

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BIOAFFINITY TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

3730
(Primary Standard Industrial Classification Code Number)

87-3159685
(I.R.S. Employer Identification No.)

22211 W. Interstate 10, Suite 1206
San Antonio, Texas 78257
(210) 698-5334

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Maria Zannes
Chief Executive Officer and President
bioAffinity Technologies, Inc.
22211 W. Interstate 10, Suite 1206
San Antonio, Texas 78257
(210) 698-5334

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement, as determined by market conditions.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as

amended, or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information contained in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, Dated November 16, 2023

PROSPECTUS

\$25,000,000

BIOAFFINITY TECHNOLOGIES, INC.

Common Stock
Preferred Stock
Debt Securities
Warrants
Units

We may, from time to time, offer and sell up to \$25,000,000 of any combination of our common stock, preferred stock, debt securities, warrants or units described in this prospectus, either individually or in combination with other securities, at prices and on terms described in one or more supplements to this prospectus. We may also offer common stock or preferred stock upon conversion of debt securities, common stock upon conversion of preferred stock, or common stock, preferred stock or debt securities upon the exercise of warrants.

This prospectus provides you with a general description of the securities that we may offer. Each time we offer and sell securities, we will provide a supplement to this prospectus that contains specific information about the offering and the amounts, prices and terms of the securities. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement and any related free writing prospectus may also add, update or change information contained in this prospectus. You should carefully read this prospectus, the applicable prospectus supplement and any related free writing prospectus, as well as the documents incorporated by reference, before buying any of the securities being offered.

Securities may be sold by us to or through underwriters or dealers, directly to purchasers or through agents designated from time to time. For additional information on the methods of sale, you should refer to the section entitled “Plan of Distribution” in this prospectus and in the applicable prospectus supplement. If any underwriters, dealers or agents are involved in the sale of any of the securities, their names and any applicable purchase price, fee, commission or discount arrangement between or among them will be set forth, or will be calculable from the information set forth, in the applicable prospectus supplement. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement. No securities may be sold without delivery of this prospectus and the applicable prospectus supplement describing the method and terms of the offering of such securities.

Our common stock and our tradeable warrants issued in our initial public offering (the “Tradeable Warrants”) are listed on the Nasdaq Capital Market (“Nasdaq”) under the symbols “BIAF” and “BIAFW,” respectively. On November 14, 2023, the last reported sale price of our common stock was \$1.44 per share, and the last reported sale price of our Tradeable Warrants was \$0.515. The applicable prospectus supplement will contain information, where applicable, as to any other listing, if any, on any securities market or other exchange of the specific security covered by such prospectus supplement.

As of the date of this prospectus, the aggregate market value of our outstanding common stock held by non-affiliates is approximately \$9,824,417, which is calculated based on 5,844,389 shares of our outstanding common stock held by non-affiliates and a price of \$1.681 per share, the closing price of our common stock on September 18, 2023, which is the highest closing sale price of our common stock on the Nasdaq Capital Market within the prior 60 days of this prospectus. During the prior 12-calendar-month period that ends on and includes the date hereof, we have not offered or sold any shares of our common stock pursuant to General Instruction I.B.6 to Form S-3.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading “Risk Factors” beginning on page 6 of this prospectus and contained in the applicable prospectus supplement and in any free writing prospectuses we have authorized for use in connection with a specific offering, and under similar headings in the other documents that are incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is [●], 2023.

TABLE OF CONTENTS

	<u>Page</u>
About this Prospectus	ii
Prospectus Summary	1
Risk Factors	6
Forward-Looking Statements	33
Use of Proceeds	34
Description of Capital Stock	35
Description of Debt Securities	39
Description of Warrants	43
Description of Units	45
Legal Ownership of Securities	45
Plan of Distribution	48
Legal Matters	49
Experts	49
Where You Can Find More Information	49

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission (the “SEC”) using a “shelf” registration process. Under this shelf registration statement, we may sell from time to time in one or more offerings up to a total dollar amount of \$25,000,000 of shares of common stock, preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or as units in combination with other securities as described in this prospectus. Each time we sell any type or series of securities under this prospectus, we will provide a prospectus supplement that will contain more specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change any of the information contained in this prospectus or in the documents we have incorporated by reference into this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in a prospectus supplement. You should carefully read both this prospectus and the applicable prospectus supplement and any related free writing prospectus, together with the additional information described under “Where You Can Find More Information,” before buying any of the securities being offered.

THIS PROSPECTUS MAY NOT BE USED TO CONSUMMATE A SALE OF SECURITIES UNLESS IT IS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT

Neither we, nor any agent, underwriter or dealer has authorized any person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus, any applicable prospectus supplement or any related free writing prospectus prepared by or on behalf of us or to which we have referred you. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus, any applicable supplement to this prospectus or any related free writing prospectus does not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor does this prospectus, any applicable supplement to this prospectus or any related free writing prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

You should not assume that the information contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus, any applicable prospectus supplement or any related free writing prospectus is delivered, or securities are sold, on a later date.

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 section entitled “Where You Can Find More Information.”

Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to “bioAffinity,” “the Company,” “we,” “us,” “our” and similar references refer to bioAffinity Technologies, Inc., an entity incorporated under the laws of the State of Delaware, and where appropriate our consolidated subsidiaries.

This prospectus and the information incorporated herein by reference include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus, any applicable prospectus supplement or any related free writing prospectus are the property of their respective owners.

PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus or incorporated by reference herein and does not contain all the information that may be important to purchasers of our securities. Prospective purchasers of our securities should carefully read the entire prospectus, the applicable prospectus supplement and any related free writing prospectus, including the risks of investing in our securities discussed under the heading “Risk Factors” contained in this prospectus, the applicable prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus. Prospective purchasers of our securities should also carefully read the information incorporated by reference into this prospectus, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part.

Overview

bioAffinity Technologies, Inc. (the “Company,” “we,” or “our”) develops noninvasive diagnostics to detect early-stage lung cancer and other diseases of the lung. We are developing our platform technologies so that, in the future, they could result in broad-spectrum cancer treatments. We develop proprietary noninvasive diagnostic tests using technology that preferentially targets cancer cells and cell populations indicative of a diseased state.

We were formed as a Delaware corporation on March 26, 2014. On June 15, 2016, we formed OncoSelect[®] Therapeutics, LLC (“OncoSelect[®]”), a Delaware limited liability company and our wholly owned subsidiary which is a preclinical-stage biopharmaceutical discovery company with a focus on therapeutics that deliver cytotoxic (cell-killing) effects on a broad selection of human cancers from diverse tissues while having little or no effect on normal cells. On August 14, 2023, we formed Precision Pathology Laboratory Services, LLC (“PPLS”), a Texas limited liability company and our wholly owned subsidiary. Research and optimization of our platform technologies for in vitro diagnostics and technologies are conducted in laboratories at The University of Texas at San Antonio and PPLS.

Our first diagnostic test, CyPath[®] Lung, addresses the need for noninvasive detection of early-stage lung cancer. Lung cancer is the leading cause of cancer-related deaths. Physicians will be able to order CyPath[®] Lung to assist in their assessment of patients who are at high risk for lung cancer. The CyPath[®] Lung test enables physicians to more confidently identify patients who will likely benefit from timely intervention and more invasive follow-up procedures and is another tool to help distinguish them from patients who are likely without lung cancer and should continue annual screening. CyPath[®] Lung has the potential to increase overall diagnostic accuracy of lung cancer, which could lead to increased survival, fewer unnecessary invasive procedures, reduced patient anxiety and lower medical costs.

CyPath[®] Lung uses flow cytometry technology to detect and analyze cell populations in a person’s sputum, or phlegm, to find characteristics indicative of lung cancer, including cancer and/or cancer-related cells that have shed from a lung tumor. The flow cytometer is a well-established instrument used in many commercial laboratories that records properties of labeled and unlabeled single cells labeled by antibodies and other dyes that can identify cell types. Sputum is an excellent sample for analysis because it is in direct contact with any malignancy in the lungs and can thus provide a snapshot of the tumor itself, its microenvironment, and its area of field cancerization. CyPath[®] Lung uses automated data analysis developed by artificial intelligence (“AI”) that allows an entire sample of sputum to be examined for cost-effective, large-scale screening or diagnosis.

We conducted a 150-patient test validation trial of people at high risk for lung cancer including patients with the disease (N=28) and those cancer-free (N=122) that resulted in

CyPath[®] Lung's overall 88% specificity, meaning the ability to correctly identify a person without cancer, and 82% sensitivity, meaning the ability to correctly identify cancer in a person with the disease. For the subset of patients in this trial who had lung nodules smaller than 20 millimeters ("mm") or no nodules at all, this trial resulted in 92% sensitivity, 87% specificity, 99% negative predictive value and 88% accuracy. In this subset of 132 individuals with small nodules, 119 patients were cancer-free and 13 had confirmed lung cancer. The detection of small lung nodules in people who have early-stage cancer can increase lung cancer survival.

Through OncoSelect[®], our research has led to discoveries of novel potential cancer therapeutics that specifically and selectively target cancer cells that have been grown in petri dishes.

Recent Developments

In September 2023, Centers for Medicare and Medicaid Services ("CMS") released a preliminary payment decision for a Current Procedural Terminology (CPT) code for use with CyPath[®] Lung that had been issued by the American Medical Association (AMA) in June, 2023. The CPT code became effective October 1, 2023, and is used for private payers and public health insurance programs. The CPT Proprietary Laboratory Analyses (PLA) code assigned to CyPath[®] Lung is 0406U with the descriptor "Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4- carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer." The Company submitted comments during the 30-day comment period in support of the preliminary decision. In November 2023, CMS is expected to finalize the 2024 payment for CPT 0406U, which will be effective January 1, 2024. The recommended CMS payment amount will favorably impact PPLS' established fee schedule for CyPath[®] Lung determining reimbursement by private insurance carriers.

On September 18, 2023, PPLS consummated the acquisition (the "Acquisition") of a clinical anatomic and clinical pathology laboratory and related services business in San Antonio, Texas (the "Laboratory Assets") pursuant to the terms of an Asset Purchase Agreement (the "Asset Purchase Agreement") dated September 18, 2023, that it entered into with Village Oaks Pathology Services, P.A., a Texas professional association ("Village Oaks") and Dr. Roby P. Joyce, M.D. PPLS is accredited by the College of American Pathologists ("CAP") and certified under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). Founded in 2007 by Dr. Joyce, the Medical Director and Laboratory Director of the clinical pathology laboratory prior to and after to the Acquisition, Village Oaks has provided pathology services to physicians practicing in a variety of outpatient settings. Since September 2021, Village Oaks has offered CyPath[®] Lung for sale as a laboratory developed test ("LDT") for the detection of early-stage lung cancer. In addition to CyPath[®] Lung, PPLS intends to continue to offer a range of laboratory services including respiratory testing for SARS-CoV-2 and influenza, anatomical pathology, morphological stains, histological services, DNA extractions, STI testing and women's and men's health testing.

1

Pursuant to the terms of the Asset Purchase Agreement, PPLS acquired the Laboratory Assets, which included all of the assets owned by Village Oaks other than medical assets, including the CLIA-certificate and CAP-accreditation, which are assets Village Oaks used in connection with its management and operation of a clinical pathology laboratory, now owned by PPLS, and related services business and assumed certain liabilities and obligations. Pursuant to the terms of the Asset Purchase Agreement Village Oaks received \$3,500,000 in consideration for the assets to be purchased by PPLS, of which \$1,000,000 was paid by the issuance of 564,972 shares of our restricted common stock to a trust controlled by Dr. Joyce (the "Joyce Trust"), which share number was determined by dividing \$1,000,000 by \$1.77, the average of the trading day closing prices for the 30 days prior to September 15, 2023, rounded to the nearest whole share.

Pursuant to the Asset Purchase Agreement, PPLS assumed all liabilities and obligations and obtained any and all rights, title and interest of Village Oaks in and to (i) all leases for equipment and personal property related to the Laboratory Assets (the "Assumed Leases"), pursuant to an Assumption Agreement by and between Village Oaks and PPLS (the "Assumption Agreement") and, (ii) certain other contracts related to the Laboratory Assets, including the license to develop, manufacture, use, market and sell CyPath[®] Lung (the "Assumed Contracts") pursuant to the Assumption Agreement; (iii) all accounts payable of Village Oaks as of September 18, 2023, that were incurred in the ordinary course of business consistent with past custom and practice; and (iv) the lease of the premises used in connection with operation of the CLIA-certified and CAP-accredited clinical pathology laboratory, pursuant to an Assignment and Assumption of Lease by and between Village Oaks and PPLS (the "Assignment of Lease").

In connection with the Asset Purchase Agreement, PPLS entered into various other agreements, including a Management Services Agreement with Village Oaks (the "Management Services Agreement"), a Succession Agreement with Village Oaks and Dr. Joyce (the "Succession Agreement") and a Professional Services Agreement with Village Oaks (the "Professional Services Agreement"). Pursuant to the Management Services Agreement, PPLS provides comprehensive management and administrative services to Village Oaks in connection with the operation of Village Oaks' professional cytopathology, histopathology, and clinical and anatomic pathology interpretation medical services practice. PPLS also provides space, equipment, administrative, management and clinical personnel, billing and collection, and related management services to Village Oaks in exchange for a management fee of 70% of the net revenues received by Village Oaks from the provision of the medical services.

The Succession Agreement provides that Dr. Joyce, as holder of 100% of the issued and outstanding stock of Village Oaks, and Village Oaks are restricted from disposing of their equity interests in Village Oaks, subject to certain exceptions, without the prior written consent of us and Village Oaks.

Pursuant to the Professional Services Agreement, Village Oaks provides pathology interpretation services as requested on behalf of PPLS based on the professional fees approved for the CPT code for the services provided under the Medicare Physician Fee Schedule in the locality where the test is performed.

In connection with the Asset Purchase Agreement, we entered into an Executive Employment Agreement with Dr. Joyce (the "Joyce Employment Agreement"), for a term of three years, pursuant to which he serves as the Medical Director and Laboratory Director of PPLS, at a base salary of \$333,333.34 per year. Pursuant to the Joyce Employment Agreement, Dr. Joyce was also appointed to serve on our Board of Directors.

Corporate Information

We were incorporated in the State of Delaware on March 26, 2014. Our principal executive office is located at 22211 West Interstate 10, Suite 1206, San Antonio, Texas 78257, and our telephone number at that address is (210) 698-5334. Our website address is <https://www.bioaffinitytech.com/>. Information contained on or that can be accessed through our website is not incorporated by reference into this prospectus. Investors should not consider any such information to be part of this prospectus.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). As an "emerging growth company," we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include, but are not limited to:

- requiring only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Securities Act of 1933, as amended (the "Securities Act"), filings;
- reduced disclosure about our executive compensation arrangements;
- no non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes Oxley Act of 2002 ("SOX").

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an “emerging growth company.” We will continue to remain an “emerging growth company” until the earliest of the following: (i) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (ii) the last day of the fiscal year in which our total annual gross revenue is equal to or more than \$1.235 billion; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We are also a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. To the extent that we continue to qualify as a “smaller reporting company” as such term is defined in Rule 12b-2 under the Exchange Act, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an “emerging growth company” may continue to be available to us as a “smaller reporting company,” including exemption from compliance with the auditor attestation requirements pursuant to SOX and reduced disclosure about our executive compensation arrangements. We will continue to be a “smaller reporting company” until we have \$250 million or more in public float (based on our common stock) measured as of the last business day of our most recently completed second fiscal quarter or, in the event we have no public float (based on our common stock) or a public float (based on our common stock) that is less than \$700 million and annual revenues of \$100 million or more during the most recently completed fiscal year.

We may choose to take advantage of some, but not all, of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of the extended transition period for complying with new or revised financial accounting standards. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies which may make comparison of our financials to those of other public companies more difficult.

Summary of Risks Associated with our Business

The following summarizes the principal factors that make an investment in our Company speculative or risky, all of which are more fully described in the section below titled “Risk Factors.” This summary should be read in conjunction with the section below titled “Risk Factors” and should not be relied upon as an exhaustive summary of the material risks facing our business. The following factors could result in harm to our business, reputation, revenue, financial results, and prospects, among other impacts:

- we may not experience the anticipated strategic benefits of the Acquisition;
- the future revenue to be generated from PPLS is uncertain;
- our limited operating history and history of net losses since our inception;
- our need to obtain substantial additional funding to complete the development and commercialization of our diagnostic tests and therapeutic product candidates;
- the impact of a material weakness identified in our internal control over financial reporting;
- the early stage of our development efforts;
- the unpredictability of future trial results;
- the difficulty in predicting the results, timing, and cost of our development of our diagnostic tests and therapeutic product candidates and the likelihood of obtaining regulatory approval;
- the risk of experiencing delays or difficulties in the enrollment and/or retention of patients in clinical trials;
- potential changes to interim, “top-line” or preliminary results from our clinical trials as more patient data becomes available and are subject to audit and verification procedures;
- the risk that the FDA may not agree with our LDT regulatory strategy or that the Congress may enact legislation giving the FDA new authorities to regulate LDTs that impacts our business;
- the lengthy, time consuming, and unpredictable nature of regulatory approval processes;
- the risk that our preclinical studies and clinical trials fail to demonstrate the safety and efficacy of our diagnostic tests or therapeutic product candidates;
- the risk that data from any clinical trials conducted outside of the United States may not be accepted by regulatory authorities;
- the impact of ongoing regulatory obligations and continued regulatory review, even if we receive regulatory approval for any of our diagnostic tests or therapeutic product candidates;

- our lack of control over the supply, regulatory status, or regulatory approval of third-party drugs or biologics with which our diagnostic tests or therapeutic product candidates are used in combination;
- our lack of control over the conduct of investigator-initiated clinical trials or other clinical trials sponsored by organizations or agencies other than us;
- the risk that we fail to develop additional diagnostic tests or therapeutic product candidates;
- the risk that we are unable to penetrate multiple markets;
- the risk that our diagnostic tests and therapeutic product candidates may fail to achieve market acceptance, even they receive marketing authorization;
- if we are unable to obtain and maintain sufficient intellectual property protection for our platform and our diagnostic tests or therapeutic product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitive position may be adversely affected;
- the price of our stock may be volatile, and you could lose all or part of your investment. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price;

- our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees;
- we face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively; and
- our business is affected by the ongoing COVID-19 pandemic and may be significantly adversely affected as the pandemic continues or if other events out of our control disrupt our business or that of our third-party providers.

The Securities We May Offer

We may offer shares of our common stock, preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or as units in combination with other securities, with a total value of up to \$25,000,000 from time to time under this prospectus at prices and on terms to be determined at the time of any offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

- designation or classification;
- aggregate principal amount or aggregate offering price;
- maturity;
- original issue discount;
- rates and times of payment of interest or dividends;
- redemption, conversion, exercise, exchange or sinking fund terms;
- ranking;
- restrictive covenants;
- voting or other rights;
- conversion or exchange prices or rates and, if applicable, any provisions for changes to or adjustments in the conversion or exchange prices or rates and in the securities or other property receivable upon conversion or exchange; and
- a discussion of material United States federal income tax considerations, if any.

The prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change information contained in this prospectus or in documents we have incorporated by reference. However, no prospectus supplement or free writing prospectus will offer a security that is not registered and described in this prospectus at the time of the effectiveness of the registration statement of which this prospectus is a part.

We may sell the securities directly to investors or to or through agents, underwriters or dealers. We and our agents, underwriters or dealers reserve the right to accept or reject all or part of any proposed purchase of securities. If we do offer securities to or through agents, underwriters or dealers, we will include in the applicable prospectus supplement:

- the names of those agents, underwriters or dealers;
- applicable fees, discounts and commissions to be paid to them;
- details regarding over-allotment options, if any; and
- the net proceeds to us.

The following is a summary of the securities we may offer with this prospectus.

Common Stock

We may issue shares of our common stock from time to time. Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our certificate of incorporation, as amended (the "Certificate of Incorporation") and amended and restated bylaws (the "Bylaws"), our stockholders do not have cumulative voting rights. Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the Board of Directors out of legally available funds. In the event of our liquidation, dissolution or winding up, holders of common stock are entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock. Holders of shares of our common stock do not have preemptive, subscription, redemption, or conversion rights, and there are no sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

We may issue shares of our preferred stock from time to time in one or more series. Our Board of Directors will determine the designations, voting powers, preferences and rights of the preferred stock, as well as the qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, preemptive rights, terms of redemption or repurchase, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of any series. Convertible preferred stock will be convertible into our common stock or exchangeable for other securities. Conversion may be mandatory or at the holder's option and would be at prescribed conversion rates. If we sell any series of preferred stock under this prospectus, we will fix the designations, voting powers, preferences and rights of such series of preferred stock, as well as the qualifications, limitations or restrictions thereof, in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock that we are offering before the issuance of the related series of preferred stock.

We urge you to read the applicable prospectus supplement (and any free writing prospectus that we may authorize to be provided to you) related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

Debt Securities

We may issue debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. The senior debt securities will rank equally with any other unsecured and unsubordinated debt. The subordinated debt securities will be subordinate and junior in right of payment, to the extent and in the manner described in the instrument governing the debt, to all of our senior indebtedness. Convertible debt securities will be convertible into or exchangeable for our common stock or other securities. Conversion may be mandatory or at the holder's option and would be at prescribed conversion rates.

Any debt securities issued under this prospectus will be issued under one or more documents called indentures, which are contracts between us and a national banking association or other eligible party as trustee. In this prospectus, we have summarized certain general features of the debt securities. We urge you, however, to read the applicable prospectus supplement (and any free writing prospectus that we may authorize to be provided to you) related to the series of debt securities being offered, as well as the complete indentures that contain the terms of the debt securities. A form of indenture has been filed as an exhibit to the registration statement of which this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of the debt securities being offered will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports that we file with the SEC.

Warrants

We may issue warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series. We may issue warrants independently or as units in combination with common stock, preferred stock and/or debt securities, and the warrants may be attached to or separate from these securities. In this prospectus, we have summarized certain general features of the warrants.

We urge you, however, to read the applicable prospectus supplement (and any free writing prospectus that we may authorize to be provided to you) related to the series of warrants being offered, as well as any warrant agreements and warrant certificates that contain the terms of the warrants. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant and/or the warrant agreement and warrant certificate, as applicable, that contain the terms of the particular series of warrants we are offering, and any supplemental agreements, before the issuance of such warrants.

Any warrants issued under this prospectus may be evidenced by warrant certificates. Warrants also may be issued under an applicable warrant agreement that we enter into with a warrant agent. We will indicate the name and address of the warrant agent, if applicable, in the prospectus supplement relating to the particular series of warrants being offered.

Units

We may issue units consisting of any combination of the other types of securities offered under this prospectus in one or more series. We may evidence each series of units by unit certificates that we will issue under a separate agreement. We may enter into unit agreements with a unit agent. Each unit agent will be a bank or trust company that we select. We will indicate the name and address of the unit agent in the applicable prospectus supplement relating to a particular series of units.

In this prospectus, we have summarized certain general features of the units under "Description of Units." We urge you, however, to read the applicable prospectus supplement (and any related free writing prospectus that we may authorize to be provided to you) related to the series of units being offered, as well as the complete unit agreement that contains the terms of the units. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the specific unit agreement that contains the terms of the particular series of units we are offering before the issuance of such units.

RISK FACTORS

Investing 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 under the heading "Risk Factors" contained in the applicable prospectus supplement and any related free writing prospectus, and the following information about these risks, together with the other information appearing elsewhere in this prospectus, together with the risks and uncertainties discussed under the section entitled "Risk Factors" contained in our most recent Annual Report on Form 10-K, as may be updated by subsequent annual, quarterly and other reports that are incorporated by reference into this prospectus in their entirety. The risks described in these documents are not the only ones we face, but those that we consider to be material. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. Please also read carefully the section below entitled "Forward-Looking Statements."

Risks Related to the Acquisition

The combined company may not experience the anticipated strategic benefits of the Acquisition.

While we anticipate benefits from the Acquisition, we may not be able to realize the expected benefits. Despite due diligence we could assume previously unidentified or contingent liabilities. Ownership of a CAP/CLIA laboratory and related services business may not have the clinical value and commercial potential which we envision. Any substantive failure of the Acquisition to meet our expectations could have a material negative effect on our results of operations. There can be no assurance that the anticipated benefits of the Acquisition will materialize or that if they materialize will result in increased stockholder value or revenue stream to the combined company.

We may not be able to enforce claims with respect to the representations, warranties and indemnities that Village Oaks has provided to us under the Asset Purchase Agreement.

In connection with the Acquisition, Village Oaks has given certain representations, warranties and indemnities. There can be no assurance we will be able to enforce any claims against Village Oaks' breaches of such representations, warranties or indemnities. Village Oaks' liability with respect to breaches of such representations and warranties and indemnities under the Asset Purchase Agreement may be limited or the amount and coverage of any insurance obtained with respect to representations and warranties may be limited. Even if we ultimately succeed in recovering any amounts, we may temporarily be required to bear these losses ourselves.

We are unable to precisely estimate when we will begin to generate significant profit from revenue, if ever, from PPLS' services, nor to estimate the amount of profit or revenue that will be generated or the expenses that will be incurred.

We do not expect to immediately derive profit from revenue from PPLSs services. Once we begin to generate such profit, there is no guarantee that it will be sufficient to realize the expected financial benefits of the Acquisition. In addition, since we have limited experience operating a clinical laboratory, we may not accurately estimate the expenses we will incur.

Operating a clinical laboratory is a new business for us and the members of our management team have limited experience operating a CAP-accredited, CLIA-certified laboratory, which may limit the ability of investors to make an informed investment decision.

We have never operated a clinical laboratory. To date, only our Chief Operating Officer, Xavier Reveles, has operated a CAP-accredited, CLIA-certified clinical laboratory and therefore it may be difficult for investors to analyze our ability to successfully operate a clinical laboratory. Our management team may not successfully or efficiently manage our transition to operating a CAP-accredited and CLIA-certified laboratory subject to significant regulatory oversight and reporting obligations. These new obligations and constituents will require significant attention from our senior management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, financial condition, and operating results.

The combined company's actual financial position or results of operations after the anticipated Acquisition may differ materially from the unaudited pro forma financial information incorporated by reference in this prospectus.

The unaudited pro forma financial information incorporated by reference in this prospectus is not necessarily indicative of what the combined company's actual financial position or results of operations would have been had the Acquisition been completed on the dates indicated. The unaudited pro forma financial information reflects adjustments, which are based upon estimates, to allocate the purchase price to tangible and identifiable intangible assets acquired and liabilities assumed, based on their estimated acquisition-date fair values. The purchase price allocation reflected in this document is preliminary, and a final determination of the fair value of assets acquired and liabilities assumed will be based on the actual net tangible and intangible assets and liabilities of Village Oaks that existed as of the date on which the Acquisition was consummated. Accordingly, the final purchase accounting adjustments may differ materially from the pro forma information

Risks Related to Our Financial Position

Our business plan relies upon our ability to obtain additional sources of capital and financing. If the amount of capital we are able to raise from financing activities, together with our revenues from operations, is not sufficient to satisfy our capital needs, we may be required to cease operations.

Prior to 2022, we had not generated any revenue. During the year ended December 31, 2022, we generated approximately \$5,000 and during the nine months ended September 30, 2023 we generated approximately \$13,000 in revenue from royalties from sales of our first diagnostic test, CyPath[®] Lung by Village Oaks, a CAP-accredited, CLIA-certified clinical pathology laboratory to whom we had previously granted a license to develop CyPath[®] Lung for commercialization and to manufacture, use, market and sell CyPath[®] Lung as an LDT prior to the Acquisition, which license was assigned to and assumed by PPLS in connection with the Acquisition, that began a limited market launch in the second quarter of 2022 to pulmonologists in South Texas. During the nine months ended September 30, 2023, we also generated revenue from clinical flow cytometry services provided to Village Oaks related to CyPath[®] Lung in the approximate amount of \$10,500 and in connection with CyPath[®] Lung tests purchased by the U.S. Department of Defense in the approximate amount of \$14,250 for an observational study.

To become and remain profitable, we must succeed in developing and commercializing our diagnostic tests and therapeutic products that we expect will generate significant income in the planned timeframe. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our diagnostic and therapeutic technologies, obtaining regulatory approval for our diagnostic and therapeutic technologies, manufacturing, marketing and selling any diagnostic tests and therapeutic products for which we may obtain regulatory approval, and establishing and managing our collaborations at various phases of each diagnostic test and therapeutic product candidate's development. We are in the preliminary phases of these activities. We may never succeed in these activities and, even if we do, may never generate sufficient income to achieve profitability.

To become profitable, we must develop our diagnostic tests and therapeutic products, which will depend in large part on our ability to:

- Develop, enhance and protect our diagnostic tests and therapeutic products;
- Raise sufficient funding to support our diagnostic tests and therapeutic product development program(s);
- Complete pre-clinical testing;
- Obtain FDA clearance for our CyPath[®] Lung as an in vitro diagnostic;
- Expand commercialization of our first diagnostic test, CyPath[®] Lung, as an LDT under the CAP/CLIA guidelines and regulations administered by CMS and CAP;
- Develop and commercialize our first diagnostic test, CyPath[®] Lung, as a CE -marked test in accordance with the In Vitro Diagnostic Device Regulation (the "IVDR") of the EU;
- Synthesize, test, and attract licensing partners for drug conjugates, siRNAs, and other therapeutics (and methods for their use) developed by us;
- Develop and conduct human clinical studies to support the regulatory approval and marketing of our diagnostic test(s) and therapeutic product(s);
- Develop and manufacture the test(s) and product(s) to FDA standards, appropriate EU standards, and appropriate standards required for the commercialization of our tests and products in countries in which we seek to sell our diagnostic test(s) and therapeutic product(s);
- Obtain the necessary regulatory approvals to market our diagnostic test(s) and therapeutic product(s);
- Secure the necessary personnel and infrastructure to support the development, commercialization, and marketing of our diagnostic test(s) and therapeutic product(s); and
- Develop strategic relationships to support development, manufacturing, and marketing of our diagnostic test(s) and therapeutic product(s).

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our Company and could impair our ability to raise capital, expand our business, maintain the research and development efforts that were initially funded by the proceeds of our initial public offering and will continue to be funded by subsequent offerings, diversify our diagnostic tests and therapeutic product offerings, or even continue our operations. A decline in the value of our Company could also cause you to lose all or part of your investment.

We must raise additional capital to fund our operations in order to continue as a going concern.

As of December 31, 2022, we had an accumulated deficit of \$36.7 million. As of September 30, 2023, we had an accumulated deficit of \$42.2 million. We will need to raise further capital through the sale of additional equity or debt securities or other debt instruments, strategic relationships or grants, or other arrangements to support our future operations. Our business plan includes expansion for our commercialization efforts which will require additional funding. If we are unable to improve our liquidity position we may not be able to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to generate revenue and raise capital from financing transactions. Management anticipates that our cash resources are sufficient to continue operations through May 2024. Our future is dependent upon its ability to obtain financing and upon future profitable operations from the development of its new business opportunities. There can be no assurance that we will be successful in accomplishing these objectives. Without such additional capital, we may be required to curtail or cease operations and be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment. We have determined that our current liquidity position raises substantial doubt about our ability to continue as a going concern.

We have a limited operating history, which makes it difficult to evaluate our current business and future prospects.

We are a company with limited operating history, and our operations are subject to all of the risks inherent in establishing a new business enterprise. The likelihood of our success must be considered in light of the problems, expenses, difficulties, complications, and delays frequently encountered in connection with the formation of a new business, the development of new technologies or those subject to clinical testing, and the competitive and regulatory environment in which we will operate. To date, we have generated revenue from a limited market launch of CyPath[®] Lung in the South Texas area which began in the second quarter of 2022. There can be no assurance that we will be able to successfully expand our commercialization efforts or that we will obtain the necessary regulatory approvals that will allow us to expand our marketing efforts. We may not be able to maintain certification of CyPath[®] Lung as an LDT in accordance with CAP/CLIA guidance and regulations, or obtain approval of our diagnostic tests in development by the CMS, the FDA, European Medicines Agency, or Chinese National Medical Products Administration. Even if we do so and are also able to commercialize our diagnostic tests, we may never generate revenue sufficient to become profitable. Our failure to generate revenue and profit would likely cause our securities to decrease in

value or become worthless.

We will require additional financing to implement our Business Plan, which may not be available on favorable terms or at all, and we may have to accept financing terms that would place restrictions on us.

We believe that we must raise additional funds to be able to continue our business operations. We may not be able to obtain equity or debt financing on acceptable terms or at all to implement our growth strategy. As a result, adequate capital may not be available to finance our current development plan, take advantage of business opportunities, or respond to competitive pressures. If we are unable to raise additional funds, we may be forced to curtail or even abandon our Business Plan and focus on fewer commercial opportunities that may result in more limited growth than forecast.

Until such time, if ever, as we can generate substantial income from sale of our diagnostic test(s) and therapeutic product candidates, we expect to finance our cash needs through a combination of equity offerings, debt financings, and license and collaboration agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of the holders of our Common Stock (the “Common Stockholders”). In addition, the terms of any future financings may impose restrictions on our right to declare dividends or on the manner in which we conduct our business. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, or making acquisitions or significant asset sales.

If we raise additional funds through collaborations, strategic alliances or marketing, or distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs; or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our Common Stock.

Risks Related to our Diagnostic Product

Until we secure FDA clearance for our CyPath[®] Lung as a Class II in vitro diagnostic, our marketing efforts are limited.

In order to market our CyPath[®] Lung as a Class II in vitro diagnostic, we must receive clearance from the FDA as a Class II in vitro diagnostic. Until such time that we receive FDA clearance, which we may never receive, our marketing efforts are limited to marketing CyPath[®] Lung as an LDT. We intend to launch a pivotal trial later this year in an effort to attain such clearance; however, there can be no assurance that the trial will have favorable results or that it will generate the results necessary to obtain such clearance.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States, such as the European Medicines Agency.

Patient enrollment is affected by many other factors, including:

- the severity of the disease under investigation;
- the patient eligibility criteria for the study in question;
- the efforts to facilitate timely enrollment in clinical trials;
- our payments for conducting clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during the trial period; and
- the proximity and availability of clinical trial sites for prospective patients.

We are unable to forecast with precision our ability to enroll patients. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs, which would cause the value of our Company to decline and limit our ability to obtain additional financing.

Clinical trials are expensive, time-consuming, and may not be successful.

Clinical trials are expensive, time-consuming, and may not be successful. They involve the evaluation of diagnostic tests and testing of potential therapeutic agents and effective treatments in humans to determine the safety and efficacy of the diagnostic tests and therapeutic products necessary for an approved diagnostic and therapeutic technology. Many tests and products in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if our tests and products progress successfully through initial or subsequent human testing, they may fail in later phases of development. We may engage others to conduct our clinical trials, including clinical research organizations and government-sponsored agencies. These trials may not start or be completed as we forecast or may not achieve desired results.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing authorization or commercialize our diagnostic and therapeutic technologies, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product and test development programs;
- the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials for various reasons, including a finding that the participants are being exposed to unacceptable health risks;

- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials may be greater than we anticipate; or
- regulators may revise the requirements for approving our diagnostic or therapeutic technologies, or such requirements may not be as we anticipate.

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

- be delayed in obtaining marketing approval;
- not obtain marketing approval at all, which would seriously impair our viability;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as we intend or desire;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the diagnostic test or therapeutic product removed from the market after obtaining marketing approval.

Our product and test development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our diagnostic technology or allow our competitors to bring diagnostic tests and therapeutic products to market before we do, potentially impairing our ability to successfully commercialize our diagnostic and therapeutic technologies and harming our business and results of operations.

Risks Related to Our Diagnostic Tests

If our tests do not perform as expected, our operating results, reputation and business will suffer.

Our success depends on the market's confidence that PPLS can provide reliable, high-quality diagnostic services. There is no guarantee that the accuracy and reproducibility PPLS has demonstrated to date will continue as its test volume increases. We believe that PPLSs customers are likely to be particularly sensitive to test limitations and errors, including inaccurate test results. As a result, if PPLS does not perform its diagnostic services as expected, our operating results, reputation and business will suffer. We may be subject to legal claims arising from such limitations, errors or inaccuracies.

We may experience difficulties that delay or prevent our development, introduction or marketing of enhanced or new tests.

Our success may also depend on our ability to effectively introduce enhanced or new tests. The development of enhanced or new tests is complex, costly and uncertain. Furthermore, enhancing or developing new tests requires us to anticipate patients', clinicians' and payers' needs and emerging technology trends accurately. We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new tests. The research and development process in diagnostics generally takes a significant amount of time from the research and design stage to commercialization. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals. We may have to abandon a test in which we have invested substantial resources. In order to successfully commercialize tests that we may develop in the future, we may need to conduct lengthy, expensive clinical trials and develop dedicated sales and marketing operations or enter into collaborative agreements to achieve market awareness and demand. Any delay in the research and development, approval, production, marketing or distribution of enhanced or new tests could adversely affect our competitive position, branding and results of operations.

We cannot be certain that:

- any tests that we may enhance or develop will prove to be effective in clinical trials;
- we will be able to obtain, in a timely manner or at all, necessary regulatory approvals;
- any tests that we may enhance or develop will be ordered and used by healthcare providers;
- any tests that we may enhance or develop can be provided at acceptable cost and with appropriate quality; or
- any of our tests can be successfully marketed.

These factors, and other factors beyond our control, could delay the launch of enhanced or new tests.

If clinical testing of a particular diagnostic test or therapeutic product candidate does not yield successful results, then we will be unable to commercialize that test or product candidate.

We must demonstrate the product safety and efficacy of our candidates for diagnostic tests and therapeutic products in humans through extensive clinical testing. Our research and development programs are at an early stage of development. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of any test or product, including the following:

- the results of pre-clinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials;
- safety and efficacy results attained in early human clinical trials may not be indicative of results that are obtained in later clinical trials;
- after reviewing test results, we may abandon projects that we might previously have believed to be promising;
- we or our regulators may suspend or terminate clinical trials because the participating subjects or patients are being exposed to unacceptable health risks; and
- our test or product candidates may not have the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

Even if our diagnostic tests or therapeutic products receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if our products receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. If we do not generate significant product revenues, we may not become profitable. The degree of market acceptance of our products and tests, if approved for commercial sale, will depend on a number of factors, including:

- their efficacy, safety, and other potential advantages compared to alternative tests or products;
- our ability to offer them for sale at competitive prices;
- their convenience and ease of administration compared to alternative diagnostics or treatments;
- the willingness of the target patient population to try new diagnostic tests and of physicians to order these tests;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of governmental agencies and third-party medical insurance and adequate reimbursement for our diagnostic tests or therapeutic products;
- any restrictions on the use of our diagnostic tests or therapeutic products together with other diagnostic methods or therapeutic treatments;
- any restrictions on the use of our diagnostic tests or therapeutic products together with other medications;
- inability of certain types of patients to produce adequate samples for analysis in the use of our diagnostic tests;
- inability of certain types of patients to use our diagnostic tests or take our therapeutic products; and
- the prevalence and severity of side effects from our therapeutic products.

If we are unable to address and overcome these and similar concerns, our business and results of operations could be substantially harmed.

If we are unable to establish effective sales, marketing, and distribution capabilities or enter into agreements with third parties with such capabilities, we may not be successful in commercializing our diagnostic tests or therapeutic products if and when they are approved.

We have a limited sales or marketing infrastructure and limited experience in the sale, marketing, or distribution of our diagnostic tests and therapeutic products. To achieve commercial success for any diagnostic test or therapeutic product for which we obtain marketing approval, we will need to successfully establish and maintain relationships directly and with third parties to perform sales and marketing functions.

Factors that may inhibit our efforts to commercialize our diagnostic tests or therapeutic products on our own include:

- our inability to recruit, train, and retain adequate numbers of effective sales, technical support, and marketing personnel;
- the inability of sales personnel to obtain access to or educate physicians on the benefits of our diagnostic tests or therapeutic products;
- the lack of complementary diagnostic tests or therapeutic products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive diagnostic tests or therapeutic product lines;
- unforeseen costs and expenses associated with creating an independent sales, technical support, and marketing organization; and
- the inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

If we do not establish sales, marketing, and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our diagnostic tests or therapeutic products.

We are currently dependent upon our subsidiary, PPLS, for processing and sale of CyPath® Lung.

PPLS, our subsidiary, is currently the only licensee of CyPath® Lung and, therefore, we are dependent upon the efforts of PPLS, a CAP/CLIA clinical laboratory that is authorized to offer and perform our CyPath® Lung test for the generation of revenue. Revenue from CyPath Lung is generated through performance of testing by PPLS. PPLS performs testing when ordered by physicians for their patients. PPLS also generates revenue when performed in the context of an observational study conducted by the Department of Defense (the “DOD”) titled “Detection of Abnormal Respiratory Cell Populations in Lung Cancer Screening Patients Using the CyPath® Lung Assay,” and when performed for research and development on using bronchoalveolar lavage fluid as a biological sample to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection.

If we are unable to convince physicians of the benefits of our proposed diagnostic tests or therapeutic products, we may incur delays or additional expense in our attempt to establish market acceptance.

Broad use of our proposed diagnostic tests and products may require pathology laboratories and physicians to be informed regarding our proposed diagnostic tests and products and their intended benefits. Inability to carry out this physician education process may adversely affect market acceptance of our proposed diagnostic tests or therapeutic products. We may be unable to timely educate physicians regarding our proposed diagnostic tests or therapeutic products in sufficient numbers to achieve our marketing plans or to achieve acceptance of our diagnostic tests or therapeutic products. Any delay in physician education may materially delay or reduce demand for our diagnostic tests or therapeutic products. In addition, we may expend significant funds toward physician education before any acceptance or demand for our proposed diagnostic tests or therapeutic products is created, if at all.

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

The development and commercialization of new diagnostic and therapeutic technologies is highly competitive. We will always face competition with respect to any diagnostic and therapeutic technology that we may seek to develop or commercialize in the future, from major diagnostic and pharmaceutical companies, LDT laboratories, smaller diagnostic and pharmaceutical companies, and biotechnology companies worldwide. In 2022, we evaluated 67 companies advancing tests for the early detection of lung cancer that provided at least a scientific foundation for their tests. These competitors are investigating lung cancer screening and diagnostic methods that use various types of collected samples (blood, breath, nasal epithelial cells, saliva, sputum, and urine) or imaging systems. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

A substantial number of the companies against which we are competing or we may compete against in the future may have, significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved diagnostic tests or therapeutic products than we do. Mergers and acquisitions in the diagnostic, pharmaceutical, and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, sales, marketing, and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring technologies complementary to or necessary for our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize diagnostic tests or therapeutic products that are more accurate, more convenient, or less expensive than any diagnostic tests or therapeutic products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their diagnostic tests or therapeutic products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a stronger market position. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors.

We may be unable to compete in our target marketplaces, which could impair our ability to generate revenues, thus causing a material adverse impact on our results of operations.

Our success depends upon our ability to retain key executives and to attract, retain, and motivate qualified personnel, and the loss of these persons could adversely affect our operations and results.

We are highly dependent on the principal members of our management, scientific, and clinical teams, including Maria Zannes, J.D., our President and Chief Executive Officer, Vivienne Rebel, M.D., Ph.D., our Chief Science and Medical Officer and Executive Vice President, Xavier Reveles, MS, CG(ASCP)^{cm}, our Chief Operating Officer, and Michael Dougherty, CPA, MBA, our Chief Financial Officer, as well as Roby Joyce, MD, the Medical and Laboratory Director of PPLS and the principal of Village Oaks.

The loss of the services of any of our executive officers or other members of our management team could impede the achievement of our research, development, and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize diagnostic tests or therapeutic products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain, or motivate key personnel on acceptable terms given the competition among numerous biotechnology companies for similar expertise. We also face competition from universities and research institutions for qualified scientific and clinical personnel. In addition, we rely and expect to continue to rely to a significant degree on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be engaged by other entities and may have commitments under consulting or advisory contracts that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Our lack of operating experience may make it difficult to manage our growth which could lead to our inability to implement our Business Plan.

We have limited experience in marketing and the selling of diagnostic tests and pharmaceutical products. Any growth will require us to expand our management and our operational and financial systems and controls. If we are unable to do so, our business and financial condition would be materially harmed. If rapid growth occurs, it may strain our operational, managerial, and financial resources.

If we fail to comply with our obligations imposed by any intellectual property licenses with third parties that we may need in the future, we could lose rights that are important to our business.

We may in the future require licenses to third-party technology and materials. Such licenses may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on our business and financial condition. We may rely on third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. Even if we acquire the right to control the prosecution, maintenance, and enforcement of the licensed and sublicensed intellectual property relating to our diagnostic tests or therapeutic product candidates, we may require the cooperation of our licensors and any upstream licensor, which may not be forthcoming. Therefore, we cannot be certain that the prosecution, maintenance, and enforcement of these patent rights will be in a manner consistent with the best interests of our business. If we or our licensor fail to maintain such patents, or if we or our licensor lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our diagnostic tests or therapeutic product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we may own in the future. Further, if we fail to comply with our diligence, development and commercialization timelines, milestone payments, royalties, insurance, and other obligations under our license agreements, we may lose our patent rights with respect to such agreement, which would affect our patent rights worldwide.

Termination of any future license agreements would reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other diagnostic tests or therapeutic product candidates, which could have a material adverse effect on our operating results and overall financial condition.

In addition, intellectual property rights that we in-license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our diagnostic tests or therapeutic product candidates may

be materially harmed.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We currently own intellectual property directed to our diagnostic tests, therapeutic product candidates and other proprietary technologies. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our diagnostic tests or therapeutic product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use, or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors access to the same technologies licensed to us.

Moreover, some of our owned and in-licensed patents or patent applications or future patents may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing diagnostic tests or therapeutic products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We will depend on third parties to manufacture and market our diagnostic tests and to design trial protocols, arrange for and monitor the clinical trials, and collect and analyze data.

We do not have, and do not now intend to develop, facilities for the manufacture of the contents of our collection kits needed for clinical or commercial production. In addition, we are not a party to any long-term agreement with any of our suppliers such as the reagents used in processing sputum samples, and accordingly, we have the products used in our diagnostic tests manufactured on a purchase-order basis from primary suppliers. We have entered into relationships with manufacturers on a contract basis but will need to expand those relationships. We expect to depend on such collaborators to supply us with reagents and other materials manufactured in compliance with standards imposed by the CMS, FDA, and foreign regulators.

Moreover, as we develop our diagnostic tests or therapeutic products eligible for clinical trials, we intend to contract with independent parties to design the trial protocols, arrange for and monitor the clinical trials, and collect and analyze the data. In addition, certain clinical trials for our products may be conducted by government-sponsored agencies and will be dependent on governmental participation and funding. Our dependence on independent parties and clinical sites involves risks including reduced control over the timing and other aspects of our clinical trials.

We are exposed to product liability and pre-clinical and clinical liability risks which could place a substantial financial burden upon us, should we be sued.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing, and marketing of diagnostic tests and therapeutic products. Such claims may be asserted against us. In addition, using diagnostic tests and therapeutic products that may be developed with potential collaborators in our clinical trials and the subsequent sale of these tests and products by bioAffinity or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim, or series of claims, brought against us could have a material adverse effect on our business, financial condition, and results of operations.

While we have obtained product liability insurance covering CyPath[®] Lung as a commercialized LDT to be sold by a CAP-accredited, CLIA-certified clinical pathology laboratory (previously Village Oaks and currently PPLS), in the future we may not be able to obtain or maintain adequate product liability insurance, when needed, on acceptable terms, if at all, or such insurance may not provide adequate coverage against our potential liabilities. Furthermore, potential partners with whom we intend to have collaborative or strategic agreements or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient liquidity to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition, and results of operations.

In addition, we may be unable to obtain or to maintain clinical trial liability insurance on acceptable terms, if at all. Any inability to obtain and/or maintain insurance coverage on acceptable terms could prevent or limit the commercialization of any tests or products we develop.

Our collection, use and disclosure of personal information, including health and employee information, is subject to U.S. state and federal privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm.

The privacy and security of personal information stored, maintained, received or transmitted, including electronically, is a major issue in the U.S. and abroad. Numerous federal and state laws and regulations, including state privacy, data security and breach notification laws, federal and state consumer protection and employment laws, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and the Genetic Information Nondiscrimination Act of 2008, govern the collection, dissemination, use and confidentiality of personal information, including genetic, biometric and health information. These laws and regulations are increasing in complexity and number, may change frequently and sometimes conflict. Penalties for violations of these laws vary, but can be severe.

While we strive to comply with all applicable privacy and security laws and regulations, including our own posted privacy policies, these laws and regulations continue to evolve and any failure or perceived failure to comply may result in proceedings or actions against us by government entities or others or could cause us to lose customers, which could have a material adverse effect on our business. Recently, there has been an increase in public awareness of privacy issues in the wake of revelations about the data-collection activities of various government agencies and in the number of private privacy-related lawsuits filed against companies. Concerns about our practices with regard to the collection, use, retention, disclosure, or security of personal information or other privacy-related matters, even if unfounded and even if we are in compliance with applicable laws, could damage our reputation and harm our business.

If users of our proposed diagnostic tests or therapeutic products are unable to obtain adequate reimbursement from third-party payors or governmental agencies or if new restrictive legislation is adopted, market acceptance of our proposed tests or products may be limited, and we may not achieve revenues.

The continuing efforts of government and insurance companies, health maintenance organizations ("HMOs") and other payors of healthcare costs to contain or reduce costs may affect our future revenues and profitability, as well as the future revenues and profitability of our potential customers, suppliers, and collaborative partners and the availability of capital. For example, in certain international markets, pricing or profitability of diagnostic tests and therapeutic products is subject to government control. In the U.S., given recent federal and state government initiatives directed at lowering the total cost of healthcare, the U.S. Congress and state legislatures will likely continue to focus on healthcare reform, the cost of medical devices, tests, and prescription pharmaceuticals, and Medicare and Medicaid reforms. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition, and results of operations.

Our ability to commercialize our proposed tests or products will depend in part on the extent to which appropriate reimbursement levels for the cost of our tests or products are obtained by governmental authorities, private health insurers, and other organizations such as HMOs. Governmental agencies and third-party payors are increasingly challenging the prices charged for medical tests, drugs, and services. Also, the trend toward managed healthcare in the U.S. and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of healthcare services, diagnostics, and drugs, as well as legislative proposals to reform healthcare or reduce government insurance programs, may all result in lower prices for or rejection of our tests or products.

Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, vendors and agents acting on behalf of us or our affiliates. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA or foreign health authorities; provide true, complete and accurate information to the FDA or foreign health authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and others play a primary role in the recommendation ordering and prescription of any diagnostic tests or therapeutic products for which we obtain marketing approval. Our operations and current and future arrangements with investigators, healthcare professionals, customers, and third-party payors are subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws, and the Physician Payments Sunshine Act and regulations. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing, and education programs and constrain the business of financial arrangements and relationships with healthcare providers and other parties through which we may market, sell, and distribute our diagnostic tests or therapeutic products for which we obtain marketing approval. In addition, we may be subject to additional healthcare, statutory, and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain arrangements with physicians who receive stock, warrants or stock options as compensation for services provided to us, do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

The market for our proposed tests and products is competitive and rapidly changing, and new diagnostic technologies which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The diagnostic, pharmaceutical, and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our proposed tests or products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from diagnostic, pharmaceutical and biotechnology companies, universities, governmental entities, and others diversifying into the field is intense and is expected to increase.

As a company engaged in the development of diagnostic technology with limited revenue generated to date, our resources are limited, and we may experience technical challenges inherent in such technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar diagnostic efficacy compared to our proposed tests or products. Our competitors may develop diagnostic technologies that are more effective or less costly than our proposed tests or products and therefore present a serious competitive threat.

The potential widespread acceptance of diagnostic tests or therapies that are alternatives to ours may limit market acceptance of our proposed tests or products, even if commercialized. Many of our targeted diseases and conditions can also be detected by other tests or treated by other medications. These tests and treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive technologies may limit the potential for our technologies, formulations, tests, and products to receive widespread acceptance if commercialized.

Healthcare cost containment initiatives and the growth of managed care may limit our returns.

Our ability to commercialize our diagnostic tests and therapeutic products successfully may be affected by the ongoing efforts of governmental and third-party payors to contain the cost of healthcare. These entities are challenging prices of healthcare products and services, denying or limiting coverage and reimbursement amounts for new diagnostic tests and therapeutic products, CAP/CLIA-validated LDTs and FDA-approved diagnostic tests and therapeutic products considered experimental or investigational or which are used for disease indications without FDA marketing authorization. Even if we succeed in bringing any tests or products to the market, they may not be considered cost-effective, and governmental or third-party reimbursement might not be available or sufficient. If adequate governmental or third-party coverage is not available, we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and development for new tests and products. In addition, legislation and regulations affecting the pricing of diagnostic tests, pharmaceuticals, or healthcare services may change in ways adverse to us before or after any of our proposed tests and products are approved for marketing.

Our competitive position depends on protection of our intellectual property.

Development and protection of our intellectual property are critical to our business. If we do not adequately protect our intellectual property, or if competitors develop technologies incorporating the same or similar technologies that already are in the public domain, those competitors may be able to develop similar technologies to our own. Our success depends in part on our ability to obtain patent protection for our diagnostic tests, therapeutic products, or processes in the U.S. and other countries, protect trade secrets, and prevent others from infringing on our proprietary rights.

Since patent applications in the U.S. are maintained in secrecy for at least portions of their pendency periods (published on U.S. patent issuance or, if earlier, 18 months from earliest filing date for most applications) and since other publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain

that we are or will be the first to make the inventions to be covered by our patent applications. The patent position of biopharmaceutical and biotechnology firms generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents.

The patent applications we file, including applications that will follow the filing of provisional patents, may not issue. As patents or the claims of any issued patents may not afford meaningful protection for our technologies, tests, or products. In addition, patents issued to us or to any future licensors may be challenged and subsequently narrowed, invalidated, or circumvented. Patent litigation is widespread in the biotechnology industry and could harm our business. Litigation might be necessary to protect our patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue such litigation or to protect our patent rights.

Although we have executed assignment of invention agreements with current scientific and technical employees and in the future will require our scientific and technical employees and consultants to enter into broad assignment of invention agreements, and all of our employees, consultants, and corporate partners with access to proprietary information enter into confidentiality agreements, these agreements may not be honored.

Diagnostic tests and therapeutic products we develop could be subject to infringement claims asserted by others.

We cannot assure that diagnostic tests and therapeutic products based on our patents or intellectual property that we license from others will not be challenged by a third-party claiming infringement of its proprietary rights. If we are not able to successfully defend patents that may be issued to us, that we may acquire, or that we may license in the future, we may have to pay substantial damages or licensing fees, possibly including treble damages, for past infringement.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming, and ultimately unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we intend to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly, or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect us.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology, we also intend to rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position. We have executed and will continue to seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors, and other third parties. We also have executed and will continue to seek to enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Our internal information technology systems, or those of our third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our diagnostic tests' or therapeutic product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party clinical research organizations and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, extortion, account takeover attacks, degradation of service attacks, denial-of-service attacks, "phishing," or social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to data leakage. We have technology security initiatives and disaster recovery plans in place to mitigate our risk to these vulnerabilities, but these measures may not be adequately designed or implemented to ensure that our operations are not disrupted or that data security breaches do not occur. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage.

Hackers and data thieves are increasingly sophisticated and operate large-scale and complex automated attacks which may remain undetected until after they occur. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our diagnostic tests and therapeutic product candidates could be delayed. In addition, the loss of clinical trial data for our diagnostic tests and therapeutic product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. Like all businesses we may be increasingly subject to ransomware or other malware that could significantly disrupt our business operations, or disable or interfere with necessary access to essential data or processes. Numerous recent attacks of this nature have also involved exfiltration and disclosure of sensitive or confidential personal or proprietary information, or intellectual property, when the victim companies have not paid the cyber criminals substantial ransom payments. For example, any such event that leads to unauthorized access, use, disclosure, unavailability, or compromised integrity of personal or other sensitive or essential information, including personal information regarding

our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, increase the costs we incur to protect against such information security breaches, such as increased investment in technology, render key personnel unable to perform duties or communicate throughout the organization and otherwise subject us to fines and other liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

The costs of mitigating cybersecurity risks are significant and are likely to increase in the future. These costs include, but are not limited to, retaining the services of cybersecurity providers; compliance costs arising out of existing and future cybersecurity, data protection and privacy laws and regulations; and costs related to maintaining redundant networks, data backups and other damage-mitigation measures. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage of any future claim.

Risks Related to the Operation of PPLS

The operations of PPLS will depend in part upon Dr. Roby Joyce and his relationship with existing customers and our ability to establish relationships with these customers.

PPLS' future success will depend in significant part upon the continued relationships with existing customers, many of whom have developed professional relationships with Dr. Roby Joyce. Dr. Joyce has executed an employment agreement to continue as is the Medical and Laboratory Director of PPLS and is a member of the bioAffinity Board of Directors. However, we cannot assure you that we will be able to retain his services. Although we have entered into a three-year employment agreement with him, there can be no assurance that the agreement will not be terminated prior to its expiration. We do not have an insurance policy on the life of Dr. Joyce, and we do not have "key person" life insurance policies for any of our other officers or advisors. The loss of the technical knowledge and management and industry expertise of Dr. Joyce or any of our key personnel could result in delays in services, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

PPLS may be unable to effectively maintain its equipment or generate revenue when its equipment is not operational.

Timely, effective service is essential to maintaining PPLS' reputation and high use rates. Although it has agreements with a third-party equipment service providers pursuant to which such service providers maintain and repair its equipment, the agreement does not compensate it for loss of revenue when its systems are not fully operational and its business interruption insurance may not provide sufficient coverage for the loss of revenue. Also, third-party equipment service providers may not be able to perform repairs or supply needed parts in a timely manner, which could result in a loss of revenue. Therefore, if PPLS experiences more equipment malfunctions than anticipated or if it is unable to promptly obtain the service necessary to keep its equipment functioning effectively, or where its business or data is compromised on account of equipment malfunctions or a cybersecurity-related attack, PPLS's ability to provide services and to fulfill its contractual arrangements would be adversely affected and our revenue could decline.

If PPLS becomes damaged or inoperable, loses its accreditation or is required to vacate the facility, PPLS' ability to sell its products or provide diagnostic assays may be jeopardized.

Our only CLIA-certified, CAP-accredited, and state-licensed laboratory is PPLS. Its facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, flooding and power outages, which may render it difficult or impossible for it to provide pathology services or perform our diagnostic assays for some period of time. The inability of PPLS to perform its services for its customers if its facility is inoperable for even a short period of time, may result in the loss of customers or harm to its reputation or relationships with its customers, and it may be unable to regain those customers or repair its reputation in the future. Furthermore, PPLS facilities and the equipment it uses to perform its services could be costly and time-consuming to repair or replace.

Further, if PPLS' current or future CLIA-certified, CAP-accredited, and state-licensed laboratory becomes inoperable or unqualified in any way it may not be able to license or transfer its technology to another facility with the necessary qualifications, including state licensure and CLIA certification, under the scope of which its current assays and its planned future assays could be performed. Even if PPLS finds a facility with such qualifications to perform its assays, it may not be available to PPLS on commercially reasonable terms.

PPLS relies on commercial delivery services to transport sputum samples to PPLS for processing the CyPath[®] Lung test in a timely and cost-efficient manner and if these delivery services are disrupted, its business will be harmed.

PPLS' business depends on its ability to quickly and reliably deliver test results to its customers. Sputum samples are received overnight within the United States through commercial delivery services for analysis at the clinical pathology laboratory located in San Antonio, Texas. Disruptions in delivery service, whether due to bad weather, natural disaster, terrorist acts or threats or for other reasons could adversely affect specimen integrity and its ability to process samples in a timely manner and to service its customers, and ultimately its reputation and its business. In addition, if PPLS is unable to continue to obtain such expedited delivery services at commercially reasonable prices, its operating results may be adversely affected.

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

In the ordinary course of its business, PPLS collects and stores sensitive data, including legally-protected health information, credit card information and personally identifiable information, such as data collected in connection with the CyPath[®] Lung diagnostic test results. PPLS also stores sensitive intellectual property and other proprietary business information, including that of its customers, payers and collaboration partners. PPLS manages and maintains its applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. These applications and data encompass a wide variety of business critical information, including research and development information, commercial information and business and financial information. PPLS is highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store this critical information. Although its policies and practices adhere to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and PPLS employs measures to protect sensitive information from unauthorized access or disclosure, its information technology and infrastructure, and that of its third-party billing and collections providers, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions.

A security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm PPLS' reputation, compel PPLS, to comply with state breach notification laws, subject PPLS to mandatory corrective action, require PPLS to verify the correctness of database contents and otherwise subject PPLS to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If PPLS is unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, its operations could be disrupted, and it may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Any such breach or interruption could compromise PPLS' networks, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure, modification of, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt PPLS' operations, including its ability to perform tests, provide test results, bill payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, develop and commercialize tests, collect, process and

prepare company financial information, provide information about tests, educate patients and clinicians about services and manage the administrative aspects of its business, any of which could damage its, and our, reputation and adversely affect our business. Any such breach could also result in the compromise of PPLS proprietary information which could adversely affect our competitive position.

In addition, the interpretation and application of health-related, privacy and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with PPLS' practices. If so, this could result in government-imposed fines or orders requiring that it change its practices, which could adversely affect our business and its, and our, reputation. Complying with these various laws could cause us to incur substantial costs or require PPLS to change its business practices and compliance procedures in a manner adverse to our business.

If PPLS uses hazardous chemicals in a manner that causes injury, it could be liable for damages.

PPLS' activities currently require the controlled use of potentially harmful chemicals. PPLS cannot eliminate the risk of accidental contamination or injury to employees or third-parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, PPLS could be held liable for any resulting damages, and any liability could exceed its resources or any applicable insurance coverage it may have. Additionally, PPLS is subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could have a material adverse effect on its, and therefore our, financial condition, results of operations and cash flows. In the event of an accident or if PPLS otherwise fails to comply with applicable regulations, it could lose its permits or approvals or be held liable for damages or penalized with fines.

If PPLS is unable to successfully scale its operations to support demand for CyPath[®] Lung, its business could suffer.

As test volume of CyPath[®] Lung grows, PPLS will need to continue to ramp up its testing capacity, implement increases in scale and related processing, customer service, billing and systems process improvements, and expand its internal quality assurance program and technology platform to support testing on a larger scale. PPLS will also need additional equipment and certified laboratory personnel to process higher volumes of our tests. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented by PPLS or that equipment and appropriate personnel will be available. As additional tests are developed, PPLS may need to bring new equipment on-line, implement new systems, technology, controls and procedures and hire personnel with different qualifications.

The value of CyPath[®] Lung depends, in large part, on PPLS' ability to perform the tests on a timely basis and at high-quality, and on its reputation for such timeliness and quality. Failure to implement necessary procedures or to hire the necessary personnel could impact its ability to meet market demand. There can be no assurance that it will be able to perform tests on a timely basis at a level consistent with demand, that its efforts to scale its commercial operations will not negatively affect the quality of test results or that it will be successful in responding to the growing complexity of testing operations.

In addition, PPLS' growth may place a significant strain on its management, operating and financial systems and its sales, marketing and administrative resources. As a result of its growth, PPLS' operating costs may escalate even faster than planned, and some of its internal systems may need to be enhanced or replaced. If we cannot effectively manage PPLS' expanding operations and its costs, we may not be able to grow effectively or we may grow at a slower pace, and our business could be adversely affected.

Billing for PPLS' services is complex, and PPLS must dedicate substantial time and resources to the billing process to be paid.

PPLS has executed an agreement for third-party billing services with a national firm specializing in pathology, laboratory and radiology billing services to provide billing services for its business. Nonetheless, PPLS is responsible for billing for clinical laboratory services that can be complex, time-consuming and expensive. Depending on the billing arrangement with insurance carriers and clients, and applicable law, PPLS bills various payors, including Medicare, insurance companies and patients, all of which have different billing requirements. It generally bills third-party payors for its diagnostic assays and pursues reimbursement on a case-by-case basis where pricing contracts or Medicare reimbursement is not in place. To the extent laws or contracts require it to bill patient co-payments or co-insurance, PPLS must also comply with these requirements. PPLS may also face increased risk in its collection efforts, including potential write-offs of doubtful accounts and long collection cycles, which could adversely affect its business, results of operations and financial condition.

Several factors make the billing process complex, including:

- the reimbursement rates of payors;
- compliance with complex federal and state regulations related to billing Medicare;
- risk of government audits related to billing Medicare;
- disputes among payors as to which party is responsible for payment;
- differences in coverage and in information and billing requirements among payors, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance;
- changes to billing codes and/or coverage policies that apply to PPLS' assays;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

PPLS uses standard industry billing codes, known as Current Procedural Terminology, or CPT, codes, to bill for its diagnostic assays. These codes can change over time. When codes change, there is a risk of an error being made in the claim adjudication process. These errors can occur with claims submission, third-party transmission or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received. Coding changes, therefore, may have an adverse effect on PPLS' revenues. There can be no assurance that payors will recognize these codes in a timely manner or that the process of transitioning to such a code and updating their billing systems and PPLS will not result in errors, delays in payments and a related increase in accounts receivable balances.

As PPLS introduces new assays, PPLS will need to add new codes to its billing process as well as its financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect its collection rates, revenue, and cost of collecting.

Additionally, PPLS' billing activities require its third-party billing provider to implement compliance procedures and oversight, train and monitor its employees, challenge coverage and payment denials, assist patients in appealing claims, and require PPLS to undertake audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that PPLS may be required to return some portion of prior payments it has received. These billing complexities, and the related uncertainty in obtaining payment for its assays, could negatively affect its revenue and cash flow, its ability to achieve profitability, and the consistency and comparability of its, and therefore our, results of operations.

PPLS relies on a third-party billing provider, and an in-house billing function, to transmit claims to payors, and any delay in transmitting claims could have an adverse effect on its revenue.

While PPLS manages the overall processing of claims, it relies on a third-party billing provider to transmit the actual claims to payors based on the specific payor billing format. Claims processing could be delayed if its third-party provider makes changes to its invoicing system. Additionally, coding for diagnostic assays may change, and such changes may cause short-term billing errors that may take significant time to resolve. If claims are not submitted to payors on a timely basis or are erroneously submitted, or if PPLS is required to switch to a different provider to handle claim submissions, it may experience delays in its ability to process these claims and receipt of payments from payors, or possibly denial of claims for lack of timely submission, which would have an adverse effect on its, and therefore our, revenue and business.

Risks Related to Intellectual Property Rights

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make diagnostic tests and therapeutic product candidates that are the same as or similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive tests and products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that are directed to our diagnostic tests and product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing diagnostic tests and product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties; and
- if enforced, a court may not hold that our patents are valid, enforceable, and infringed.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our diagnostic tests and therapeutic product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "***Leahy-Smith Act***"), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the United States Patent and Trademark Office (the "***USPTO***") during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering

an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our diagnostic tests and therapeutic product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date. Thus the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the 2013 case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse, can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our diagnostic tests or therapeutic product candidates, our competitive position would be adversely affected.

Patent terms may be inadequate to protect our competitive position on our diagnostic tests or therapeutic product candidates for an adequate amount of time.

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors obtain patents covering our diagnostic tests and therapeutic product candidates, when the terms of all patents covering a diagnostic test or therapeutic product expire, our business may become subject to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review and approval of new diagnostic test or therapeutic product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing diagnostic tests and therapeutic products similar or identical to ours.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or a licensee initiate legal proceedings against a third party to enforce a patent covering one of our diagnostic tests or therapeutic product candidates, the defendant could counterclaim that the patent covering our diagnostic tests or therapeutic product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our diagnostic tests or therapeutic product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our diagnostic tests or therapeutic product candidates. Such a loss of patent protection could have a material adverse impact on our business.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our diagnostic tests or therapeutic product candidates, our business may be harmed.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing authorization of our diagnostic tests or therapeutic product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "*Hatch-Waxman Act*"), which permits a patent term extension of up to five years for a patent covering an approved diagnostic test or therapeutic product as compensation for effective patent term lost during diagnostic test or therapeutic product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of diagnostic test or therapeutic product approval, and only claims covering such approved diagnostic test or drug product, a method for using it or a method for manufacturing it may be extended. In Europe, our diagnostic test or therapeutic product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such an extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing diagnostic tests or products sooner. The resulting reduction of years of revenue from applicable diagnostic tests or products could be substantial.

We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering our diagnostic tests and therapeutic product candidates in all countries throughout the world would be prohibitively expensive, and even in countries where we have sought protection for our intellectual property, such protection can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. In-licensing patents covering our diagnostic tests and therapeutic product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. And in-licensing or filing, prosecuting, and defending patents even in only those jurisdictions in which we develop or commercialize our diagnostic tests and therapeutic product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own diagnostic tests and therapeutic products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but where enforcement is not as strong as that in the United States or Europe. These diagnostic tests and products may compete with our diagnostic tests and therapeutic product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, particularly those relating to biotechnology tests and products, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing tests and products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put at risk our or our licensors' patents of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' patent applications not issuing, or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our diagnostic tests and product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our diagnostic tests and product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition in those jurisdictions.

In some jurisdictions including European countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions.

Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and tradenames to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and tradenames may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our therapeutic product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Government Regulations

CyPath[®] Lung is currently being offered as an LDT by PPLS. Should the FDA disagree that CyPath[®] Lung is an LDT, or if the FDA's regulatory approach to LDTs should change in the future, our commercialization strategy may be adversely affected, which would negatively affect our results of operations and financial condition.

The FDA considers an LDT to be a test that is developed, validated, and performed within a single laboratory. The FDA has historically asserted its authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), but it has generally exercised enforcement discretion with regard to LDTs. This means that even though the FDA believes it can impose regulatory requirements on LDTs, such as requirements to obtain premarket approval, *de novo* classification, or clearance of LDTs, it has generally chosen not to enforce those requirements. The FDA has, on occasion, sent warning letters to laboratories offering LDTs that the agency believed were not eligible for enforcement discretion because of how they were developed, validated, performed or marketed and consequent risks to the public.

There have been numerous legislative proposals to clarify the FDA's regulatory authority over medical devices. These include two bills reintroduced in 2021: the VALID Act, which would expressly grant the FDA authority to regulate LDTs under a risk-based framework; and the VITAL Act, which would assign LDTs to regulation solely under CLIA and would direct CMS to update its CLIA regulations. We cannot predict if either of these bills will be enacted in their current (or any other) form and cannot quantify the effect of these bills on our business. In the meantime, the regulation by the FDA of LDTs remains uncertain.

If FDA premarket review, classification or approval is required for CyPath[®] Lung before we obtain *de novo* classification, our phased strategy for market entry would be adversely affected. Our laboratory licensee, PPLS, could be forced to stop marketing CyPath[®] Lung while we work to obtain *de novo* classification. Our business, results of operations and financial condition would be negatively affected unless and until such review were completed and our request for *de novo* classification were granted.

Although we do intend to conduct clinical trials in order to receive clearance from the FDA as a Class II in vitro diagnostic, there can be no assurance that the trial will have favorable results or that it will generate the results necessary to obtain such clearance.

Delay by or failure of the FDA to grant our request for de novo classification, or failure on our part to comply with applicable requirements, would adversely affect our business, results of operations and financial condition.

The FDCA requires that medical devices introduced to the United States market, unless exempted by regulation, be authorized by the FDA pursuant to either the premarket notification pathway, known as 510(k) clearance, the *de novo* classification pathway, or the Premarket Approval ("*PMA*") pathway. We plan to seek *de novo* classification for the CyPath[®] Lung test in the second quarter of 2026. The FDA may not agree that CyPath[®] Lung meets the criteria for *de novo* classification, in which case we would be required to submit a PMA to obtain marketing authorization, which would require manufacturing information and a pre-approval inspection of the manufacturing facilities and could require review by an FDA advisory panel comprised of experts outside the FDA. Any delay by or failure of the FDA to grant our *de novo* request or PMA could adversely affect our consolidated revenues, results of operations and financial condition.

Additionally, obtaining FDA marketing authorization, approval or *de novo* classification for diagnostics can be expensive, time consuming and uncertain, and for higher-risk devices can take several years and requires detailed and comprehensive scientific and clinical data. In addition, medical devices are subject to ongoing FDA obligations and continued regulatory oversight and review. Ongoing compliance with FDA regulations increases the cost of conducting our business and subjects us to heightened regulation by the FDA and penalties for failure to comply with these requirements.

Failure by us or our subsidiary, PPLS, to comply with applicable laws pertaining to LDTs or IVDs could adversely affect our business, results of operations and financial condition.

The clinical laboratory testing sector is highly regulated in the United States. PPLS, our subsidiary and laboratory licensee, is accredited by CAP and holds a CLIA certificate of accreditation. Any failure by PPLS to comply with CLIA/CAP requirements could result in adverse findings on inspection that, if not timely corrected, could result in loss of accreditation and the inability to perform laboratory testing.

Additionally, certain states, including California, Maryland, Nevada, Pennsylvania, and Rhode Island, require laboratories testing specimens from their jurisdictions to hold an out-of-state laboratory license or permit. New York is exempt from, and imposes requirements in addition to, CLIA, including a requirement for test-specific permits of LDTs before they can be used to test specimens from patients in New York. The failure of PPLS to obtain state licenses or permits, where required, could interfere with our strategy for a national rollout of CyPath[®] Lung.

ICU Medical is providing the acapella[®] Choice Blue device to assist patients in expelling sputum out of the lungs into a collection cup noninvasively. This device is 510(k) cleared as a positive expiratory pressure device to help mobilize lung secretions in people with certain lung conditions. The device does not have a cleared indication for use as a specimen collection device. Promotion of the device by us or our partners for use of the device for specimen collection could cause the FDA to consider the device to be adulterated or misbranded in violation of the FDCA, and to require a 510(k) clearance for a specimen collection indication as a condition of distributing the device. Any disruption to our ability to distribute the acapella[®] Choice Blue could interfere with our ability to collect adequate patient samples necessary for CyPath[®] Lung.

CyPath[®] Lung also relies on a proprietary algorithm we used to develop and validate software integrated into the test procedure that generates the quantitative and qualitative diagnostic results that are included in the laboratory report. Certain types of standalone diagnostics software are subject to FDA regulation as a medical device (specifically, software as a medical device or “SaMD”). Some types of SaMD are subject to premarket authorization requirements. If the FDA were to conclude that we or our laboratory licensee is required to obtain premarket authorization for the software, our ability to offer CyPath[®] Lung as an LDT could be delayed or prevented, which would adversely affect our business.

The third-party licensors of our future therapeutic products, when ready, may be unable to obtain regulatory approval. The denial or delay of any such approval would delay commercialization of our future therapeutic products and have a material adverse effect on our potential to generate revenue, our business and our results of operations.

We plan to license our therapeutic candidates to third parties for development including clinical testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, recordkeeping, marketing, distribution, post-approval monitoring and reporting, and export and import. These activities that are to be undertaken by third-party licensees of our future therapeutic products are subject to extensive regulation by the FDA, and by foreign health authorities in other countries. These regulations differ from country to country. In the United States, we are not permitted to market our therapeutic product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following research and development, and thereafter the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. For our licensors to gain approval to market our product candidates, they must provide clinical data that adequately demonstrate the safety and efficacy of the product for the intended indication. We or any third party has not yet obtained regulatory approval to market any of our product candidates in the United States or any other country. Our business depends upon licensing our therapeutic products to third-party pharmaceutical companies that would obtain these regulatory approvals. The FDA can delay, limit or deny approval of these product candidates for many reasons, including:

- the inability of our licensors to satisfactorily demonstrate that the product candidates have acceptable safety and efficacy profiles for the requested indication;
- the FDA’s disagreement with the trial designs of our licensors or the interpretation of data from preclinical studies or clinical trials;
- the population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the full population for which we seek approval;
- the licensors’ inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA’s determination that additional preclinical or clinical trials are required;
- the FDA’s non-approval of the formulation, labeling or the specifications of our product candidates;
- the FDA’s failure to accept the manufacturing processes, drug product characteristics or facilities of third-party manufacturers with which we or the third-party licensors contract; or
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering clinical data related to any therapeutic product candidate insufficient for approval.

Even if eventually clinical testing approval of any regulatory filing for our product candidates is completed, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than the third party originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. If the FDA requires the licensors to narrow the indications to smaller patient subsets, the market opportunities for our product candidates, if approved, and the ability to generate revenues and royalties may be materially limited. To the extent the licensors seeks regulatory approval in foreign countries, they may face challenges similar to those described above with regulatory authorities in applicable jurisdictions.

Obtaining and maintaining regulatory approval of our diagnostic tests or therapeutic product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Failure to obtain regulatory approval in foreign jurisdictions would prevent our product candidates from being marketed abroad.

In addition to regulations in the United States, to market and sell our diagnostic tests and therapeutic products in the EU, many Asian countries and other jurisdictions, we must

obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing authorization of a diagnostic test or therapeutic product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the diagnostic test or therapeutic product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a diagnostic test or therapeutic product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our diagnostic tests or therapeutic products is also subject to approval. A diagnostic test or therapeutic product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the United States on a timely basis, if at all.

We may also submit marketing applications in other countries, such as countries in Europe or Asia. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our diagnostic tests or therapeutic products in any jurisdiction. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of diagnostic tests or therapeutic product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our diagnostic tests or therapeutic products in certain countries. We do not have any diagnostic tests or therapeutic product candidates approved for sale in any foreign jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we are unable to obtain approval of any of our diagnostic tests or therapeutic product candidates by regulatory or payor authorities in the EU, Asia or elsewhere, or if we fail to comply with the regulatory requirements in foreign jurisdictions, the commercial prospects of that diagnostic test or therapeutic product candidate may be significantly diminished, and our target market will be reduced and our ability to realize the full market potential of our diagnostic tests or therapeutic product candidates will be harmed.

Even if we obtain FDA approval of any of our diagnostic tests or therapeutic product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any diagnostic test or therapeutic product outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional diagnostic and therapeutic product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials, which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our diagnostic tests or therapeutic products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any diagnostic test or therapeutic product candidate approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or fail to obtain and maintain required approvals, our ability to realize the full market potential of our diagnostic tests or therapeutic products will be harmed.

The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown, and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare tests, products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, including proposals aimed at lowering prescription drug prices and increasing competition for prescription drugs, as well as additional regulation on pharmaceutical transparency and reporting requirements, any of which could negatively impact our future profitability and increase our compliance burden. We cannot predict the initiatives that may be adopted in the future, including future challenges or significant revisions to the Affordable Care Act. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our diagnostic tests or therapeutic product candidates, if we or our licensors obtain regulatory approval
- the ability to set a price that we believe is fair for our diagnostic tests and therapeutic products;
- the ability to obtain coverage and reimbursement approval for a diagnostic test and therapeutic product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Risks Related to Ownership of Our Common Stock

We do not expect to pay dividends in the foreseeable future. Any return on investment may be limited to the value of our Common Stock.

We do not anticipate paying cash dividends on our Common Stock in the foreseeable future. The payment of dividends on our Common Stock will depend on earnings, financial condition, and other business and economic factors affecting it at such time as our Board of Directors may consider relevant. If we do not pay dividends, our Common Stock may be less valuable because a return on your investment will occur only if our stock price appreciates.

Future sales of substantial amounts of shares of our Common Stock by existing shareholders could adversely affect the trading price of our Common Stock.

If our existing shareholders sell substantial amounts of shares of our Common Stock, the market price of our Common Stock could fall. In addition, the exercise of currently outstanding warrants or options could impact the market price of our Common Stock. Such sales by our existing stockholders might make it more difficult for us to issue new equity or equity-related securities in the future at a time and place we deem appropriate. If any existing stockholders sell a substantial amount of shares, the prevailing market price for our Common Stock could be adversely affected.

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that are incorporated by reference herein or our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, clinical and regulatory timelines, production and supply matters, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, regulatory, economic, market, and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There may be differences between actual and projected results, and actual results may be materially different from those contained in the projections.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our Common Stock.

Our shares of our Common Stock are listed for trading on The Nasdaq Capital Market under the symbol “BIAF and our Tradeable Warrants are listed under the symbol “BIAFW.” If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market such as the corporate governance requirements, the stockholder’s equity requirement or the minimum closing bid price requirement, The Nasdaq Capital Market may take steps to de-list our common stock or warrants. Such a de-listing or even notification of failure to comply with such requirements would likely have a negative effect on the price of our Common Stock and warrants would impair your ability to sell or purchase our Common Stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with The Nasdaq Capital Market’s listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below The Nasdaq Capital Market, minimum bid price requirement or prevent future non-compliance with The Nasdaq Capital Market’s listing requirements.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as “covered securities.” Because our common stock is listed on The Nasdaq Capital Market, our Common Stock is a covered security. Although the states are preempted from regulating the sale of covered securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were to be delisted from The Nasdaq Capital Market, our Common Stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities.

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future, and as a result, investors in our Common Stock could incur substantial losses.

Investors should consider an investment in our Common Stock risky and invest only if they can withstand a significant loss and wide fluctuations in the market value of their investment. Investors who purchase our Common Stock may not be able to sell their shares at or above the purchase price. Our stock price has been volatile and may be volatile in the future. The stock market in general has been, and the market price of our Common Stock in particular, will likely be subject to fluctuation, whether due to, or irrespective of, our operating results and financial condition. The market price of our Common Stock may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated variations in our and our competitors’ results of operations and financial condition;
- market acceptance of our diagnostic tests and therapeutic products;
- the mix of products that we sell and related services that we provide;
- changes in earnings estimates or recommendations by securities analysts, if our Common Stock is covered by analysts;
- development of technological innovations or new competitive diagnostic tests or therapeutic products by others;
- announcements of technological innovations or new diagnostic tests or therapeutic products by us;
- our failure to achieve a publicly announced milestone;
- delays between our expenditures to develop and market new or enhanced diagnostic tests or therapeutic products and the generation of sales from those diagnostic tests and therapeutic products;
- developments concerning intellectual property rights, including our involvement in litigation;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified diagnostic tests or therapeutic products;
- changes in the amounts that we spend to develop, acquire, or license new diagnostic tests or therapeutic products, technologies, or businesses;
- changes in our expenditures to promote our diagnostic tests or therapeutic products;
- our sale or proposed sale, or the sale by our significant shareholders, of our Common Stock or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our Common Stock; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our Common Stock and result in substantial losses being incurred by our investors. In the past, following periods of market volatility, public company shareholders have often instituted securities class action litigation. If we were involved in securities litigation, it could impose a substantial cost upon us and divert the resources and attention of our management from our business.

Our Common Stock has often been thinly traded, so investors may be unable to sell at or near ask prices or at all if investors need to sell shares to raise money or otherwise desire to liquidate their shares.

To date, there have been many days on which limited trading of our Common Stock took place. We cannot predict the extent to which investors’ interests will lead to an active trading market for our common stock or whether the market price of our common stock will be volatile. If an active trading market does not develop, investors may have difficulty selling any of our common stock that they buy. We are likely to be too small to attract the interest of many brokerage firms and analysts. We cannot give investors any

assurance that an active public trading market for our common stock will develop or be sustained. The market price of our Common Stock could be subject to wide fluctuations in response to quarterly variations in our revenues and operating expenses, announcements of new products or services by us, significant sales of our common stock, including “short” sales, the operating and stock price performance of other companies that investors may deem comparable to us, and news reports relating to trends in our markets or general economic conditions.

An investment in our Company may involve tax implications, and you are encouraged to consult your own advisors as neither we nor any related party is offering any tax assurances or guidance regarding our Company or your investment.

The formation of our Company, as well as an investment in our Company generally, involves complex federal, state, and local income tax considerations. Neither the Internal Revenue Service nor any state or local taxing authority has reviewed the transactions described herein and may take different positions than the ones contemplated by management. You are strongly urged to consult your own tax and other advisors prior to investing, as neither we nor any of our officers, directors, or related parties can offer tax or similar advice, nor are any such persons making any representations and warranties regarding such matters.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, referred to as the Internal Revenue Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation’s ability to use its pre-change net operating loss carry-forwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, taken together with other transactions we may consummate in the succeeding three-year period. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carry-forwards to offset U.S. federal taxable income may be subject to limitations, which potentially could result in increased future tax liability.

Our Certificate of Incorporation permits “blank check” Preferred Stock, which can be designated by our Board of Directors without stockholder approval.

We are authorized to issue 20,000,000 shares of Preferred Stock. The shares of our Preferred Stock may be issued from time to time in one or more series, each of which shall have a distinctive designation or title as is determined by our Board of Directors prior to the issuance of any shares thereof. The Preferred Stock may have such voting powers, full, enhanced or limited, or no voting powers, and such preferences and relative, participating, optional, or other special rights and such qualifications, limitations, or restrictions thereof as adopted by the Board of Directors, which may include enhanced dividend rights, rights of redemption, sinking funds to pay dividends, liquidation and other rights that would be different than, and preferential to, the rights of the common stockholders. Because our Board of Directors is able to designate the powers and preferences of the Preferred Stock without the vote of a majority of our stockholders, Common stockholders will have no control over what designations and preferences our Preferred Stock will have. If Preferred Stock is designated and issued, then depending upon the designation and preferences, the holders of the Preferred Stock may exercise voting control. As a result, our stockholders would have no control over the operations of our Company.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation, as amended (our “Charter”) and amended and restated bylaws (our “A&R Bylaws”) may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our Common Stock, thereby depressing the market price of our Common Stock. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Among other things, these provisions:

- allow the authorized number of our directors to be changed only by resolution of our Board of Directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board of Directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders; and
- authorize our Board of Directors to issue Preferred Stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the “DGCL”), which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our Common Stock, including transactions that may be your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Certain provisions in our Charter and A&R Bylaws could make a merger, tender offer, or proxy contest difficult, thereby depressing the trading price of our Common Stock.

Our Charter and A&R Bylaws contain provisions that could depress the trading price of our Common Stock by acting to discourage, delay or prevent a change of control of our Company or changes in our management that the stockholders of our Company may deem advantageous. These provisions include the following:

- permit the Board of Directors to establish the number of directors and fill any vacancies and newly-created directorships;
- authorize the issuance of “blank check” preferred stock that our Board of Directors could use to implement a stockholder rights plan;
- prohibit stockholders from calling special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- provide that the Board of Directors is expressly authorized to adopt, amend, alter or repeal our bylaws;
- restrict the forum for certain litigation against us to Delaware; and

- establish advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

Any provision in our Charter or A&R Bylaws that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our Common Stock and could also affect the price that some investors are willing to pay for our Common Stock.

Certain provisions of the DGCL may have anti-takeover effects that could delay, defer, or discourage another party from acquiring control of us, prevent changes in our Board of Directors or management, and make certain transactions more challenging that stockholders might otherwise believe to be in their best interests.

We are subject to the provisions of Section 203 of the DGCL, which generally prohibits us from engaging in a “business combination,” meaning a merger, asset sale, or other transaction resulting in a stockholder’s financial benefit, with an “interested stockholder” for a three-year period following the time that such stockholder becomes an interested stockholder, unless the business combination is approved in a manner prescribed by Section 203. Section 203 defines an “interested stockholder” as a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of a corporation’s outstanding voting stock. These provisions may have the effect of delaying, deferring, or preventing changes in control of our Company and of averting changes in our Board of Directors or management. They are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our Common Stock that often result from actual or rumored hostile takeover attempts. These provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

Our Charter designates a state or federal court located within the state of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to choose the judicial forum for disputes with us or our directors, officers or employees.

Our Charter provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, stockholder or employees to us or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL, our Charter or our A&R Bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) in all cases subject to the court having jurisdiction over indispensable parties named as defendants. These exclusive-forum provisions do not apply to claims under the Securities Act.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our Charter and our A&R Bylaws contain a federal forum provision which provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. We note, however, that there is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. This exclusive forum provision may limit a stockholder’s ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find the exclusive forum provision in our Charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations.

Certain limitation-of-liability and indemnification provisions in our Charter and A&R Bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breaches of their fiduciary duties, may reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit the Company and other stockholders, and may adversely impact stockholders’ investments to the extent that the Company pays the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Our Charter contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by the DGCL. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director’s duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

Our Charter and our A&R Bylaws require us to indemnify our directors and officers, and allow us to indemnify other employees and agents, to the fullest extent permitted by the DGCL. Subject to certain limitations and limited exceptions, our Charter and A&R Bylaws also require us to advance expenses incurred by our directors and officers for the defense of any action for which indemnification is required or permitted.

While we believe that including the limitation-of-liability and indemnification provisions in our Charter, A&R Bylaws, and indemnification agreements is necessary to attract and retain qualified persons such as directors, officers and key employees, those provisions may discourage stockholders from bringing a lawsuit against our directors and officers for breaches of their fiduciary duties. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder’s investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Our management collectively owns a substantial majority of our Common Stock.

Based on the provisions for determining beneficial ownership in accordance with Rule 13d-3 and Item 403 of Regulation S-K under the Exchange Act, our officers and directors currently own or exercise control of approximately 38.5% of the voting power of our outstanding Common Stock. As a result, investors may be prevented from affecting matters involving our Company, including:

- the composition of our Board of Directors and, through it, any determination with respect to our business direction and policies, including the appointment and removal of officers;
- any determinations with respect to mergers or other business combinations;

- our acquisition or disposition of assets; and
- our corporate financing activities.

Furthermore, this concentration of voting power could have the effect of delaying, deterring, or preventing a change of control or other business combination that might otherwise be beneficial to our stockholders. This significant concentration of share ownership may also adversely affect the trading price for our Common Stock because investors may perceive disadvantages in owning stock in a company that is controlled by a small number of stockholders.

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

The trading market for our Common Stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our Company. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our Common Stock would be negatively affected. If one or more of the analysts who cover us downgrade our Common Stock or publish inaccurate or unfavorable research about our business, our Common Stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our Common Stock could decrease, which might cause our Common Stock price and trading volume to decline.

If we fail to establish and maintain an effective system of internal control or disclosure controls and procedures are not effective, we may not be able to report our financial results accurately and timely or to prevent fraud. Any inability to report and file our financial results accurately and timely could harm our reputation and adversely impact the trading price of our Common Stock.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. Section 404 of the Sarbanes-Oxley Act of 2002 (the “*Sarbanes-Oxley Act*”) requires us to evaluate and report on our internal controls over financial reporting and, depending on our future growth, may require our independent registered public accounting firm to annually attest to our evaluation, as well as issue its own opinion on our internal controls over financial reporting. The process of implementing and maintaining proper internal controls and complying with Section 404 is expensive and time consuming. We cannot be certain that the measures we will undertake will ensure that we will maintain adequate controls over our financial processes and reporting in the future. Furthermore, if we are able to rapidly grow our business, the internal controls that we will need may become more complex, and significantly more resources will be required to ensure our internal controls remain effective. Failure to implement required controls or difficulties encountered in their implementation could harm our operating results or cause us to fail to meet our reporting obligations. If we or our auditors discover a material weakness in our internal controls, the disclosure of that fact, even if the weakness is quickly remedied, could diminish investors’ confidence in our financial statements and harm our stock price. In addition, non-compliance with Section 404 could subject us to a variety of administrative sanctions, including the suspension of trading, ineligibility for future listing on one of the Nasdaq Stock Markets or national securities exchanges, and the inability of registered broker-dealers to make a market in our Common Stock, which may reduce our stock price.

General Risks

We are an “emerging growth company” and a “smaller reporting company,” and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our Units less attractive to investors.

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act (the “*JOBS Act*”), and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced MD&A disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

In addition, as an “emerging growth company” the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies, unless we later irrevocably elect not to avail ourselves of this exemption. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (1) following the fifth anniversary of the completion of our initial public offering, (2) in which we have total annual gross revenue of at least \$1.235 billion, or (3) in which we are deemed to be a large accelerated filer, which means the market value of our Common Stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th; and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We are also a “smaller reporting company” meaning that the market value of our stock held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements in our Annual Report on Form 10-K, and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common shares held by non-affiliates exceeds \$250 million as of the end of that year’s second fiscal quarter, or (ii) our annual revenues exceeded \$100 million during such completed fiscal year and the market value of our common shares held by non-affiliates exceeds \$700 million as of the end of that year’s second fiscal quarter.

Investors may find our Common Stock less attractive to the extent we will rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

We have incurred significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we have incurred and will continue to incur legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are required to comply with the applicable requirements of the Sarbanes-

Oxley Act of 2002, or SOX, and the Dodd-Frank Wall Street Reform and Consumer Protection Act, or Dodd-Frank. The listing requirements of the Nasdaq Stock Market, and the rules of the SEC require that we satisfy certain corporate governance requirements. Our management and other personnel are required to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Beginning with the second annual report on Form 10-K that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation.

As of September 30, 2023, our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of our "disclosure controls and procedures" (as defined in the Exchange Act) Rules 13a-15I and 15d-15(e). Based on that evaluation, management has concluded that due to limited resources and limited number of employees, its internal control over financial reporting was ineffective as of September 30, 2023, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. To mitigate the limited resources and employees, we rely heavily on direct management oversight of transactions, along with the use of legal and accounting professionals. As we grow, we expect to increase the number of employees, which we believe will enable us to implement adequate segregation of duties within the internal control framework.

In the future, if we identify any additional material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline, and we could also become subject to investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities, which could require additional financial and management resources. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from Nasdaq or other adverse consequences that would materially harm our business and reputation.

For so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (i) following the fifth anniversary of the completion of our initial public offering, (ii) in which we have total annual gross revenue of at least \$1.235 billion, or (iii) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our Charter and A&R Bylaws provide that we will indemnify our directors and officers, in each case, to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our A&R Bylaws provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our A&R Bylaws also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We believe that these Charter and A&R Bylaws provisions are necessary to attract and retain qualified persons as directors and officers.

While we maintain directors' and officers' liability insurance, such insurance may not be adequate to cover all liabilities that we may incur, which may reduce our available

FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference herein, contains and any applicable prospectus supplement or free writing prospectus including the documents we incorporate by reference therein may contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including statements regarding our future financial condition, business strategy and plans, and objectives of management for future operations. Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terminology such as “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “might,” “approximately,” “expect,” “predict,” “could,” “potentially” or the negative of these terms or other similar expressions. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations.

Discussions containing these forward-looking statements may be found, among other places, in the sections entitled “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in the documents incorporated by reference herein, including our most recent Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q, as well as any amendments thereto.

These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. We discuss in greater detail, and incorporate by reference into this prospectus in their entirety, many of these risks and uncertainties under the heading “Risk Factors” contained in the applicable prospectus supplement, in any free writing prospectus we may authorize for use in connection with a specific offering, and in the documents incorporated by reference herein. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

USE OF PROCEEDS

We will retain broad discretion over the use of the net proceeds from the sale of the securities offered hereby. Except as described in any prospectus supplement or in any related free writing prospectus that we may authorize to be provided to you, we currently intend to use the net proceeds from the sale of the securities offered by us hereunder primarily for working capital and general corporate purposes. We will set forth in the applicable prospectus supplement or free writing prospectus our intended use for the net proceeds received from the sale of any securities sold pursuant to the prospectus supplement or free writing prospectus.

DESCRIPTION OF CAPITAL STOCK

General

The following is a description of the material terms of our capital stock. This is a summary only and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Certificate of Incorporation and our Bylaws, each of which are incorporated by reference as an exhibit to the registration statement of which this prospectus forms a part. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Delaware General Corporation Law (the “DGCL”), for additional information.

Our authorized capital stock consists of:

- 25,000,000 shares of common stock, par value \$0.007 per share; and
- 20,000,000 shares of preferred stock, par value \$0.001 per share.

We currently have 9,502,243 shares of common stock outstanding and no shares of preferred stock outstanding.

Common Stock

Holders of shares of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders. Except as otherwise provided in our Certificate of Incorporation, Bylaws, or as required by law, all matters to be voted on by our stockholders other than matters relating to the election and removal of directors must be approved by a majority of the shares present in person or by proxy at the meeting and entitled to vote on the subject matter. The holders of our common stock do not have cumulative voting rights in the election of directors.

Holders of shares of our common stock are entitled to receive dividends when and if declared by our Board of Directors out of funds legally available therefor, subject to any statutory or contractual restrictions on the payment of dividends and to any restrictions on the payment of dividends imposed by the terms of any outstanding preferred stock.

Upon our dissolution or liquidation, after payment in full of all amounts required to be paid to creditors and subject to any rights of preferred stockholders, the holders of shares of our common stock will be entitled to receive pro rata our remaining assets available for distribution.

Holders of shares of our common stock do not have preemptive, subscription, redemption or conversion rights. There are no sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

The following summary of terms of our preferred stock is not complete. We will file as an exhibit to the registration statement of which this prospectus is a part or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock that we are offering before the issuance of the related series of preferred stock. We urge you to read the applicable prospectus supplement (and any free writing prospectus that we may authorize to be provided to you) related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

Our Board of Directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of 20,000,000 shares of preferred stock in one or more series and authorize their issuance. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms

of redemption, liquidation preferences, sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock.

Our Board of Directors will fix the designations, voting powers, preferences and rights of the preferred stock of each series we issue under this prospectus, as well as the qualifications, limitations or restrictions thereof, in the certificate of designation relating to that series. We will describe in the applicable prospectus supplement the terms of the series of preferred stock being offered, including, to the extent applicable:

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- the purchase price;
- the dividend rate, period and payment date, and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing;
- the provisions for a sinking fund;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price, or how it will be calculated, and the conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price, or how it will be calculated, and the exchange period;
- voting rights of the preferred stock;
- preemptive rights;
- restrictions on transfer, sale or other assignment;
- whether interests in the preferred stock will be represented by depositary shares;
- a discussion of material United States federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on the issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

35

Series A Preferred Stock

There are currently 5,400,000 shares of Preferred Stock designated as “Series A Convertible Preferred Stock,” par value \$0.001 per share (the “Series A Preferred Stock”), of which no shares are outstanding. Immediately prior to the closing of our initial public offering, all outstanding shares of our Series A Preferred Stock were automatically converted into shares of our common stock. We do not intend to issue any further shares of Series A Preferred Stock. Set forth below is a summary of the terms of the Series A Preferred Stock:

Voting Rights

Holders of the shares of Series A Preferred Stock have the right to one vote for each share of common stock into which such Series A Preferred Stock could then be converted. In addition, for so long as 30% of the shares of Series A Preferred Stock remained outstanding, the Series A Preferred Stock holders, voting together as a single class, may exercise the Series A Director Designation Right, pursuant to which they were entitled to elect one director of the Company as the Series A Representative. The Series A Director Designation Right ceased to exist because no shares of Series A Preferred Stock remain outstanding.

Dividend Rights

Holders of shares of the Series A Preferred Stock are entitled to receive dividends, in preference to any declaration or payment of a dividend to holders of the common stock, of 8% per share per annum when, as and if declared by the Board. Such dividends are not cumulative.

Rights Upon Liquidation

In the event of any liquidation, dissolution or similar event, the holders of shares of Series A Preferred Stock are entitled to receive in preference to any distribution of any of our assets to the holders of our common stock, \$7.70 per share (as adjusted for a prior reverse-stock-split). Unless otherwise decided by holders of a majority of the Series A Preferred Stock outstanding, a liquidation includes a sale of substantially all of the assets of the Company and a merger, unless such merger is solely for the purpose of changing the Company’s state of incorporation or a majority of the voting power of the surviving entity will be owned by persons who were stockholders of the Company prior to the merger. Holders of shares of Series A Preferred Stock will not participate with the holders of Common Stock in the distribution of the remainder of the Company’s assets.

Conversion Rights

The conversion rate of Series A Preferred Stock into common stock was initially 1 for 7 (as adjusted for a prior reverse-stock-split). Shares of Series A Preferred Stock are convertible, at the option of the holder thereof, into shares of our common stock at any time. Shares of Series A Preferred Stock automatically convert into shares of our common stock following the closing of an underwritten initial public offering of our Common Stock in which at least \$10,000,000 in shares of our common stock are sold at a price of \$3.00 per share or more or such other date as agreed to by holders of a majority of the outstanding shares of Series A Preferred Stock. The holders of a more than a majority of our outstanding shares of Series A Preferred Stock executed a written consent such that all of the issued and outstanding shares of Series A Preferred Stock automatically converted into fully paid and nonassessable shares of our common stock immediately prior to the closing of our initial public offering at the then-effective conversion rate of the Series A Preferred Stock.

Forum Selection

Our Certificate of Incorporation and Bylaws provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the State of Delaware) will, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, employee or agent to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our Certificate of Incorporation or our Bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or (iv) any action asserting a claim governed by the internal affairs doctrine. Our Certificate of Incorporation and Bylaws further provide that the choice of the Court of Chancery as the sole and exclusive forum does not apply to suits to enforce a duty or liability created by the Exchange Act, and unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933.

36

Anti-Takeover Effects of Delaware Law and Provisions of Our Certificate of Incorporation and Bylaws

Delaware Law

We are subject to Section 203 of the DGCL. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a “business combination” with any “interested stockholder” for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of our Board of Directors or unless the business combination is approved in a prescribed manner. A “business combination” includes, among other things, a merger or consolidation involving us and the “interested stockholder” and the sale of more than 10% of our assets. In general, an “interested stockholder” is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

Our Certificate of Incorporation and Bylaws

Our Certificate of Incorporation and Bylaws contain provisions that may delay, defer, or discourage another party from acquiring control of us. We expect that these provisions, which are summarized below, will discourage coercive takeover practices or inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board of Directors, which we believe may result in an improvement of the terms of any such acquisition in favor of our stockholders. However, they also give our Board of Directors the power to discourage acquisitions that some stockholders may favor.

Preferred Stock. Our certificate of incorporation provides that our Board of Directors is authorized to approve the issuance of preferred stock without stockholder approval and to determine the number of shares, the designations and the relative preferences, rights, restrictions and qualifications of any series of preferred stock. As a result, our Board of Directors could, without stockholder approval, authorize the issuance of preferred stock with voting, dividend, redemption, liquidation, sinking fund, conversion and other rights that could proportionately reduce, minimize or otherwise adversely affect the voting power and other rights of holders of the Company’s capital stock or that could have the effect of delaying, deferring or preventing a change in control.

Authorized but Unissued Shares. The authorized but unissued shares of our common stock are available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of the Nasdaq Stock 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.

Director Vacancies. Our Bylaws authorize the Board of Directors to fill vacant directorships and provide that the number of directors constituting our Board of Directors may be set by resolution of the incumbent directors.

Special Meetings of Stockholders. Our Bylaws provide that special meetings of our stockholders may only be called pursuant to a resolution approved by the Board of Directors. The only business that may be conducted at a special meeting of our stockholders is the matter or matters set forth in the notice of such special meeting.

Prohibition of Stockholder Action by Written Consent. Our Certificate of Incorporation and Bylaws prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders.

37

Advance Notice Requirements. Stockholders wishing to nominate persons for election to our Board of Directors or to propose any business to be considered by our stockholders at an annual meeting must comply with certain advance notice and other requirements which are set forth in our Bylaws. Likewise, if our Board of Directors has determined that directors shall be elected at a special meeting of stockholders, stockholders wishing to nominate persons for election to our Board of Directors at such special meeting must comply with certain advance notice and other requirements which are set forth in our Bylaws. These provisions could have the effect of delaying stockholder actions that are favored by the holders of a majority of our outstanding voting securities until the next stockholder meeting.

Amendment to the Certificate of Incorporation and Bylaws. As required by the DGCL, any amendment of our Certificate of Incorporation must first be approved by a majority of our Board of Directors. Our Certificate of Incorporation and Bylaws provide for amendment of the Bylaws by our Board of Directors or our stockholders.

Limitations on Liability and Indemnification of Officers and Directors

Our Certificate of Incorporation and our Bylaws provide indemnification for our directors and officers to the fullest extent permitted by the DGCL. In addition, as permitted by Delaware law, our Certificate of Incorporation includes provisions that eliminate the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of these provisions is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director for breach of fiduciary duties as a director, except that a director will be personally liable for:

- any breach of his duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- any transaction from which the director derived an improper personal benefit; or
- improper distributions to stockholders.

These provisions may be held not to be enforceable for violations of the federal securities laws of the United States.

Transfer Agent and Registrar

The transfer agent and registrar for the Company’s Common Stock is VStock Transfer, LLC. The transfer agent and registrar’s address is 18 Lafayette Place, Woodmere, New York 11598.

Listing on the Nasdaq Capital Market.

Our common stock and the Tradeable Warrants trade on The Nasdaq Capital Market under the symbols “BIAF” and “BIAFW,” respectively.

38

DESCRIPTION OF DEBT SECURITIES

We may issue debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. While the terms we have summarized below will apply generally to any debt securities that we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities offered under a prospectus supplement may differ from the terms described

below. Unless the context requires otherwise, whenever we refer to the indenture, we also are referring to any supplemental indentures that specify the terms of a particular series of debt securities.

We will issue the debt securities under the indenture that we will enter into with the trustee named in the indenture. The indenture will be qualified under the Trust Indenture Act of 1939, as amended (the “Trust Indenture Act”). We have filed the form of indenture as an exhibit to the registration statement of which this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of the debt securities being offered will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports that we file with the SEC.

The following summary of material provisions of the debt securities and the indenture is subject to, and qualified in its entirety by reference to, all of the provisions of the indenture applicable to a particular series of debt securities. We urge you to read the applicable prospectus supplement and any related free writing prospectus related to the debt securities that we may offer under this prospectus, as well as the complete indenture that contains the terms of the debt securities.

General

The indenture will not limit the amount of debt securities that we may issue. It provides that we may issue debt securities up to the principal amount that we may authorize and may be in any currency or currency unit that we may designate. Except for the limitations on consolidation, merger and sale of all or substantially all of our assets contained in the indenture, the terms of the indenture do not contain any covenants or other provisions designed to give holders of any debt securities protection against changes in our operations, financial condition or transactions involving us.

We may issue the debt securities issued under the indenture as “discount securities,” which means they may be sold at a discount below their stated principal amount. These debt securities, as well as other debt securities that are not issued at a discount, may be issued with original issue discount (“OID”), for U.S. federal income tax purposes because of interest payment and other characteristics or terms of the debt securities. Material U.S. federal income tax considerations applicable to debt securities issued with OID will be described in more detail in any applicable prospectus supplement.

We will describe in the applicable prospectus supplement the terms of the series of debt securities being offered, including:

- the title of the series of debt securities;
- any limit upon the aggregate principal amount that may be issued;
- the maturity date or dates;
- the form of the debt securities of the series;
- the applicability of any guarantees;
- whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;
- whether the debt securities rank as senior debt, senior subordinated debt, subordinated debt or any combination thereof, and the terms of any subordination;
- if the price (expressed as a percentage of the aggregate principal amount thereof) at which such debt securities will be issued is a price other than the principal amount thereof, the portion of the principal amount thereof payable upon declaration of acceleration of the maturity thereof, or if applicable, the portion of the principal amount of such debt securities that is convertible into another security or the method by which any such portion shall be determined;
- the interest rate or rates, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- our right, if any, to defer payment of interest and the maximum length of any such deferral period;
- if applicable, the date or dates after which, or the period or periods during which, and the price or prices at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;
- the date or dates, if any, on which, and the price or prices at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder’s option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;
- the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof;
- any and all terms, if applicable, relating to any auction or remarketing of the debt securities of that series and any security for our obligations with respect to such debt securities and any other terms which may be advisable in connection with the marketing of debt securities of that series;
- any and all terms, if applicable, relating to any auction or remarketing of the debt securities of that series and any security for our obligations with respect to such debt securities and any other terms which may be advisable in connection with the marketing of debt securities of that series;

- whether the debt securities of the series shall be issued in whole or in part in the form of a global security or securities; the terms and conditions, if any, upon which such global security or securities may be exchanged in whole or in part for other individual securities; and the depository for such global security or securities;
- if applicable, the provisions relating to conversion or exchange of any debt securities of the series and the terms and conditions upon which such debt securities will be so convertible or exchangeable, including the conversion or exchange price, as applicable, or how it will be calculated and may be adjusted, any mandatory or optional (at our option or the holders’ option) conversion or exchange features, the applicable conversion or exchange period and the manner of settlement for any conversion or exchange;
- if other than the full principal amount thereof, the portion of the principal amount of debt securities of the series which shall be payable upon declaration of acceleration of the maturity thereof;
- additions to or changes in the covenants applicable to the particular debt securities being issued, including, among others, the consolidation, merger or sale covenant;
- additions to or changes in the events of default with respect to the securities and any change in the right of the trustee or the holders to declare the principal, premium, if any, and interest, if any, with respect to such securities to be due and payable;
- additions to or changes in or deletions of the provisions relating to covenant defeasance and legal defeasance;
- additions to or changes in the provisions relating to satisfaction and discharge of the indenture;
- additions to or changes in the provisions relating to the modification of the indenture both with and without the consent of holders of debt securities issued under the indenture;
- the currency of payment of debt securities if other than U.S. dollars and the manner of determining the equivalent amount in U.S. dollars;
- whether interest will be payable in cash or additional debt securities at our or the holders’ option and the terms and conditions upon which the election may be made;
- the terms and conditions, if any, upon which we will pay amounts in addition to the stated interest, premium, if any, and principal amounts of the debt securities of the series to any holder that is not a “United States person” for federal tax purposes;
- any restrictions on transfer, sale or assignment of the debt securities of the series; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities, any other additions or changes in the provisions of the indenture, and any terms that may be required by us or advisable under applicable laws or regulations.

Conversion or Exchange Rights

We will set forth in the applicable prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for our common stock or our other securities. We will include provisions as to settlement upon conversion or exchange and whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of our common stock or our other securities that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger or Sale

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the indenture will not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of our assets as an entirety or substantially as an entirety. However, any successor to or acquirer of such assets (other than a subsidiary of ours) must assume all of our obligations under the indenture or the debt securities, as appropriate.

Events of Default under the Indenture

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the following are events of default under the indenture with respect to any series of debt securities that we may issue:

- if we fail to pay any installment of interest on any series of debt securities, as and when the same shall become due and payable, and such default continues for a period of 90 days; provided, however, that a valid extension of an interest payment period by us in accordance with the terms of any indenture supplemental thereto shall not constitute a default in the payment of interest for this purpose;
- if we fail to pay the principal of, or premium, if any, on any series of debt securities as and when the same shall become due and payable whether at maturity, upon redemption, by declaration or otherwise, or in any payment required by any sinking or analogous fund established with respect to such series; provided, however, that a valid extension of the maturity of such debt securities in accordance with the terms of any indenture supplemental thereto shall not constitute a default in the payment of principal or premium, if any;
- if we fail to observe or perform any other covenant or agreement contained in the debt securities or the indenture, other than a covenant specifically relating to another series of debt securities, and our failure continues for 90 days after we receive written notice of such failure, requiring the same to be remedied and stating that such is a notice of default thereunder, from the trustee or holders of at least 25% in aggregate principal amount of the outstanding debt securities of the applicable series; and
- if specified events of bankruptcy, insolvency or reorganization occur.

If an event of default with respect to debt securities of any series occurs and is continuing, other than an event of default specified in the last bullet point above, the trustee or the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series, by notice to us in writing, and to the trustee if notice is given by such holders, may declare the unpaid principal of, premium, if any, and accrued interest, if any, due and payable immediately. If an event of default specified in the last bullet point above occurs with respect to us, the principal amount of and accrued interest, if any, of each issue of debt securities then outstanding shall be due and payable without any notice or other action on the part of the trustee or any holder.

The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

Subject to the terms of the indenture, if an event of default under an indenture shall occur and be continuing, the trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the trustee, or exercising any trust or power conferred on the trustee, with respect to the debt securities of that series, provided that:

- the direction so given by the holder is not in conflict with any law or the applicable indenture; and
- subject to its duties under the Trust Indenture Act, the trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will have the right to institute a proceeding under the indenture or to appoint a receiver or trustee, or to seek other remedies only if:

- the holder has given written notice to the trustee of a continuing event of default with respect to that series;
- the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made written request,
- such holders have offered to the trustee indemnity satisfactory to it against the costs, expenses and liabilities to be incurred by the trustee in compliance with the request; and
- the trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions within 90 days after the notice, request and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the trustee regarding our compliance with specified covenants in the indenture.

Modification of Indenture; Waiver

We and the trustee may change an indenture without the consent of any holders with respect to specific matters:

- to cure any ambiguity, defect or inconsistency in the indenture or in the debt securities of any series;
- to comply with the provisions described above under “Description of Debt Securities—Consolidation, Merger or Sale;”
- to provide for uncertificated debt securities in addition to or in place of certificated debt securities;
- to add to our covenants, restrictions, conditions or provisions such new covenants, restrictions, conditions or provisions for the benefit of the holders of all or any series of debt securities, to make the occurrence, or the occurrence and the continuance, of a default in any such additional covenants, restrictions, conditions or provisions an event of default or to surrender any right or power conferred upon us in the indenture;
- to add to, delete from or revise the conditions, limitations, and restrictions on the authorized amount, terms, or purposes of issue, authentication and delivery of debt securities, as set forth in the indenture;
- to make any change that does not adversely affect the interests of any holder of debt securities of any series in any material respect;
- to provide for the issuance of and establish the form and terms and conditions of the debt securities of any series as provided above under “Description of Debt Securities—General” to establish the form of any certifications required to be furnished pursuant to the terms of the indenture or any series of debt securities, or to add to the rights of the holders of any series of debt securities;
- to evidence and provide for the acceptance of appointment under any indenture by a successor trustee; or
- to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act.

In addition, under the indenture, the rights of holders of a series of debt securities may be changed by us and the trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, we and the trustee may make the following changes only with the consent of each holder of any outstanding debt securities affected:

- extending the fixed maturity of any debt securities of any series;

- reducing the principal amount, reducing the rate of or extending the time of payment of interest, or reducing any premium payable upon the redemption of any series of any debt securities; or
- reducing the percentage of debt securities, the holders of which are required to consent to any amendment, supplement, modification or waiver.

Discharge

Each indenture provides that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for specified obligations, including obligations to:

- provide for payment;
- register the transfer or exchange of debt securities of the series;
- replace stolen, lost or mutilated debt securities of the series;
- pay principal of and premium and interest on any debt securities of the series;
- maintain paying agencies;
- hold monies for payment in trust;
- recover excess money held by the trustee;
- compensate and indemnify the trustee; and
- appoint any successor trustee.

In order to exercise our rights to be discharged, we must deposit with the trustee money or government obligations sufficient to pay all the principal of, any premium, if any, and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we provide otherwise in the applicable prospectus supplement, in denominations of \$1,000 and any integral multiple thereof. The indenture provides that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company, (“DTC”), or another depository named by us and identified in the applicable prospectus supplement with respect to that series. To the extent the debt securities of a series are issued in global form and as book-entry, a description of terms relating such securities will be set forth in the applicable prospectus supplement.

At the option of the holder, subject to the terms of the indenture and the limitations applicable to global securities described in the applicable prospectus supplement, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indenture and the limitations applicable to global securities set forth in the applicable prospectus supplement, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will impose no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in the applicable prospectus supplement the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

If we elect to redeem the debt securities of any series, we will not be required to:

- issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or
- register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

Information Concerning the Trustee

The trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the trustee is under no obligation to exercise any of the powers given it by the indenture at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses and liabilities that it might incur.

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless we otherwise indicate in the applicable prospectus supplement, we will make interest payments by check that we will mail to the holder or by wire transfer to certain holders. Unless we otherwise indicate in the applicable prospectus supplement, we will designate the corporate trust office of the trustee as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the trustee for the payment of the principal of or any premium or interest on any debt securities that remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the debt security thereafter may look only to us for payment thereof.

Governing Law

The indenture and the debt securities will be governed by and construed in accordance with the internal laws of the State of New York, except to the extent that the Trust Indenture Act is applicable.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplement and in any related free writing prospectus, summarizes the material terms and provisions of the warrants that we may offer under this prospectus, which may consist of warrants to purchase common stock, preferred stock or debt securities and may be issued in one or more series. Warrants may be offered independently or in combination with common stock, preferred stock or debt securities offered by any prospectus supplement. While the terms we have summarized below will apply generally to any warrants that we may offer under this prospectus, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. The following description of warrants will apply to the warrants offered by this prospectus unless we provide otherwise in the applicable prospectus supplement. The applicable prospectus supplement for a particular series of warrants may specify different or additional terms.

We have filed or will file forms of the warrant agreements and forms of warrant certificates containing the terms of the warrants that may be offered as exhibits to the registration statement of which this prospectus is a part. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant and/or the warrant agreement and warrant certificate, as applicable, that contain the terms of the particular series of warrants we are offering, and any supplemental agreements, before the issuance of such warrants. The following summaries of material terms and provisions of the warrants are subject to, and qualified in their entirety by reference to, all the provisions of the form of warrant and/or the warrant agreement and warrant certificate, as applicable, and any supplemental agreements applicable to a particular series of warrants that we may offer under this prospectus. We urge you to read the applicable prospectus supplement related to the particular series of warrants that we may offer under this prospectus, as well as any related free writing prospectus, and the complete form of warrant and/or the warrant agreement and warrant certificate, as applicable, and any supplemental agreements, that contain the terms of the warrants.

General

We will describe in the applicable prospectus supplement the terms of the series of warrants being offered, including, to the extent applicable:

- the offering price and aggregate number of warrants offered;
- the currency for which the warrants may be purchased;
- the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- the date on and after which the warrants and the related securities will be separately transferable;
- in the case of warrants to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one warrant and the price at, and currency in which, this principal amount of debt securities may be purchased upon such exercise;
- in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreements and the warrants;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire;
- the manner in which the warrant agreements and warrants may be modified;
- a discussion of material United States federal income tax consequences of holding or exercising the warrants;
- the terms of the securities issuable upon exercise of the warrants; and
- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including:

- in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any; or
- in the case of warrants to purchase debt securities, the right to receive payments of principal of, or premium, if any, or interest on, the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture.

Exercise of Warrants

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to the specified time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

43

Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants by delivering the warrant or warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent, if applicable, in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of any warrant certificate and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to any warrant agent in connection with the exercise of the warrant.

Upon receipt of payment and the warrant or warrant certificate, as applicable, properly completed and duly executed at the corporate trust office of the warrant agent, if any, or any other office, including ours, indicated in the prospectus supplement, we will, as soon as practicable, issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants (or the warrants represented by such warrant certificate) are exercised, a new warrant or a new warrant certificate, as applicable, will be issued for the remaining warrants.

Governing Law

Unless we provide otherwise in the applicable prospectus supplement, the warrants and warrant agreements, and any claim, controversy or dispute arising under or related to the warrants or warrant agreements, will be governed by and construed in accordance with the laws of the State of New York.

Enforceability of Rights by Holders of Warrants

Each warrant agent, if any, will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

44

DESCRIPTION OF UNITS

The following description, together with the additional information we may include in any applicable prospectus supplement and related free writing prospectus, summarizes the material terms and provisions of the units that we may offer under this prospectus. We may issue units consisting of any combination of the other types of securities offered under this prospectus in one or more series. We will issue each unit so that the holder of the unit is also the holder of each security included in the unit. As a result, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. We may evidence each series of units by unit certificates that we will issue under a separate agreement. We may enter into unit agreements with a unit agent. Each unit agent will be a bank or trust company that we select. We will indicate the name and address of any unit agent in the applicable prospectus supplement relating to a particular series of units. The summary below and that contained in any prospectus supplement is qualified in its entirety by reference to all of the provisions of the unit agreement and/or unit certificate, and depositary arrangements, if applicable. We urge you to read the applicable prospectus supplements and any related free writing prospectuses related to the units that we may offer under this prospectus, as well as the complete unit agreement and/or unit certificate, and depositary arrangements, as applicable, that contain the terms of the units.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of unit agreement and/or unit certificate, and depositary arrangements, as applicable, that contain the terms of the particular series of units we are offering, and any supplemental agreements, before the issuance of such units.

We will describe in the applicable prospectus supplement the terms of the series of units being offered, including:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities composing the units;
- whether the units will be issued in fully registered or global form; and
- any other terms of the units.

LEGAL OWNERSHIP OF SECURITIES

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee, depositary or warrant agent maintain for this purpose as the “holders” of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names as “indirect holders” of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-entry form or in street name will be indirect holders.

Book-Entry Holders

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depositary on behalf of other financial institutions that participate in the depositary’s book-entry system. These participating institutions, which are referred to as participants, in turn hold beneficial interests in the securities on behalf of themselves or their customers.

Only the person in whose name a security is registered is recognized as the holder of that security. Global securities will be registered in the name of the depositary or its participants. Consequently, for global securities, we will recognize only the depositary as the holder of the securities, and we will make all payments on the securities to the depositary. The depositary passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depositary and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

As a result, investors in a global security will not own securities directly. Instead, they will own beneficial interests in a global security through a bank, broker or other financial institution that participates in the depositary’s book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not legal holders, of the securities.

Street Name Holders

We may terminate a global security or issue securities that are not issued in global form. In these cases, investors may choose to hold their securities in their own names or in “street name.” Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

For securities held in street name, we or any applicable trustee or depositary will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we or any such trustee or depositary will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

Legal Holders

Our obligations, as well as the obligations of any applicable trustee or third party employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the holder, we have no further responsibility for the payment or notice even if that holder is required, under agreements with its participants or customers or by law, to pass it along to the indirect holders but does not do so. Similarly, we may want to obtain the approval of the holders to amend an indenture, to relieve us of the consequences of a default or of our obligation to comply with a particular provision of an indenture, or for other purposes. In such an event, we would seek approval only from the legal holders, and not the indirect holders, of the securities. Whether and how the legal holders contact the indirect holders is up to the legal holders.

Special Considerations for Indirect Holders

If you hold securities through a bank, broker or other financial institution, either in book-entry form because the securities are represented by one or more global securities or in street name, you should check with your own institution to find out:

- how it handles securities payments and notices;

- whether it imposes fees or charges;
- how it would handle a request for the holders' consent, if ever required;
- whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;
- how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and
- if the securities are in book-entry form, how the depository's rules and procedures will affect these matters.

Global Securities

A global security is a security that represents one or any other number of individual securities held by a depository. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we issue to, deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depository. Unless we specify otherwise in the applicable prospectus supplement, The Depository Trust Company, New York, New York, known as DTC, will be the depository for all securities issued in book-entry form.

A global security may not be transferred to or registered in the name of anyone other than the depository, its nominee or a successor depository, unless special termination situations arise. We describe those situations below under "Special Situations When a Global Security Will Be Terminated." As a result of these arrangements, the depository, or its nominee, will be the sole registered owner and legal holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depository or with another institution that does. Thus, an investor whose security is represented by a global security will not be a legal holder of the security, but only an indirect holder of a beneficial interest in the global security.

If the prospectus supplement for a particular security indicates that the security will be issued in global form only, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

Special Considerations for Global Securities

As an indirect holder, an investor's rights relating to a global security will be governed by the account rules of the investor's financial institution and of the depository, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a holder of securities and instead deal only with the depository that holds the global security.

46

If securities are issued only as global securities, an investor should be aware of the following:

- an investor cannot cause the securities to be registered in his or her name, and cannot obtain non-global certificates for his or her interest in the securities, except in the special situations we describe below;
- an investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as we describe above;
- an investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form;
- an investor may not be able to pledge his or her interest in the global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;
- the depository's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in the global security;
- we and any applicable trustee have no responsibility for any aspect of the depository's actions or for its records of ownership interests in the global security, nor will we or any applicable trustee supervise the depository in any way;
- the depository may, and we understand that DTC will, require that those who purchase and sell interests in the global security within its book-entry system use immediately available funds, and your broker or bank may require you to do so as well; and
- financial institutions that participate in the depository's book-entry system, and through which an investor holds its interest in the global security, may also have their own policies affecting payments, notices and other matters relating to the securities.

There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

Special Situations When a Global Security Will Be Terminated

In a few special situations described below, a global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in securities transferred to their own names, so that they will be direct holders. We have described the rights of holders and street name investors above.

Unless we provide otherwise in the applicable prospectus supplement, a global security will terminate when the following special situations occur:

- if the depository notifies us that it is unwilling, unable or no longer qualified to continue as depository for that global security and we do not appoint another institution to act as depository within 90 days;
- if we notify any applicable trustee that we wish to terminate that global security; or
- if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

The applicable prospectus supplement may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by the applicable prospectus supplement. When a global security terminates, the depository, and neither we nor any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

47

PLAN OF DISTRIBUTION

We may sell the securities from time to time pursuant to underwritten public offerings, direct sales to the public, "at the market" offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities to or through one or more underwriters or dealers (acting as principal or agent), through agents, or directly to one or more purchasers. We may distribute securities from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

A prospectus supplement or supplements (and any related free writing prospectus that we may authorize to be provided to you) will describe the terms of the offering of the securities, including to the extent applicable:

- the name or names of the underwriters, dealers, agents or other purchasers, if any;
- the purchase price of the securities or other consideration therefor, and the proceeds we will receive from the sale;
- any option to purchase additional shares or other options under which underwriters, dealers, agents or other purchasers may purchase additional securities from us;
- any agency fees or underwriting discounts to be allowed or paid to the agent or underwriters and other items constituting agents' or underwriters' compensation;
- any public offering price;
- any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

Only underwriters named in the prospectus supplement will be underwriters of the securities offered by the prospectus supplement. Dealers and agents participating in the distribution of the securities may be deemed to be underwriters, and compensation received by them on resale of the securities may be deemed to be underwriting discounts. If such dealers or agents were deemed to be underwriters, they may be subject to statutory liabilities under the Securities Act.

If underwriters are used in the sale, they will acquire the securities for their own account and may resell the securities from time to time in one or more transactions at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement other than securities covered by any option to purchase additional shares or other option. If a dealer is used in the sale of securities, we or an underwriter will sell the securities to the dealer as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. To the extent required, we will set forth in the prospectus supplement the name of the dealer and the terms of the transaction. Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may change from time to time. We may use underwriters, dealers or agents with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, dealer or agent, the nature of any such relationship.

We may sell securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities, and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, the agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

We may provide agents, dealers and underwriters with indemnification against civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents, dealers or underwriters may make with respect to these liabilities. Agents, dealers and underwriters or their affiliates may engage in transactions with or perform services for us in the ordinary course of business.

All securities we may offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

Any underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids. Overallotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum price. Syndicate covering or other short-covering transactions involve purchases of the securities, either through exercise of the option to purchase additional shares or in the open market after the distribution is completed, to cover short positions. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time. These transactions may be effected on any exchange or over-the-counter market or otherwise.

Any underwriters, dealers or agents that are qualified market makers on the Nasdaq Capital Market may engage in passive market making transactions in our common stock on the Nasdaq Capital Market in accordance with Regulation M under the Exchange Act, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the securities. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

The anticipated date of delivery of offered securities will be set forth in the applicable prospectus supplement relating to each offer.

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, the validity of the securities offered by this prospectus, and any supplement thereto, will be passed upon for us by Blank Rome LLP, New York, New York. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

EXPERTS

The consolidated financial statements of bioAffinity Technologies, Inc. at December 31, 2022, and for the year ended December 31, 2022, have been incorporated by reference herein in reliance upon the report of WithumSmith+Brown, PC, independent registered public accounting firm, as set forth in their report thereon and are included in reliance upon the authority of such firm as experts in auditing and accounting.

The financial statements of Village Oaks Pathology Services, P.A. d/b/a Precision Pathology Services at December 31, 2022, and for the year ended December 31, 2022, have been incorporated by reference herein in reliance upon the report of WithumSmith+Brown, PC, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about Village Oaks Pathology Services, P.A.'s ability to continue as a going concern

as described in Note 1 to the financial statements of Village Oaks Pathology Services, P.A., which are incorporated herein by reference) and are included in reliance upon authority of such firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. Neither we nor any agent, underwriter or dealer has authorized any person to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of the securities offered by this prospectus.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public at the SEC's website at www.sec.gov. Our SEC filings are also available on our website, www.bioaffinitytech.com under the heading "Investor Relations—SEC Filings." The reference to our website is an inactive textual reference only, and the information contained in, and that can be accessed through our website, is not incorporated into and is not a part of this prospectus. We make available on our website our SEC filings as soon as reasonably practicable after those reports are filed with the SEC.

49

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The SEC file number for the documents incorporated by reference in this prospectus is 001-41463. The documents incorporated by reference into this prospectus contain important information about us that you should read.

The following documents are incorporated by reference into this prospectus:

- Our Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2022, filed with the SEC on March 31, 2023;
- Our Quarterly Report on [Form 10-Q](#) for the fiscal quarter ended March 31, 2023, filed with the SEC on May 15, 2023, our Quarterly Report on [Form 10-Q](#) for the quarter ended June 30, 2023, filed with the SEC on August 14, 2023, and our Quarterly Report on [Form 10-Q](#) for the quarter ended September 30, 2023, filed with the SEC on November 14, 2023;
- Our Current Reports on Form 8-K filed with the SEC on [January 4, 2023](#), [January 24, 2023](#), [February 13, 2023](#), [March 24, 2023](#), as amended, [March 24, 2023](#), [March 28, 2023](#), [April 5, 2023](#), [April 25, 2023](#), [May 1, 2023](#), [June 7, 2023](#), [July 28, 2023](#), [September 20, 2023](#), as amended [November 3, 2023](#); and
- The description of our common stock set forth in: our registration statement on [Form 8-A](#) (Commission File No. 001-41463) filed with the SEC on August 23, 2023, including any amendments thereto or reports filed for the purposes of updating this description.

We also incorporate by reference into this prospectus all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items or other information "furnished" to the SEC which is not deemed filed and not incorporated in this prospectus) that are filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the initial filing of the registration statement of which this prospectus forms a part and prior to effectiveness of the registration statement, or (ii) after the date of this prospectus and before the completion of the offering of the securities included in this prospectus. These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits that are specifically incorporated by reference into such documents. You can request a copy of these filings, at no cost, by writing or telephoning us at the following address or telephone number:

BioAffinity Technologies, Inc.
22211 W. Interstate 10, Suite 1206
San Antonio, Texas 78257
(210) 698-5334
Attn: Chief Financial Officer

Any statement contained in this prospectus or contained in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded to the extent that a statement contained in this prospectus or any subsequently filed supplement to this prospectus, or document deemed to be incorporated by reference into this prospectus, modifies or supersedes such statement.

50

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following sets forth the estimated costs and expenses, all of which shall be borne by bioAffinity Technologies, Inc. (the "Registrant"), in connection with the offering of the securities pursuant to this registration statement.

SEC registration fee	\$	3,690
FINRA filing fee		4,250
Transfer agent and registrar expenses		(1)
		(1)
Accounting fees and expenses		(1)
Legal fees and expenses		(1)
Printing and engraving expenses		(1)
Miscellaneous	\$	(1)
Total	\$	(1)

- (1) These fees are calculated based on the securities offered and the number of issuances and, accordingly, cannot be estimated at this time. An estimate of the aggregate expenses in connection with the sale and distribution of securities being offered will be included in the applicable prospectus supplement.

Item 15. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law empowers a corporation to indemnify its directors and officers and to purchase insurance with respect to liability arising out of their capacity or status as directors and officers, provided that the person acted in good faith and in a manner the person reasonably believed to be in our best interests, and, with respect to any criminal action, had no reasonable cause to believe the person's actions were unlawful. The Delaware General Corporation Law further provides that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation's bylaws, any agreement, a vote of stockholders or otherwise. The certificate of incorporation of the Registrant provides for the indemnification of the registrant's directors and officers to the fullest extent permitted under the Delaware General Corporation Law. In addition, the amended and restated bylaws of the Registrant require the registrant to fully indemnify any person who was or is made or is threatened to be made a party to or is otherwise involved in any action, suit, or proceeding, whether civil, criminal, administrative, or investigative (a "Proceeding"), by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee, or agent of another corporation, partnership, joint venture, trust, enterprise, or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) actually and reasonably incurred by such person. Notwithstanding the preceding sentence, the Bylaws provide that Corporation shall be required to indemnify a person in connection with a Proceeding (or part thereof) commenced by such person only if the commencement of such Proceeding (or part thereof) by the person was authorized in the specific case by the Board of Directors.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except (i) for any breach of the director's duty of loyalty to the corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) for payments of unlawful dividends or unlawful stock repurchases or redemptions; or (iv) for any transaction from which the director derived an improper personal benefit. The registrant's certificate of incorporation provides that the liability of the registrant's directors for monetary damages shall be eliminated to the fullest extent under applicable law.

The Registrant has an insurance policy in place that covers its officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise.

Any underwriting agreement, agency agreement, equity distribution agreement or similar agreement that the Registrant may enter into will likely provide for indemnification by any underwriters or agents of the Registrant, its directors, its officers who sign the registration statement and the Registrant's controlling persons for some liabilities, including liabilities arising under the Securities Act.

Item 16. Exhibits

The exhibits to this registration statement are listed in the Exhibit Index to this registration statement, which immediately precedes the Signature Page and which Exhibit Index is hereby incorporated by reference.

Item 17. Undertakings

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that the undertakings set forth in paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are incorporated by reference in this registration statement or are contained in a form of prospectus filed pursuant to Rule 424(b) that is part of this registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

- (i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
- (ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
- (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) That, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(7) To file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the SEC under Section 305(b)(2) of the Trust Indenture Act.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

EXHIBIT INDEX

Exhibit Number	Description
1.1**	Form of Underwriting Agreement
3.1	Certificate of Incorporation of the Registrant as filed with the Delaware Secretary of State on March 26, 2014 (Incorporated by reference as Exhibit 3.1 to the Registrant's Form S-1 (File No. 333-274608) filed with the SEC on September 20, 2023)
3.2	Amended and Restated Bylaws of Registrant (Incorporated by reference as Exhibit 3.6 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on June 16, 2022)
3.3	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on May 31, 2016 (Incorporated by reference as Exhibit 3.3 to the Registrant's Form S-1 (File No. 333-274608) filed with the SEC on September 20, 2023)
3.4	Certificate of Designation of Series A Convertible Preferred Stock of the Registrant filed with the Delaware Secretary of State on July 13, 2017 (Incorporated by reference as Exhibit 3.4 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)
3.5	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on November 29, 2021 (Incorporated by reference as Exhibit 3.5 to the Registrant's Form S-1 (File No. 333-274608) filed with the SEC on September 20, 2023)
3.6	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 23, 2022 (Incorporated by reference as Exhibit 3.2 to the Registrant's Form S-1/A (File No. 333-264463) filed with the SEC on May 25, 2022)
3.7	Certificate of Amendment to the Certificate of Incorporation of Registrant, as filed with the Delaware Secretary of State on June 6, 2023 (Incorporated by reference as Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-41463) filed with the SEC on June 7, 2023)
4.1	Form of Registrant's Common Stock Certificate (Incorporated by reference as Exhibit 4.1 to the Registrant's Form S-1/A filed with the SEC on June 16, 2022)
4.2**	Specimen Preferred Stock Certificate and Form of Certificate of Designation of Preferred Stock
4.3*	Form of Indenture
4.4**	Form of Debt Securities
4.5**	Form of Common Stock Warrant Agreement and Warrant Certificate
4.6**	Form of Preferred Stock Warrant Agreement and Warrant Certificate
4.7**	Form of Debt Securities Warrant Agreement and Warrant Certificate
4.8**	Form of Unit Agreement
5.1*	Opinion of Blank Rome LLP
23.1*	Consent of WithumSmith+Brown, PC, independent registered public accounting firm for bioAffinity Technologies Inc.
23.2*	Consent of Blank Rome LLP (included in Exhibit 5.1)
23.3*	Consent of WithumSmith+Brown, PC, independent registered public accounting firm for Village Oaks Pathology Services, P.A.
24.1*	Power of Attorney (included on the signature page)

* Filed herewith.

** To be filed, if applicable, by amendment or by a report filed under the Exchange Act and incorporated herein by reference.

*** To be filed separately, if applicable, in accordance with the requirements of Section 305(b)(2) of the Trust Indenture Act of 1939 as amended, and the appropriate rules and regulations thereunder.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of San Antonio, Texas, on November 16, 2023.

bioAffinity Technologies, Inc.By: /s/ Maria Zannes

Maria Zannes

Chief Executive Officer, President, Founder, and Director

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints Maria Zannes and Michael Dougherty our true and lawful attorneys and agents with full power of substitution and resubstitution, with full power to sign for us, and in our names in the capacities indicated below, any and all amendments to this registration statement, any subsequent registration statements pursuant to Rule 462 of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof. This power of attorney may be executed in counterparts.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Maria Zannes</u> Maria Zannes	Founder, President, Chief Executive Officer, and Director (Principal Executive Officer)	November 16, 2023
<u>/s/ Michael Dougherty</u> Michael Dougherty	Chief Financial Officer	November 16, 2023
<u>/s/ Steven Girgenti</u> Steven Girgenti	Founder, Executive Chairman, and Director	November 16, 2023
<u>/s/ Robert Anderson</u> Robert Anderson	Director	November 16, 2023
<u>/s/ Stuart Diamond</u> Stuart Diamond	Director	November 16, 2023
<u>/s/ Peter S. Knight</u> Peter S. Knight	Director	November 16, 2023
<u>/s/ Mohsin Meghji</u> Mohsin Meghji	Director	November 16, 2023
<u>/s/ Gary Rubin</u> Gary Rubin	Director	November 16, 2023
<u>/s/ Roby Joyce, MD</u> Roby Joyce, MD	Director	November 16, 2023

BIOAFFINITY TECHNOLOGIES, INC.

Issuer

AND

[TRUSTEE],
Trustee

INDENTURE

Dated as of _____, 202_

Debt Securities

TABLE OF CONTENTS

	<u>PAGE</u>
ARTICLE 1 DEFINITIONS	1
Section 1.01 Definitions of Terms	1
ARTICLE 2 ISSUE, DESCRIPTION, TERMS, EXECUTION, REGISTRATION AND EXCHANGE OF SECURITIES	3
Section 2.01 Designation and Terms of Securities	3
Section 2.02 Form of Securities and Trustee’s Certificate	5
Section 2.03 Denominations: Provisions for Payment	5
Section 2.04 Execution and Authentications	6
Section 2.05 Registration of Transfer and Exchange	6
Section 2.06 Temporary Securities	7
Section 2.07 Mutilated, Destroyed, Lost or Stolen Securities	7
Section 2.08 Cancellation	7
Section 2.09 Benefits of Indenture	7
Section 2.10 Authenticating Agent	8
Section 2.11 Global Securities	8
Section 2.12 CUSIP Numbers	8
ARTICLE 3 REDEMPTION OF SECURITIES AND SINKING FUND PROVISIONS	9
Section 3.01 Redemption	9
Section 3.02 Notice of Redemption	9

TABLE OF CONTENTS

(CONTINUED)

	<u>PAGE</u>
Section 3.03 Payment Upon Redemption	9
Section 3.04 Sinking Fund	10
Section 3.05 Satisfaction of Sinking Fund Payments with Securities	10
Section 3.06 Redemption of Securities for Sinking Fund	10
ARTICLE 4 COVENANTS	10
Section 4.01 Payment of Principal, Premium and Interest	10
Section 4.02 Maintenance of Office or Agency	10
Section 4.03 Paying Agents	11

Section 4.04	Appointment to Fill Vacancy in Office of Trustee	11
ARTICLE 5 SECURITYHOLDERS' LISTS AND REPORTS BY THE COMPANY AND THE TRUSTEE		11
Section 5.01	Company to Furnish Trustee Names and Addresses of Securityholders	11
Section 5.02	Preservation Of Information; Communications With Securityholders	11
Section 5.03	Reports by the Company	11
Section 5.04	Reports by the Trustee	12
ARTICLE 6 REMEDIES OF THE TRUSTEE AND SECURITYHOLDERS ON EVENT OF DEFAULT		12
Section 6.01	Events of Default	12
Section 6.02	Collection of Indebtedness and Suits for Enforcement by Trustee	13
Section 6.03	Application of Moneys Collected	14

ii

TABLE OF CONTENTS
(CONTINUED)

	<u>PAGE</u>	
Section 6.04	Limitation on Suits	14
Section 6.05	Rights and Remedies Cumulative; Delay or Omission Not Waiver	14
Section 6.06	Control by Securityholders	14
Section 6.07	Undertaking to Pay Costs	15
ARTICLE 7 CONCERNING THE TRUSTEE		15
Section 7.01	Certain Duties and Responsibilities of Trustee	15
Section 7.02	Certain Rights of Trustee	16
Section 7.03	Trustee Not Responsible for Recitals or Issuance or Securities	17
Section 7.04	May Hold Securities	17
Section 7.05	Moneys Held in Trust	17
Section 7.06	Compensation and Reimbursement	17
Section 7.07	Reliance on Officer's Certificate	17
Section 7.08	Disqualification; Conflicting Interests	17
Section 7.09	Corporate Trustee Required; Eligibility	18
Section 7.10	Resignation and Removal; Appointment of Successor	18
Section 7.11	Acceptance of Appointment By Successor	18
Section 7.12	Merger, Conversion, Consolidation or Succession to Business	19
Section 7.13	Preferential Collection of Claims Against the Company	19
Section 7.14	Notice of Default	19

iii

TABLE OF CONTENTS
(CONTINUED)

	<u>PAGE</u>	
ARTICLE 8 CONCERNING THE SECURITYHOLDERS		19
Section 8.01	Evidence of Action by Securityholders	19
Section 8.02	Proof of Execution by Securityholders	20
Section 8.03	Who May be Deemed Owners	20

Section 8.04	Certain Securities Owned by Company Disregarded	20
Section 8.05	Actions Binding on Future Securityholders	20
ARTICLE 9 SUPPLEMENTAL INDENTURES		20
Section 9.01	Supplemental Indentures Without the Consent of Securityholders	20
Section 9.02	Supplemental Indentures With Consent of Securityholders	21
Section 9.03	Effect of Supplemental Indentures	21
Section 9.04	Securities Affected by Supplemental Indentures	21
Section 9.05	Execution of Supplemental Indentures	22
ARTICLE 10 SUCCESSOR ENTITY		22
Section 10.01	Company May Consolidate, Etc.	22
Section 10.02	Successor Entity Substituted	22
ARTICLE 11 SATISFACTION AND DISCHARGE		22
Section 11.01	Satisfaction and Discharge of Indenture	22
Section 11.02	Discharge of Obligations	23
Section 11.03	Deposited Moneys to be Held in Trust	23
Section 11.04	Payment of Moneys Held by Paying Agents	23
Section 11.05	Repayment to Company	23

iv

TABLE OF CONTENTS

(CONTINUED)

	<u>PAGE</u>
ARTICLE 12 IMMUNITY OF INCORPORATORS, STOCKHOLDERS, OFFICERS AND DIRECTORS	23
Section 12.01	No Recourse 23
ARTICLE 13 MISCELLANEOUS PROVISIONS 24	
Section 13.01	Effect on Successors and Assigns 24
Section 13.02	Actions by Successor 24
Section 13.03	Surrender of Company Powers 24
Section 13.04	Notices 24
Section 13.05	Governing Law; Jury Trial Waiver 24
Section 13.06	Treatment of Securities as Debt 24
Section 13.07	Certificates and Opinions as to Conditions Precedent 24
Section 13.08	Payments on Business Days 24
Section 13.09	Conflict with Trust Indenture Act 24
Section 13.10	Counterparts 25
Section 13.11	Separability 25
Section 13.12	Compliance Certificates 25
Section 13.13	Patriot Act 25
Section 13.14	Force Majeure 25
Section 13.12	Table of Contents; Headings 25

v

INDENTURE, dated as of [●], 2023, among bioAffinity Technologies, Inc., a Delaware corporation (the “Company”), and [TRUSTEE], as trustee (the “Trustee”):

WHEREAS, for its lawful corporate purposes, the Company has duly authorized the execution and delivery of this Indenture to provide for the issuance of debt securities (hereinafter referred to as the “Securities”), in an unlimited aggregate principal amount to be issued from time to time in one or more series as in this Indenture provided, as registered Securities without coupons, to be authenticated by the certificate of the Trustee;

WHEREAS, to provide the terms and conditions upon which the Securities are to be authenticated, issued and delivered, the Company has duly authorized the execution of this Indenture; and

WHEREAS, all things necessary to make this Indenture a valid agreement of the Company, in accordance with its terms, have been done.

NOW, THEREFORE, in consideration of the premises and the purchase of the Securities by the holders thereof, it is mutually covenanted and agreed as follows for the equal and ratable benefit of the holders of Securities:

ARTICLE 1

DEFINITIONS

Section 1.01 Definitions of Terms.

The terms defined in this Section (except as in this Indenture or any indenture supplemental hereto otherwise expressly provided or unless the context otherwise requires) for all purposes of this Indenture and of any indenture supplemental hereto shall have the respective meanings specified in this Section and shall include the plural as well as the singular. All other terms used in this Indenture that are defined in the Trust Indenture Act of 1939, as amended, or that are by reference in such Act defined in the Securities Act of 1933, as amended (except as herein or any indenture supplemental hereto otherwise expressly provided or unless the context otherwise requires), shall have the meanings assigned to such terms in said Trust Indenture Act and in said Securities Act as in force at the date of the execution of this instrument.

“*Authenticating Agent*” means the Trustee or an authenticating agent with respect to all or any of the series of Securities appointed by the Trustee pursuant to Section 2.10.

“*Bankruptcy Law*” means Title 11, U.S. Code, or any similar federal or state law for the relief of debtors.

“*Board of Directors*” means the Board of Directors (or the functional equivalent thereof) of the Company or any duly authorized committee of such Board.

“*Board Resolution*” means a copy of a resolution certified by the Secretary or an Assistant Secretary of the Company to have been duly adopted by the Board of Directors (or duly authorized committee thereof) and to be in full force and effect on the date of such certification.

“*Business Day*” means, with respect to any series of Securities, any day other than a day on which federal or state banking institutions in the Borough of Manhattan, the City of New York, or in the city of the Corporate Trust Office of the Trustee, are authorized or obligated by law, executive order or regulation to close.

“*Commission*” means the Securities and Exchange Commission, as from time to time constituted, created under the Exchange Act, or, if at any time after the execution of this instrument such Commission is not existing and performing the duties now assigned to it under the Trust Indenture Act, then the body performing such duties at such time.

“*Company*” means bioAffinity Technologies, Inc., a corporation duly organized and existing under the laws of the State of Delaware, and, subject to the provisions of Article Ten, shall also include its successors and assigns.

“*Corporate Trust Office*” means the office of the Trustee at which, at any particular time, its corporate trust business shall be principally administered, which office at the date hereof is located at .

“*Custodian*” means any receiver, trustee, assignee, liquidator or similar official under any Bankruptcy Law.

“*Defaulted Interest*” has the meaning set forth in Section 2.03.

“*Depository*” means, with respect to Securities of any series for which the Company shall determine that such Securities will be issued as a Global Security, The Depository Trust Company, another clearing agency, or any successor registered as a clearing agency under the Exchange Act, or other applicable statute or regulation, which, in each case, shall be designated by the Company pursuant to either Section 2.01 or 2.11.

“*Event of Default*” means, with respect to Securities of a particular series, any event specified in Section 6.01, continued for the period of time, if any, therein designated.

1

“*Exchange Act*” means the United States Securities and Exchange Act of 1934, as amended, and the rules and regulations promulgated by the Commission thereunder.

The term “*given*”, “*mailed*”, “*notify*” or “*sent*” with respect to any notice to be given to a Securityholder pursuant to this Indenture, shall mean notice (x) given to the Depository (or its designee) pursuant to the standing instructions from the Depository or its designee, including by electronic mail in accordance with accepted practices or procedures at the Depository (in the case of a Global Security) or (y) mailed to such Holder by first class mail, postage prepaid, at its address as it appears on the Security Register (in the case of a definitive Security). Notice so “*given*” shall be deemed to include any notice to be “*mailed*” or “*delivered*,” as applicable, under this Indenture.

“*Global Security*” means a Security issued to evidence all or a part of any series of Securities which is executed by the Company and authenticated and delivered by the Trustee to the Depository or pursuant to the Depository’s instruction, all in accordance with the Indenture, which shall be registered in the name of the Depository or its nominee.

“*Governmental Obligations*” means securities that are (a) direct obligations of the United States of America for the payment of which its full faith and credit is pledged or (b) obligations of a Person controlled or supervised by and acting as an agency or instrumentality of the United States of America, the payment of which is unconditionally guaranteed as a full faith and credit obligation by the United States of America that, in either case, are not callable or redeemable at the option of the issuer thereof at any time prior to the stated maturity of the Securities, and shall also include a depository receipt issued by a bank or trust company as custodian with respect to any such Governmental Obligation or a specific payment of principal of or interest on any such Governmental Obligation held by such custodian for the account of the holder of such depository receipt; provided, however, that (except as required by law) such custodian is not authorized to make any deduction from the amount payable to the holder of such depository receipt from any amount received by the custodian in respect of the Governmental Obligation or the specific payment of principal of or interest on the Governmental Obligation evidenced by such depository receipt.

“*herein*”, “*hereof*” and “*hereunder*”, and other words of similar import, refer to this Indenture as a whole and not to any particular Article, Section or other subdivision.

“*Indenture*” means this instrument as originally executed or as it may from time to time be supplemented or amended by one or more indentures supplemental hereto entered into in accordance with the terms hereof and shall include the terms of particular series of Securities established as contemplated by Section 2.01.

“**Interest Payment Date**”, when used with respect to any installment of interest on a Security of a particular series, means the date specified in such Security or in a Board Resolution or in an indenture supplemental hereto with respect to such series as the fixed date on which an installment of interest with respect to Securities of that series is due and payable.

“**Officer**” means, with respect to the Company, the chairman of the Board of Directors, a chief executive officer, a president, a chief financial officer, a chief operating officer, any executive vice president, any senior vice president, any vice president, the treasurer or any assistant treasurer, the controller or any assistant controller or the secretary or any assistant secretary.

“**Officer’s Certificate**” means a certificate signed by any Officer. Each such certificate shall include the statements provided for in Section 13.07, if and to the extent required by the provisions thereof.

“**Opinion of Counsel**” means an opinion in writing subject to customary exceptions of legal counsel, who may be an employee of or counsel for the Company, that is delivered to the Trustee in accordance with the terms hereof. Each such opinion shall include the statements provided for in Section 13.07, if and to the extent required by the provisions thereof.

“**Outstanding**”, when used with reference to Securities of any series, means, subject to the provisions of Section 8.04, as of any particular time, all Securities of that series theretofore authenticated and delivered by the Trustee under this Indenture, except (a) Securities theretofore canceled by the Trustee or any paying agent, or delivered to the Trustee or any paying agent for cancellation or that have previously been canceled; (b) Securities or portions thereof for the payment or redemption of which moneys or Governmental Obligations in the necessary amount shall have been deposited in trust with the Trustee or with any paying agent (other than the Company) or shall have been set aside and segregated in trust by the Company (if the Company shall act as its own paying agent); provided, however, that if such Securities or portions of such Securities are to be redeemed prior to the maturity thereof, notice of such redemption shall have been given as provided in Article Three, or provision satisfactory to the Trustee shall have been made for giving such notice; and (c) Securities in lieu of or in substitution for which other Securities shall have been authenticated and delivered pursuant to the terms of Section 2.07.

“**Person**” means any individual, corporation, partnership, joint venture, joint-stock company, limited liability company, association, trust, unincorporated organization, any other entity or organization, including a government or political subdivision or an agency or instrumentality thereof.

“**Predecessor Security**” of any particular Security means every previous Security evidencing all or a portion of the same debt as that evidenced by such particular Security; and, for the purposes of this definition, any Security authenticated and delivered under Section 2.07 in lieu of a lost, destroyed or stolen Security shall be deemed to evidence the same debt as the lost, destroyed or stolen Security.

“**Responsible Officer**” when used with respect to the Trustee means any officer within the Corporate Trust Office of the Trustee (or any successor group of the Trustee) or any other officer of the Trustee customarily performing functions similar to those performed by any of the above designated officers and also means, with respect to a particular corporate trust matter, any other officer to whom such matter is referred because of his or her knowledge of and familiarity with the particular subject and in each case who shall have direct responsibility for the administration of this Indenture.

“**Securities**” has the meaning stated in the first recital of this Indenture and more particularly means any Securities authenticated and delivered under this Indenture.

“**Securities Act**” means the Securities Act of 1933, as amended.

“**Securityholder**”, “**holder of Securities**”, “**registered holder**”, or other similar term, means the Person or Persons in whose name or names a particular Security is registered on the Security Register kept for that purpose in accordance with the terms of this Indenture.

“**Security Register**” and “**Security Registrar**” shall have the meanings as set forth in Section 2.05.

“**Subsidiary**” means, with respect to any Person, any corporation, association, partnership or other business entity of which more than 50% of the total voting power of shares of capital stock or other interests (including partnership interests) entitled (without regard to the occurrence of any contingency) to vote in the election of directors, managers, general partners or trustees thereof is at the time owned or controlled, directly or indirectly, by (i) such Person; (ii) such Person and one or more Subsidiaries of such Person; or (iii) one or more Subsidiaries of such Person.

“**Trustee**” means, and, subject to the provisions of Article Seven, shall also include its successors and assigns, and, if at any time there is more than one Person acting in such capacity hereunder, “Trustee” shall mean each such Person. The term “Trustee” as used with respect to a particular series of the Securities shall mean the trustee with respect to that series.

“**Trust Indenture Act**” means the Trust Indenture Act of 1939, as amended.

“**U.S.A. Patriot Act**” means the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Pub. L. 107-56, as amended and signed into law October 26, 2001.

ARTICLE 2

ISSUE, DESCRIPTION, TERMS, EXECUTION, REGISTRATION AND EXCHANGE OF SECURITIES

Section 2.01 Designation and Terms of Securities.

(a) The aggregate principal amount of Securities that may be authenticated and delivered under this Indenture is unlimited. The Securities may be issued in one or more series up to the aggregate principal amount of Securities of that series from time to time authorized by or pursuant to a Board Resolution or pursuant to one or more indentures supplemental hereto. Prior to the initial issuance of Securities of any series, there shall be established in or pursuant to a Board Resolution, and set forth in an Officer’s Certificate, or established in one or more indentures supplemental hereto:

(1) the title of the Securities of the series (which shall distinguish the Securities of that series from all other Securities);

(2) any limit upon the aggregate principal amount of the Securities of that series that may be authenticated and delivered under this Indenture (except for Securities authenticated and delivered upon registration of transfer of, or in exchange for, or in lieu of, other Securities of that series);

(3) the maturity date or dates on which the principal of the Securities of the series is payable;

(4) the form of the Securities of the series including the form of the certificate of authentication for such series;

(5) the applicability of any guarantees;

(6) whether or not the Securities will be secured or unsecured, and the terms of any secured debt;

(7) whether the Securities rank as senior debt, senior subordinated debt, subordinated debt or any combination thereof, and the terms of any subordination;

(8) if the price (expressed as a percentage of the aggregate principal amount thereof) at which such Securities will be issued is a price other than the principal amount thereof, the portion of the principal amount thereof payable upon declaration of acceleration of the maturity thereof, or if applicable, the portion of the principal amount of such Securities that is convertible into another security or the method by which any such portion shall be determined;

(9) the interest rate or rates, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;

(10) the Company's right, if any, to defer the payment of interest and the maximum length of any such deferral period;

3

(11) if applicable, the date or dates after which, or the period or periods during which, and the price or prices at which, the Company may at its option, redeem the series of Securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;

(12) the date or dates, if any, on which, and the price or prices at which the Company is obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the Securityholder's option to purchase, the series of Securities and the currency or currency unit in which the Securities are payable;

(13) the denominations in which the Securities of the series shall be issuable, if other than denominations of one thousand U.S. dollars (\$1,000) or any integral multiple thereof;

(14) any and all terms, if applicable, relating to any auction or remarketing of the Securities of that series and any security for the obligations of the Company with respect to such Securities and any other terms which may be advisable in connection with the marketing of Securities of that series;

(15) whether the Securities of the series shall be issued in whole or in part in the form of a Global Security or Securities; the terms and conditions, if any, upon which such Global Security or Securities may be exchanged in whole or in part for other individual Securities; and the Depositary for such Global Security or Securities;

(16) if applicable, the provisions relating to conversion or exchange of any Securities of the series and the terms and conditions upon which such Securities will be so convertible or exchangeable, including the conversion or exchange price, as applicable, or how it will be calculated and may be adjusted, any mandatory or optional (at the Company's option or the holders' option) conversion or exchange features, the applicable conversion or exchange period and the manner of settlement for any conversion or exchange, which may, without limitation, include the payment of cash as well as the delivery of securities;

(17) if other than the full principal amount thereof, the portion of the principal amount of Securities of the series which shall be payable upon declaration of acceleration of the maturity thereof pursuant to Section 6.01;

(18) additions to or changes in the covenants applicable to the series of Securities being issued, including, among others, the consolidation, merger or sale covenant;

(19) additions to or changes in the Events of Default with respect to the Securities and any change in the right of the Trustee or the Securityholders to declare the principal, premium, if any, and interest, if any, with respect to such Securities to be due and payable;

(20) additions to or changes in or deletions of the provisions relating to covenant defeasance and legal defeasance;

(21) additions to or changes in the provisions relating to satisfaction and discharge of this Indenture;

(22) additions to or changes in the provisions relating to the modification of this Indenture both with and without the consent of Securityholders of Securities issued under this Indenture;

(23) the currency of payment of Securities if other than U.S. dollars and the manner of determining the equivalent amount in U.S. dollars;

(24) whether interest will be payable in cash or additional Securities at the Company's or the Securityholders' option and the terms and conditions upon which the election may be made;

(25) the terms and conditions, if any, upon which the Company shall pay amounts in addition to the stated interest, premium, if any and principal amounts of the Securities of the series to any Securityholder that is not a "United States person" for federal tax purposes;

(26) any restrictions on transfer, sale or assignment of the Securities of the series; and

(27) any other specific terms, preferences, rights or limitations of, or restrictions on, the Securities, any other additions or changes in the provisions of this Indenture, and any terms that may be required by us or advisable under applicable laws or regulations.

All Securities of any one series shall be substantially identical except as may otherwise be provided in or pursuant to any such Board Resolution or in any indentures supplemental hereto.

If any of the terms of the series are established by action taken pursuant to a Board Resolution of the Company, a copy of an appropriate record of such action shall be certified by the secretary or an assistant secretary of the Company and delivered to the Trustee at or prior to the delivery of the Officer's Certificate of the Company setting forth the terms of the series.

Securities of any particular series may be issued at various times, with different dates on which the principal or any installment of principal is payable, with different rates of interest, if any, or different methods by which rates of interest may be determined, with different dates on which such interest may be payable and with different redemption dates.

4

The Securities of any series and the Trustee's certificate of authentication to be borne by such Securities shall be substantially of the tenor and purport as set forth in one or more indentures supplemental hereto or as provided in a Board Resolution, and set forth in an Officer's Certificate, and they may have such letters, numbers or other marks of identification or designation and such legends or endorsements printed, lithographed or engraved thereon as the Company may deem appropriate and as are not inconsistent with the provisions of this Indenture, or as may be required to comply with any law or with any rule or regulation made pursuant thereto or with any rule or regulation of any securities exchange on which Securities of that series may be listed, or to conform to usage.

Section 2.03 Denominations: Provisions for Payment.

The Securities shall be issuable as registered Securities and in the denominations of one thousand U.S. dollars (\$1,000) or any integral multiple thereof, subject to Section 2.01(a)(13). The Securities of a particular series shall bear interest payable on the dates and at the rate specified with respect to that series. Subject to Section 2.01(a)(23), the principal of and the interest on the Securities of any series, as well as any premium thereon in case of redemption or repurchase thereof prior to maturity, and any cash amount due upon conversion or exchange thereof, shall be payable in the coin or currency of the United States of America that at the time is legal tender for public and private debt, at the office or agency of the Company maintained for that purpose. Each Security shall be dated the date of its authentication. Interest on the Securities shall be computed on the basis of a 360-day year composed of 12 30-day months.

The interest installment on any Security that is payable, and is punctually paid or duly provided for, on any Interest Payment Date for Securities of that series shall be paid to the Person in whose name said Security (or one or more Predecessor Securities) is registered at the close of business on the regular record date for such interest installment. In the event that any Security of a particular series or portion thereof is called for redemption and the redemption date is subsequent to a regular record date with respect to any Interest Payment Date and prior to such Interest Payment Date, interest on such Security will be paid upon presentation and surrender of such Security as provided in Section 3.03.

Any interest on any Security that is payable, but is not punctually paid or duly provided for, on any Interest Payment Date for Securities of the same series (herein called "Defaulted Interest") shall forthwith cease to be payable to the registered holder on the relevant regular record date by virtue of having been such holder; and such Defaulted Interest shall be paid by the Company, at its election, as provided in clause (1) or clause (2) below:

(1) The Company may make payment of any Defaulted Interest on Securities to the Persons in whose names such Securities (or their respective Predecessor Securities) are registered in the Security Register at the close of business on a special record date for the payment of such Defaulted Interest, which shall be fixed in the following manner: the Company shall notify the Trustee in writing of the amount of Defaulted Interest proposed to be paid on each such Security and the date of the proposed payment, and at the same time the Company shall deposit with the Trustee an amount of money equal to the aggregate amount proposed to be paid in respect of such Defaulted Interest or shall make arrangements satisfactory to the Trustee for such deposit prior to the date of the proposed payment, such money when deposited to be held in trust for the benefit of the Persons entitled to such Defaulted Interest as in this clause provided. Thereupon the Trustee shall fix a special record date for the payment of such Defaulted Interest which shall not be more than 15 nor less than 10 days prior to the date of the proposed payment and not less than 10 days after the receipt by the Trustee of the notice of the proposed payment. The Trustee shall promptly notify the Company of such special record date and, in the name and at the expense of the Company, shall cause notice of the proposed payment of such Defaulted Interest and the special record date therefor to be sent, to each Securityholder not less than 10 days prior to such special record date. Notice of the proposed payment of such Defaulted Interest and the special record date therefor having been sent as aforesaid, such Defaulted Interest shall be paid to the Persons in whose names such Securities (or their respective Predecessor Securities) are registered in the Security Register on such special record date.

(2) The Company may make payment of any Defaulted Interest on any Securities in any other lawful manner not inconsistent with the requirements of any securities exchange on which such Securities may be listed, and upon such notice as may be required by such exchange, if, after notice given by the Company to the Trustee of the proposed payment pursuant to this clause, such manner of payment shall be deemed practicable by the Trustee.

Unless otherwise set forth in a Board Resolution or one or more indentures supplemental hereto establishing the terms of any series of Securities pursuant to Section 2.01 hereof, the term "regular record date" as used in this Section with respect to a series of Securities and any Interest Payment Date for such series shall mean either the fifteenth day of the month immediately preceding the month in which an Interest Payment Date established for such series pursuant to Section 2.01 hereof shall occur, if such Interest Payment Date is the first day of a month, or the first day of the month in which an Interest Payment Date established for such series pursuant to Section 2.01 hereof shall occur, if such Interest Payment Date is the fifteenth day of a month, whether or not such date is a Business Day.

Subject to the foregoing provisions of this Section, each Security of a series delivered under this Indenture upon transfer of or in exchange for or in lieu of any other Security of such series shall carry the rights to interest accrued and unpaid, and to accrue, that were carried by such other Security.

Section 2.04 Execution and Authentications.

The Securities shall be signed on behalf of the Company by one of its Officers. Signatures may be in the form of a manual or facsimile signature.

The Company may use the facsimile signature of any Person who shall have been an Officer (at the time of execution), notwithstanding the fact that at the time the Securities shall be authenticated and delivered or disposed of such Person shall have ceased to be such an officer of the Company. The Securities may contain such notations, legends or endorsements required by law, stock exchange rule or usage. Each Security shall be dated the date of its authentication by the Trustee.

A Security shall not be valid until authenticated manually by an authorized signatory of the Trustee, or by an Authenticating Agent. Such signature shall be conclusive evidence that the Security so authenticated has been duly authenticated and delivered hereunder and that the holder is entitled to the benefits of this Indenture. At any time and from time to time after the execution and delivery of this Indenture, the Company may deliver Securities of any series executed by the Company to the Trustee for authentication, together with a written order of the Company for the authentication and delivery of such Securities, signed by an Officer, and the Trustee in accordance with such written order shall authenticate and deliver such Securities.

Upon the Company's delivery of any such authentication order to the Trustee at any time after the initial issuance of Securities under this Indenture, the Trustee shall be provided with, and (subject to Sections 315(a) through 315(d) of the Trust Indenture Act) shall be fully protected in relying upon, (1) an Opinion of Counsel or reliance letter and (2) an Officer's Certificate stating that all conditions precedent to the execution, authentication and delivery of such Securities are in conformity with the provisions of this Indenture.

The Trustee shall not be required to authenticate such Securities if the issue of such Securities pursuant to this Indenture will affect the Trustee's own rights, duties or immunities under the Securities and this Indenture or otherwise in a manner that is not reasonably acceptable to the Trustee.

Section 2.05 Registration of Transfer and Exchange.

(a) Securities of any series may be exchanged upon presentation thereof at the office or agency of the Company designated for such purpose, for other Securities of such series of authorized denominations, and for a like aggregate principal amount, upon payment of a sum sufficient to cover any tax or other governmental charge in relation thereto, all as provided in this Section. In respect of any Securities so surrendered for exchange, the Company shall execute, the Trustee shall authenticate and such office or agency shall deliver in exchange therefor the Security or Securities of the same series that the Securityholder making the exchange shall be entitled to receive, bearing numbers not contemporaneously outstanding.

(b) The Company shall keep, or cause to be kept, at its office or agency designated for such purpose a register or registers (herein referred to as the “Security Register”) in which, subject to such reasonable regulations as it may prescribe, the Company shall register the Securities and the transfers of Securities as in this Article provided and which at all reasonable times shall be open for inspection by the Trustee. The registrar for the purpose of registering Securities and transfer of Securities as herein provided shall be appointed as authorized by Board Resolution or Supplemental Indenture (the “Security Registrar”).

Upon surrender for transfer of any Security at the office or agency of the Company designated for such purpose, the Company shall execute, the Trustee shall authenticate and such office or agency shall deliver in the name of the transferee or transferees a new Security or Securities of the same series as the Security presented for a like aggregate principal amount.

The Company initially appoints the Trustee as initial Security Registrar for each series of Securities

All Securities presented or surrendered for exchange or registration of transfer, as provided in this Section, shall be accompanied (if so required by the Company or the Security Registrar) by a written instrument or instruments of transfer, in form satisfactory to the Company or the Security Registrar, duly executed by the registered holder or by such holder’s duly authorized attorney in writing.

(c) Except as provided pursuant to Section 2.01 pursuant to a Board Resolution, and set forth in an Officer’s Certificate, or established in one or more indentures supplemental to this Indenture, no service charge shall be made for any exchange or registration of transfer of Securities, or issue of new Securities in case of partial redemption of any series or repurchase, conversion or exchange of less than the entire principal amount of a Security, but the Company may require payment of a sum sufficient to cover any tax or other governmental charge in relation thereto, other than exchanges pursuant to Section 2.06, Section 3.03(b) and Section 9.04 not involving any transfer.

(d) The Company and the Security Registrar shall not be required (i) to issue, exchange or register the transfer of any Securities during a period beginning at the opening of business 15 days before the day of the sending of a notice of redemption of less than all the Outstanding Securities of the same series and ending at the close of business on the day of such sending, nor (ii) to register the transfer of or exchange any Securities of any series or portions

thereof called for redemption or surrendered for repurchase, but not validly withdrawn, other than the unredeemed portion of any such Securities being redeemed in part or not surrendered for repurchase, as the case may be. The provisions of this Section 2.05 are, with respect to any Global Security, subject to Section 2.11 hereof.

The Trustee shall have no obligation or duty to monitor, determine or inquire as to compliance with any restrictions on transfer imposed under this Indenture or under applicable law with respect to any transfer of any interest in any Security (including any transfers between or among Depository participants or beneficial owners of interests in any Global Security) other than to require delivery of such certificates and other documentation or evidence as are expressly required by, and to do so if and when expressly required by the terms of, this Indenture, and to examine the same to determine substantial compliance as to form with the express requirements hereof.

Section 2.06 Temporary Securities.

Pending the preparation of definitive Securities of any series, the Company may execute, and the Trustee shall authenticate and deliver, temporary Securities (printed, lithographed or typewritten) of any authorized denomination. Such temporary Securities shall be substantially in the form of the definitive Securities in lieu of which they are issued, but with such omissions, insertions and variations as may be appropriate for temporary Securities, all as may be determined by the Company. Every temporary Security of any series shall be executed by the Company and be authenticated by the Trustee upon the same conditions and in substantially the same manner, and with like effect, as the definitive Securities of such series. Without unnecessary delay the Company will execute and will furnish definitive Securities of such series and thereupon any or all temporary Securities of such series may be surrendered in exchange therefor (without charge to the Securityholders), at the office or agency of the Company designated for the purpose, and the Trustee shall authenticate and such office or agency shall deliver in exchange for such temporary Securities an equal aggregate principal amount of definitive Securities of such series, unless the Company advises the Trustee to the effect that definitive Securities need not be executed and furnished until further notice from the Company. Until so exchanged, the temporary Securities of such series shall be entitled to the same benefits under this Indenture as definitive Securities of such series authenticated and delivered hereunder.

Section 2.07 Mutilated, Destroyed, Lost or Stolen Securities.

In case any temporary or definitive Security shall become mutilated or be destroyed, lost or stolen, the Company (subject to the next succeeding sentence) shall execute, and upon the Company’s request the Trustee (subject as aforesaid) shall authenticate and deliver, a new Security of the same series, bearing a number not contemporaneously outstanding, in exchange and substitution for the mutilated Security, or in lieu of and in substitution for the Security so destroyed,

lost or stolen. In every case the applicant for a substituted Security shall furnish to the Company and the Trustee such security or indemnity as may be required by them to save each of them harmless, and, in every case of destruction, loss or theft, the applicant shall also furnish to the Company and the Trustee evidence to their satisfaction of the destruction, loss or theft of the applicant’s Security and of the ownership thereof. The Trustee may authenticate any such substituted Security and deliver the same upon the written request or authorization of any

officer of the Company. Upon the issuance of any substituted Security, the Company may require the payment of a sum sufficient to cover any tax or other governmental charge that may be imposed in relation thereto and any other expenses (including the fees and expenses of the Trustee) connected therewith.

In case any Security that has matured or is about to mature shall become mutilated or be destroyed, lost or stolen, the Company may, instead of issuing a substitute Security, pay or authorize the payment of the same (without surrender thereof except in the case of a mutilated Security) if the applicant for such payment shall furnish to the Company and the Trustee such security or indemnity as they may require to save them harmless, and, in case of destruction, loss or theft, evidence to the satisfaction of the Company and the Trustee of the destruction, loss or theft of such Security and of the ownership thereof.

Every replacement Security issued pursuant to the provisions of this Section shall constitute an additional contractual obligation of the Company whether or not the mutilated, destroyed, lost or stolen Security shall be found at any time, or be enforceable by anyone, and shall be entitled to all the benefits of this Indenture equally and proportionately with any and all other Securities of the same series duly issued hereunder. All Securities shall be held and owned upon the express condition that the foregoing provisions are exclusive with respect to the replacement or payment of mutilated, destroyed, lost or stolen Securities, and shall preclude (to the extent lawful) any and all other rights or remedies, notwithstanding any law or statute existing or hereafter enacted to the contrary with respect to the replacement or payment of negotiable instruments or other securities without their surrender.

Section 2.08 Cancellation.

All Securities surrendered for the purpose of payment, redemption, repurchase, exchange, registration of transfer or conversion shall, if surrendered to the Company or any paying agent (or any other applicable agent), be delivered to the Trustee for cancellation, or, if surrendered to the Trustee, shall be cancelled by it, and no Securities shall be issued in lieu thereof except as expressly required or permitted by any of the provisions of this Indenture. On request of the Company at the time of such surrender, the Trustee shall deliver to the Company canceled Securities held by the Trustee. In the absence of such request the Trustee may dispose of canceled Securities in accordance with its standard procedures and deliver a certificate of disposition to the Company. If the Company shall otherwise acquire any of the Securities, however, such acquisition shall not operate as a redemption or satisfaction of the indebtedness represented by such Securities unless and until the same are delivered to the Trustee for cancellation.

Section 2.09 Benefits of Indenture.

Nothing in this Indenture or in the Securities, express or implied, shall give or be construed to give to any Person, other than the parties hereto and the holders of the Securities any legal or equitable right, remedy or claim under or in respect of this Indenture, or under any covenant, condition or provision herein contained; all such covenants, conditions and provisions being for the sole benefit of the parties hereto and of the holders of the Securities.

Section 2.10 Authenticating Agent.

So long as any of the Securities of any series remain Outstanding there may be an Authenticating Agent for any or all such series of Securities which the Trustee shall have the right to appoint. Said Authenticating Agent shall be authorized to act on behalf of the Trustee to authenticate Securities of such series issued upon exchange, transfer or partial redemption, repurchase or conversion thereof, and Securities so authenticated shall be entitled to the benefits of this Indenture and shall be valid and obligatory for all purposes as if authenticated by the Trustee hereunder. All references in this Indenture to the authentication of Securities by the Trustee shall be deemed to include authentication by an Authenticating Agent for such series. Each Authenticating Agent shall be acceptable to the Company and shall be a corporation that has a combined capital and surplus, as most recently reported or determined by it, sufficient under the laws of any jurisdiction under which it is organized or in which it is doing business to conduct a trust business, and that is otherwise authorized under such laws to conduct such business and is subject to supervision or examination by federal or state authorities. If at any time any Authenticating Agent shall cease to be eligible in accordance with these provisions, it shall resign immediately.

Any Authenticating Agent may at any time resign by giving written notice of resignation to the Trustee and to the Company. The Trustee may at any time (and upon request by the Company shall) terminate the agency of any Authenticating Agent by giving written notice of termination to such Authenticating Agent and to the Company. Upon resignation, termination or cessation of eligibility of any Authenticating Agent, the Trustee may appoint an eligible successor Authenticating Agent acceptable to the Company. Any successor Authenticating Agent, upon acceptance of its appointment hereunder, shall become vested with all the rights, powers and duties of its predecessor hereunder as if originally named as an Authenticating Agent pursuant hereto.

Section 2.11 Global Securities.

(a) If the Company shall establish pursuant to Section 2.01 that the Securities of a particular series are to be issued as a Global Security, then the Company shall execute and the Trustee shall, in accordance with Section 2.04, authenticate and deliver, a Global Security that (i) shall represent, and shall be denominated in an amount equal to the aggregate principal amount of, all of the Outstanding Securities of such series, (ii) shall be registered in the name of the Depository or its nominee, (iii) shall be delivered by the Trustee to the Depository or pursuant to the Depository's instruction (or if the Depository names the Trustee as its custodian, retained by the Trustee), and (iv) shall bear a legend substantially to the following effect: "Except as otherwise provided in Section 2.11 of the Indenture, this Security may be transferred, in whole but not in part, only to another nominee of the Depository or to a successor Depository or to a nominee of such successor Depository."

(b) Notwithstanding the provisions of Section 2.05, the Global Security of a series may be transferred, in whole but not in part and in the manner provided in Section 2.05, only to another nominee of the Depository for such series, or to a successor Depository for such series selected or approved by the Company or to a nominee of such successor Depository.

(c) If at any time the Depository for a series of the Securities notifies the Company that it is unwilling or unable to continue as Depository for such series or if at any time the Depository for such series shall no longer be registered or in good standing under the Exchange Act, or other applicable statute or regulation, and a successor Depository for such series is not appointed by the Company within 90 days after the Company receives such notice or becomes aware of such condition, as the case may be, or if an Event of Default has occurred and is continuing and the Company has received a request from the Depository or from the Trustee, this Section 2.11 shall no longer be applicable to the Securities of such series and the Company will execute, and subject to Section 2.04, the Trustee will authenticate and deliver the Securities of such series in definitive registered form without coupons, in authorized denominations, and in an aggregate principal amount equal to the principal amount of the Global Security of such series in exchange for such Global Security. In addition, the Company may at any time determine that the Securities of any series shall no longer be represented by a Global Security and that the provisions of this Section 2.11 shall no longer apply to the Securities of such series. In such event the Company will execute and, subject to Section 2.04, the Trustee, upon receipt of an Officer's Certificate evidencing such determination by the Company, will authenticate and deliver the Securities of such series in definitive registered form without coupons, in authorized denominations, and in an aggregate principal amount equal to the principal amount of the Global Security of such series in exchange for such Global Security. Upon the exchange of the Global Security for such Securities in definitive registered form without coupons, in authorized denominations, the Global Security shall be canceled by the Trustee. Such Securities in definitive registered form issued in exchange for the Global Security pursuant to this Section 2.11(c) shall be registered in such names and in such authorized denominations as the Depository, pursuant to instructions from its direct or indirect participants or otherwise, shall instruct the Trustee. The Trustee shall deliver such Securities to the Depository for delivery to the Persons in whose names such Securities are so registered.

Section 2.12 CUSIP Numbers.

The Company in issuing the Securities may use "CUSIP" numbers (if then generally in use), and, if so, the Trustee shall use "CUSIP" numbers in notices of redemption as a convenience to Holders; provided that any such notice may state that no representation is made as to the correctness of such numbers either as printed on the Securities or as contained in any notice of a redemption and that reliance may be placed only on the other elements of identification printed on the Securities, and any such redemption shall not be affected by any defect in or omission of such numbers. The Company will promptly notify the Trustee of any change in the "CUSIP" numbers.

ARTICLE 3

REDEMPTION OF SECURITIES AND SINKING FUND PROVISIONS

Section 3.01 Redemption.

The Company may redeem the Securities of any series issued hereunder on and after the dates and in accordance with the terms established for such series pursuant to Section 2.01 hereof.

Section 3.02 Notice of Redemption.

(a) In case the Company shall desire to exercise such right to redeem all or, as the case may be, a portion of the Securities of any series in accordance with any right the Company reserved for itself to do so pursuant to Section 2.01 hereof, the Company shall, or shall cause the Trustee to, give notice of such redemption to holders of the Securities of such series to be redeemed by mailing, first class postage prepaid (or with regard to any Global Security held in book entry form, by electronic mail in accordance with the applicable procedures of the Depository), a notice of such redemption not less than 30 days and not more than 90 days before the date fixed for redemption of that series to such Securityholders, unless a shorter period is specified in the Securities to be redeemed. Any notice that is mailed in the manner herein provided shall be conclusively presumed to have been duly given, whether or not the registered holder receives the notice. In any case, failure duly to give such notice to the holder of any Security of any series designated for redemption in whole or in part, or any defect in the notice, shall not affect the validity of the proceedings for the redemption of any other Securities of such series or any other series. In the case of any redemption of Securities prior to the expiration of any restriction on such redemption provided in the terms of such Securities or elsewhere in this Indenture, the Company shall furnish the Trustee with an Officer's Certificate evidencing compliance with any such restriction.

Each such notice of redemption shall identify the Securities to be redeemed (including CUSIP numbers, if any), specify the date fixed for redemption and the redemption price at which Securities of that series are to be redeemed, and shall state that payment of the redemption price of such Securities to be redeemed will be made at the office or agency of the Company, upon presentation and surrender of such Securities, that interest accrued to the date fixed for redemption will be paid as specified in said notice, that from and after said date interest will cease to accrue and that the redemption is from a sinking fund, if such is the case. If less than all the Securities of a series are to be redeemed, the notice to the holders of Securities of that series to be redeemed in part shall specify the particular Securities to be so redeemed.

In case any Security is to be redeemed in part only, the notice that relates to such Security shall state the portion of the principal amount thereof to be redeemed, and shall state that on and after the redemption date, upon surrender of such Security, a new Security or Securities of such series in principal amount equal to the unredeemed portion thereof will be issued.

(b) If less than all the Securities of a series are to be redeemed, the Company shall give the Trustee at least 45 days' notice (unless a shorter notice shall be satisfactory to the Trustee) in advance of the date fixed for redemption as to the aggregate principal amount of Securities of the series to be redeemed, and thereupon the Securities to be redeemed shall be selected, by lot, on a pro rata basis, or in such other manner as the Company shall deem appropriate and fair in its discretion and that may provide for the selection of a portion or portions (equal to one thousand U.S. dollars (\$1,000) or any integral multiple thereof) of the principal amount of such Securities of a denomination larger than \$1,000, the Securities to be redeemed and shall thereafter promptly notify the Company in writing of the numbers of the Securities to be redeemed, in whole or in part. The Company may, if and whenever it shall so elect, by delivery of instructions signed on its behalf by an Officer, instruct the Trustee or any paying agent to call all or any part of the Securities of a particular series for redemption and to give notice of redemption in the manner set forth in this Section, such notice to be in the name of the Company or its own name as the Trustee or such paying agent may deem advisable. In any case in which notice of redemption is to be given by the Trustee or any such paying agent, the Company shall deliver or cause to be delivered to, or permit to remain with, the Trustee or such paying agent, as the case may be, such Security Register, transfer books or other records, or suitable copies or extracts therefrom, sufficient to enable the Trustee or such paying agent to give any notice by mail that may be required under the provisions of this Section.

Section 3.03 Payment Upon Redemption.

(a) If the giving of notice of redemption shall have been completed as above provided, the Securities or portions of Securities of the series to be redeemed specified in such notice shall become due and payable on the date and at the place stated in such notice at the applicable redemption price, together with interest accrued to, but excluding, the date fixed for redemption and interest on such Securities or portions of Securities shall cease to accrue on and after the date fixed for redemption, unless the Company shall default in the payment of such redemption price and accrued interest with respect to any such Security or portion thereof. On presentation and surrender of such Securities on or after the date fixed for redemption at the place of payment specified in the notice, said Securities shall be paid and redeemed at the applicable redemption price for such series, together with interest accrued thereon to, but excluding, the date fixed for redemption (but if the date fixed for redemption is an Interest Payment Date, the interest installment payable on such date shall be payable to the registered holder at the close of business on the applicable record date pursuant to Section 2.03).

(b) Upon presentation of any Security of such series that is to be redeemed in part only, the Company shall execute and the Trustee shall authenticate and the office or agency where the Security is presented shall deliver to the Securityholder thereof, at the expense of the Company, a new Security of the same series of authorized denominations in principal amount equal to the unredeemed portion of the Security so presented.

Section 3.04 Sinking Fund.

The provisions of Sections 3.04, 3.05 and 3.06 shall be applicable to any sinking fund for the retirement of Securities of a series, except as otherwise specified as contemplated by Section 2.01 for Securities of such series.

The minimum amount of any sinking fund payment provided for by the terms of Securities of any series is herein referred to as a "mandatory sinking fund payment," and any payment in excess of such minimum amount provided for by the terms of Securities of any series is herein referred to as an "optional sinking fund payment". If provided for by the terms of Securities of any series, the cash amount of any sinking fund payment may be subject to reduction as provided in Section 3.05. Each sinking fund payment shall be applied to the redemption of Securities of any series as provided for by the terms of Securities of such series.

Section 3.05 Satisfaction of Sinking Fund Payments with Securities.

The Company (i) may deliver Outstanding Securities of a series and (ii) may apply as a credit Securities of a series that have been redeemed either at the election of the Company pursuant to the terms of such Securities or through the application of permitted optional sinking fund payments pursuant to the terms of such Securities, in each case in satisfaction of all or any part of any sinking fund payment with respect to the Securities of such series required to be made pursuant to the terms of such Securities as provided for by the terms of such series, provided that such Securities have not been previously so credited. Such Securities shall be received and credited for such purpose by the Trustee at the redemption price specified in such Securities for redemption through operation of the sinking fund and the amount of such sinking fund payment shall be reduced accordingly.

Section 3.06 Redemption of Securities for Sinking Fund.

Not less than 45 days prior to each sinking fund payment date for any series of Securities (unless a shorter period shall be satisfactory to the Trustee), the Company will deliver to the Trustee an Officer's Certificate specifying the amount of the next ensuing sinking fund payment for that series pursuant to the terms of the series, the portion thereof, if any, that is to be satisfied by delivering and crediting Securities of that series pursuant to Section 3.05 and the basis for such credit and will, together with such Officer's Certificate, deliver to the Trustee any Securities to be so delivered. Not less than 30 days before each such sinking fund payment date the Securities to be redeemed upon such sinking fund payment date shall be selected in the manner specified in Section 3.02 and the Company shall cause notice of the redemption thereof to be given in the name of and at the expense of the Company in the manner provided in Section 3.02. Such notice having been duly given, the redemption of such Securities shall be made upon the terms and in the manner stated in Section 3.03.

ARTICLE 4

COVENANTS

Section 4.01 Payment of Principal, Premium and Interest.

The Company will duly and punctually pay or cause to be paid the principal of (and premium, if any) and interest on the Securities of that series at the time and place and in the manner provided herein and established with respect to such Securities. Payments of principal on the Securities may be made at the time provided herein and established with respect to such Securities by U.S. dollar check drawn on and mailed to the address of the Securityholder entitled thereto as such address shall appear in the Security Register, or U.S. dollar wire transfer to,

a U.S. dollar account if such Securityholder shall have furnished wire instructions to the Trustee no later than 15 days prior to the relevant payment date. Payments of interest on the Securities may be made at the time provided herein and established with respect to such Securities by U.S. dollar check mailed to the address of the Securityholder entitled thereto as such address shall appear in the Security Register, or U.S. dollar wire transfer to, a U.S. dollar account if such Securityholder shall have furnished wire instructions in writing to the Security Registrar and the Trustee no later than 15 days prior to the relevant payment date.

Section 4.02 Maintenance of Office or Agency.

So long as any series of the Securities remain Outstanding, the Company agrees to maintain an office or agency with respect to each such series and at such other location or locations as may be designated as provided in this Section 4.02, where (i) Securities of that series may be presented for payment, (ii) Securities of that series may be presented as herein above authorized for registration of transfer and exchange, and (iii) notices and demands to or upon the Company in respect of the Securities of that series and this Indenture may be given or served, such designation to continue with respect to such office or agency until the Company shall, by written notice signed by any officer authorized to sign an Officer's Certificate and delivered to the Trustee, designate some other office or agency for such purposes or any of them. If at any time the Company shall fail to maintain any such required office or agency or shall fail to furnish the Trustee with the address thereof, such presentations, notices and demands may be made or served at the Corporate Trust Office of the Trustee, and the Company hereby appoints the Trustee as its agent to receive all such presentations, notices and demands. The Company initially appoints the Corporate Trust Office of the Trustee as its paying agent with respect to the Securities.

10

Section 4.03 Paying Agents.

(a) If the Company shall appoint one or more paying agents for all or any series of the Securities, other than the Trustee, the Company will cause each such paying agent to execute and deliver to the Trustee an instrument in which such agent shall agree with the Trustee, subject to the provisions of this Section:

(1) that it will hold all sums held by it as such agent for the payment of the principal of (and premium, if any) or interest on the Securities of that series (whether such sums have been paid to it by the Company or by any other obligor of such Securities) in trust for the benefit of the Persons entitled thereto;

(2) that it will give the Trustee notice of any failure by the Company (or by any other obligor of such Securities) to make any payment of the principal of (and premium, if any) or interest on the Securities of that series when the same shall be due and payable;

(3) that it will, at any time during the continuance of any failure referred to in the preceding paragraph (a)(2) above, upon the written request of the Trustee, forthwith pay to the Trustee all sums so held in trust by such paying agent; and

(4) that it will perform all other duties of paying agent as set forth in this Indenture.

(b) If the Company shall act as its own paying agent with respect to any series of the Securities, it will on or before each due date of the principal of (and premium, if any) or interest on Securities of that series, set aside, segregate and hold in trust for the benefit of the Persons entitled thereto a sum sufficient to pay such principal (and premium, if any) or interest so becoming due on Securities of that series until such sums shall be paid to such Persons or otherwise disposed of as herein provided and will promptly notify the Trustee of such action, or any failure (by it or any other obligor on such Securities) to take such action. Whenever the Company shall have one or more paying agents for any series of Securities, it will, prior to each due date of the principal of (and premium, if any) or interest on any Securities of that series, deposit with the paying agent a sum sufficient to pay the principal (and premium, if any) or interest so becoming due, such sum to be held in trust for the benefit of the Persons entitled to such principal, premium or interest, and (unless such paying agent is the Trustee) the Company will promptly notify the Trustee of this action or failure so to act.

(c) Notwithstanding anything in this Section to the contrary, (i) the agreement to hold sums in trust as provided in this Section is subject to the provisions of Section 11.05, and (ii) the Company may at any time, for the purpose of obtaining the satisfaction and discharge of this Indenture or for any other purpose, pay, or direct any paying agent to pay, to the Trustee all sums held in trust by the Company or such paying agent, such sums to be held by the Trustee upon the same terms and conditions as those upon which such sums were held by the Company or such paying agent; and, upon such payment by the Company or any paying agent to the Trustee, the Company or such paying agent shall be released from all further liability with respect to such money.

Section 4.04 Appointment to Fill Vacancy in Office of Trustee.

The Company, whenever necessary to avoid or fill a vacancy in the office of Trustee, will appoint, in the manner provided in Section 7.10, a Trustee, so that there shall at all times be a Trustee hereunder.

ARTICLE 5

SECURITYHOLDERS' LISTS AND REPORTS BY THE COMPANY AND THE TRUSTEE

Section 5.01 Company to Furnish Trustee Names and Addresses of Securityholders.

The Company will furnish or cause to be furnished to the Trustee (a) within 15 days after each regular record date (as defined in Section 2.03) a list, in such form as the Trustee may reasonably require, of the names and addresses of the holders of each series of Securities as of such regular record date, provided that the Company shall not be obligated to furnish or cause to furnish such list at any time that the list shall not differ in any respect from the most recent list furnished to the Trustee by the Company and (b) at such other times as the Trustee may request in writing within 30 days after the receipt by the Company of any such request, a list of similar form and content as of a date not more than 15 days prior to the time such list is furnished; provided, however, that, in either case, no such list need be furnished for any series for which the Trustee shall be the Security Registrar.

Section 5.02 Preservation Of Information; Communications With Securityholders.

(a) The Trustee shall preserve, in as current a form as is reasonably practicable, all information as to the names and addresses of the holders of Securities contained in the most recent list furnished to it as provided in Section 5.01 and as to the names and addresses of holders of Securities received by the Trustee in its capacity as Security Registrar (if acting in such capacity).

(b) The Trustee may destroy any list furnished to it as provided in Section 5.01 upon receipt of a new list so furnished.

(c) Securityholders may communicate as provided in Section 312(b) of the Trust Indenture Act with other Securityholders with respect to their rights under this Indenture or under the Securities, and, in connection with any such communications, the Trustee shall satisfy its obligations under Section 312(b) of the Trust Indenture Act in accordance with the provisions of Section 312(b) of the Trust Indenture Act.

Section 5.03 Reports by the Company.

(a) The Company will at all times comply with Section 314(a) of the Trust Indenture Act. The Company covenants and agrees to provide (which delivery may be via electronic mail) to the Trustee within 30 days, after the Company files the same with the Commission, copies of the annual reports and of the information, documents and other reports (or copies of such portions of any of the foregoing as the Commission may from time to time by rules and regulations prescribe) that the Company is required to file with the Commission pursuant to Section 13 or Section 15(d) of the Exchange Act; provided, however, the Company shall not be required to deliver to the Trustee any correspondence filed with the Commission or any materials for which the Company has sought and received confidential treatment by the Commission; and provided further, that so long as such filings by the Company are available on the Commission's Electronic Data Gathering, Analysis and Retrieval System (EDGAR), or any successor system, such filings shall be deemed to have been filed with the Trustee for purposes hereof without any further action required by the Company. For the avoidance of doubt, a failure

(b) Delivery of reports, information and documents to the Trustee under Section 5.03 is for informational purposes only and the information and the Trustee's receipt of the foregoing shall not constitute constructive notice of any information contained therein, or determinable from information contained therein including the Company's compliance with any of their covenants thereunder (as to which the Trustee is entitled to rely exclusively on an Officer's Certificate). The Trustee is under no duty to examine any such reports, information or

documents delivered to the Trustee or filed with the Commission via EDGAR to ensure compliance with the provision of this Indenture or to ascertain the correctness or otherwise of the information or the statements contained therein. The Trustee shall have no responsibility or duty whatsoever to ascertain or determine whether the above referenced filings with the Commission on EDGAR (or any successor system) has occurred.

Section 5.04 Reports by the Trustee.

(a) If required by Section 313(a) of the Trust Indenture Act, the Trustee, within sixty (60) days after each May 1, shall send to the Securityholders a brief report dated as of such May 1, which complies with Section 313(a) of the Trust Indenture Act.

(b) The Trustee shall comply with Section 313(b) and 313(c) of the Trust Indenture Act.

(c) A copy of each such report shall, at the time of such transmission to Securityholders, be filed by the Trustee with the Company, with each securities exchange upon which any Securities are listed (if so listed) and also with the Commission. The Company agrees to notify the Trustee when any Securities become listed on any securities exchange.

ARTICLE 6

REMEDIES OF THE TRUSTEE AND SECURITYHOLDERS ON EVENT OF DEFAULT

Section 6.01 Events of Default.

(a) Whenever used herein with respect to Securities of a particular series, "Event of Default" means any one or more of the following events that has occurred and is continuing:

(1) The Company defaults in the payment of any installment of interest upon any of the Securities of that series, as and when the same shall become due and payable, and such default continues for a period of 90 days; provided, however, that a valid extension of an interest payment period by the Company in accordance with the terms of any indenture supplemental hereto shall not constitute a default in the payment of interest for this purpose;

(2) The Company defaults in the payment of the principal of (or premium, if any, on) any of the Securities of that series as and when the same shall become due and payable whether at maturity, upon redemption, by declaration or otherwise, or in any payment required by any sinking or analogous fund established with respect to that series; provided, however, that a valid extension of the maturity of such Securities in accordance with the terms of any indenture supplemental hereto shall not constitute a default in the payment of principal or premium, if any;

(3) The Company fails to observe or perform any other of its covenants or agreements with respect to that series contained in this Indenture or otherwise established with respect to that series of Securities pursuant to Section 2.01 hereof (other than a covenant or agreement that has been expressly included in this Indenture solely for the benefit of one or more series of Securities other than such series) for a period of 90 days after the date on which written notice of such failure, requiring the same to be remedied and stating that such notice is a "Notice of Default" hereunder, shall have been given to the Company by the Trustee, by registered or certified mail, or to the Company and the Trustee by the holders of at least 25% in principal amount of the Securities of that series at the time Outstanding;

(4) The Company pursuant to or within the meaning of any Bankruptcy Law (i) commences a voluntary case, (ii) consents to the entry of an order for relief against it in an involuntary case, (iii) consents to the appointment of a Custodian of it or for all or substantially all of its property or (iv) makes a general assignment for the benefit of its creditors; or

(5) a court of competent jurisdiction enters an order under any Bankruptcy Law that (i) is for relief against the Company in an involuntary case, (ii) appoints a Custodian of the Company for all or substantially all of its property or (iii) orders the liquidation of the Company, and the order or decree remains unstayed and in effect for 90 days.

(b) In each and every such case (other than an Event of Default specified in clause (4) or clause (5) above), unless the principal of all the Securities of that series shall have already become due and payable, either the Trustee or the holders of not less than 25% in aggregate principal amount of the Securities of that series then Outstanding hereunder, by notice in writing to the Company (and to the Trustee if given by such Securityholders), may declare the principal of (and premium, if any, on) and accrued and unpaid interest on all the Securities of that series to be due and payable immediately, and upon any such declaration the same shall become and shall be immediately due and payable. If an Event of Default specified in clause (4) or clause (5) above occurs, the principal of and accrued and unpaid interest on all the Securities of that series shall automatically be immediately due and payable without any declaration or other act on the part of the Trustee or the holders of the Securities.

(c) At any time after the principal of (and premium, if any, on) and accrued and unpaid interest on the Securities of that series shall have been so declared due and payable, and before any judgment or decree for the payment of the moneys due shall have been obtained or entered as hereinafter provided, the holders of a majority in aggregate principal amount of the Securities of that series then Outstanding hereunder, by written notice to the Company and the Trustee, may rescind and annul such declaration and its consequences if: (i) the Company has paid or deposited with the Trustee a sum sufficient to pay all matured installments of interest upon all the Securities of that series and the principal of (and premium, if any, on) any and all Securities of that series that shall have become due otherwise than by acceleration (with interest upon such principal and premium, if any, and, to the extent that such payment is enforceable under applicable law, upon overdue installments of interest, at the rate per annum expressed in the Securities of that series to the date of such payment or deposit) and the amount payable to the Trustee under Section 7.06, and (ii) any and all Events of Default under the Indenture with respect to such series, other than the nonpayment of principal on (and premium, if any, on) and accrued and unpaid interest on Securities of that series that shall not have become due by their terms, shall have been remedied or waived as provided in Section 6.06.

No such rescission and annulment shall extend to or shall affect any subsequent default or impair any right consequent thereon.

(d) In case the Trustee shall have proceeded to enforce any right with respect to Securities of that series under this Indenture and such proceedings shall have been discontinued or abandoned because of such rescission or annulment or for any other reason or shall have been determined adversely to the Trustee, then and in every such case, subject to any determination in such proceedings, the Company and the Trustee shall be restored respectively to their former positions and rights hereunder, and all rights,

remedies and powers of the Company and the Trustee shall continue as though no such proceedings had been taken.

Section 6.02 Collection of Indebtedness and Suits for Enforcement by Trustee

(a) The Company covenants that (i) in case it shall default in the payment of any installment of interest on any of the Securities of a series, or in any payment required by any sinking or analogous fund established with respect to that series as and when the same shall have become due and payable, and such default shall have continued for a period of 90 days, or (ii) in case it shall default in the payment of the principal of (or premium, if any, on) any of the Securities of a series when the same shall have become due and payable, whether upon maturity of the Securities of a series or upon redemption or upon declaration or otherwise then, upon demand of the Trustee, the Company will pay to the Trustee, for the benefit of the holders of the Securities of that series, the whole amount that then shall have been become due and payable on all such Securities for principal (and premium, if any) or interest, or both, as the case may be, with interest upon the overdue principal (and premium, if any) and (to the extent that payment of such interest is enforceable under applicable law) upon overdue installments of interest at the rate per annum expressed in the Securities of that series; and, in addition thereto, such further amount as shall be sufficient to cover the costs and expenses of collection, and the amount payable to the Trustee under Section 7.06.

(b) If the Company shall fail to pay such amounts forthwith upon such demand, the Trustee, in its own name and as trustee of an express trust, shall be entitled and empowered to institute any action or proceedings at law or in equity for the collection of the sums so due and unpaid, and may prosecute any such action or proceeding to judgment or final decree, and may enforce any such judgment or final decree against the Company or other obligor upon the Securities of that series and collect the moneys adjudged or decreed to be payable in the manner provided by law or equity out of the property of the Company or other obligor upon the Securities of that series, wherever situated.

(c) In case of any receivership, insolvency, liquidation, bankruptcy, reorganization, readjustment, arrangement, composition or judicial proceedings affecting the Company, or its creditors or property, the Trustee shall have power to intervene in such proceedings and take any action therein that may be permitted by the court and shall (except as may be otherwise provided by law) be entitled to file such proofs of claim and other papers and documents as may be necessary or advisable in order to have the claims of the Trustee and of the holders of Securities of such series allowed for the entire amount due and payable by the Company under the Indenture at the date of institution of such proceedings and for any additional amount that may become due and payable by the Company after such date, and to collect and receive any moneys or other property payable or deliverable on any such claim, and to distribute the same after the deduction of the amount payable to the Trustee under Section 7.06; and any receiver, assignee or trustee in bankruptcy or reorganization is hereby authorized by each of the holders of Securities of such series to make such payments to the Trustee, and, in the event that the Trustee shall consent to the making of such payments directly to such Securityholders, to pay to the Trustee any amount due it under Section 7.06.

(d) All rights of action and of asserting claims under this Indenture, or under any of the terms established with respect to Securities of that series, may be enforced by the Trustee without the possession of any of such Securities, or the production thereof at any trial or other proceeding relative thereto, and any such suit or proceeding instituted by the Trustee shall be brought in its own name as trustee of an express trust, and any recovery of judgment shall, after provision for payment to the Trustee of any amounts due under Section 7.06, be for the ratable benefit of the holders of the Securities of such series.

In case of an Event of Default hereunder, the Trustee may in its discretion proceed to protect and enforce the rights vested in it by this Indenture by such appropriate judicial proceedings as the Trustee shall deem most effectual to protect and enforce any of such rights, either at law or in equity or in bankruptcy or otherwise, whether for the specific enforcement of any covenant or agreement contained in the Indenture or in aid of the exercise of any power granted in this Indenture, or to enforce any other legal or equitable right vested in the Trustee by this Indenture or by law.

Nothing contained herein shall be deemed to authorize the Trustee to authorize or consent to or accept or adopt on behalf of any Securityholder any plan of reorganization, arrangement, adjustment or composition affecting the Securities of that series or the rights of any Securityholder thereof or to authorize the Trustee to vote in respect of the claim of any Securityholder in any such proceeding.

Section 6.03 Application of Moneys Collected

Any moneys collected by the Trustee pursuant to this Article with respect to a particular series of Securities shall be applied in the following order, at the date or dates fixed by the Trustee and, in case of the distribution of such moneys on account of principal (or premium, if any) or interest, upon presentation of the Securities of that series, and notation thereon of the payment, if only partially paid, and upon surrender thereof if fully paid:

FIRST: To the payment of costs and expenses of collection and of all amounts payable to the Trustee under Section 7.06;

SECOND: To the payment of the amounts then due and unpaid upon Securities of such series for principal (and premium, if any) and interest, in respect of which or for the benefit of which such money has been collected, ratably, without preference or priority of any kind, according to the amounts due and payable on such Securities for principal (and premium, if any) and interest, respectively; and

THIRD: To the payment of the remainder, if any, to the Company or any other Person lawfully entitled thereto.

Section 6.04 Limitation on Suits

No holder of any Security of any series shall have any right by virtue or by availing of any provision of this Indenture to institute any suit, action or proceeding in equity or at law upon or under or with respect to this Indenture or for the appointment of a receiver or trustee, or for any other remedy hereunder, unless (i) such Securityholder previously shall have given to the Trustee written notice of an Event of Default and of the continuance thereof with respect to the Securities of such series specifying such Event of Default, as hereinbefore provided; (ii) the holders of not less than 25% in aggregate principal amount of the Securities of such series then Outstanding shall have made written request upon the Trustee to institute such action, suit or proceeding in its own name as Trustee hereunder; (iii) such Securityholder or Securityholders shall have offered to the Trustee indemnity satisfactory to it against the costs, expenses and liabilities to be incurred in compliance with such request; (iv) the Trustee for 90 days after its receipt of such notice, request and offer of indemnity, shall have failed to institute any such action, suit or proceeding and (v) during such 90 day period, the holders of a majority in principal amount of the Securities of that series do not give the Trustee a direction inconsistent with the request.

Notwithstanding anything contained herein to the contrary or any other provisions of this Indenture, the right of any holder of any Security to receive payment of the principal of (and premium, if any) and interest on such Security, as therein provided, on or after the respective due dates expressed in such Security (or in the case of redemption, on the redemption date), or to institute suit for the enforcement of any such payment on or after such respective dates or redemption date, shall not be impaired or affected without the consent of such holder and by accepting a Security hereunder it is expressly understood, intended and covenanted by the taker and holder of every Security of such series with every other such taker and holder and the Trustee, that no one or more holders of Securities of such series shall have any right in any manner whatsoever by virtue or by availing of any provision of this Indenture to affect, disturb or prejudice the rights of the holders of any other of such Securities, or to obtain or seek to obtain priority over or preference to any other such holder, or to enforce any right under this Indenture, except in the manner herein provided and for the equal, ratable and common benefit of all holders of Securities of such series. For the protection and enforcement of the provisions of this Section, each and every Securityholder and the Trustee shall be entitled to such relief as can be given either at law or in equity.

Section 6.05 Rights and Remedies Cumulative; Delay or Omission Not Waiver

(a) Except as otherwise provided in Section 2.07, all powers and remedies given by this Article to the Trustee or to the Securityholders shall, to the extent permitted by law, be deemed cumulative and not exclusive of any other powers and remedies available to the Trustee or the holders of the Securities, by judicial proceedings or otherwise,

to enforce the performance or observance of the covenants and agreements contained in this Indenture or otherwise established with respect to such Securities.

(b) No delay or omission of the Trustee or of any holder of any of the Securities to exercise any right or power accruing upon any Event of Default occurring and continuing as aforesaid shall impair any such right or power, or shall be construed to be a waiver of any such default or an acquiescence therein; and, subject to the provisions of Section 6.04, every power and remedy given by this Article or by law to the Trustee or the Securityholders may be exercised from time to time, and as often as shall be deemed expedient, by the Trustee or by the Securityholders.

Section 6.06 Control by Securityholders

The holders of a majority in aggregate principal amount of the Securities of any series at the time Outstanding, determined in accordance with Section 8.04, shall have the right to direct the time, method and place of conducting any proceeding for any remedy available to the Trustee, or exercising any trust or power conferred on the Trustee with respect to such series; provided, however, that such direction shall not be in conflict with any rule of law or with this Indenture or subject the Trustee in its sole discretion to personal liability. Subject to the provisions of Section 7.01, the Trustee shall have the right to decline to follow any such direction if the Trustee in good faith shall, by a Responsible Officer or officers of the Trustee, determine that the proceeding so directed, subject to the Trustee's duties under the Trust Indenture Act, would involve the Trustee in personal liability or might be unduly prejudicial to the Securityholders not involved in the proceeding. The holders of a majority in aggregate principal amount of the Securities of any series at the time Outstanding affected thereby, determined in accordance with Section 8.04, may on behalf of the holders of all of the Securities of such series waive any past default in the performance of any of the covenants contained herein or established pursuant to Section 2.01 with respect to such series and its consequences, except a default in the payment of the principal of, or premium, if any, or interest on, any of the Securities of that series as and when the same shall become due by the terms of such Securities otherwise than by acceleration (unless such default has been cured and a sum sufficient to pay all matured installments of interest and principal and any premium has been deposited with the Trustee (in accordance with Section 6.01(c)). Upon any such waiver, the default covered thereby shall be deemed to be cured for all purposes of this Indenture and the Company, the Trustee and the holders of the Securities of such series shall be restored to their former positions and rights hereunder, respectively; but no such waiver shall extend to any subsequent or other default or impair any right consequent thereon.

14

Section 6.07 Undertaking to Pay Costs.

All parties to this Indenture agree, and each holder of any Securities by such holder's acceptance thereof shall be deemed to have agreed, that any court may in its discretion require, in any suit for the enforcement of any right or remedy under this Indenture, or in any suit against the Trustee for any action taken or omitted by it as Trustee, the filing by any party litigant in such suit of an undertaking to pay the costs of such suit, and that such court may in its discretion assess reasonable costs, including reasonable attorneys' fees and expenses, against any party litigant in such suit, having due regard to the merits and good faith of the claims or defenses made by such party litigant; but the provisions of this Section shall not apply to any suit instituted by the Trustee, to any suit instituted by any Securityholder, or group of Securityholders, holding more than 10% in aggregate principal amount of the Outstanding Securities of any series, or to any suit instituted by any Securityholder for the enforcement of the payment of the principal of (or premium, if any) or interest on any Security of such series, on or after the respective due dates expressed in such Security or established pursuant to this Indenture.

ARTICLE 7

CONCERNING THE TRUSTEE

Section 7.01 Certain Duties and Responsibilities of Trustee.

(a) The Trustee, prior to the occurrence of an Event of Default with respect to the Securities of a series and after the curing of all Events of Default with respect to the Securities of that series that may have occurred, shall undertake to perform with respect to the Securities of such series such duties and only such duties as are specifically set forth in this Indenture, and no implied covenants shall be read into this Indenture against the Trustee. In case an Event of Default with respect to the Securities of a series has occurred (that has not been cured or waived), the Trustee shall exercise with respect to Securities of that series such of the rights and powers vested in it by this Indenture, and use the same degree of care and skill in their exercise, as a prudent man would exercise or use under the circumstances in the conduct of his or her own affairs.

(b) No provision of this Indenture shall be construed to relieve the Trustee from liability for its own negligent action, its own negligent failure to act, or its own willful misconduct, except that:

(i) prior to the occurrence of an Event of Default with respect to the Securities of a series and after the curing or waiving of all such Events of Default with respect to that series that may have occurred:

(A) the duties and obligations of the Trustee shall with respect to the Securities of such series be determined solely by the express provisions of this Indenture, and the Trustee shall not be liable with respect to the Securities of such series except for the performance of such duties and obligations as are specifically set forth in this Indenture, and no implied covenants or obligations shall be read into this Indenture against the Trustee; and

(B) in the absence of bad faith on the part of the Trustee, the Trustee may with respect to the Securities of such series conclusively rely, as to the truth of the statements and the correctness of the opinions expressed therein, upon any certificates or opinions furnished to the Trustee and conforming to the requirements of this Indenture; but in the case of any such certificates or opinions that by any provision hereof are specifically required to be furnished to the Trustee, the Trustee shall be under a duty to examine the same to determine whether or not they conform to the requirements of this Indenture;

(ii) the Trustee shall not be liable to any Securityholder or to any other Person for any error of judgment made in good faith by a Responsible Officer or Responsible Officers of the Trustee, unless it shall be proved that the Trustee was negligent in ascertaining the pertinent facts;

(iii) the Trustee shall not be liable with respect to any action taken or omitted to be taken by it in good faith in accordance with the direction of the holders of not less than a majority in principal amount of the Securities of any series at the time Outstanding relating to the time, method and place of conducting any proceeding for any remedy available to the Trustee, or exercising any trust or power conferred upon the Trustee under this Indenture with respect to the Securities of that series;

(iv) none of the provisions contained in this Indenture shall require the Trustee to expend or risk its own funds or otherwise incur personal financial liability in the performance of any of its duties or in the exercise of any of its rights or powers if there is reasonable ground for believing that the repayment of such funds or liability is not reasonably assured to it under the terms of this Indenture or adequate indemnity against such risk is not reasonably assured to it;

(v) The Trustee shall not be required to give any bond or surety in respect of the performance of its powers or duties hereunder;

(vi) The permissive right of the Trustee to do things enumerated in this Indenture shall not be construed as a duty of the Trustee; and

(vii) No Trustee shall have any duty or responsibility for any act or omission of any other Trustee appointed with respect to a series of Securities hereunder.

15

Section 7.02 Certain Rights of Trustee.

Except as otherwise provided in Section 7.01:

(a) The Trustee may conclusively rely and shall be protected in acting or refraining from acting upon any resolution, certificate, statement, instrument, opinion, report, notice, request, consent, order, approval, bond, security or other paper or document believed by it to be genuine and to have been signed or presented by the proper party or parties;

(b) Any request, direction, order or demand of the Company mentioned herein shall be sufficiently evidenced by a Board Resolution or an instrument signed in the name of the Company by any authorized Officer of the Company (unless other evidence in respect thereof is specifically prescribed herein);

(c) The Trustee may consult with counsel and the opinion or written advice of such counsel or, if requested, any Opinion of Counsel shall be full and complete authorization and protection in respect of any action taken or suffered or omitted hereunder in good faith and in reliance thereon;

(d) The Trustee shall be under no obligation to exercise any of the rights or powers vested in it by this Indenture at the request, order or direction of any of the Securityholders pursuant to the provisions of this Indenture, unless such Securityholders shall have offered to the Trustee security or indemnity reasonably acceptable to the Trustee against the costs, expenses and liabilities that may be incurred therein or thereby; nothing contained herein shall, however, relieve the Trustee of the obligation, upon the occurrence of an Event of Default with respect to a series of the Securities (that has not been cured or waived), to exercise with respect to Securities of that series such of the rights and powers vested in it by this Indenture, and to use the same degree of care and skill in their exercise, as a prudent man would exercise or use under the circumstances in the conduct of his or her own affairs;

(e) The Trustee shall not be liable for any action taken or omitted to be taken by it in good faith and believed by it to be authorized or within the discretion or rights or powers conferred upon it by this Indenture;

(f) The Trustee shall not be bound to make any investigation into the facts or matters stated in any resolution, certificate, statement, instrument, opinion, report, notice, request, consent, order, approval, bond, security, or other papers or documents or inquire as to the performance by the Company of one of its covenants under this Indenture, unless requested in writing so to do by the holders of not less than a majority in principal amount of the Outstanding Securities of the particular series affected thereby (determined as provided in Section 8.04); provided, however, that if the payment within a reasonable time to the Trustee of the costs, expenses or liabilities likely to be incurred by it in the making of such investigation is, in the opinion of the Trustee, not reasonably assured to the Trustee by the security afforded to it by the terms of this Indenture, the Trustee may require security or indemnity reasonably acceptable to the Trustee against such costs, expenses or liabilities as a condition to so proceeding. The reasonable expense of every such examination shall be paid by the Company or, if paid by the Trustee, shall be repaid by the Company upon demand;

(g) The Trustee may execute any of the trusts or powers hereunder or perform any duties hereunder either directly or by or through agents or attorneys and the Trustee shall not be responsible for any misconduct or negligence on the part of any agent or attorney appointed with due care by it hereunder;

(h) In no event shall the Trustee be responsible or liable for any failure or delay in the performance of its obligations hereunder arising out of or caused by, directly or indirectly, forces beyond its control, including, without limitation, strikes, work stoppages, accidents, acts of war or terrorism, civil or military disturbances, nuclear or natural catastrophes or acts of God, and interruptions, loss or malfunctions of utilities, communications or computer (software and hardware) services; it being understood that the Trustee shall use reasonable efforts which are consistent with accepted practices in the banking industry to resume performance as soon as practicable under the circumstances;

(i) In no event shall the Trustee be responsible or liable for special, indirect, punitive or consequential loss or damage of any kind whatsoever (including, but not limited to, loss of profit) irrespective of whether the Trustee has been advised of the likelihood of such loss or damage and regardless of the form of action; and

(j) The Trustee agrees to accept and act upon instructions or directions pursuant to this Indenture sent by unsecured e-mail, facsimile transmission or other similar unsecured electronic methods; provided, however, that such instructions or directions shall be signed by an authorized representative of the party providing such instructions or directions. If the party elects to give the Trustee e-mail or facsimile instructions (or instructions by a similar electronic method) and the Trustee in its discretion elects to act upon such instructions, the Trustee's understanding of such instructions shall be deemed controlling. The Trustee shall not be liable for any losses, costs or expenses arising directly or indirectly from the Trustee's reliance upon and compliance with such instructions notwithstanding such instructions conflict or are inconsistent with a subsequent written instruction. The party providing electronic instructions agrees to assume all risks arising out of the use of such electronic methods to submit instructions and directions to the Trustee, including without limitation the risk of the Trustee acting on unauthorized instructions, and the risk of interception and misuse by third parties. The Trustee may request that the Company deliver an Officer's Certificate setting forth the names of individuals and/or titles of officers authorized at such time to furnish the Trustee with Officer's Certificates, Company Orders and any other matters or directions pursuant to this Indenture.

(k) The rights, privileges, protections, immunities and benefits given to the Trustee, including, without limitation, its right to be indemnified, are extended to, and shall be enforceable by, the Trustee in each of its capacities hereunder and under the Securities, and each agent, custodian or other person employed to act under this Indenture.

(l) The Trustee shall not be deemed to have knowledge of any Default or Event of Default (other than an Event of Default constituting the failure to pay the interest on, or the principal of, the Securities if the Trustee also serves the paying agent for such Securities) until the Trustee shall have received written notification in the manner set forth in this Indenture or a Responsible Officer of the Trustee shall have obtained actual knowledge.

Section 7.03 Trustee Not Responsible for Recitals or Issuance of Securities

(a) The recitals contained herein and in the Securities shall be taken as the statements of the Company, and the Trustee assumes no responsibility for the correctness of the same. The Trustee shall not be responsible for any statement in any registration statement, prospectus, or any other document in connection with the sale of Securities. The Trustee shall not be responsible for any rating on the Securities or any action or omission of any rating agency.

(b) The Trustee makes no representations as to the validity or sufficiency of this Indenture or of the Securities.

(c) The Trustee shall not be accountable for the use or application by the Company of any of the Securities or of the proceeds of such Securities, or for the use or application of any moneys paid over by the Trustee in accordance with any provision of this Indenture or established pursuant to Section 2.01, or for the use or application of any moneys received by any paying agent other than the Trustee.

Section 7.04 May Hold Securities

The Trustee or any paying agent or Security Registrar, in its individual or any other capacity, may become the owner or pledgee of Securities with the same rights it would have if it were not Trustee, paying agent or Security Registrar.

Section 7.05 Moneys Held in Trust

Subject to the provisions of Section 11.05, all moneys received by the Trustee shall, until used or applied as herein provided, be held in trust for the purposes for which they were received, but need not be segregated from other funds except to the extent required by law. The Trustee shall be under no liability for interest on any moneys received

by it hereunder except such as it may agree with the Company to pay thereon.

Section 7.06 Compensation and Reimbursement.

(a) The Company shall pay to the Trustee for each of its capacities hereunder from time to time compensation for its services as the Company and the Trustee shall from time to time agree upon in writing. The Trustee's compensation shall not be limited by any law on compensation of a trustee of an express trust. The Company shall reimburse the Trustee upon request for all reasonable out-of-pocket expenses incurred by it. Such expenses shall include the reasonable compensation and expenses of the Trustee's agents and counsel.

(b) The Company shall indemnify each of the Trustee in each of its capacities hereunder against any loss, liability or expense (including the cost of defending itself and including the reasonable compensation and expenses of the Trustee's agents and counsel) incurred by it except as set forth in Section 7.06(c) in the exercise or performance of its powers, rights or duties under this Indenture as Trustee or Agent. The Trustee shall notify the Company promptly of any claim for which it may seek indemnity. The Company shall defend the claim and the Trustee shall cooperate in the defense. The Trustee may have one separate counsel and the Company shall pay the reasonable fees and expenses of such counsel. The Company need not pay for any settlement made without its consent, which consent shall not be unreasonably withheld. This indemnification shall apply to officers, directors, employees, shareholders and agents of the Trustee.

(c) The Company need not reimburse any expense or indemnify against any loss or liability incurred by the Trustee or by any officer, director, employee, shareholder or agent of the Trustee through negligence or bad faith.

(d) To ensure the Company's payment obligations in this Section, the Trustee shall have a lien prior to the Securities on all funds or property held or collected by the Trustee, except that held in trust to pay principal of or interest on particular Securities. When the Trustee incurs expenses or renders services in connection with an Event of Default specified in Section 6.01(4) or (5), the expenses (including the reasonable fees and expenses of its counsel) and the compensation for services in connection therewith are to constitute expenses of administration under any bankruptcy law. The provisions of this Section 7.06 shall survive the termination of this Indenture and the resignation or removal of the Trustee.

Section 7.07 Reliance on Officer's Certificate.

Except as otherwise provided in Section 7.01, whenever in the administration of the provisions of this Indenture the Trustee shall deem it reasonably necessary or desirable that a matter be proved or established prior to taking or suffering or omitting to take any action hereunder, such matter (unless other evidence in respect thereof be herein specifically prescribed) may, in the absence of negligence or bad faith on the part of the Trustee, be deemed to be conclusively proved and established by an Officer's Certificate delivered to the Trustee and such certificate, in the absence of negligence or bad faith on the part of the Trustee, shall be full warrant to the Trustee for any action taken, suffered or omitted to be taken by it under the provisions of this Indenture upon the faith thereof.

Section 7.08 Disqualification; Conflicting Interests

If the Trustee has or shall acquire any "conflicting interest" within the meaning of Section 310(b) of the Trust Indenture Act, the Trustee and the Company shall in all respects comply with the provisions of Section 310(b) of the Trust Indenture Act.

Section 7.09 Corporate Trustee Required; Eligibility.

There shall at all times be a Trustee with respect to the Securities issued hereunder which shall at all times be a corporation organized and doing business under the laws of the United States of America or any state or territory thereof or of the District of Columbia, or a corporation or other Person permitted to act as trustee by the Commission, authorized under such laws to exercise corporate trust powers, having a combined capital and surplus of at least fifty million U.S. dollars (\$50,000,000), and subject to supervision or examination by federal, state, territorial, or District of Columbia authority.

If such corporation or other Person publishes reports of condition at least annually, pursuant to law or to the requirements of the aforesaid supervising or examining authority, then for the purposes of this Section, the combined capital and surplus of such corporation or other Person shall be deemed to be its combined capital and surplus as set forth in its most recent report of condition so published. The Company may not, nor may any Person directly or indirectly controlling, controlled by, or under common control with the Company, serve as Trustee. In case at any time the Trustee shall cease to be eligible in accordance with the provisions of this Section, the Trustee shall resign immediately in the manner and with the effect specified in Section 7.10.

Section 7.10 Resignation and Removal; Appointment of Successor.

(a) The Trustee or any successor hereafter appointed may at any time resign with respect to the Securities of one or more series by giving written notice thereof to the Company and the Securityholders of such series. Upon receiving such notice of resignation, the Company shall promptly appoint a successor trustee with respect to Securities of such series by written instrument, in duplicate, executed by order of the Board of Directors, one copy of which instrument shall be delivered to the resigning Trustee and one copy to the successor trustee. If no successor trustee shall have been so appointed and have accepted appointment within 30 days after the sending of such notice of resignation, the resigning Trustee may petition any court of competent jurisdiction for the appointment of a successor trustee with respect to Securities of such series, or any Securityholder of that series who has been a bona fide holder of a Security or Securities for at least six months may on behalf of himself and all others similarly situated, petition any such court for the appointment of a successor trustee. Such court may thereupon after such notice, if any, as it may deem proper and prescribe, appoint a successor trustee.

(b) In case at any time any one of the following shall occur:

(i) the Trustee shall fail to comply with the provisions of Section 7.08 after written request therefor by the Company or by any Securityholder who has been a bona fide holder of a Security or Securities for at least six months; or

(ii) the Trustee shall cease to be eligible in accordance with the provisions of Section 7.09 and shall fail to resign after written request therefor by the Company or by any such Securityholder; or

(iii) the Trustee shall become incapable of acting, or shall be adjudged a bankrupt or insolvent, or commence a voluntary bankruptcy proceeding, or a receiver of the Trustee or of its property shall be appointed or consented to, or any public officer shall take charge or control of the Trustee or of its property or affairs for the purpose of rehabilitation, conservation or liquidation; then, in any such case, the Company may remove the Trustee with respect to all Securities and appoint a successor trustee by written instrument, in duplicate, executed by order of the Board of Directors, one copy of which instrument shall be delivered to the Trustee so removed and one copy to the successor trustee, or any Securityholder who has been a bona fide holder of a Security or Securities for at least six months may, on behalf of that holder and all others similarly situated, petition any court of competent jurisdiction for the removal of the Trustee and the appointment of a successor trustee. Such court may thereupon after such notice, if any, as it may deem proper and prescribe, remove the Trustee and appoint a successor trustee.

(c) The holders of a majority in aggregate principal amount of the Securities of any series at the time Outstanding may at any time remove the Trustee with respect to such series by so notifying the Trustee and the Company and may appoint a successor Trustee for such series with the consent of the Company.

(d) Any resignation or removal of the Trustee and appointment of a successor trustee with respect to the Securities of a series pursuant to any of the provisions of this

Section shall become effective upon acceptance of appointment by the successor trustee as provided in Section 7.11.

(e) Any successor trustee appointed pursuant to this Section may be appointed with respect to the Securities of one or more series or all of such series, and at any time there shall be only one Trustee with respect to the Securities of any particular series.

Section 7.11 Acceptance of Appointment By Successor:

(a) In case of the appointment hereunder of a successor trustee with respect to all Securities, every such successor trustee so appointed shall execute, acknowledge and deliver to the Company and to the retiring Trustee an instrument accepting such appointment, and thereupon the resignation or removal of the retiring Trustee shall become effective and such successor trustee, without any further act, deed or conveyance, shall become vested with all the rights, powers, trusts and duties of the retiring Trustee; but, on the request of the Company or the successor trustee, such retiring Trustee shall, upon payment of any amounts due to it pursuant to the provisions of Section 7.06, execute and deliver an instrument transferring to such successor trustee all the rights, powers, and trusts of the retiring Trustee and shall duly assign, transfer and deliver to such successor trustee all property and money held by such retiring Trustee hereunder.

(b) In case of the appointment hereunder of a successor trustee with respect to the Securities of one or more (but not all) series, the Company, the retiring Trustee and each successor trustee with respect to the Securities of one or more series shall execute and deliver an indenture supplemental hereto wherein each successor trustee shall accept such appointment and which (i) shall contain such provisions as shall be necessary or desirable to transfer and confirm to, and to vest in, each successor trustee all the rights, powers, trusts and duties of the retiring Trustee with respect to the Securities of that or those series to which the appointment of such successor trustee relates, (ii) shall contain such provisions as shall be deemed necessary or desirable to confirm that all the rights, powers, trusts and duties of the retiring Trustee with respect to the Securities of that or those series as to which the retiring Trustee is not retiring shall continue to be vested in the retiring Trustee, and (iii) shall add to or change any of the provisions of this Indenture as shall be necessary to provide for or facilitate the administration of the trusts hereunder by more than one Trustee, it being understood that nothing herein or in such supplemental indenture shall constitute such Trustees co-trustees of the same trust, that each such Trustee shall be trustee of a trust or trusts hereunder separate and apart from any trust or trusts hereunder administered by any other such Trustee and that no Trustee shall be responsible for any act or failure to act on the part of any other Trustee hereunder; and upon the execution and delivery of such supplemental indenture the resignation or removal of the retiring Trustee shall become effective to the extent provided therein, such retiring Trustee shall with respect to the Securities of that or those series to which the appointment of such successor trustee relates have no further responsibility for the exercise of rights and powers or for the performance of the duties and obligations vested in the Trustee under this Indenture, and each such successor trustee, without any further act, deed or conveyance, shall become vested with all the rights, powers, trusts and duties of the retiring Trustee with respect to the Securities of that or those series to which the appointment of such successor trustee relates; but, on request of the Company or any successor trustee, such retiring Trustee shall duly assign, transfer and deliver to such successor trustee, to the extent contemplated by such supplemental indenture, the property and money held by such retiring Trustee hereunder with respect to the Securities of that or those series to which the appointment of such successor trustee relates.

18

(c) Upon request of any such successor trustee, the Company shall execute any and all instruments for more fully and certainly vesting in and confirming to such successor trustee all such rights, powers and trusts referred to in paragraph (a) or (b) of this Section, as the case may be.

(d) No successor trustee shall accept its appointment unless at the time of such acceptance such successor trustee shall be qualified and eligible under this Article.

(e) Upon acceptance of appointment by a successor trustee as provided in this Section, the Company shall send notice of the succession of such trustee hereunder to the Securityholders. If the Company fails to transmit such notice within ten days after acceptance of appointment by the successor trustee, the successor trustee shall cause such notice to be transmitted at the expense of the Company.

Section 7.12 Merger, Conversion, Consolidation or Succession to Business

Any corporation into which the Trustee may be merged or converted or with which it may be consolidated, or any corporation resulting from any merger, conversion or consolidation to which the Trustee shall be a party, or any corporation succeeding to all or substantially all the corporate trust business of the Trustee, including the administration of the trust created by this Indenture, shall be the successor of the Trustee hereunder, provided that such corporation shall be qualified under the provisions of Section 7.08 and eligible under the provisions of Section 7.09, without the execution or filing of any paper or any further act on the part of any of the parties hereto, anything herein to the contrary notwithstanding. In case any Securities shall have been authenticated, but not delivered, by the Trustee then in office, any successor by merger, conversion or consolidation to such authenticating Trustee may adopt such authentication and deliver the Securities so authenticated with the same effect as if such successor Trustee had itself authenticated such Securities.

Section 7.13 Preferential Collection of Claims Against the Company

The Trustee shall comply with Section 311(a) of the Trust Indenture Act, excluding any creditor relationship described in Section 311(b) of the Trust Indenture Act. A Trustee who has resigned or been removed shall be subject to Section 311(a) of the Trust Indenture Act to the extent included therein.

Section 7.14 Notice of Default

If any Event of Default occurs and is continuing and if such Event of Default is known to a Responsible Officer of the Trustee, the Trustee shall send to each Securityholder in the manner and to the extent provided in Section 313(c) of the Trust Indenture Act notice of the Event of Default within the earlier of 90 days after it occurs and 30 days after it is known to a Responsible Officer of the Trustee or written notice of it is received by the Trustee, unless such Event of Default has been cured; *provided, however,* that, except in the case of a default in the payment of the principal of (or premium, if any) or interest on any Security, the Trustee shall be protected in withholding such notice if and so long as the Responsible Officers of the Trustee in good faith determine that the withholding of such notice is in the interest of the Securityholders.

ARTICLE 8

CONCERNING THE SECURITYHOLDERS

Section 8.01 Evidence of Action by Securityholders.

Whenever in this Indenture it is provided that the holders of a majority or specified percentage in aggregate principal amount of the Securities of a particular series may take any action (including the making of any demand or request, the giving of any notice, consent or waiver or the taking of any other action), the fact that at the time of taking any such action the holders of such majority or specified percentage of that series have joined therein may be evidenced by any instrument or any number of instruments of similar tenor executed by such holders of Securities of that series in person or by agent or proxy appointed in writing.

If the Company shall solicit from the Securityholders of any series any request, demand, authorization, direction, notice, consent, waiver or other action, the Company may, at its option, as evidenced by an Officer's Certificate, fix in advance a record date for such series for the determination of Securityholders entitled to give such request, demand, authorization, direction, notice, consent, waiver or other action, but the Company shall have no obligation to do so. If such a record date is fixed, such request, demand, authorization, direction, notice, consent, waiver or other action may be given before or after the record date, but only the Securityholders of record at the close of business on the record date shall be deemed to be Securityholders for the purposes of determining whether Securityholders of the requisite proportion of Outstanding Securities of that series have authorized or agreed or consented to such request, demand, authorization, direction, notice, consent, waiver or other action, and for that purpose the Outstanding Securities of that series shall be computed as of the record date; provided, however, that no such authorization, agreement or consent by such Securityholders on the record date shall be

Section 8.02 Proof of Execution by Securityholders.

Subject to the provisions of Section 7.01, proof of the execution of any instrument by a Securityholder (such proof will not require notarization) or his or her agent or proxy and proof of the holding by any Person of any of the Securities shall be sufficient if made in the following manner:

- (a) The fact and date of the execution by any such Person of any instrument may be proved in any reasonable manner acceptable to the Trustee.
- (b) The ownership of Securities shall be proved by the Security Register of such Securities or by a certificate of the Security Registrar thereof.

The Trustee may require such additional proof of any matter referred to in this Section as it shall deem necessary.

Section 8.03 Who May be Deemed Owners

Prior to the due presentment for registration of transfer of any Security, the Company, the Trustee, any paying agent and any Security Registrar may deem and treat the Person in whose name such Security shall be registered upon the books of the Security Registrar as the absolute owner of such Security (whether or not such Security shall be overdue and notwithstanding any notice of ownership or writing thereon made by anyone other than the Security Registrar) for the purpose of receiving payment of or on account of the principal of, premium, if any, and (subject to Section 2.03) interest on such Security and for all other purposes; and neither the Company nor the Trustee nor any paying agent nor any Security Registrar shall be affected by any notice to the contrary.

Section 8.04 Certain Securities Owned by Company Disregarded.

In determining whether the holders of the requisite aggregate principal amount of Securities of a particular series have concurred in any direction, consent or waiver under this Indenture, the Securities of that series that are owned by the Company or any other obligor on the Securities of that series or by any Person directly or indirectly controlling or controlled by or under common control with the Company or any other obligor on the Securities of that series shall be disregarded and deemed not to be Outstanding for the purpose of any such determination, except that for the purpose of determining whether the Trustee shall be protected in relying on any such direction, consent or waiver, only Securities of such series that the Trustee actually knows are so owned shall be so disregarded. The Securities so owned that have been pledged in good faith may be regarded as Outstanding for the purposes of this Section, if the pledgee shall establish to the satisfaction of the Trustee the pledgee's right so to act with respect to such Securities and that the pledgee is not a Person directly or indirectly controlling or controlled by or under direct or indirect common control with the Company or any such other obligor. In case of a dispute as to such right, any decision by the Trustee taken upon the advice of counsel shall be full protection to the Trustee.

Section 8.05 Actions Binding on Future Securityholders

At any time prior to (but not after) the evidencing to the Trustee, as provided in Section 8.01, of the taking of any action by the holders of the majority or percentage in aggregate principal amount of the Securities of a particular series specified in this Indenture in connection with such action, any holder of a Security of that series that is shown by the evidence to be included in the Securities the holders of which have consented to such action may, by filing written notice with the Trustee, and upon proof of holding as provided in Section 8.02, revoke such action so far as concerns such Security. Except as aforesaid any such action taken by the holder of any Security shall be conclusive and binding upon such holder and upon all future holders and owners of such Security, and of any Security issued in exchange therefor, on registration of transfer thereof or in place thereof, irrespective of whether or not any notation in regard thereto is made upon such Security. Any action taken by the holders of the majority or percentage in aggregate principal amount of the Securities of a particular series specified in this Indenture in connection with such action shall be conclusively binding upon the Company, the Trustee and the holders of all the Securities of that series.

ARTICLE 9

SUPPLEMENTAL INDENTURES

Section 9.01 Supplemental Indentures Without the Consent of Securityholders

In addition to any supplemental indenture otherwise authorized by this Indenture, the Company and the Trustee may from time to time and at any time enter into an indenture or indentures supplemental hereto (which shall conform to the provisions of the Trust Indenture Act as then in effect), without the consent of the Securityholders, for one or more of the following purposes:

- (a) to cure any ambiguity, defect, or inconsistency herein or in the Securities of any series;
- (b) to comply with Article Ten;
- (c) to provide for uncertificated Securities in addition to or in place of certificated Securities;

(d) to add to the covenants, restrictions, conditions or provisions relating to the Company for the benefit of the holders of all or any series of Securities (and if such covenants, restrictions, conditions or provisions are to be for the benefit of less than all series of Securities, stating that such covenants, restrictions, conditions or provisions are expressly being included solely for the benefit of such series), to make the occurrence, or the occurrence and the continuance, of a default in any such additional covenants, restrictions, conditions or provisions an Event of Default, or to surrender any right or power herein conferred upon the Company;

(e) to add to, delete from, or revise the conditions, limitations, and restrictions on the authorized amount, terms, or purposes of issue, authentication, and delivery of Securities, as herein set forth;

(f) to make any change that does not adversely affect the rights of any Securityholder in any material respect;

(g) to provide for the issuance of and establish the form and terms and conditions of the Securities of any series as provided in Section 2.01, to establish the form of any certifications required to be furnished pursuant to the terms of this Indenture or any series of Securities, or to add to the rights of the holders of any series of Securities;

(h) to evidence and provide for the acceptance of appointment hereunder by a successor trustee; or

(i) to comply with any requirements of the Commission or any successor in connection with the qualification of this Indenture under the Trust Indenture Act.

The Trustee is hereby authorized to join with the Company in the execution of any such supplemental indenture, and to make any further appropriate agreements and

stipulations that may be therein contained, but the Trustee shall not be obligated to enter into any such supplemental indenture that affects the Trustee's own rights, duties or immunities under this Indenture or otherwise.

Any supplemental indenture authorized by the provisions of this Section may be executed by the Company and the Trustee without the consent of the holders of any of the Securities at the time Outstanding, notwithstanding any of the provisions of Section 9.02.

Section 9.02 Supplemental Indentures With Consent of Securityholders

With the consent (evidenced as provided in Section 8.01) of the holders of not less than a majority in aggregate principal amount of the Securities of each series affected by such supplemental indenture or indentures at the time Outstanding, the Company, when authorized by a Board Resolution, and the Trustee may from time to time and at any time enter into an indenture or indentures supplemental hereto (which shall conform to the provisions of the Trust Indenture Act as then in effect) for the purpose of adding any provisions to or changing in any manner or eliminating any of the provisions of this Indenture or of any supplemental indenture or of modifying in any manner not covered by Section 9.01 the rights of the holders of the Securities of such series under this Indenture; provided, however, that no such supplemental indenture shall, without the consent of the holders of each Security then Outstanding and affected thereby, (a) extend the fixed maturity of any Securities of any series, or reduce the principal amount thereof, or reduce the rate or extend the time of payment of interest thereon, or reduce any premium payable upon the redemption thereof or (b) reduce the aforesaid percentage of Securities, the holders of which are required to consent to any such supplemental indenture.

It shall not be necessary for the consent of the Securityholders of any series affected thereby under this Section to approve the particular form of any proposed supplemental indenture, but it shall be sufficient if such consent shall approve the substance thereof.

Section 9.03 Effect of Supplemental Indentures.

Upon the execution of any supplemental indenture pursuant to the provisions of this Article or of Section 10.01, this Indenture shall, with respect to such series, be and be deemed to be modified and amended in accordance therewith and the respective rights, limitations of rights, obligations, duties and immunities under this Indenture of the Trustee, the Company and the holders of Securities of the series affected thereby shall thereafter be determined, exercised and enforced hereunder subject in all respects to such modifications and amendments, and all the terms and conditions of any such supplemental indenture shall be and be deemed to be part of the terms and conditions of this Indenture for any and all purposes.

Section 9.04 Securities Affected by Supplemental Indentures.

Securities of any series affected by a supplemental indenture, authenticated and delivered after the execution of such supplemental indenture pursuant to the provisions of this Article or of Section 10.01, may bear a notation in form approved by the Company, provided such form meets the requirements of any securities exchange upon which such series may be listed, as to any matter provided for in such supplemental indenture. If the Company shall so determine, new Securities of that series so modified as to conform, in the opinion of the Board of Directors, to any modification of this Indenture contained in any such supplemental indenture may be prepared by the Company, authenticated by the Trustee and delivered in exchange for the Securities of that series then Outstanding.

Section 9.05 Execution of Supplemental Indentures.

Upon the request of the Company, accompanied by its Board Resolutions authorizing the execution of any such supplemental indenture, and upon the filing with the Trustee of evidence of the consent of Securityholders required to consent thereto as aforesaid, the Trustee shall join with the Company in the execution of such supplemental indenture unless such supplemental indenture affects the Trustee's own rights, duties or immunities under this Indenture or otherwise, in which case the Trustee may in its discretion but shall not be obligated to enter into such supplemental indenture. The Trustee, subject to the provisions of Section 7.01, shall receive an Officer's Certificate or an Opinion of Counsel as conclusive evidence that any supplemental indenture executed pursuant to this Article is authorized or permitted by the terms of this Article and that all conditions precedent to the execution of the supplemental indenture have been complied with; provided, however, that such Officer's Certificate or Opinion of Counsel need not be provided in connection with the execution of a supplemental indenture that establishes the terms of a series of Securities pursuant to Section 2.01 hereof.

Promptly after the execution by the Company and the Trustee of any supplemental indenture pursuant to the provisions of this Section, the Company shall (or shall direct the Trustee to) send a notice, setting forth in general terms the substance of such supplemental indenture, to the Securityholders of all series affected thereby as their names and addresses appear upon the Security Register. Any failure of the Company to send, or cause the sending of, such notice, or any defect therein, shall not, however, in any way impair or affect the validity of any such supplemental indenture.

ARTICLE 10

SUCCESSOR ENTITY

Section 10.01 Company May Consolidate, Etc.

Nothing contained in this Indenture shall prevent any consolidation or merger of the Company with or into any other Person (whether or not affiliated with the Company) or successive consolidations or mergers in which the Company or its successor or successors shall be a party or parties, or shall prevent any sale, conveyance, transfer or other disposition of the property of the Company or its successor or successors as an entirety, or substantially as an entirety, to any other Person (whether or not affiliated with the Company or its successor or successors); provided, however, the Company hereby covenants and agrees that, upon any such consolidation or merger (in each case, if the Company is not the survivor of such transaction) or any such sale, conveyance, transfer or other disposition (other than a sale, conveyance, transfer or other disposition to a Subsidiary of the Company), the due and punctual payment of the principal of (premium, if any) and interest on all of the Securities of all series in accordance with the terms of each series, according to their tenor, and the due and punctual performance and observance of all the covenants and conditions of this Indenture with respect to each series or established with respect to such series pursuant to Section 2.01 to be kept or performed by the Company shall be expressly assumed, by supplemental indenture (which shall conform to the provisions of the Trust Indenture Act, as then in effect) reasonably satisfactory in form to the Trustee executed and delivered to the Trustee by the entity formed by such consolidation, or into which the Company shall have been merged, or by the entity which shall have acquired such property.

Section 10.02 Successor Entity Substituted.

(a) In case of any such consolidation, merger, sale, conveyance, transfer or other disposition and upon the assumption by the successor entity by supplemental indenture, executed and delivered to the Trustee and satisfactory in form to the Trustee, of the obligations set forth under Section 10.01 on all of the Securities of all series Outstanding, such successor entity shall succeed to and be substituted for the Company with the same effect as if it had been named as the Company herein, and thereupon the predecessor corporation shall be relieved of all obligations and covenants under this Indenture and the Securities.

(b) In case of any such consolidation, merger, sale, conveyance, transfer or other disposition, such changes in phraseology and form (but not in substance) may be made in the Securities thereafter to be issued as may be appropriate.

(c) Nothing contained in this Article shall require any action by the Company in the case of a consolidation or merger of any Person into the Company where the Company is the survivor of such transaction, or the acquisition by the Company, by purchase or otherwise, of all or any part of the property of any other Person (whether or not affiliated with the Company).

ARTICLE 11

SATISFACTION AND DISCHARGE

Section 11.01 Satisfaction and Discharge of Indenture.

If at any time: (a) the Company shall have delivered to the Trustee for cancellation all Securities of a series theretofore authenticated and not delivered to the Trustee for cancellation (other than any Securities that shall have been destroyed, lost or stolen and that shall have been replaced or paid as provided in Section 2.07 and Securities for whose payment money or Governmental Obligations have theretofore been deposited in trust or segregated and held in trust by the Company and thereupon repaid to the Company or discharged from such trust, as provided in Section 11.05); or (b) all such Securities of a particular series not theretofore delivered to the Trustee for cancellation shall have become due and payable, or are by their terms to become due and payable within one year or are to be called for redemption within one year under arrangements satisfactory to the Trustee for the giving of notice of redemption, and the Company shall deposit or cause to be deposited with the Trustee as trust funds the entire amount in moneys or Governmental Obligations or a combination thereof, sufficient in the opinion of a nationally recognized firm of independent public accountants expressed in a written certification thereof delivered to the Trustee, to pay at maturity or upon redemption all Securities of that series not theretofore delivered to the Trustee for cancellation, including principal (and premium, if any) and interest due or to become due to such date of maturity or date fixed for redemption, as the case may be, and if the Company shall also pay or cause to be paid all other sums payable hereunder with respect to such series by the Company then this Indenture shall thereupon cease to be of further effect with respect to such series except for the provisions of Sections 2.03, 2.05, 2.07, 4.01, 4.02, 4.03, 7.10, 11.5 and 13.04, that shall survive until the date of maturity or redemption date, as the case may be, and Sections 7.06 and 11.05, that shall survive to such date and thereafter, and the Trustee, on demand of the Company and at the cost and expense of the Company shall execute proper instruments acknowledging satisfaction of and discharging this Indenture with respect to such series.

22

Section 11.02 Discharge of Obligations.

If at any time all such Securities of a particular series not heretofore delivered to the Trustee for cancellation or that have not become due and payable as described in Section 11.01 shall have been paid by the Company by depositing irrevocably with the Trustee as trust funds moneys or an amount of Governmental Obligations sufficient to pay at maturity or upon redemption all such Securities of that series not theretofore delivered to the Trustee for cancellation, including principal (and premium, if any) and interest due or to become due to such date of maturity or date fixed for redemption, as the case may be, and if the Company shall also pay or cause to be paid all other sums payable hereunder by the Company with respect to such series, then after the date such moneys or Governmental Obligations, as the case may be, are deposited with the Trustee the obligations of the Company under this Indenture with respect to such series shall cease to be of further effect except for the provisions of Sections 2.03, 2.05, 2.07, 4.01, 4.02, 4.03, 7.06, 7.10, 11.05 and 13.04 hereof that shall survive until such Securities shall mature and be paid.

Thereafter, Sections 7.06 and 11.05 shall survive.

Section 11.03 Deposited Moneys to be Held in Trust

All moneys or Governmental Obligations deposited with the Trustee pursuant to Sections 11.01 or 11.02 shall be held in trust and shall be available for payment as due, either directly or through any paying agent (including the Company acting as its own paying agent), to the holders of the particular series of Securities for the payment or redemption of which such moneys or Governmental Obligations have been deposited with the Trustee.

Section 11.04 Payment of Moneys Held by Paying Agents

In connection with the satisfaction and discharge of this Indenture all moneys or Governmental Obligations then held by any paying agent under the provisions of this Indenture shall, upon demand of the Company, be paid to the Trustee and thereupon such paying agent shall be released from all further liability with respect to such moneys or Governmental Obligations.

Section 11.05 Repayment to Company.

Any moneys or Governmental Obligations deposited with any paying agent or the Trustee, or then held by the Company, in trust for payment of principal of or premium, if any, or interest on the Securities of a particular series that are not applied but remain unclaimed by the holders of such Securities for at least two years after the date upon which the principal of (and premium, if any) or interest on such Securities shall have respectively become due and payable, or such other shorter period set forth in applicable escheat or abandoned or unclaimed property law, shall be repaid to the Company on May 31 of each year or upon the Company's request or (if then held by the Company) shall be discharged from such trust; and thereupon the paying agent and the Trustee shall be released from all further liability with respect to such moneys or Governmental Obligations, and the holder of any of the Securities entitled to receive such payment shall thereafter, as a general creditor, look only to the Company for the payment thereof.

ARTICLE 12

IMMUNITY OF INCORPORATORS, STOCKHOLDERS, OFFICERS AND DIRECTORS

Section 12.01 No Recourse

No recourse under or upon any obligation, covenant or agreement of this Indenture, or of any Security, or for any claim based thereon or otherwise in respect thereof, shall be had against any incorporator, stockholder, officer or director, past, present or future as such, of the Company or of any predecessor or successor corporation, either directly or through the Company or any such predecessor or successor corporation, whether by virtue of any constitution, statute or rule of law, or by the enforcement of any assessment or penalty or otherwise; it being expressly understood that this Indenture and the obligations issued hereunder are solely corporate obligations, and that no such personal liability whatever shall attach to, or is or shall be incurred by, the incorporators, stockholders, officers or directors as such, of the Company or of any predecessor or successor corporation, or any of them, because of the creation of the indebtedness hereby authorized, or under or by reason of the obligations, covenants or agreements contained in this Indenture or in any of the Securities or implied therefrom; and that any and all such personal liability of every name and nature, either at common law or in equity or by constitution or statute, of, and any and all such rights and claims against, every such incorporator, stockholder, officer or director as such, because of the creation of the indebtedness hereby authorized, or under or by reason of the obligations, covenants or agreements contained in this Indenture or in any of the Securities or implied therefrom, are hereby expressly waived and released as a condition of, and as a consideration for, the execution of this Indenture and the issuance of such Securities.

23

ARTICLE 13

MISCELLANEOUS PROVISIONS

Section 13.01 Effect on Successors and Assigns

All the covenants, stipulations, promises and agreements in this Indenture made by or on behalf of the Company shall bind its successors and assigns, whether so expressed or not.

Section 13.02 Actions by Successor.

Any act or proceeding by any provision of this Indenture authorized or required to be done or performed by any board, committee or officer of the Company shall and may be done and performed with like force and effect by the corresponding board, committee or officer of any corporation that shall at the time be the lawful successor of the Company.

Section 13.03 Surrender of Company Powers

The Company by instrument in writing executed by authority of its Board of Directors and delivered to the Trustee may surrender any of the powers reserved to the Company, and thereupon such power so surrendered shall terminate both as to the Company and as to any successor corporation.

Section 13.04 Notices

Except as otherwise expressly provided herein, any notice, request or demand that by any provision of this Indenture is required or permitted to be given, made or served by the Trustee, the Security Registrar, any paying or other agent under this Indenture or by the holders of Securities or by any other Person pursuant to this Indenture to or on the Company may be given or served by being deposited in first class mail, postage prepaid, addressed (until another address is filed in writing by the Company with the Trustee), as follows: . Any notice, election, request or demand by the Company or any Securityholder or by any other Person pursuant to this Indenture to or upon the Trustee shall be deemed to have been sufficiently given or made, for all purposes, if given or made in writing at the Corporate Trust Office of the Trustee.

Section 13.05 Governing Law; Jury Trial Waiver.

This Indenture and each Security shall be governed by, and construed in accordance with, the internal laws of the State of New York, except to the extent that the Trust Indenture Act is applicable.

EACH PARTY HERETO, AND EACH HOLDER OF A SECURITY BY ACCEPTANCE THEREOF, HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS INDENTURE.

Section 13.06 Treatment of Securities as Debt.

It is intended that the Securities will be treated as indebtedness and not as equity for federal income tax purposes. The provisions of this Indenture shall be interpreted to further this intention.

Section 13.07 Certificates and Opinions as to Conditions Precedent.

(a) Upon any application or demand by the Company to the Trustee to take any action under any of the provisions of this Indenture, the Company shall furnish to the Trustee an Officer's Certificate stating that all conditions precedent provided for in this Indenture (other than the certificate to be delivered pursuant to Section 13.12) relating to the proposed action have been complied with and, if requested, an Opinion of Counsel stating that in the opinion of such counsel all such conditions precedent have been complied with, except that in the case of any such application or demand as to which the furnishing of such documents is specifically required by any provision of this Indenture relating to such particular application or demand, no additional certificate or opinion need be furnished.

(b) Each certificate or opinion provided for in this Indenture and delivered to the Trustee with respect to compliance with a condition or covenant in this Indenture (other than the certificate to be delivered pursuant to Section 13.12 of this Indenture or Section 314(a)(1) of the Trust Indenture Act) shall include (i) a statement that the Person making such certificate or opinion has read such covenant or condition; (ii) a brief statement as to the nature and scope of the examination or investigation upon which the statements or opinions contained in such certificate or opinion are based; (iii) a statement that, in the opinion of such Person, he has made such examination or investigation as is reasonably necessary to enable him to express an informed opinion as to whether or not such covenant or condition has been complied with; and (iv) a statement as to whether or not, in the opinion of such Person, such condition or covenant has been complied with.

Section 13.08 Payments on Business Days

Except as provided pursuant to Section 2.01 pursuant to a Board Resolution, and set forth in an Officer's Certificate, or established in one or more indentures supplemental to this Indenture, in any case where the date of maturity of interest or principal of any Security or the date of redemption of any Security shall not be a Business Day, then payment of interest or principal (and premium, if any) may be made on the next succeeding Business Day with the same force and effect as if made on the nominal date of maturity or redemption, and no interest shall accrue for the period after such nominal date.

Section 13.09 Conflict with Trust Indenture Act

If and to the extent that any provision of this Indenture limits, qualifies or conflicts with the duties imposed by Section 318(c) of the Trust Indenture Act, such imposed duties shall control.

Section 13.10 Counterparts.

This Indenture may be executed in any number of counterparts, each of which shall be an original, but such counterparts shall together constitute but one and the same instrument. The exchange of copies of this Indenture and of signature pages by facsimile or PDF transmission shall constitute effective execution and delivery of this Indenture as to the parties hereto and may be used in lieu of the original Indenture for all purposes. Signatures of the parties hereto transmitted by facsimile or PDF shall be deemed to be their original signatures for all purposes.

Section 13.11 Separability.

In case any one or more of the provisions contained in this Indenture or in the Securities of any series shall for any reason be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Indenture or of such Securities, but this Indenture and such Securities shall be construed as if such invalid or illegal or unenforceable provision had never been contained herein or therein.

Section 13.12 Compliance Certificates

The Company shall deliver to the Trustee, within 120 days after the end of each fiscal year during which any Securities of any series were outstanding, an officer's certificate stating whether or not the signers know of any Event of Default that occurred during such fiscal year. Such certificate shall contain a certification from the principal executive officer, principal financial officer or principal accounting officer of the Company that a review has been conducted of the activities of the Company and the

Company's performance under this Indenture and that the Company has complied with all conditions and covenants under this Indenture. For purposes of this Section 13.12, such compliance shall be determined without regard to any period of grace or requirement of notice provided under this Indenture. If the officer of the Company signing such certificate has knowledge of such an Event of Default, the certificate shall describe any such Event of Default and its status.

Section 13.13 U.S.A. Patriot Act

The parties hereto acknowledge that in accordance with Section 326 of the U.S.A. Patriot Act, the Trustee, like all financial institutions and in order to help fight the funding of terrorism and money laundering, is required to obtain, verify, and record information that identifies each person or legal entity that establishes a relationship or opens an account with the Trustee. The parties to this Indenture agree that they will provide the Trustee with such information as it may request in order for the Trustee to satisfy the requirements of the U.S.A. Patriot Act.

Section 13.14 Force Majeure.

In no event shall the Trustee, the Security Registrar, any paying agent or any other agent under this Indenture be responsible or liable for any failure or delay in the performance of its obligations hereunder arising out of or caused by, directly or indirectly, forces beyond its control, including without limitation, strikes, work stoppages, accidents, acts of war or terrorism, civil or military disturbances, nuclear or natural catastrophes or acts of God, and interruptions, loss or malfunctions or utilities, communications or computer (software and hardware) services; it being understood that the Trustee, the Security Registrar, any paying agent or any other agent under this Indenture shall use reasonable efforts which are consistent with accepted practices in the banking industry to resume performance as soon as practicable under the circumstances.

Section 13.15 Table of Contents; Headings.

The table of contents and headings of the articles and sections of this Indenture have been inserted for convenience of reference only, are not intended to be considered a part hereof, and will not modify or restrict any of the terms or provisions hereof.

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused this Indenture to be duly executed all as of the day and year first above written.

BIOAFFINITY TECHNOLOGIES, INC.

By: _____

Name: _____

Title: _____

[TRUSTEE], as Trustee

By: _____

Name: _____

Title: _____

CROSS-REFERENCE TABLE (1)

Section of Trust Indenture Act of 1939, as Amended	Section of Indenture
310(a)	7.09
310(b)	7.08
	7.10
310(c)	Inapplicable
311(a)	7.13
311(b)	7.13
311(c)	Inapplicable
312(a)	5.01
	5.02(a)
312(b)	5.02(c)
312(c)	5.02(c)
313(a)	5.04(a)
313(b)	5.04(b)
313(c)	5.04(a)
	5.04(b)
313(d)	5.04(c)
314(a)	5.03
	13.12
314(b)	Inapplicable
314(c)	13.07(a)
314(d)	Inapplicable
314(e)	13.07(b)
314(f)	Inapplicable
315(a)	7.01(a)
	7.01(b)
315(b)	7.14
315(c)	7.01

315(d)	7.01(b)
315(e)	6.07
316(a)	6.06
	8.04
316(b)	6.04
316(c)	8.01
317(a)	6.02
317(b)	4.03
318(a)	13.09

(1) This Cross-Reference Table does not constitute part of the Indenture and shall not have any bearing on the interpretation of any of its terms or provisions.

BLANKROME

1271 Avenue of the Americas | New York, NY 10020
blankrome.com

November 16, 2023

The Board of Directors
bioAffinity Technologies, Inc.
22211 W. Interstate 10, Suite 1206
San Antonio, Texas 78257

Re: bioAffinity Technologies, Inc.
Registration Statement on Form S-3

Ladies and Gentlemen:

We have acted as counsel to bioAffinity Technologies, Inc., a Delaware corporation (the “Company”), in connection with the preparation and filing by the Company with the Securities and Exchange Commission (the “Commission”) of a Registration Statement on Form S-3 (the “Registration Statement”) under the Securities Act of 1933, as amended (the “Securities Act”), with respect to the contemplated issuance from time to time of up to \$25,000,000 of any combination of the following securities (the “Registered Securities”): (i) shares of common stock of the Company, par value \$0.007 per share (the “Common Stock”); (ii) shares of preferred stock of the Company, par value \$0.001 per share (the “Preferred Stock”); (iii) debt securities, in one or more series (the “Debt Securities”), which may be issued pursuant to an indenture to be dated on or about the date of the first issuance of Debt Securities thereunder, by and between a trustee to be selected by the Company (the “Trustee”) and the Company, in the form filed as Exhibit 4.3 to the Registration Statement and one or more indentures supplemental thereto with respect to any particular series of Debt Securities (the “Indenture”); (iv) warrants to purchase Common Stock, Preferred Stock or Debt Securities (the “Warrants”), which may be issued under one or more warrant agreements, to be dated on or about the date of the first issuance of the Warrants thereunder, by and between a warrant agent to be selected by the Company (the “Warrant Agent”) and the Company (each, a “Warrant Agreement”); and (v) units consisting of one or more of the other securities described in (i) through (iv) above in any combination (the “Units”). This opinion is being furnished in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act.

In rendering the opinions set forth herein, we have examined originals or copies, certified or otherwise identified to our satisfaction, of (i) the Registration Statement, (ii) the Indenture, (iii) resolutions adopted by the Board of Directors of the Company (the “Board”), (iv) the certificate of incorporation of the Company, as amended (the “Certificate of Incorporation”), (v) the amended and restated bylaws of the Company, and (vi) such other corporate records, agreements, certificates, including, but not limited to, certificates or comparable documents of public officials and of officers and representatives of the Company, statutes and other instruments and documents as we considered relevant and necessary as a basis for the opinions hereinafter expressed. In rendering this opinion, we have assumed, without inquiry, (i) the authenticity of all documents submitted to us as originals; (ii) the conformity to the original documents of all documents submitted to us as facsimile, electronic, certified or photostatic copies, and the authenticity of the originals of such copies; (iii) the legal capacity of all natural persons and the genuineness of all signatures on the Registration Statement and all documents submitted to us; and (iv) that the books and records of the Company are maintained in accordance with proper corporate procedures.

In making our examination of executed documents or documents to be executed, we have assumed that the parties thereto had or will have the power, corporate or other, to enter into and perform all obligations thereunder and we have also assumed the due authorization by all requisite action, corporate or other, and execution and delivery by such parties of such documents and (except to the extent we have opined on such matters below) the validity and binding effect on such parties. In addition, we have assumed that (i) a purchase, underwriting or similar agreement with respect to any Registered Securities will have been duly authorized and validly executed and delivered by the Company and the other parties thereto; (ii) the Registration Statement and any amendments thereto will have become effective and comply with all applicable laws at the time the Registered Securities are offered or issued as contemplated by the Registration Statement and no stop order suspending its effectiveness will have been issued and remain in effect; (iii) all Registered Securities will be issued and sold in compliance with applicable federal and state securities laws and in the manner stated in the Registration Statement and the applicable prospectus supplement; (iv) a prospectus supplement or term sheet will have been prepared and filed with the Commission describing the Registered Securities offered thereby and will comply at all relevant times with all applicable laws; (v) the applicable Indenture or Indentures and indenture Trustees will have been duly qualified under the Trust Indenture Act of 1939, as amended, and a Statement of Eligibility of the Trustee on a Form T-1 has been or will be filed with the Commission with respect to each such Trustee; (vi) the choice of New York law to govern the Indentures is a valid and legal provision; (vii) the Company will have obtained any legally required consents, approvals, authorizations and other orders of the Commission and any other regulatory authorities necessary (x) to issue and sell the Registered Securities being offered, and (y) to execute and deliver the applicable Indenture, purchase, underwriting or similar agreement, or other applicable operative document; (viii) any securities issuable upon conversion, exchange, redemption or exercise of any Registered Securities being offered will be duly authorized, created and, if appropriate, reserved for issuance upon such conversion, exchange, redemption or exercise and, with respect to shares of Common Stock or Preferred Stock offered, there will be sufficient shares of Common Stock or Preferred Stock, as applicable, authorized under the Certificate of Incorporation and not otherwise reserved for issuance; (ix) at the time of issuance of the Registered Securities, the Company validly exists and is duly qualified and in good standing under the laws of its jurisdiction of incorporation, and has the necessary corporate power for such issuance; (x) at the time of issuance of the Registered Securities, the Certificate of Incorporation and then-operative bylaws of the Company are in full force and effect and have not been amended, restated, supplemented or otherwise altered, and there has been no authorization of any such amendment, restatement, supplement or other alteration, in either case since the date hereof; and (xi) the terms, execution and delivery of the Registered Securities (x) do not result in breaches of, or defaults under, agreements or instruments to which the Company is bound or violations of applicable statutes, rules, regulations or court or governmental orders, and (y) comply with any applicable requirement or restriction imposed by any court or governmental body having jurisdiction over the Company. As to any facts material to the opinions expressed herein that we have not independently established or verified, we have relied upon, and assumed the accuracy of, statements and representations of officers and other representatives of the Company and others.

BLANKROME

The Board of Directors
bioAffinity Technologies, Inc.
November 16, 2023
Page 2

Based on the foregoing, and subject to the qualifications, exceptions and assumptions stated herein, we are of the opinion that:

1. With respect to shares of Common Stock, when (i) the Board or a committee thereof has taken all necessary corporate action to approve the issuance and terms of the offering thereof and related matters; and (ii) certificates representing the shares of Common Stock have been duly executed, countersigned, registered and delivered, or if uncertificated, valid book-entry notations have been made in the share register of the Company, in each case in accordance with the Certificate of Incorporation and then-operative bylaws, either (A) in accordance with the applicable purchase, underwriting or similar agreement approved by the Board or a committee thereof, then upon payment of the consideration therefor (not less than the par value of the Common Stock) provided for therein; or (B) upon conversion, exchange or exercise of any other security in

accordance with the terms of the security or the instrument governing the security providing for the conversion, exchange or exercise as approved by the Board or a committee thereof, for the consideration approved by the Board or a committee thereof (not less than the par value of the Common Stock), such shares of Common Stock will be validly issued, fully paid and non-assessable.

2. With respect to shares of any class or series of Preferred Stock, when (i) the Board or a committee thereof has taken all necessary corporate action to approve the issuance and terms of the shares of the class or series, the terms of the offering thereof and related matters, including the adoption of a resolution establishing and designating the series and fixing and determining the preferences, limitations and relative rights thereof and the filing of a certificate of designation with respect to the class or series with the Secretary of State of the State of Delaware as required by applicable law (the "Certificate of Designation"); and (ii) certificates representing the shares of the series of Preferred Stock have been duly executed, countersigned, registered and delivered, or if uncertificated, valid book-entry notations have been made in the share register of the Company, in each case in accordance with the Certificate of Incorporation, Certificate of Designations and then-operative bylaws, either (A) in accordance with the applicable purchase, underwriting or similar agreement approved by the Board or a committee thereof, then upon payment of the consideration therefor (not less than the par value of the Preferred Stock) provided for therein; or (B) upon conversion, exchange or exercise of any other security in accordance with the terms of the security or the instrument governing the security providing for the conversion, exchange or exercise as approved by the Board or a committee thereof, for the consideration approved by the Board or a committee thereof (not less than the par value of the Preferred Stock), such shares of such series of Preferred Stock will be validly issued, fully paid and non-assessable.

3. With respect to Debt Securities, when (i) the Indenture has been duly authorized, executed and delivered by the Company and the Trustee; (ii) the Board or a committee thereof has taken all necessary corporate action to approve the issuance and terms of such Debt Securities, the terms of the offering thereof and related matters; and (iii) such Debt Securities have been duly executed, authenticated, issued and delivered in accordance with the provisions of the Indenture and in accordance with the applicable purchase, underwriting, similar agreement or other security approved by the Board or a committee thereof, then upon payment of the consideration provided for therein, such Debt Securities will constitute valid and binding obligations of the Company.

4. With respect to Warrants, when (i) the Board or a committee thereof has taken all necessary corporate action to approve the issuance and terms of the Warrants, the terms of the offering thereof and related matters; (ii) the Warrant Agreement relating to the Warrants has been duly authorized and validly executed and delivered by the Company and the Warrant Agent appointed by the Company; and (iii) the Warrants or certificates representing the Warrants have been duly executed, countersigned, registered and delivered in accordance with the appropriate Warrant Agreement and the applicable purchase, underwriting or similar agreement approved by the Board or a committee thereof, then upon payment of the consideration provided for therein, the Warrants will constitute valid and binding obligations of the Company.

5. With respect to Units, when (i) the Board or a committee thereof has taken all necessary corporate action to approve the terms of the Units, the terms of the offering thereof and related matters; and (ii) the Units have been duly executed and delivered in accordance with the applicable purchase, underwriting or similar agreement approved by or on behalf of the Board or a committee thereof, then upon payment of the consideration therefor provided therein, the Units will constitute valid and binding obligations of the Company.

In addition to the assumptions, comments, qualifications, limitations and exceptions set forth above, the opinions set forth herein are further limited by, subject to and based upon the following:

BLANKROME

The Board of Directors
bioAffinity Technologies, Inc.
November 16, 2023
Page 3

- a. Our opinions herein are expressed solely with respect to the Delaware General Corporation Law, and, as to the Debt Securities, Warrants and Units constituting valid and binding obligations of the Company, the applicable laws of the State of New York that, in our experience, are normally applicable to transactions of the type contemplated by the Registration Statement. The opinion set forth herein related to the Units assumes that such Units are governed by New York law. The opinions set forth herein are made as of the date hereof and are subject to, and may be limited by, future changes in the factual matters set forth herein, and we undertake no duty to advise you of the same that may occur after the Registration Statement becomes effective. The opinions expressed herein are based upon the law in effect (and published or otherwise generally available) on the date hereof, which laws are subject to change with possible retroactive effect, and we assume no obligation to revise or supplement these opinions should such law be changed by legislative action, judicial decision or otherwise after the Registration Statement becomes effective. In rendering our opinions, we have not considered, and hereby disclaim any opinion as to, the application or impact of any laws, cases, decisions, rules or regulations of any other jurisdiction, court or administrative agency.
- b. Our opinions set forth above are subject to and may be limited by (i) applicable bankruptcy, reorganization, insolvency, conservatorship, moratorium, fraudulent conveyance, debtor and creditor, and similar laws which relate to or affect creditors' rights generally, and (ii) general principles of equity (including, without limitation, concepts of materiality, reasonableness, impossibility of performance, good faith and fair dealing) regardless of whether considered in a proceeding in equity or at law.
- c. Our opinions are subject to the qualification that the availability of specific performance, an injunction or other equitable remedies is subject to the discretion of the court before which the request is brought.
- d. You have informed us that you intend to issue the Registered Securities from time to time on a delayed or continuous basis, and this opinion is limited to the laws, including the rules and regulations, as in effect on the date hereof. We understand that prior to issuing any Registered Securities you will afford us an opportunity to review the operative documents pursuant to which such Registered Securities are to be issued (including the applicable prospectus supplement) and will file such supplement or amendment to this opinion (if any) as we may reasonably consider necessary or appropriate by reason of the terms of such Registered Securities.

We consent to the use of this opinion as an exhibit to the Registration Statement. We also consent to any and all references to us in the prospectus which is part of said Registration Statement. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission promulgated thereunder. This opinion is strictly limited to the matters stated herein and no other or more extensive opinion is intended, implied or to be inferred beyond the matters expressly stated herein. This opinion letter is not a guaranty nor may one be inferred or implied.

Very truly yours,

/s/ Blank Rome LLP

Blank Rome LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in this Registration Statement on Form S-3 of our report dated March 31, 2023, relating to the consolidated financial statements of bioAffinity Technologies, Inc., as of and for the years ended December 31, 2022 and 2021. We also consent to the reference to our Firm under the caption "Experts" in the Prospectus.

/s/ WithumSmith+Brown, PC

New York, New York
November 16, 2023

We hereby consent to the incorporation by reference in this Registration Statement on Form S-3 of our report dated September 19, 2023, relating to the financial statements of Village Oaks Pathology Services, P.A. (the "Company"), as of and for the years ended December 31, 2022 and 2021, which included an explanatory paragraph related to substantial doubt about the Company's ability to continue as a going concern. We also consent to the reference to our Firm under the caption "Experts" in the Prospectus.

/s/ WithumSmith+Brown, PC

New York, New York
November 16, 2023

Calculation of Filing Fee Table

Form S-3

(Form Type)

bioAffinity Technologies, Inc.

(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered(2)	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Fees to be paid	Equity(1)	Common Stock, \$0.007 par value per share	—	—	—	—	—	—
Fees to be paid	Equity(1)	Preferred Stock, \$0.001 par value per share	—	—	—	—	—	—
Fees to be paid	Debt(1)	Debt securities	—	—	—	—	—	—
Fees to be paid	Other(1)	Warrants	—	—	—	—	—	—
Fees to be paid	Other(1)	Units	—	—	—	—	—	—
Fees to be paid	Unallocated (Universal) Shelf	Unallocated (Universal) Shelf	457(o)	(2)	(2)	\$ 25,000,000	\$ 0.0001476	\$ 3,690
Total Offering Amounts								\$ 3,690
Total Fees Previously Paid								—
Total Fee Offsets								—
Net Fee Due								\$ 3,690

(1) Represents securities that may be offered and sold from time-to-time in one or more offering by the Registrant.

(2) This registration statement covers an indeterminate amount and number of securities of each identified class of securities up to a proposed maximum aggregate offering price of \$25,000,000, which may be offered from time to time in unspecified numbers and indeterminate prices, and as may be issued upon conversion, exchange, or exercise of any securities registered hereunder, including any applicable anti-dilution provisions. Separate consideration may or may not be received for securities that are issuable on conversion, redemption, repurchase or exchange of other securities. Pursuant to Rule 416(a) promulgated under the Securities Act of 1933, as amended, this registration statement also covers an indeterminate number of securities that may become issuable as a result of stock splits, stock dividends or similar transactions relating to the securities registered hereunder.