI M.D Richard Toselli	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2023
/s/ RICHARD CHRISTOPHER Richard Christopher	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 1, 2023
/s/ C. ANN MERRIFIELD C. Ann Merrifield	Chair of the Board	March 1, 2023
/s/ DANIEL R. MARSHAK Daniel R. Marshak	Director	March 1, 2023
/s/ CHRISTINA MORRISON Christina Morrison	Director	March 1, 2023
/s/ RICHARD J. ROBERTS Richard J. Roberts	Director	March 1, 2023
/s/ ROBERT ROSENTHAL Robert Rosenthal	Director	March 1, 2023

2022 Annual Report

BOARD OF DIRECTORS

Richard M. Toselli, M.D.
President, Chief Executive Officer & Director
InVivo Therapeutics Holdings Corp.

C. Ann Merrifield
Former President & CEO, PathoGenetix, Inc., a genomics company
Chair of the Board
Nominating and Corporate Governance Committee (Chair)
Compensation Committee (Member)
Audit Committee (Member)

Christina Morrison
Chief Financial Officer, ValenzHealth, a service provider for self-funded health plans
Compensation Committee (Chair)
Audit Committee (Member)

Richard J. Roberts, Ph.D.
Chief Scientific Officer, New England Biolabs, a life sciences company
Scientific Advisory Board (Member)
Compensation Committee (Member)
Nominating and Corporate Governance Committee (Member)

Robert J. Rosenthal, Ph.D.
Current Chairman and Former CEO, Taconic Biosciences, Inc., a provider of research models for the pharmaceutical and biotech industry
Audit Committee (Chair)
Nominating and Corporate Governance Committee (Member)

SENIOR MANAGEMENT

Richard M. Toselli, M.D.
President, Chief Executive Officer & Director

Richard Christopher
Chief Financial Officer

Heather M. Hamel, J.D.
Chief Legal Officer & General Counsel
Corporate Secretary

STOCKHOLDER INFORMATION

Corporate Headquarters
InVivo Therapeutics Holdings Corp.
1500 District Avenue
Burlington, MA 01803
(617) 863-5500
www.invivotherapeutics.com

Investor Relations
1500 District Avenue
Burlington, MA 01803
https://investors.invivotherapeutics.com/

Transfer Agent
Continental Stock Transfer & Trust Company
1 State Street, 30th Floor
New York, NY 10004
(212) 509-4000
www.continentalstock.com

Independent Auditors
RSM US LLP
80 City Square
Boston, MA 02129

Stock Listing
InVivo Therapeutics Holdings Corp.
is listed on the Nasdaq Capital Market
under the symbol "NVIV"

A COPY OF OUR ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2022 AS FILED WITH THE SEC, EXCLUDING EXHIBITS, WILL BE FURNISHED WITHOUT CHARGE TO ANY STOCKHOLDER UPON WRITTEN REQUEST TO: INVESTOR RELATIONS DEPARTMENT, INVIVO THERAPEUTICS HOLDINGS CORP., 1500 DISTRICT AVENUE, BURLINGTON, MA 01803. EXHIBITS WILL BE PROVIDED UPON WRITTEN REQUEST AND PAYMENT OF AN APPROPRIATE PROCESSING FEE.

The 2022 Annual Report, 2022 Form 10-K, and other investor information can be viewed online at the InVivo Therapeutics Holdings Corp. website: www.invivotherapeutics.com