

Prospectus



InVivo Therapeutics Holdings Corp.
11,785,000 Shares of Common Stock and
Warrants to Purchase 11,785,000 Shares of Common Stock
and
Pre-funded Warrants to Purchase 6,965,000 Shares of Common Stock and
Warrants to Purchase 6,965,000 Shares of Common Stock

We are offering 11,785,000 shares of common stock, together with warrants (the “Series A warrants”) to purchase 11,785,000 shares of common stock at a combined public offering price of \$0.80 per share and Series A warrant (and the shares issuable from time to time upon exercise of the Series A warrants) pursuant to this prospectus. The shares of common stock and Series A warrant will be separately issued, but the shares of common stock and Series A warrants will be issued to purchasers in the ratio of one to one. Each Series A warrant will have an exercise price of \$0.80 per share, will be exercisable upon issuance and will expire five years from the date of issuance.

We are also offering 6,965,000 pre-funded warrants (the “Series B pre-funded warrants” and collectively with the Series A warrants, the “warrants”) to those purchasers, whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering in lieu of the shares of our common stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each Series B pre-funded warrant will be exercisable for one share of common stock at an exercise price of \$0.00001 per share. Each Series B pre-funded warrant is being issued together with the same Series A warrant described above being issued with each share common stock. The combined public offering price for each such Series B pre-funded warrant, together with the Series A warrant, is \$0.79999 which is equal to the per share public offering price for the common stock in this offering less the \$0.00001 per share exercise price of each such Series B pre-funded warrant. Each Series B pre-funded warrant will be exercisable upon issuance and will expire when exercised in full. The Series B pre-funded warrants and Series A warrants are immediately separable and will be issued separately in this offering.

There is no established public trading market for the warrants, and we do not expect a market to develop. We do not intend to apply for listing of the warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the warrants will be limited.

We have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent in connection with this offering. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agent is not purchasing or selling any of the securities we are offering and the placement agent is not required to arrange the purchase or sale of any specific number or dollar amount of securities. We have agreed to pay to the placement agent the placement agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. There is no arrangement for funds to be received in escrow, trust or similar arrangement. There is no minimum offering requirement. We will bear all costs associated with the offering. See “Plan of Distribution” on page 29 of this prospectus for more information regarding these arrangements.

Our common stock is listed on the Nasdaq Capital Market under the symbol “NVIV.” On October 21, 2020, the last reported sale price of our common stock on the Nasdaq Capital Market was \$1.14 per share.

Investing in the offered securities involves a high degree of risk. See “Risk Factors” beginning on page 6 of this prospectus and the section entitled “Risk Factors” included in our most recent [Annual Report on Form 10-K](#), as revised or supplemented by our subsequent [Quarterly Reports on Form 10-Q](#), which are incorporated herein by reference, for a discussion of information that you should consider before investing in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share and Series A Warrant	Per Series B Pre-Funded Warrant and Series A Warrant	Total
Public offering price	\$ 0.80	\$0.79999	\$14,999,930
Placement Agent’s fees ⁽¹⁾	\$0.056	\$ 0.056	\$ 1,050,000
Proceeds, before expenses, to us	\$0.744	\$ 0.744	\$13,949,930

- (1) We have agreed to reimburse the placement agent for certain of its expenses. In addition, we have agreed to issue to the placement agent, or its designees, warrants to purchase a number of shares of our common stock equal to 6.5% of the aggregate number of shares of common stock and Series B pre-funded warrants being offered at an exercise price equal to 125% of the combined public offering price per share of common stock and Series A warrant. We refer you to “Plan of Distribution” on page 29 of this prospectus for additional information regarding placement agent compensation.

The placement agent expects to deliver the shares and warrants to purchasers in the offering on or about October 26, 2020, subject to satisfaction of certain conditions.

H.C. Wainwright & Co.

Prospectus dated October 22, 2020

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ABOUT THIS PROSPECTUS

The registration statement we filed with the Securities and Exchange Commission (the “SEC”) includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus, the related exhibits filed with the SEC, and the documents incorporated by reference herein before making your investment decision. You should rely only on the information provided in this prospectus and the documents incorporated by reference herein or any amendment thereto. In addition, this prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading “Where You Can Find Additional Information.”

We have not, and the placement agent has not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus, the documents incorporated by reference herein or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The information contained in this prospectus, the documents incorporated by reference herein or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. We are not, and the placement agent is not, making an offer to sell these securities in any state or jurisdiction where the offer or sale is not permitted.

All other trademarks, trade names and service marks appearing in this prospectus or the documents incorporated by reference herein are the property of their respective owners. Use or display by us of other parties’ trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owner. Solely for convenience, trademarks, tradenames and service marks referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and trade names.

PROSPECTUS SUMMARY

This summary provides an overview of selected information contained elsewhere or incorporated by reference in this prospectus and does not contain all of the information you should consider before investing in our securities. You should carefully read the prospectus, the information incorporated by reference and the registration statement of which this prospectus is a part in their entirety before investing in our securities, including the information discussed under “Risk Factors” in this prospectus and the documents incorporated by reference and our financial statements and notes thereto that are incorporated by reference in this prospectus. Some of the statements in this prospectus and the documents incorporated by reference herein constitute forward-looking statements that involve risks and uncertainties. See information set forth under the section “Special Note Regarding Forward-Looking Statements.” Except where the context otherwise requires, the terms “we,” “us,” “our,” “InVivo” or “the Company” refer to the business of InVivo Therapeutics Holdings Corp., a Nevada corporation, and its wholly-owned subsidiary.

Business Overview

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, or BCH, and the Massachusetts Institute of Technology, or 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.

For additional information regarding our business, see the section entitled “Business” included in our , as well as the sections entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the related notes thereto included in our [Annual Report on Form 10-K for the year ended December 31, 2019](#) and our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), each of which is incorporated by reference into this prospectus.

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 U.S. Food and Drug Administration, or 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 INPSIRE 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 screen failures or deaths that would prevent a patient from reaching the primary endpoint visit. As of October 15, 2020, eight patients in the INSPIRE 2.0 Study have been enrolled and 18 sites are open. We estimate that enrollment in the INSPIRE 2.0 Study will be complete in the second quarter of 2021, with the final patient enrolled in the INSPIRE 2.0 study reaching their six-month primary endpoint visit in the fourth quarter of 2021.

The primary endpoint is defined as the proportion of patients achieving an improvement of at least one ASIA Impairment Scale, or 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 neurological level of injury, 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 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 Humanitarian Device Exemption, or 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.

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 three 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 three 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 (preclinical) module in March 2017 and received feedback in June 2017. We submitted an updated first module in the fourth quarter of 2019 and received feedback in September 2020. The HDE submission will not be complete until the manufacturing and clinical modules are also submitted.

Risks Associated with this Offering

This offering is subject to numerous risks and uncertainties, including those highlighted in the section entitled “Risk Factors” immediately following this prospectus summary and the section entitled “Risk Factors” included in our [Annual Report on Form 10-K for the fiscal year ended December 31, 2019](#) as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q including our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which are incorporated herein by reference. These risks include, but are not limited to, the following:

- We have broad discretion over the use of our cash and cash equivalents, including the net proceeds we receive in this offering, and may not use them effectively.
- Even if this offering is successful, we will need additional funding to continue our operations. 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 will affect our ability to obtain future financing and may require us to curtail our operations.
- You may experience future dilution as a result of future equity offerings.
- 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.
- There is no public market for the Series A warrants or the Series B pre-funded warrants being issued by us in this offering.
- Holders of Series B pre-funded warrants or Series A warrants purchased in this offering will have no rights as common stockholders until such holders exercise their Series B pre-funded warrants or Series A warrants and acquire our common stock, except as otherwise provided in the Series B pre-funded warrants.
- The Series A warrants are speculative in nature.

Corporate Information

We were incorporated on April 2, 2003, under the name of Design Source, Inc. On October 26, 2010, we acquired the business of InVivo Therapeutics Corporation, which was founded in 2005, 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, 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 prospectus.

THE OFFERING

<i>Securities offered by us in this offering:</i>	11,785,000 shares of our common stock and Series A warrants to purchase 11,785,000 shares of common stock, and 6,965,000 Series B pre-funded warrants to purchase shares of common stock and Series A warrants to purchase 6,965,000 shares of common stock.
<i>Description of Series A warrants:</i>	The shares, or Series B pre-funded warrants, and Series A warrants will be separately transferable immediately upon issuance, but the shares, or Series B pre-funded warrants, and Series A warrants will be issued to purchasers in the ratio of one to one. Each Series A warrant will have an exercise price of \$0.80 per share, will be exercisable upon issuance and will expire five years from the date of issuance.
<i>Description of Series B pre-funded warrants:</i>	If the issuance of shares of our common stock to a purchaser in this offering would result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, then such purchaser may purchase, if they so choose, in lieu of the shares of our common stock that would result in such excess ownership, a Series B pre-funded warrant to purchase shares of our common stock for a purchase price per share of common stock subject to such Series B pre-funded warrant equal to the per share public offering price for the common stock in this offering less \$0.00001. Each Series B pre-funded warrant will have an exercise price of \$0.00001 per share, will be exercisable upon issuance and will expire when exercised in full. Purchasers of Series B pre-funded warrants will also receive Series A warrants as if such purchasers were buying shares of our common stock in this offering. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of these Series B pre-funded warrants.
<i>Common stock outstanding after this offering:</i>	23,632,420 shares of common stock, assuming no exercise of the Series A warrants being issued in this offering, and the full exercise of the Series B pre-funded warrants issued in this offering.
<i>Use of proceeds:</i>	We intend to use the net proceeds from this offering for working capital, business development activities, and general corporate purposes. See “Use of Proceeds” on page 12 of this prospectus.
<i>Dividend policy:</i>	We have never paid cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate

Risk factors:

declaring or paying any cash dividends for the foreseeable future.

See “Risk Factors” beginning on page 6 and the section entitled “Risk Factors” included in our [Annual Report on Form 10-K for the fiscal year ended December 31, 2019](#) as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q including our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which are incorporated herein by reference, and the other information included or incorporated by reference elsewhere in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

Nasdaq Capital Market symbol:

Our common stock is listed on the Nasdaq Capital Market under the symbol “NVIV.” There is no established trading market for the Series A warrants or the Series B pre-funded warrants, and we do not expect a trading market to develop. We do not intend to list the Series A warrants or the Series B pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Series A warrants or Series B pre-funded warrants will be extremely limited.

The number of shares of common stock to be outstanding immediately after this offering is based on 4,882,420 shares of our common stock outstanding as of September 30, 2020, and excludes:

- 4,745,334 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2020 at a weighted average exercise price of \$7.08 per share;
- 4,187 shares of common stock issuable upon the exercise of options at a weighted average exercise price of \$1,077.78 per share and 150 shares of common stock issuable upon vesting of restricted stock units outstanding as of September 30, 2020 pursuant to our stock incentives plans (collectively, the “Incentive Plans”);
- 426,807 shares of common stock available for future issuance under the Incentive Plans and our 401(k) plan as of September 30, 2020; and
- 264 shares of common stock reserved for future sale under our employee stock purchase plan as of September 30, 2020.

Unless otherwise indicated, all information contained in this prospectus assumes:

- no exercise of the outstanding options or warrants described in the bullets above; and
- no sale of Series B pre-funded warrants in this offering and no exercise of the Series A warrants being issued in this offering.

RISK FACTORS

An investment in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks and uncertainties described below and in the section entitled “Risk Factors” included in our [Annual Report on Form 10-K for the fiscal year ended December 31, 2019](#) as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q including our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which are incorporated herein by reference, and other filings we make with the Securities and Exchange Commission, or SEC, from time to time, which are incorporated by reference herein in their entirety, together with the other information in this prospectus and the information incorporated by reference herein and in any free writing prospectus that we may authorize for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

Risks Related to This Offering

We have broad discretion over the use of our cash and cash equivalents, including the net proceeds we receive in this offering, and may not use them effectively.

Our management has broad discretion to use our cash and cash equivalents, including the net proceeds we receive in this offering, to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use to fund operations, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

Even if this offering is successful, we will need additional funding to continue our operations. 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.

Even if this offering is successful, we will need to secure additional resources to support our continued operations, including resources needed to complete any potential HDE application process or regulatory approval process with the FDA, plus resources for engaging in potential business development activities. In addition, we expect that our expenses will increase in connection with our ongoing activities, particularly as we conduct 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 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. 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; and the impact of the COVID-19 pandemic on such scope, progress, results, and costs;

- 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 will affect our ability to obtain future financing and may require us to curtail our operations.

Our consolidated financial statements as of June 30, 2020 were prepared under the assumption that we will continue as a going concern. At June 30, 2020, we had cash and cash equivalents of \$9.8 million. We estimate that our existing cash resources, together with the anticipated proceeds of this offering, will be sufficient to fund our operations into the third quarter of 2022. 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 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.

Our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern in its report dated February 20, 2020 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, which we filed with the SEC on February 20, 2020. In our most recent quarterly report on Form 10-Q, our management has determined that there continues to be substantial doubt regarding our ability to continue as a going concern. 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 consolidated financial statements, and it is likely that investors will lose all

or part of their investment. If we seek additional financing to fund our business activities in the future and there remains 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.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the public offering price for the securities in this offering. We may sell shares or other securities in any other offering at prices that are less than the price paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders.

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.

There is no public market for the Series A warrants or the Series B pre-funded warrants being issued by us in this offering.

There is no established public trading market for the Series A warrants or the Series B pre-funded warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the Series A warrants or the Series B pre-funded warrants on any national securities exchange or other nationally recognized trading system, including the Nasdaq Capital Market. Without an active market, the liquidity of the Series A warrants and the Series B pre-funded warrants will be limited.

Holders of Series B pre-funded warrants or Series A warrants purchased in this offering will have no rights as common stockholders until such holders exercise their Series B pre-funded warrants or Series A warrants and acquire our common stock, except as otherwise provided in the Series B pre-funded warrants.

Until holders of Series B pre-funded warrants or Series A warrants acquire shares of our common stock upon exercise thereof, such holders will have no rights with respect to the shares of our common stock underlying the Series B pre-funded warrants and Series A warrants, except to the extent that holders of the Series B pre-funded warrants will have certain rights to participate in distributions or dividends paid on our common stock as set forth in the Series B pre-funded warrants. Upon exercise of the Series B pre-funded warrants or Series A warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The Series A warrants are speculative in nature.

The Series A warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the Series A warrants may exercise their right to acquire the common stock and pay an exercise price of \$0.80 per share of common stock, subject to certain adjustments, prior to five years from the date of issuance of the Series A warrants, after which date any unexercised Series A warrants will expire and have no further value. Moreover, following this offering, the market value of the Series A warrants, if any, is uncertain and there can be no assurance that the market value of the Series A warrants will equal or exceed their imputed offering price. The Series A warrants will not be listed or quoted for trading on any market or exchange. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the Series A warrants, and consequently, it may not ever be profitable for holders of the Series A warrants to exercise such warrants.

This is a best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans, including our near-term business plans.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for

the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to support our continued operations, including our near-term continued operations. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds to complete such short-term operations, which may include funds necessary to complete enrollment in our INSPIRE 2.0 Study and to reach submission of the HDE application to the FDA. Such additional fundraises may not be available or available on terms acceptable to us.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain “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, 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*; 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 this prospectus and in the section entitled “Risk Factors” included in our [Annual Report on Form 10-K for the year ended December 31, 2019](#), as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q including our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which are incorporated herein by reference, and other filings we make with the SEC from time to time, which are incorporated herein by reference. 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 complete the INSPIRE 2.0 Study to support our existing Humanitarian Device Exemption application;
- the impact of the COVID-19 pandemic on our business, including our clinical trials;
- 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;
- 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;
- 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 prospectus. 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.

For a more detailed discussion of these and other that may affect our business and that could cause our actual results to differ materially from those projected in these forward-looking statements, see the risk factors and uncertainties described under the heading “Risk Factors” in this prospectus and in the section entitled “Risk Factors” included in our [Annual Report on Form 10-K for the year ended December 31, 2019](#), as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q including our [Quarterly Report on Form 10-Q for the quarter ended June 30, 2020](#), which are incorporated herein by reference, and other filings we make with the SEC from time to time, which are incorporated herein by reference. The forward-looking statements contained in this prospectus and in any of the documents incorporated by reference are expressly qualified in their entirety by this cautionary statement. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events, except as required by law.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$13.5 million, after deducting the placement agent fees and estimated offering expenses payable by us, and assuming no exercise of the Series A warrants being issued in this offering.

These estimates exclude the proceeds, if any, from the exercise of Series A warrants issued in this offering. If all of the Series A warrants issued in this offering were to be exercised in cash at an assumed exercise price of \$0.80 per share of common stock, we would receive additional proceeds of approximately \$15.0 million. We cannot predict when or if these Series A warrants will be exercised. It is possible that these Series A warrants may expire and may never be exercised. Additionally, the Series A warrants contain a cashless exercise provision that permit exercise of Series A warrants on a cashless basis at any time where there is no effective registration statement under the Securities Act of 1933, as amended, covering the issuance of the underlying shares.

We intend to use the net proceeds from this offering for working capital, business development activities, and general corporate purposes. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. Accordingly, our management will have broad discretion and flexibility in applying the net proceeds from the sale of securities issued pursuant to this prospectus. Even if this offering is successful, we will need to secure additional resources to support our continued operations, including resources needed to complete any potential HDE application process or regulatory approval process with the FDA, plus resources for engaging in potential business development activities. Pending the uses described above, we intend to invest the net proceeds from this offering in a variety of capital preservation investments, including short-term, investment-grade and interest-bearing instruments.

DIVIDEND POLICY

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.

CAPITALIZATION

The following table sets forth our cash and cash equivalents, as well as our capitalization, as of June 30, 2020 as follows:

- on an actual basis; and
- on a pro forma as adjusted basis to give further effect to the sale by us of 18,750,000 shares of common stock (assuming all of the Series B pre-funded warrants issued in this offering are exercised) and Series A warrants to purchase 18,750,000 shares of common stock in this offering at combined public offering price of \$0.80 per share of common stock and Series A warrant, after deducting the placement agent fees and estimated offering expenses payable by us, and assuming no exercise of the Series A warrants being issued in this offering.

The pro forma as adjusted information set forth below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this information together with our consolidated financial statements and related notes incorporated by reference in this prospectus. All share and per share numbers included in this section, and elsewhere in this prospectus, give effect to the 2020 Reverse Split.

	As of June 30, 2020	
	Actual	Pro Forma As Adjusted ⁽¹⁾
	(Unaudited)	
Cash and cash equivalents	\$ 9,825	\$ 23,350
Stockholders' equity		
Common stock, \$0.00001 par value – 16,666,667 shares authorized, 4,882,420 shares issued and outstanding, on an actual basis; 50,000,000 ⁽¹⁾ shares authorized, 23,632,420 shares issued and outstanding on a pro forma as adjusted basis	2	2
Additional paid-in capital	233,791	247,316
Accumulated deficit	(223,763)	(223,763)
Total stockholders' equity	10,030	23,555
Total capitalization	\$ 10,030	\$ 23,555

- (1) On August 4, 2020, we effected an amendment to our certificate of incorporation that increased the number of authorized shares of common stock from 16,666,667 to 50,000,000.

The information above is based on 4,882,420 shares of our common stock outstanding as of June 30, 2020, and excludes:

- 4,745,334 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2020 at a weighted average exercise price of \$7.08 per share;
- 4,187 shares of common stock issuable upon the exercise of options at a weighted average exercise price of \$1,077.78 per share and 150 shares of common stock issuable upon vesting of restricted stock units outstanding as of June 30, 2020 pursuant to our stock incentives plans (collectively, the "Incentive Plans");
- 26,807 shares of common stock available for future issuance under the Incentive Plans and our 401(k) plan as of June 30, 2020; and
- 264 shares of common stock reserved for future sale under our employee stock purchase plan as of June 30, 2020.

DESCRIPTION OF OUR CAPITAL STOCK

General

The following description of our capital stock is intended as a summary only and therefore is not a complete description of our capital stock. This description is based upon, and is qualified by reference to, applicable provisions of the Nevada Revised Statutes (the “NRS”), our articles of incorporation, as amended, and our amended and restated bylaws and, which are filed as exhibits to the registration statement of which this prospectus forms a part.

Authorized Capital Stock

Our authorized capital stock consists of 50,000,000 shares of common stock, par value \$0.00001 per share. As of September 30, 2020, 4,882,420 shares of common stock were outstanding. Our common stock is registered under Section 12(b) of the Exchange Act.

Common Stock

Voting Rights. The holders of our common stock are entitled to one vote per share on all matters submitted to a vote of the stockholders, including the election of directors. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by all shares of common stock that are present in person or represented by proxy. Except as otherwise provided by law, amendments to our articles of incorporation generally must be approved by a majority of the votes entitled to be cast by all outstanding shares of common stock. Our articles of incorporation do not provide for cumulative voting in the election of directors.

Dividends. Except as provided by law or in our articles of incorporation, the holders of common stock will be entitled to such cash dividends as may be declared from time to time by our board of directors from funds available.

Liquidation, Dissolution and Winding Up. Upon liquidation, dissolution or winding up of our Company, the holders of common stock will be entitled to receive pro rata all assets available for distribution to such holders after payment of our liabilities.

Other Rights. The holders of common stock have no preferential or preemptive right and no subscription, redemption or conversion privileges with respect to the issuance of additional shares of our common stock.

Provisions of Our Articles of Incorporation and Bylaws and the NRS That May Have Anti-Takeover Effects

Anti-Takeover Effects of Provisions of Nevada State Law

We may be or in the future 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. We currently have less than 100 stockholders of record who are residents of Nevada.

The control share law focuses on the acquisition of a “controlling interest,” which means the ownership of outstanding voting shares that would be sufficient, but for the operation of the control share law, to enable the acquiring person to exercise the following proportions of the voting power of the corporation in the election of directors: (1) one-fifth or more but less than one-third; (2) one-third or more but less than a majority; or (3) a majority or more. The ability to exercise this voting power may be direct or indirect, as well as individual or in association with others.

The effect of the control share law is that an acquiring person, and those acting in association with that person, will obtain only such voting rights in the control shares as are conferred by a resolution of the stockholders of the corporation, approved at a special or annual meeting of stockholders. The control share law contemplates that voting rights will be considered only once by the other stockholders. Thus, there is

no authority to take away voting rights from the control shares of an acquiring person once those rights have been approved. If the stockholders do not grant voting rights to the control shares acquired by an acquiring person, those shares do not become permanent non-voting shares. The acquiring person is free to sell the shares to others. If the buyer or buyers of those shares themselves do not acquire a controlling interest, the shares are not governed by the control share law.

If control shares are accorded full voting rights and the acquiring person has acquired control shares with a majority or more of the voting power, a stockholder of record, other than the acquiring person, who did not vote in favor of approval of voting rights, is entitled to demand fair value for such stockholder's shares.

In addition to the control share law, Nevada has a business combination law, which prohibits certain business combinations between Nevada corporations and "interested stockholders" for two years after the interested stockholder first becomes an interested stockholder, unless the corporation's board of directors approves the combination in advance. For purposes of Nevada law, an interested stockholder is any person who is: (a) the beneficial owner, directly or indirectly, of 10% or more of the voting power of the outstanding voting shares of the corporation, or (b) an affiliate or associate of the corporation and at any time within the previous two years was the beneficial owner, directly or indirectly, of 10% or more of the voting power of the then-outstanding shares of the corporation. The definition of "business combination" contained in the statute is sufficiently broad to cover virtually any kind of transaction that would allow a potential acquirer to use the corporation's assets to finance the acquisition or otherwise to benefit its own interests rather than the interests of the corporation and its other stockholders.

The effect of Nevada's business combination law is to potentially discourage parties interested in taking control of the Company from doing so if it cannot obtain the approval of our board of directors.

Anti-Takeover Effects of Provisions of Our Articles of Incorporation and Bylaws

Our articles of incorporation provide for a classified board of directors. This provision could prevent a party who acquires control of a majority of our outstanding common stock from obtaining control of the board until our second annual stockholders meeting following the date the acquirer obtains the controlling stock interest. The classified board provision could have the effect of discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us and could increase the likelihood that incumbent directors will retain their positions. In addition, under our amended and restated bylaws, directors may be removed only for cause and only by the affirmative vote of the holders of at least 80% of the voting power of our then outstanding shares of capital stock entitled to vote generally in the election of directors, voting together as a single class.

Our amended and restated bylaws also provide that stockholders may only act at meetings of stockholders and not by written consent in lieu of a stockholders' meeting. Our amended and restated bylaws provide that stockholders may not call a special meeting of stockholders. Rather, only the Chairman of our board of directors, the President, or the board of directors pursuant to a resolution approved by a majority of the entire board of directors are able to call special meetings of stockholders. These provisions may discourage another person or entity from making a tender offer, even if it acquired a majority of our outstanding voting stock, because the person or entity could only take action at a duly called stockholders' meeting relating to the business specified in the notice of meeting and not by written consent.

Our amended and restated bylaws also provide that stockholders may only conduct business at special meetings of stockholders that was specified in the notice of the meeting, and a stockholder must notify us in writing, within timeframes specified in our bylaws, of any stockholder nomination of a director and of any other business that the stockholders intends to bring at a meeting of stockholders. Our amended and restated bylaws also provide that our bylaws may be amended by our board of directors or by the affirmative vote of at least 80% of our voting stock then outstanding. These provisions could have the effect of discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us because the foregoing provisions may limit the proposals that may be acted upon at a stockholders' meeting, and the amendment provisions in our bylaws make such provisions difficult to change.

Listing on The Nasdaq Capital Market

Our common stock is listed on the Nasdaq Capital Market under the symbol “NVIV.” On October 21, 2020, the reported closing price per share of our common stock on the Nasdaq Capital Market was \$1.14.

Authorized but Unissued Shares

The authorized but unissued shares of common stock are available for future issuance without stockholder approval, subject to any limitations imposed by the listing requirements of the Nasdaq Capital Market. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock could make it more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering 11,785,000 shares of common stock, together with warrants (the “Series A warrants”) to purchase 11,785,000 shares of common stock. We are also offering 6,965,000 pre-funded warrants (the “Series B pre-funded warrants”), together with the Series A warrants to purchase 6,965,000 shares of common stock (the Series B pre-funded warrants together with the Series A warrants, the “warrants”) to those purchasers, whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering in lieu of the shares of our common stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each Series B pre-funded warrant will be exercisable for one share of common stock. Each Series B pre-funded warrant is being issued together with the same Series A warrant described above being issued with each share of common stock. The shares of common stock or Series B pre-funded warrants, as the case may be, and the Series A warrants, can only be purchased together in this offering, but the Series B pre-funded warrants and Series A warrants are immediately separable and will be issued separately in this offering. We are also registering the shares of common stock and the shares of common stock issuable from time to time upon exercise of the Series B pre-funded warrants and Series A warrants offered hereby.

Common Stock

The description of our common stock under the section “Description of Our Capital Stock” in this prospectus is incorporated herein by reference.

Series B Pre-Funded Warrants

The following summary of certain terms and provisions of the Series B pre-funded warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Series B pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Series B pre-funded warrant for a complete description of the terms and conditions of the Series B pre-funded warrants.

Duration and Exercise Price

Each Series B pre-funded warrant offered hereby will have an initial exercise price per share equal to \$0.00001. The Series B pre-funded warrants will be exercisable upon issuance and will expire when exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The Series B pre-funded warrants will be issued separately from the accompanying Series A warrants with Series B pre-funded warrants.

Exercisability

The Series B pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Series B pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days’ prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding stock after exercising the holder’s Series B pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series B pre-funded warrants and Nevada law. Purchasers of Series B pre-funded warrants in this offering may also elect prior to the issuance of the Series B pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Series B pre-funded warrants.

Transferability

Subject to applicable laws, a Series B pre-funded warrant may be transferred at the option of the holder upon surrender of the Series B pre-funded warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Series B pre-funded warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Trading Market

There is no trading market available for the Series B pre-funded warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Series B pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Series B pre-funded warrants will be extremely limited. The common stock issuable upon exercise of the Series B pre-funded warrants is currently listed on the Nasdaq Capital Market.

Right as a Stockholder

Except as otherwise provided in the Series B pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Series B pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Series B pre-funded warrants. The Series B pre-funded warrants will provide that holders have the right to participate in distributions or dividends paid on our common stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Series B pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the Series B pre-funded warrants will be entitled to receive upon exercise of the Series B pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Series B pre-funded warrants immediately prior to such fundamental transaction.

Series A Warrants

The following summary of certain terms and provisions of the Series A warrants included with the shares of common stock and the Series B pre-funded warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Series A warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Series A warrant for a complete description of the terms and conditions of the Series A warrants.

Duration and Exercise Price

Each Series A warrant offered hereby will have an initial exercise price equal to \$0.80 per share of common stock. The Series A warrants will be immediately exercisable and will expire five years from the

date of issuance. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The Series A warrants will be issued separately from the common stock, or the Series B pre-funded warrants, as the case may be.

Exercisability

The Series A warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Series A warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding stock after exercising the holder's Series A warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series A warrants and Nevada law.

Cashless Exercise

If, at the time a holder exercises its Series A warrants, a registration statement registering the issuance of the shares of common stock underlying the Series A warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Series A warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Series A warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Transferability

Subject to applicable laws, a Series A warrant may be transferred at the option of the holder upon surrender of the Series A warrant to us together with the appropriate instruments of transfer.

Trading Market

There is no trading market available for the Series A warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Series A warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Series A warrants will be extremely limited. The common stock issuable upon exercise of the Series A warrants is currently listed on the Nasdaq Capital Market.

Right as a Stockholder

Except as otherwise provided in the Series A warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Series A warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Series A warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Series A warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the Series A warrants will be entitled to receive upon exercise of the Series A warrants the kind

and amount of securities, cash or other property that the holders would have received had they exercised the Series A warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our Board, the holders of the Series A warrants have the right to require us or a successor entity to redeem the Series A warrant for cash in the amount of the Black-Scholes value of the unexercised portion of the Series A warrant on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by our Board, the holders of the Series A warrants have the right to require us or a successor entity to redeem the Series A warrant for the consideration paid in the fundamental transaction in the amount of the Black Scholes value of the unexercised portion of the Series A warrant on the date of the consummation of the fundamental transaction.

Placement Agent Warrants

The following summary of certain terms and provisions of the Placement Agent Warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Placement Agent Warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Placement Agent Warrant for a complete description of the terms and conditions of the Placement Agent Warrant.

Duration and Exercise Price

Each Placement Agent Warrant offered hereby will have an initial exercise price equal to \$1.00 per share of common stock. The Placement Agent Warrants will be immediately exercisable and will expire five years from the commencement of sales in this offering. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

Exercisability

The Placement Agent Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Placement Agent Warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding stock after exercising the holder's Placement Agent Warrant up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Placement Agent Warrants and Nevada law.

Cashless Exercise

If, at the time a holder exercises its Placement Agent Warrants, a registration statement registering the issuance of the shares of common stock underlying the Placement Agent Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Placement Agent Warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Placement Agent Warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Transferability

Subject to applicable laws, a Placement Agent Warrant may be transferred at the option of the holder upon surrender of the Placement Agent Warrant to us together with the appropriate instruments of transfer.

Trading Market

There is no trading market available for the Placement Agent Warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Placement Agent Warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Placement Agent Warrants will be extremely limited. The common stock issuable upon exercise of the Placement Agent Warrants is currently listed on the Nasdaq Capital Market.

Right as a Stockholder

Except as otherwise provided in the Placement Agent Warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Placement Agent Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Placement Agent Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Placement Agent Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the Placement Agent Warrants will be entitled to receive upon exercise of the Placement Agent Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Placement Agent Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our Board, the holders of the Placement Agent Warrants have the right to require us or a successor entity to redeem the Placement Agent Warrant for cash in the amount of the Black-Scholes value of the unexercised portion of the Placement Agent Warrant on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by our Board, the holders of the Placement Agent Warrants have the right to require us or a successor entity to redeem the Placement Agent Warrants for the consideration paid in the fundamental transaction in the amount of the Black Scholes value of the unexercised portion of the Placement Agent Warrant on the date of the consummation of the fundamental transaction.

**MATERIAL U.S. FEDERAL TAX CONSIDERATIONS FOR HOLDERS OF OUR COMMON STOCK,
SERIES B PRE-FUNDED WARRANTS AND SERIES A WARRANTS**

The following discussion describes the material U.S. federal income and estate tax consequences of the acquisition, ownership and disposition of our common stock, Series B pre-funded warrants and Series A warrants acquired in this offering. This discussion is based on the current provisions of the Internal Revenue Code of 1986, as amended (referred to as the “Code”), existing and proposed U.S. Treasury regulations promulgated thereunder, and administrative rulings and court decisions in effect as of the date hereof, all of which are subject to change at any time, possibly with retroactive effect. No ruling has been or will be sought from the Internal Revenue Service, or IRS, with respect to the matters discussed below, and there can be no assurance the IRS will not take a contrary position regarding the tax consequences of the acquisition, ownership or disposition of our common stock, Series B pre-funded warrants or Series A warrants, or that any such contrary position would not be sustained by a court.

We assume in this discussion that the shares of our common stock, Series B pre-funded warrants and Series A warrants will be held as capital assets (generally, property held for investment). This discussion does not address all aspects of U.S. federal income taxes, does not discuss the potential application of the Medicare contribution tax, the alternative minimum tax and does not deal with state or local taxes or U.S. federal gift and estate tax laws, except as specifically provided below with respect to non-U.S. holders, or any non-U.S. tax consequences that may be relevant to holders in light of their particular circumstances. This discussion also does not address the special tax rules applicable to particular holders, such as:

- financial institutions;
- brokers or dealers in securities;
- tax-exempt organizations;
- pension plans;
- regulated investment companies;
- owners that hold our common stock, Series B pre-funded warrants or Series A warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- insurance companies;
- controlled foreign corporations, passive foreign investment companies, or corporations that accumulate earnings to avoid U.S. federal income tax; and
- certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships or other pass-through entities or persons who hold our common stock, Series B pre-funded warrants or Series A warrants through partnerships or other entities which are pass-through entities for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock, Series B pre-funded warrants or Series A warrants should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock, Series B pre-funded warrants or Series A warrants through a partnership or other pass-through entity, as applicable.

The discussion of U.S. federal income and estate tax considerations is for information purposes only and is not tax advice. Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of acquiring, holding and disposing of our common stock, Series B pre-funded warrants and Series A warrants.

For the purposes of this discussion, a “U.S. Holder” means a beneficial owner of our common stock, Series B pre-funded warrants or Series A warrants that is for U.S. federal income tax purposes (a) an individual citizen or resident of the United States, (b) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes), created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons (within the meaning of Section 7701(a)(30) of the

Code) has the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person. A “Non-U.S. Holder” is, for U.S. federal income tax purposes, a beneficial owner of common stock, Series B pre-funded warrants or Series A warrants that is not a U.S. Holder or a partnership for U.S. federal income tax purposes.

Allocation of Purchase Price to Common Stock, Series B Pre-Funded Warrants and Series A Warrants

For U.S. federal income tax purposes, a holder’s acquisition of the Series A warrants and common stock or Series B pre-funded warrants, as applicable, will be treated as the acquisition of an “investment unit” consisting of one share of common stock or one Series B pre-funded warrant, as applicable, and a Series A warrant to acquire one share of our common stock, subject to adjustment. The purchase price for each investment unit will be allocated between these two components in proportion to their relative fair market values at the time the investment unit is purchased by the holder. This allocation of the purchase price for each investment unit will establish the holder’s initial tax basis for U.S. federal income tax purposes in the common stock or Series B pre-funded warrant, as applicable, and the Series A warrant included in each investment unit. The separation of the share of common stock or Series B pre-funded warrant, as applicable, and the Series A warrant included in each investment unit should not be a taxable event for U.S. federal income tax purposes. Each holder should consult his, her or its own tax advisor regarding the allocation of the purchase price for an investment unit.

Treatment of Series B Pre-Funded Warrants

Although it is not entirely free from doubt, a Series B pre-funded warrant should be treated as a share of our common stock for U.S. federal income tax purposes and a holder of Series B pre-funded warrants should generally be taxed in the same manner as a holder of common stock as described below. Accordingly, upon exercise, the holding period of a Series B pre-funded warrant should carry over to the share of common stock received. Similarly, the tax basis of the Series B pre-funded warrant should carry over to the share of common stock received upon exercise increased by the exercise price of \$0.00001. Each holder should consult his, her or its own tax advisor regarding the risks associated with the acquisition of an investment unit pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

Tax Considerations Applicable to U.S. Holders

Exercise and Expiration of Series A Warrants

In general, a U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a warrant. The U.S. Holder will take a tax basis in the shares acquired on the exercise of a Series A warrant equal to the exercise price of the Series A warrant, increased by the U.S. Holder’s adjusted tax basis in the Series A warrant exercised (as determined pursuant to the rules discussed above). The U.S. Holder’s holding period in the shares of our common stock acquired on exercise of the Series A warrant will begin on the date of exercise of the Series A warrant, and will not include any period for which the U.S. Holder held the Series A warrant.

In certain limited circumstances, a U.S. Holder may be permitted to undertake a cashless exercise of Series A warrants into our common stock. The U.S. federal income tax treatment of a cashless exercise of Series A warrants into our common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a Series A warrant described in the preceding paragraph. U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of Series A warrants.

The lapse or expiration of a Series A warrant will be treated as if the U.S. Holder sold or exchanged the Series A warrant and recognized a capital loss equal to the U.S. Holder’s tax basis in the Series A warrant. The deductibility of capital losses is subject to limitations.

Certain Adjustments to and Distributions on the Series A Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock issued on the exercise of the Series A warrants, or an adjustment to the exercise price of the Series A warrants, may be treated as a constructive distribution to a U.S. Holder of the Series A warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. Holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). In addition, if we were to make a distribution in cash or other property with respect to our common stock after the issuance of the Series A warrants, then we may, in certain circumstances, make a corresponding distribution to a Series A warrant holder. The taxation of a distribution received with respect to a Series A warrant is unclear. It is possible such a distribution would be treated as a distribution (or constructive distribution), although other treatments are possible. For more information regarding the tax considerations related to distributions, see the discussion below regarding "Distributions." U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to and distributions on the Series A warrants.

Distributions

As discussed above, 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. In the event that we do make distributions on our common stock or Series B pre-funded warrants to a U.S. Holder, those distributions generally will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a U.S. Holder's adjusted tax basis in our common stock or Series B pre-funded warrant, as applicable. Any remaining excess will be treated as gain realized on the sale or exchange of our common stock or Series B pre-funded warrants as described below under the section titled "— Gain on Disposition of Our Common Stock, Series B Pre-Funded Warrants or Series A Warrants."

Disposition of Our Common Stock, Series B Pre-Funded Warrants or Series A Warrants

Upon a sale or other taxable disposition of our common stock, Series B pre-funded warrants or Series A warrants, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the common stock, Series B pre-funded warrants or Series A warrants. Capital gain or loss will constitute long-term capital gain or loss if the U.S. Holder's holding period for the common stock, Series B pre-funded warrant or Series A warrant exceeds one year. The deductibility of capital losses is subject to certain limitations. U.S. Holders who recognize losses with respect to a disposition of our common stock, Series B pre-funded warrants or Series A warrants should consult their own tax advisors regarding the tax treatment of such losses.

Information Reporting and Backup Withholding

Information reporting requirements generally will apply to payments of dividends (including constructive dividends) on our common stock, Series B pre-funded warrants and Series A warrants and to the proceeds of a sale or other disposition of common stock, Series A warrants and Series B pre-funded warrants by a U.S. Holder unless such U.S. Holder is an exempt recipient, such as a corporation. Backup withholding will apply to those payments if the U.S. Holder fails to provide the holder's taxpayer identification number, or certification of exempt status, or if the holder otherwise fails to comply with applicable requirements to establish an exemption. Backup withholding is not an additional tax. Rather, any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against the U.S. Holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Tax Considerations Applicable to Non-U.S. Holders

Exercise and Expiration of Series A Warrants

In general, a Non-U.S. Holder will not be subject to U.S. federal income tax on the exercise of the Series A warrants into shares of common stock. The U.S. federal income tax treatment of a cashless

exercise of Series A warrants into our common stock is unclear. A Non-U.S. Holder should consult his, her, or its own tax advisor regarding the U.S. federal income tax consequences of a cashless exercise of Series A warrants.

The expiration of a Series A warrant will be treated as if the Non-U.S. Holder sold or exchanged the Series A warrant and recognized a capital loss equal to the Non-U.S. Holder's tax basis in the Series A warrant. However, a Non-U.S. Holder will not be able to utilize a loss recognized upon expiration of a Series A warrant against the Non-U.S. Holder's U.S. federal income tax liability unless the loss is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment or fixed base in the United States) or is treated as a U.S.-source loss and the Non-U.S. Holder is an individual nonresident and present 183 days or more in the taxable year of disposition in the United States and certain other conditions are met.

Certain Adjustments to and Distributions on the Series A Warrants

As described under "— U.S. Holders — Certain Adjustments and Distributions on to the Series A Warrants," an adjustment to the Series A warrants could result in a constructive distribution to a Non-U.S. Holder, which would be treated as described under "Distributions" below, and the tax treatment of a distribution on a warrant is unclear. Any resulting withholding tax attributable to deemed dividends would be collected from other amounts payable or distributable to the Non-U.S. Holder. Non-U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to and distributions on the Series A warrants.

Distributions

As discussed above, 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. In the event that we do make distributions on our common stock or Series B pre-funded warrants to a Non-U.S. Holder, those distributions generally will constitute dividends for U.S. federal income tax purposes as described in "— U.S. Holders — Distributions."

Any distribution (including constructive distributions) on our common stock or Series B pre-funded warrants that is treated as a dividend paid to a Non-U.S. Holder that is not effectively connected with the holder's conduct of a trade or business in the United States will generally be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and the Non-U.S. Holder's country of residence. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. Such form must be provided prior to the payment of dividends and must be updated periodically. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent may then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If a Non-U.S. Holder is eligible for a reduced rate of U.S. withholding tax under an income tax treaty, such Non-U.S. Holder should consult with its tax advisor to determine if it is able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid (or constructive dividends deemed paid) to a Non-U.S. Holder that are effectively connected with such holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that the holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to the applicable withholding agent). In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates applicable to U.S. persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

See also the sections below titled “— Information Reporting and Backup Withholding” and “— Foreign Accounts” for additional withholding rules that may apply to dividends paid to certain foreign financial institutions or non-financial foreign entities.

Gain on Disposition of Our Common Stock, Series B Pre-Funded Warrants or Series A Warrants

Subject to the discussions below under the sections titled “— Information Reporting and Backup Withholding” and “— Foreign Accounts,” a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock, Series B pre-funded warrants or Series A warrants unless

- the gain is effectively connected with the Non-U.S. Holder’s conduct of a trade or business in the United States, and if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the United States; in these cases, the Non-U.S. Holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to U.S. persons, and if the Non-U.S. Holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;
- the Non-U.S. Holder is a nonresident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the Non-U.S. Holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence) on the net gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the Non-U.S. Holder, if any; or
- we are, or have been at any time during the five-year period preceding such disposition (or the Non-U.S. Holder’s holding period of the common stock, Series B pre-funded warrants or Series A warrants, if shorter), a “U.S. real property holding corporation,” unless our common stock is regularly traded on an established securities market and the Non-U.S. Holder held no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the five-year period ending on the date of the disposition or the period that the Non-U.S. Holder held our common stock. Special rules may apply to the determination of the 5% threshold in the case of a holder of a Series B pre-funded warrant or Series A warrant. Non-U.S. Holders are urged to consult their own tax advisors regarding the effect of holding our Series B pre-funded warrants or Series A warrants on the calculation of such 5% threshold. Generally, a corporation is a “U.S. real property holding corporation” if the fair market value of its “U.S. real property interests” (as defined in the Code and applicable regulations) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a “U.S. real property holding corporation” for U.S. federal income tax purposes. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

See the sections titled “— Information Reporting and Backup Withholding” and “— Foreign Accounts” below for additional information regarding withholding rules that may apply to proceeds of a disposition of our common stock, Series B pre-funded warrants or Series A warrants paid to foreign financial institutions or non-financial foreign entities.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each Non-U.S. Holder the gross amount of the distributions (including constructive distributions) on our common stock, Series B pre-funded warrants or Series A warrants paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. Holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate, currently 24%, with respect to dividends (including constructive dividends) on our common stock, Series B pre-funded warrants, or Series A warrants. Generally, a Non-U.S. Holder will comply with such procedures if it provides

a properly executed IRS Form W-8BEN (or other applicable Form W-8) or otherwise meets documentary evidence requirements for establishing that it is a Non-U.S. Holder, or otherwise establishes an exemption. Dividends paid to Non-U.S. Holders subject to withholding of U.S. federal income tax, as described above under the heading “— Distributions,” will generally be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock, Series B pre-funded warrants or Series A warrants by a Non-U.S. Holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the Non-U.S. Holder certifies its status as a Non-U.S. Holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. Holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the Non-U.S. Holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder can be refunded or credited against the Non-U.S. Holder’s U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

Foreign Accounts

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a 30% withholding tax on dividends on, and gross proceeds from the sale or other disposition of, common stock, Series B pre-funded warrants and Series A warrants if paid to a non-U.S. entity unless (i) if the non-U.S. entity is a “foreign financial institution,” the non-U.S. entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the non-U.S. entity is not a “foreign financial institution,” the non-U.S. entity identifies certain of its U.S. investors, if any, or (iii) the non-U.S. entity is otherwise exempt under FATCA.

Withholding under FATCA generally applies to payments of dividends on our common stock, Series B pre-funded warrants and Series A warrants. While withholding under FATCA may apply to payments of gross proceeds from a sale or other disposition of our common stock, Series B pre-funded warrants and Series A warrants, under proposed U.S. Treasury Regulations, withholding on payments of gross proceeds is not required. Although such regulations are not final, applicable withholding agents may rely on the proposed regulations until final regulations are issued.

An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Under certain circumstances, a holder may be eligible for refunds or credits of the tax. Holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock, Series B pre-funded warrants or Series A warrants.

Federal Estate Tax

Common stock or Series B pre-funded warrants owned or treated as owned by an individual who is a Non-U.S. Holder (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual’s gross estate for U.S. federal estate tax purposes and, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise. The foregoing may also apply to Series A warrants.

The preceding discussion of material U.S. federal tax considerations is for information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, Series B pre-funded warrants or Series A warrants, including the consequences of any proposed changes in applicable laws.

PLAN OF DISTRIBUTION

We engaged H.C. Wainwright & Co., LLC (“H.C. Wainwright” or the “placement agent”) to act as our exclusive placement agent to solicit offers to purchase the securities offered by this prospectus on a reasonable best efforts basis. H.C. Wainwright is not purchasing or selling any securities, nor are they required to arrange for the purchase and sale of any specific number or dollar amount of securities, other than to use their “reasonable best efforts” to arrange for the sale of the securities offered by us. Therefore, we may not sell the entire amount of securities being offered. There is no minimum amount of proceeds that is a condition to closing of this offering. We will enter into a securities purchase agreement directly with the institutional investors, at the investor’s option, who purchase our securities in this offering. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering. H.C. Wainwright may engage one or more sub-placement agents or selected dealers to assist with the offering.

Fees and Expenses

The following table show the per share and Series A warrant and Series B pre-funded warrant and Series A warrant placement agent fees and total placement agent fees we will pay in connection with the sale of the securities in this offering, assuming the purchase of all of the securities we are offering.

Per share and Series A warrant placement agent cash fees	\$ 0.056
Per Series B pre-funded warrant and Series A warrant placement agent cash fees	\$ 0.056
Total	\$1,050,000

We have agreed to pay the placement agent a total cash fee equal to 7.0% of the gross proceeds of this offering and a management fee equal to 1.0% of the gross proceeds raised in this offering. We will also pay the placement agent \$12,900 for the expenses of its clearing firm and will reimburse the placement agent’s legal fees and expenses in an amount up to \$66,000. We estimate the total offering expenses of this offering that will be payable by us, excluding the placement agent fees and expenses, will be approximately \$0.2 million. After deducting the placement agent fees and our estimated offering expenses, we expect the net proceeds from this offering to be approximately \$13.5 million.

Placement Agent Warrants

We have agreed to grant compensation warrants to H.C. Wainwright (the “Placement Agent Warrant”) to purchase a number of shares of our common stock equal to 6.5% of the aggregate number of shares of common stock and Series B pre-funded warrants sold to the investors in this offering. The Placement Agent Warrants will have an exercise price of \$1.00 (125% of the combined public offering price per share of common stock and Series A warrant) and will terminate on the five year anniversary of commencement of sales in this offering. The Placement Agent Warrants are registered on the registration statement of which this prospectus is a part.

Other Relationships

The placement agent acted as the placement agent in connection with our previous offerings consummated in November 2019, March 2020 and April 2020, for which it has received customary fees and expenses. The placement agent may, from time to time, engage in transactions with or perform services for us in the ordinary course of its business and may continue to receive compensation from us for such services.

Determination of Offering Price

The combined public offering price per share and Series A warrant and the combined public offering price per Series B pre-funded warrant and Series A warrant we are offering and the exercise prices and other terms of the warrants were negotiated between us and the investors, in consultation with the placement agent, based on the trading of our common stock prior to this offering, among other things. Other factors considered in determining the public offering prices of the securities we are offering and the exercise prices and other terms of the warrants include the history and prospects of our company, the stage of

development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Lock-up Agreements

We and each of our officers and directors have agreed with the placement agent to be subject to a lock-up period of ninety (90) days following the date of this prospectus. This means that, during the applicable lock-up period, we may not offer for sale, contract to sell, or sell any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock subject to certain customary exception such as issuing stock options to directors, officers, employees and consultants under our existing plans. The placement agent may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements. In addition, we have agreed to not issue any shares of common stock or securities exercisable or convertible into shares of common stock for a period of ninety (90) days following the closing date of this offering, subject to certain exceptions, and to not issue any securities that are subject to a price reset based on trading prices of our common stock or upon a specified or contingent event in the future, or enter into an agreement to issue securities at a future determined price, until the date that no warrants are outstanding.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer and Trust Company.

Nasdaq Listing

Our common stock is currently listed on the Nasdaq Capital Market under the symbol “NVIV.” On October 21, 2020, the reported closing price per share of our common stock was \$1.14.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act of 1933, or to contribute to payments the placement agent may be required to make with respect to any of these liabilities.

Regulation M

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any fees received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent will be required to comply with the requirements of the Securities Act and the Exchange Act of 1934, as amended (the “Exchange Act”), including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

LEGAL MATTERS

The validity of the common stock offered by this prospectus will be passed upon for us by Ballard Spahr LLP, Las Vegas, Nevada, and certain other legal matters will be passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP, Boston, Massachusetts. Ellenoff Grossman & Schole LLP, New York, New York, has acted as counsel for the placement agent in connection with certain legal matters related to this offering.

EXPERTS

The consolidated financial statements of InVivo Therapeutics Holdings Corp. and subsidiary as of December 31, 2019 and 2018 and for the years then ended, incorporated in this Prospectus by reference from the InVivo Therapeutics Holdings Corp.'s [Annual Report on Form 10-K for the year ended December 31, 2019](#) have been audited by RSM US LLP, an independent registered public accounting firm, as stated in their report thereon (which report expresses an unqualified opinion and includes an explanatory paragraph relating to InVivo Therapeutics Holdings Corp.'s ability to continue as a going concern), incorporated herein by reference, and have been incorporated in this Prospectus and Registration Statement in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to you on the SEC's Internet site at www.sec.gov. Copies of certain information filed by us with the SEC are also available on our website at www.invivotherapeutics.com. The information on our Internet website is not incorporated by reference in this prospectus.

This prospectus is part of a registration statement that we filed with the SEC. This prospectus does not contain all of the information included in the registration statement, including certain exhibits and schedules. You should review the information and exhibits in the registration statement for further information about us and the securities we are offering. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to these filings. You should review the complete document to evaluate these statements. You can obtain a copy of the registration statement and exhibits from the SEC's Internet site.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference into this prospectus information and reports that we file with the SEC. This means that we can disclose important information to you by referring to other documents that contain that information. Any information that we incorporate by reference is considered part of this prospectus. The documents and reports that we list below are incorporated by reference into this prospectus, other than any portion of any such documents that are not deemed “filed” under the Exchange Act in accordance with the Exchange Act and applicable SEC rules.

In addition, all documents and reports which we file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the termination of the offering made hereby are incorporated by reference in this prospectus as of the respective filing dates of these documents and reports.

We have filed the following documents with the SEC. These documents are incorporated in this prospectus by reference as of their respective dates of filing:

- (1) [Our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on February 20, 2020;](#)
- (2) Our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2020 and June 30, 2020, filed with the SEC on [May 13, 2020](#) and [August 11, 2020](#), respectively;
- (3) [Our Definitive Proxy Statement on Schedule 14A for our annual meeting of stockholders held on August 4, 2020, filed with the SEC on June 22, 2020;](#)
- (4) Our Current Reports on Form 8-K, filed with the SEC on [January 16, 2020](#), [January 24, 2020](#), [February 3, 2020](#), [February 11, 2020](#), [February 24, 2020](#), [March 2, 2020](#); [March 11, 2020](#), [April 16, 2020](#), [June 5, 2020](#) and [August 5, 2020](#); and
- (5) [The description of our common stock contained in our Registration Statement on Form 8-A filed on April 15, 2015, including any amendments or reports filed for the purpose of updating such description.](#)

You may request a copy of these documents, which will be provided to you at no cost, by writing or telephoning us at:

InVivo Therapeutics Holdings Corp.
One Kendall Square, Suite B14402
Cambridge, Massachusetts 02139
Attn: Investor Relations
(617) 863-5500

Statements contained in documents that we file with the SEC and that are incorporated by reference in this prospectus will automatically update and supersede information contained in this prospectus, including information in previously filed documents or reports that have been incorporated by reference in this prospectus, to the extent the new information differs from or is inconsistent with the old information. Any statement so modified or superseded will not be deemed to be a part of this prospectus, except as so modified or superseded. Because information that we later file with the SEC will update and supersede previously incorporated information, you should look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any documents previously incorporated by reference have been modified or superseded.



**11,785,000 Shares of Common Stock and
Warrants to Purchase 11,785,000 Shares of Common Stock
and
Pre-funded Warrants to Purchase 6,965,000 Shares of Common Stock and
Warrants to Purchase 6,965,000 Shares of Common Stock**

Prospectus

H.C. Wainwright & Co.

October 22, 2020
