Filed Pursuant to Rule 424(b)(5)
Registration No. 333-275608

Prospectus Supplement
(to Prospectus dated November 27, 2023)

720,000 Shares of Common Stock

bioAffinity Technologies, Inc.

We are offering 720,000 shares of our common stock, $0.007 par value per share (the "common stock"), directly to institutional investors pursuant to this prospectus supplement and the accompanying prospectus. The per share offering price of the shares is $2.50.

Our common stock is listed on The Nasdaq Capital Market under the symbol "BIAF." On October 7, 2025, the last reported sale price of our common stock on The Nasdaq Capital Market was $2.45 per share.

As of the date of this prospectus supplement, the aggregate market value of our outstanding common stock held by non-affiliates is approximately $38,804,591, which is calculated based on 3,692,159 shares of our outstanding common stock held by non-affiliates and a price of $10.51 per share, the closing price of our common stock on September 15, 2025, which is the highest closing sale price of our common stock on the Nasdaq Capital Market within the prior 60 days of this prospectus supplement. During the prior twelve-calendar-month period that ends on and includes the date hereof, we have offered and sold $4,849,353 of shares of our common stock pursuant to General Instruction I.B.6 to Form S-3.

Investing in our common stock involves a high degree of risk. Before buying any of our securities, you should carefully read "Risk Factors" on page S-4 of this prospectus supplement, and under similar headings in the other documents that are incorporated by reference into this prospectus supplement and the accompanying prospectus.

We have engaged WallachBeth Capital, LLC ("WallachBeth") to act as our exclusive placement agent in connection with this offering to use its reasonable best efforts to place the shares of common stock offered by this prospectus supplement. We have agreed to pay WallachBeth the fees set forth in the table below.

	Per Share	Total
Offering price	$ 2.50	$ 1,800,000.00
Placement agent fees[(1)]	$ 0.20	$ 144,000.00
Proceeds, before expenses, to us	$ 2.30	$ 1,656,000.00

(1) In addition, we have agreed to pay for certain expenses of WallachBeth up to $75,000. See "Plan of Distribution" beginning on page S-8 of this prospectus supplement for additional information regarding compensation payable to WallachBeth.

Delivery of the shares of our common stock is expected to be made on or about October 9, 2025.

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

WallachBeth Capital, LLC

The date of this prospectus supplement is October 8, 2025

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Prospectus Supplement

Prospectus

No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus supplement or the accompanying prospectus. You must not rely on any unauthorized information or representations. This prospectus supplement and the accompanying prospectus are an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus supplement and the accompanying prospectus is current only as of their respective dates.

ABOUT THIS PROSPECTUS SUPPLEMENT

On November 16, 2023, we filed with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-3 (File No. 333-275608) utilizing a shelf registration process relating to the securities described in this prospectus supplement, which registration statement was declared effective on November 27, 2023. Under this shelf registration process, we may, from time to time, sell up to $25 million in the aggregate of shares of common stock, shares of preferred stock, debt securities, warrants, and units.

This document consists of two parts. The first part is the prospectus supplement, including the documents incorporated by reference herein, which describes the specific terms of this offering. The second part, the accompanying prospectus, including the documents incorporated by reference therein, provides more general information. In general, when we refer only to the prospectus, we are referring to both parts of this document combined. Before you invest, you should carefully read this prospectus supplement, the accompanying prospectus, all information incorporated by reference herein and therein, as well as the additional information described under the heading "Where You Can Find More Information." These documents contain information you should carefully consider when deciding whether to invest in our securities.

This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent there is a conflict between the information contained in this prospectus supplement and the accompanying prospectus, you should rely on information contained in this prospectus supplement, provided that if any statement in, or incorporated by reference into, one of these documents is inconsistent with a statement in another document having a later date, the statement in the document having the later date modifies or supersedes the earlier statement. Any statement so modified will be deemed to constitute a part of this prospectus only as so modified, and any statement so superseded will be deemed not to constitute a part of this prospectus.

You should rely only on the information contained in this prospectus supplement, the accompanying prospectus, any document incorporated by reference herein or therein, or any free writing prospectuses we may provide to you in connection with this offering. Neither we nor WallachBeth have authorized anyone to provide you with any different information. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may provide to you. The information contained in this prospectus supplement, the accompanying prospectus, and in the documents incorporated by reference herein or therein is accurate only as of the date such information is presented. Our business, financial condition, results of operations and prospects may have changed since that date.

This prospectus supplement and the accompanying prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the shares of common stock to which it relates, nor does this prospectus supplement and the accompanying 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.

Securities offered pursuant to the registration statement to which this prospectus supplement relates may only be offered and sold if not more than three years have elapsed since November 27, 2023, the initial effective date of the registration statement, subject to the extension of this period in compliance with applicable SEC rules.

We note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreement, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

References in this prospectus to "bioAffinity", "the Company", "we", "us", "our" or "its", unless the context otherwise requires, refer to bioAffinity Technologies, Inc., a Delaware corporation, together with its consolidated subsidiaries.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This prospectus includes “forward-looking statements”, as such term is used within the meaning of the Private Securities Litigation Reform Act of 1995. These “forward-looking statements” are not based on historical fact and involve assessments of certain risks, developments, and uncertainties in our business looking to the future. Such forward-looking statements can be identified by the use of terminology such as “may”, “will”, “should”, “expect”, “anticipate”, “estimate”, “intend”, “continue”, or “believe”, or the negatives or other variations of these terms or comparable terminology. Forward-looking statements may include projections, forecasts, or estimates of future performance and developments. Forward-looking statements contained in this prospectus are based upon assumptions and assessments that we believe to be reasonable as of the date of this prospectus. Whether those assumptions and assessments will be realized will be determined by future factors, developments, and events, which are difficult to predict and may be beyond our control. Actual results, factors, developments, and events may differ materially from those we assumed and assessed. Risks, uncertainties, contingencies, and developments, including those identified in the “Risk Factors” section of this prospectus and in our most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and other filings we make with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), incorporated by reference herein, could cause our future operating results to differ materially from those set forth in any forward-looking statement. There can be no assurance that any such forward-looking statement, projection, forecast or estimate contained can be realized or that actual returns, results, or business prospects will not differ materially from those set forth in any forward-looking statement. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. We disclaim any obligation to update any such factors or to publicly announce the results of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments.

PROSPECTUS SUPPLEMENT SUMMARY

This summary contains basic information about us and this offering. Because it is a summary, it does not contain all of the information that you should consider before deciding to invest in our securities. Before you decide to invest in our securities, you should read this entire prospectus carefully, any related free writing prospectus that we have authorized for use in connection with the offering and the documents incorporated by reference herein, including the information included under the heading titled "Risk Factors."

Our Company

bioAffinity Technologies, Inc. (the "Company," "bioAffinity," "we," or "our") develops noninvasive diagnostics to detect early-stage lung cancer and other diseases of the lung using flow cytometry and automated analysis developed by machine learning, a form of artificial intelligence ("AI"). Our diagnostic platform analyzes cell populations that are indicative of a specific disease and uses AI to standardize sample data analysis and patient test results. state.

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 worldwide. Physicians order CyPath® Lung to assist in their decision-making in the diagnosis 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 including biopsy and those who are likely without lung cancer and should continue screening in accordance with guidelines. CyPath® Lung has been shown to detect lung cancer at Stage 1A, its earliest stage, and 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.

Commercial laboratory services, including CyPath® Lung, are performed at our wholly owned subsidiary Precision Pathology Laboratory Services ("PPLS") which we acquired by purchasing the assets of Village Oaks Pathology Services, P.A., a Texas professional association d/b/a Precision Pathology Services, that included the CAP-accredited and CLIA-certified commercial laboratory it owned. We own and operate the clinical anatomic and clinical pathology laboratory. CyPath® Lung is offered for sale to physicians by PPLS.

We continue to advance development of our flow cytometry+AI platform for companion diagnostic tests targeted at chronic obstructive pulmonary disease ("COPD") and asthma. Diagnostics under development are designed to detect specific receptors in sputum that determine the effectiveness of new and emerging therapies for asthma and COPD that have proven to effectively treat some but not all patients.

Through our wholly owned subsidiary, OncoSelect® Therapeutics, LLC, we have conducted research that has led to discoveries and advancement of novel cancer therapeutic approaches that specifically and selectively target cancer cells. We continue to advance research and development for use of this technology for topical treatment of squamous cell skin cancer. We expect to present our findings at conferences and publish our research in peer-reviewed journals in the near future. We intend to seek strategic partners to develop our therapeutic discoveries which could result in broad-spectrum cancer treatments in the future.

Recent Developments

On August 12, 2025, Roberto Rios, CPA and John J. Oppenheimer, M.D. were appointed to our board of directors.

On August 14, 2025, we completed a private placement with certain institutional and accredited investors for gross proceeds of approximately $1.2 million, before deducting Placement Agent fees and other estimated expenses payable by us. The offering consisted of 990 shares of our newly designated Series B Convertible Preferred Stock, with a par value $0.001 per share and stated value of $1,000 per share initially convertible into 143,476 shares of our Common Stock at an initial conversion price of $6.90 per share and (ii) warrants to purchase up to 223,824 shares of our Common Stock at an exercise price of $10.52 per share of Common Stock (the "August 2025 Warrants").

On August 14, 2025, we also completed a warrant inducement transaction with the holder of a warrant, pursuant to which such holder exercised for cash a total of 36,666 warrants originally issued in August 2024 and October 2024, at the reduced exercise price of $6.90 per share, for aggregate gross proceeds of approximately $253,000. In connection with the immediate exercise of the August 2024 and October 2024 Warrants, we issued unregistered common warrants to purchase an aggregate of up to 36,666 shares of Common Stock at an exercise price of $10.52 per share, which warrants are not exercisable until our stockholder approve such exercise.

On September 2, 2025, we entered into agreements with the holders of our August 2025 Warrants and the warrants issued in our May 2025 public offering (the "May 2025 Warrants") pursuant to which the Floor Price (as such term is defined in each of the August 2025 Warrants and the May 2025 Warrants) was increased, effective as of August 12, 2025, from $3.00 to $4.50 per share.

On September 17, 2025, we filed with the Secretary of State of the State of Delaware a certificate of amendment to our certificate of incorporation to effect a one-for-thirty (1-for-30) reverse split of our issued and outstanding shares of Common Stock. The Reverse Stock Split became effective as of 4:01 p.m. Eastern Time on September 18, 2025, and our Common Stock began trading on a split-adjusted basis when Nasdaq opened on September 19, 2025. All share and per share information in this prospectus (other than in the historical financial statements incorporated herein by reference) has been adjusted to reflect the reverse stock split.

On September 29, 2025, we consummated a best efforts public offering of an aggregate of (i) 1,047,694 shares of Common Stock and (ii) pre-funded warrants to purchase up to 874,067 shares of Common Stock in lieu of Shares. Each share of Common Stock was sold at a public offering price of $2.50. Each pre-Funded warrant was sold at a public offering price of $2.493. The aggregate gross proceeds from the offering was approximately $4.8 million, before deducting placement agent fees and other offering expenses.

Corporate Information

We were incorporated in the State of Delaware on March 26, 2014. Our principal executive office is located at 3300 Nacogdoches Road, Suite 216, San Antonio, Texas 78217, 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 until 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.

THE OFFERING

Securities offered by us in this offering	720,000 shares of our common stock
Offering price per share of common stock	$2.50 per share
Common stock outstanding immediately before this offering	3,778,709 shares
Common stock outstanding immediately after this offering	4,498,709 shares
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $1.5 million, after deducting WallachBeth's fees and estimated offering expenses payable by us. We intend to use the net proceeds of this offering for general corporate purposes, including using funds for working capital. See "Use of Proceeds" for a more complete description of the intended use of proceeds from this offering.
Risk factors	An investment in our securities involves substantial risks. You should read carefully the "Risk Factors" included and incorporated by reference in this prospectus, including the risk factors incorporated by reference from our filings with the SEC.
Nasdaq Capital Market symbol for common stock	"BIAF"

The number of shares of our common stock that will be outstanding immediately after this offering as shown above is based on 4,498,709 shares outstanding as of October 7, 2025, and excludes:

- 101,448 shares of common stock issuable upon the conversion of 700 shares of Series B Convertible Preferred Stock at an initial conversion price of $6.90 per share;
- 1,355,273 shares of common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price equal to $29.09 per share;
- 9,054 shares of common stock issuable upon the exercise of stock options issued under our equity incentive plans with a weighted average exercise price equal to $211.57 per share; and
- 41,908 shares of our common stock that are reserved for equity awards that may be granted under our 2024 Equity Incentive Plan.

RISK FACTORS

Investing in our securities involves a high degree of risk You should carefully consider the risks described below and all of the information contained or incorporated by reference in this prospectus, including the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2024, any subsequent Quarterly Reports on Form 10-Q, and all other information contained or incorporated by reference into this prospectus supplement and the accompanying base prospectus before deciding whether to purchase the securities offered hereby. Our business, financial condition, results of operations and prospects could be materially and adversely affected by these risks.

Risks Related to This Offering

Our management will have broad discretion over the use of the net proceeds from this offering, you may not agree with how we use the proceeds and the proceeds may not be invested successfully.

Our management will have broad discretion as to the use of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of commencement of this offering. Accordingly, you will be relying on the judgment of our management regarding the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that, pending their use, we may invest the net proceeds in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flows.

You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on an offering price of $2.50 per share, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $1.16 per share with respect to the net tangible book value of the common stock. See the section entitled “Dilution” below for a more detailed discussion of the dilution you will incur if you invest in this offering.

You may experience future dilution as a result of future equity offerings and other issuances of our common stock or other securities. In addition, this offering and future equity offerings and other issuances of our common stock or other securities may adversely affect our common stock price.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We may not be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by the investor in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or securities convertible into common stock in future transactions may be higher or lower than the price per share in this offering. You will incur dilution upon exercise of any outstanding stock options, warrants or upon the issuance of shares of common stock under our stock incentive programs. In addition, the sale of shares in this offering and any future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock. We cannot predict the effect, if any, that market sales of those shares of common stock or the availability of those shares for sale will have on the market price of our common stock.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $1.5 million, after deducting WallachBeth's fees and the estimated offering expenses payable by us.

The precise amount and timing of the application of such net proceeds will depend upon our funding requirements and the availability and cost of other funds. Our Board and management will have considerable discretion in the application of the net proceeds from this offering, and it is possible that we may allocate the proceeds differently than investors in the offering may desire or that we may fail to maximize the return on these proceeds. You will be relying on the judgment of our management with regard to the use of proceeds from this offering, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately.

We intend to use the proceeds of this offering for working capital and general corporate purposes, which may include laboratory test and therapeutic product development, general and administrative matters, and capital expenditures.

We may temporarily invest the net proceeds in short-term, interest-bearing instruments or other investment-grade securities.

DIVIDEND POLICY

We have not declared or paid dividends to holders of our common stock since inception and do not plan to pay cash dividends in the foreseeable future.

CAPITALIZATION

The following table sets forth our capitalization:

- on an actual basis as of June 30, 2025;
- on a pro forma basis to give effect to: (i) an aggregate of 21,666 shares of common stock upon the exercise of warrants that were originally issued on October 21, 2024, at the reduced exercise price of $6.90 per share, and our receipt of approximately $149,500 in gross proceeds upon such exercise, (ii) an aggregate of 15,000 shares of common stock upon the exercise of warrants that were originally issued on August 5, 2024, at the reduced exercise price of $6.90 per share, and our receipt of approximately $103,500 in gross proceeds upon such exercise, (iii) an aggregate of 114,672 shares of common stock were sold under the Company's ATM Agreement, and our receipt of approximately $1.2 million in net proceeds upon the sale, (iv) an aggregate of 990 shares of Series B Convertible Preferred Stock were issued on August 13, 2025, and our receipt of approximately $990,000 in gross proceeds upon issuance, (v) an aggregate of 673,661 shares of common stock that we issued in May 7, 2025 upon the exercise of warrants at a price of $4.50, and our receipt of approximately $3.0 million in net proceeds, (vi) an aggregate of 42,028 shares of common stock upon the conversion of 290 shares of Series B Convertible Preferred Stock that we issued on August 13, 2025, (vii) an aggregate of 41,353 shares of common stock that we issued in May 7, 2025, upon the exercise of warrants through a cashless transaction, and (vii) an aggregate of 1,921,761 shares of common stock that were sold in the Company's public offering on September 30, 2025 at a price of $2.50 per share and our receipt of approximately $4.1 million in aggregate net proceeds;
- on a pro forma, as adjusted basis to give effect to the pro forma adjustments and issuance and sale by us of 720,000 shares of common stock at offering prices of $2.50 per share and the receipt of $1.5 million in aggregate net proceeds after deducting WallachBeth's fees and estimated offering costs payable by us.

	As of June 30, 2025		
	Actual	Pro Forma	Pro Forma, As Adjusted (1)
Cash and cash equivalents	$ 802,835	10,149,889	$ 11,670,889
Stockholders' equity:			
Preferred stock, par value $0.001 per share; 20,000,000 shares authorized; no shares issued and outstanding at June 30, 2025, 700 shares issued and outstanding pro forma, and 700 shares issued and outstanding pro forma, as adjusted	—	1	1
Common Stock, par value $0.007 per share; 100,000,000 shares authorized; 948,651 issued and outstanding at June 30, 2025, 3,778,709 shares issued and outstanding pro forma, and 4,498,709 shares issued and outstanding pro forma, as adjusted	6,641	26,451	31,491
Additional paid-in capital	58,222,765	67,550,008	69,065,968
Accumulated deficit	(60,365,514)	(60,365,514)	(60,365,514)
Total stockholders' equity (deficit)	$ (2,136,108)	7,210,946	$ 8,731,946
Total capitalization	$ (2,136,108)	7,210,946	$ 8,731,946

(1) The number of shares of common stock to be outstanding immediately after this offering is based on 948,651 shares of common stock outstanding as of June 30, 2025, and excludes, as of such date:

- 939,680 shares of common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price equal to $41.60 per share;
- 9,530 shares of common stock issuable upon the exercise of stock options issued under our equity incentive plans with a weighted average exercise price equal to $207.30 per share; and
- 41,908 shares of our common stock that are reserved for equity awards that may be granted under our 2024 Equity Incentive Plan.

DILUTION

If you purchase securities in the offering, you will experience immediate dilution to the extent of the difference between the effective offering price per share of $2.50 per share of common stock and our as-adjusted net tangible book value per share immediately after the offering. Net tangible book value per share is equal to the amount of our total tangible assets, less total liabilities, divided by the number of outstanding shares of our common stock. As of June 30, 2025, our net tangible book value was approximately $(4.3) million, or approximately $(4.52) per share.

Our pro forma net tangible book value as of June 30, 2025, was approximately $5.0 million or $1.19 per share of common stock, based upon 3,778,709 shares of common stock outstanding as of October 8, 2025. Pro forma net tangible book value represents net tangible book value adjusted to take into account the issuance, subsequent to June 30, 2025, of: (i) an aggregate of 21,666 shares of common stock that we issued on October 21, 2024, upon the exercise of warrants, at the reduced exercise price of $6.90 per share, and our receipt of approximately $149,500 in proceeds upon such exercise and (ii) an aggregate of 15,000 shares of common stock that we issued on August 5, 2024, upon the exercise of warrants, at the reduced exercise price of $6.90 per share, and our receipt of approximately $103,500 in proceeds upon such exercise, (iii) an aggregate of 114,672 shares of common stock were sold under the Company's ATM Agreement, and our receipt of approximately $1.3 million in proceeds upon the sale, and (iv) an aggregate of 990 shares of Series B Convertible Preferred Stock were issued on August 13, 2025, and our receipt of approximately $990,000 in proceeds upon issuance and (v) an aggregate of 673,661 shares of common stock that we issued upon the exercise of warrants, at the reduced exercise price of $4.50 per share, and our receipt of approximately $3.0 million in proceeds upon such exercise, (vi) an aggregate of 39,782 shares of common stock that we issued on August 13, 2025, upon the conversion of 274.5 shares of Series B Convertible Preferred Stock, (vii) an aggregate of 105,260 shares of common stock that we issued in May 7, 2025, upon the exercise of warrants through a cashless transaction, and (vii) an aggregate of 1,921,761 shares of common stock that were sold in the Company's public offering on September 30, 2025 at a price of $2.50 per share and our receipt of approximately $4.1 million in net proceeds.

Dilution represents the difference between the amount per share paid by purchasers in this offering and the pro forma as adjusted net tangible book value per share of common stock after the offering. After giving effect to the issuance and sale of 720,000 shares of common stock in this offering at the offering price of $2.50 per share, and after deducting estimated underwriting discounts and commissions and estimated offering expenses, our pro forma as adjusted net tangible book value as of June 30, 2025, would have been $1.19 per share. This represents an immediate increase in net tangible book value of $0.15 per share to existing stockholders and an immediate dilution in net tangible book value of $1.16 per share to purchasers of common stock in this offering, based on the offering price of $2.50 per share. The following table illustrates this per share dilution:

Offering price per share of common stock	$	2.50
Historical net tangible book value per share as of June 30, 2025	$	(4.52)
Pro forma net tangible book value per share	$	0.20
Increase in pro forma net tangible book value per share attributable to this offering	$	0.15
Pro forma as adjusted net tangible book value per share after giving effective to this offering	$	1.34
Dilution per share to the new investor in this offering	$	1.19

The number of shares of common stock to be outstanding immediately after this offering is based on 948,651 shares of common stock outstanding as of June 30, 2025, and excludes, as of such date:

- 939,680 shares of common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price equal to $41.60 per share;
- 9,530 shares of common stock issuable upon the exercise of stock options issued under our equity incentive plans with a weighted average exercise price equal to $207.30 per share; and
- 41,908 shares of our common stock that are reserved for equity awards that may be granted under our 2024 Equity Incentive Plan.

PLAN OF DISTRIBUTION

WallachBeth has agreed to act as the exclusive placement agent for us in connection with this offering, subject to the terms and conditions of the placement agency agreement dated October 8, 2025. WallachBeth is not purchasing or selling any of the shares of our common stock offered by this prospectus supplement, nor are they required to arrange the purchase or sale of any specific number or dollar amount of shares of our common stock, but WallachBeth has agreed to use its reasonable best efforts to arrange for the sale of all of the shares of our common stock offered hereby. Therefore, we have entered into the securities purchase agreements directly with investors in connection with this offering, and we may not sell the entire amount of shares of our common stock offered pursuant to this prospectus supplement. We made offers only to a limited number of institutional accredited investors.

We have agreed to indemnify WallachBeth against specified liabilities, including liabilities under the Securities Act, and to contribute to payments WallachBeth may be required to make in respect thereof.

Fees and Expenses

We have agreed to pay WallachBeth a placement agent fee equal to 8.0% of the aggregate purchase price of the shares of our common stock sold in this offering. The following table shows the per share and total cash placement agent fees we will pay to WallachBeth in connection with the sale of the shares of our common stock offered pursuant to this prospectus supplement and the accompanying prospectus, assuming the purchase of all of the shares of common stock offered hereby.

	Per Share	Total
Offering price	$ 2.50	$ 1,800,000.00
Placement agent fees	$ 0.20	$ 144,000.00
Proceeds, before expenses, to us	$ 2.30	$ 1,656,000.00

In addition, we have agreed to reimburse the actual out-of-pocket expenses of WallachBeth up to $75,000.

We estimate that the total expenses of the offering payable by us, excluding the placement agent fees and expenses, will be approximately $279,000.

WallachBeth may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by them and any profit realized on the resale of the shares sold by them while acting as principals might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, WallachBeth would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares by WallachBeth acting as principal. Under these rules and regulations, WallachBeth:

- may not engage in any stabilization activity in connection with our securities; and
- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

This prospectus supplement and the accompanying prospectus may be made available in electronic format on websites or through other online services maintained by any of WallachBeth or by an affiliate of WallachBeth. Other than this prospectus supplement and the accompanying prospectus, the information on WallachBeth's website and any information contained in any other website maintained by WallachBeth is not part of this prospectus supplement and the accompanying prospectus or the registration statement of which this prospectus supplement and the accompanying prospectus form a part, has not been approved and/or endorsed by us or WallachBeth, and should not be relied upon by investors.

Our directors and officers have entered into lock-up agreements. Under these agreements, these individuals have agreed, subject to specified exceptions, not to sell or transfer any shares of common stock or securities convertible into, or exchangeable or exercisable for, our common stock during a period ending 60 days after the date of the closing of this offering, without first obtaining the written consent of WallachBeth. Specifically, these individuals have agreed, in part, not to:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Exchange Act;
- enter into any swap or other agreement, arrangement, hedge or transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of our securities, whether any such transaction is to be settled by delivery of shares of our common stock, in cash or otherwise;
- publicly announce the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge; or
- other arrangement relating to any of our securities.

Notwithstanding these limitations, these shares of common stock may be transferred under limited circumstances, including, without limitation, by gift, will or intestate succession.

Additionally, pursuant to the terms of the placement agency agreement (the "Placement Agency Agreement") with WallachBeth, subject to certain exceptions, until November 14, 2025, we may not issue, enter into any agreement to issue, or announce the issuance or proposed issuance of any shares of common stock or Common Stock Equivalents (as defined in the Placement Agency Agreement), or, subject to certain exceptions, file any registration statement. We have also agreed, subject to certain exceptions, not to enter into a Variable Rate Transaction (as defined in the Placement Agency Agreement) for 6 months after the closing date of this offering, provided, however, that the prohibition on "at-the-market offerings" and the issuance of common stock pursuant to an equity line of credit shall expire on the six-month anniversary of the closing date of this offering.

The foregoing does not purport to be a complete statement of the terms and conditions of the Placement Agency Agreement and the securities purchase agreements. A copy of the form of securities purchase agreements will be included as an exhibit to our Current Report on Form 8-K to be filed with the SEC and incorporated by reference into the registration statement of which this prospectus supplement and the accompanying prospectus form a part. See "Incorporation of Certain Information By Reference" and "Where You Can Find More Information."

No action has been or will be taken in any jurisdiction (except in the United States) that would permit a public offering of the securities offered by this prospectus supplement and accompanying prospectus, or the possession, circulation or distribution of this prospectus supplement and accompanying prospectus or any other material relating to us or the securities offered hereby in any jurisdiction where action for that purpose is required. Accordingly, the securities offered hereby may not be offered or sold, directly or indirectly, and neither of this prospectus supplement and accompanying prospectus nor any other offering material or advertisements in connection with the securities offered hereby may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of any such country or jurisdiction. WallachBeth may arrange to sell securities offered by this prospectus supplement and accompanying prospectus in certain jurisdictions outside the United States, either directly or through affiliates, where they are permitted to do so.

Right of First Refusal

According to the terms of the placement agency agreement, WallachBeth shall have the right of first refusal until January 30, 2026 to participate in each and every future public and private equity and debt offerings of the Company, or any successor to or any subsidiary of the Company.

Tail Rights

If the Company, within six (6) months after the closing of this offering, effects a sale of any securities with a party brought "over-the-wall" by WallachBeth in connection with this offering, the Company shall pay to WallachBeth the cash discount and warrants set forth above upon the completion of such transaction (to the extent allowable by FINRA).

Other Relationships

From time to time, the WallachBeth may provide in the future various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. However, except as disclosed in this prospectus, we have no present arrangements with the WallachBeth for any further services.

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 Tradeable Warrants trade on The Nasdaq Capital Market under the symbols "BIAF" and "BIAFW," respectively.

LEGAL MATTERS

The validity of the securities being offered by this prospectus supplement will be passed upon for us by Sheppard, Mullin, Richter & Hampton LLP, New York, New York. Sichenzia Ross Ference Carmel LLP, New York, New York, is acting as counsel for WallachBeth in connection with the securities offered hereby.

EXPERTS

The consolidated financial statements of bioAffinity Technologies, Inc. as of and for the years ended December 31, 2024 and 2023, incorporated by reference in this prospectus and registration statement have been audited by 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 bioAffinity Technologies, Inc.'s ability to continue as a going concern as described in Note 1 to the consolidated financial statements) have been incorporated in reliance upon such report given the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the securities offered by this prospectus supplement. This prospectus supplement and the accompanying prospectus, which are part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement, as permitted by the SEC. For further information pertaining to us and the securities offered in this prospectus supplement, reference is made to that registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus supplement and the accompanying prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public on a website maintained by the SEC at *www.sec.gov*.

General information about our company, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as any amendments and exhibits to those reports, are available free of charge through our website at *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.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference into this prospectus supplement the information contained in other documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents. Any statement contained in any document incorporated or deemed to be incorporated by reference in this prospectus supplement shall be deemed to be modified or superseded, for purposes of this prospectus, to the extent that a statement contained in or omitted from this prospectus supplement, or in any other subsequently filed document that also is or is deemed to be incorporated by reference in this prospectus supplement, modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement. We incorporate by reference the documents listed below which have been filed by us and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (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 unless such Form 8-K expressly provides to the contrary) subsequent to the date of this prospectus supplement and before the termination or completion of the offering of the securities covered by this prospectus. We incorporate by reference into this prospectus supplement and accompanying prospectus and the registration statement of which this prospectus supplement and the accompanying prospectus form a part the information or documents listed below that we have filed with the SEC (Commission File No. 001-41463):

- Current Reports on Form 8-K, filed with the SEC on January 14, 2025, February 7, 2025, February 27, 2025, April 14, 2025, May 8, 2025, May 19, 2025, May 27, 2025, May 30, 2025, July 25, 2025, August 13, 2025, August 14, 2025, August 18, 2025, September 2, 2025, September 17, 2025, and September 30, 2025;
- Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 31, 2025, as amended by the Form 10-K/A filed on April 29, 2025;
- Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2025, and June 30, 2025, filed with the SEC on May 15, 2025 and August 14, 2025;
- Proxy Statement on Schedule 14A filed on June 2, 2025; 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, 2022, including any amendments thereto or reports filed for the purposes of updating this description.

Any statement contained in a document incorporated or deemed to be incorporated by reference into this prospectus supplement will be deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained in this prospectus supplement or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus supplement modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement.

We will provide each person to whom a prospectus supplement is delivered a copy of all of the information that has been incorporated by reference in this prospectus supplement but not delivered with the prospectus supplement. You may obtain copies of these filings, at no cost, through the "Investor Relations" section of our website (*www.bioaffinitytech.com*) and you may request a copy of these filings (other than an exhibit to any filing unless we have specifically incorporated that exhibit by reference into the filing), at no cost, by writing or telephoning us at the following address:

bioAffinity Technologies, Inc.
3300 Nacogdoches Road, Suite 216
San Antonio, Texas 78217
(210) 698-5334
Attn: Chief Executive Officer

Information on, or that can be accessed through, our website is not incorporated into this prospectus supplement or other securities filings and is not a part of these filings.

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 27, 2023, the last reported sale price of our common stock was $1.41 per share, and the last reported sale price of our Tradeable Warrants was $0.12. 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 November 27, 2023.

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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.

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 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 to 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 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 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 funds to satisfy third-party claims and may adversely impact our cash position.

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.

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.

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.

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.

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;
- 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 depositary 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 depositary 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.

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.

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 depositary'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 depositary. 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 depositary. Unless we specify otherwise in the applicable prospectus supplement, The Depository Trust Company, New York, New York, known as DTC, will be the depositary 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 depositary, its nominee or a successor depositary, 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 depositary, 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 depositary 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 depositary, 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 depositary that holds the global security.

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 depositary'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 depositary's actions or for its records of ownership interests in the global security, nor will we or any applicable trustee supervise the depositary in any way;
- the depositary 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 depositary'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 depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary 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 depositary, and neither we nor any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

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 reallowed 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 reallowed 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.

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.

720,000 Shares of Common Stock

bioAffinity Technologies, Inc.

PROSPECTUS

WallachBeth Capital, LLC

October 8, 2025