AmpliPhi Biosciences Corp
Form S-1
January 21, 2014

As filed with the Securities and Exchange Commission on January 21, 2014

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

AMPLIPHI BIOSCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Washington (prior to reincorporation) Delaware (after reincorporation)	2836	91-1549568
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number	(I.R.S. Employer Identification No.)

4870 Sadler Road, Suite 300
Glen Allen, Virginia 23060
(804) 205-5069

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

Philip J. Young
President and Chief Executive Officer
AmpliPhi Biosciences Corporation
4870 Sadler Road, Suite 300
Glen Allen, Virginia 23060
(804) 205-5069

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

Copies to:

Stephen Thau
Morrison & Foerster LLP
2000 Pennsylvania Avenue NW
Washington, DC 20006
(202) 887-1500

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement, as determined by selling stockholders.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x

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

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

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

offering. o

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

Large accelerated filer o
Accelerated filer o
Non-accelerated filer o
(Do not check if a smaller reporting company)
Smaller reporting company x

The registrant is an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012. This registration statement complies with the requirements that apply to an issuer that is an emerging growth company.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered[1]	Proposed maximum offering price per share[2]	Proposed maximum aggregate offering price[2]	Amount of registration fee[2]
Common Stock, par value $0.01 per share	73,362,164	$ 0.57	$41,449,622.66	$ 5,338.71

(1) Represents shares of Common Stock, par value $0.01 per share that may be sold by the selling stockholders named in this registration statement. Pursuant to Rule 416 of the Securities Act of 1933, as amended, this registration statement also covers such an indeterminate amount of shares of Common Stock as may become issuable to prevent dilution resulting from stock splits, stock dividends and similar events.

(2) Pursuant to Rule 457(c), calculated on the basis of the average of the high and low prices of the registrant s Common Stock quoted on the OTC Pink market on January 16, 2014.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Prospectus (Subject to Completion) Dated January 21, 2014.

73,362,164 Shares

Common Stock

This prospectus covers the sale of an aggregate of up to 73,362,164 shares, or the Shares, of our common stock, par value $0.01 per share, by the selling stockholders identified in this prospectus (collectively with any such holder s transferee, pledgee, donee or successor, referred to below as the Selling Stockholders). The Shares consist of 72,007,000 shares of our common stock that were issued pursuant to a Subscription Agreement, dated as of December 19, 2013 and 1,355,164 shares underlying the exercise of warrants held by certain of the Selling Stockholders.

We will not receive any proceeds from the sale by the Selling Stockholders of the shares covered by this prospectus. We are paying the cost of registering the shares covered by this prospectus, as well as various related expenses. The shares included in this prospectus may be offered and sold directly by the Selling Stockholders in accordance with one or more of the methods described in the plan of distribution, which begins on page 29 of this prospectus. The Selling Stockholders are responsible for all selling commissions, transfer taxes and other costs related to the offer and sale of their shares under this prospectus. If required, the number of shares to be sold, the public offering price of those shares, the names of any broker-dealers and any applicable commission or discount will be included in a supplement to this prospectus, called a prospectus supplement.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and a smaller reporting company as that term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, and as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings. See Prospectus Summary Implications of Being an Emerging Growth Company.

Our business and an investment in our common stock involve significant risks. These risks are described under the caption Risk Factors beginning on page 5 of this prospectus.

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

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The date of this prospectus is , 2014.

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You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

PROSPECTUS SUMMARY

This summary provides an overview of selected information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our common stock. You should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, including the information discussed under Risk Factors beginning on page 5 and our financial statements and notes thereto that appear elsewhere in this prospectus. As used in this prospectus, unless the context requires otherwise, the Company, we, us and our refer to AmpliPhi Biosciences Corporation, a Washington corporation, or, where appropriate, Targeted Genetics Corporation or AmpliPhi Biosciences Corporation, a Delaware corporation to be formed in connection with the Company s planned reincorporation.

Our Company

AmpliPhi Biosciences is a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Our proprietary pipeline is based on the use of bacteriophages, a family of viruses that infect only bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacterial pathogens, including the so-called multi-drug-resistant (MDR) or Superbug strains.

We believe that we are a leading developer of phage-based therapeutics. We are combining our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages with that of our collaboration partners in bacteriophage biology, drug engineering, development and manufacturing, to develop second-generation bacteriophage products. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current medicines.

Our lead programs consist of three product candidates: AmpliPhage-001 for the treatment of *P. aeruginosa* lung infections in cystic fibrosis (CF) patients; AmpliPhage-002, for the treatment of methicillin-resistant *S. aureus* (MRSA) infections; and AmpliPhage-004 for the treatment of *C. difficile* infections.

We currently plan to develop these phage product candidates using our proprietary discovery and development platform, which is designed for rapid identification, characterization and manufacturing of multiple phage therapies. Each product candidate combines several carefully chosen phages which target a specific disease-causing bacterial pathogen such as MRSA. We believe that our understanding of bacteriophage biology combined with the clinical and scientific expertise of our collaboration partners will enable the rapid advancement of phage treatments through the clinic and eventually to the market.

We plan to initiate at least one new clinical study in 2014.

Our Risks

An investment in our common stock involves a high degree of risk. You should carefully consider the risks summarized below. These risks are discussed more fully in the Risk Factors section of this prospectus immediately following this prospectus summary. These risks include, but are not limited to, the following:

we are seeking to develop antibacterial agents using bacteriophage technology, which has not resulted in any approved product on the market to date;
we have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain;

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we depend on the U.S. Army for manufacturing process development and initial manufacturing of our lead product candidates and any disruption of this relationship or the U.S. Army s operations would materially and negatively affect our business; their failure to comply with manufacturing regulations could result in an interruption in the supply of our product candidates;

we must develop commercial-scale manufacturing capabilities;

we are dependent on patents and proprietary technology. If we fail to adequately protect our intellectual property or if we otherwise do not have exclusivity for the marketing of our products, our ability to commercialize products could suffer;

if our competitors are able to develop and market products that are more effective, safer or more affordable than ours, or obtain marketing approval before we do, our commercial opportunities may be limited;

the price of our common stock has been and may continue to be volatile; and

our auditors have expressed substantial doubt about our ability to continue as a going concern and we must raise additional capital to continue operations.

Implications of Being an Emerging Growth Company

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earliest of (1) the last day of the first fiscal year (a) following the fifth anniversary of the completion of an initial public offering, (b) in which we have total annual gross revenue of at least $1.0 billion or (c) 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 exceeded $700.0 million as of the prior June 30th; or (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the JOBS Act and references herein to emerging growth company shall have the meaning associated with it in the JOBS Act.

As an emerging growth company, we intend to take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

only two years of audited consolidated financial statements in addition to any required unaudited interim financial statements with correspondingly reduced Management s Discussion and Analysis of Financial Conditions and Results of Operations disclosure;

reduced disclosure about our executive compensation arrangements;

no requirement that we hold non-binding advisory votes on executive compensation or golden parachute arrangements; and

exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We also qualify as a smaller reporting company, as defined by Regulation S-K under the Securities Act of 1933, as amended, which we refer to as the Securities Act. As such, we also are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and also are subject to less extensive disclosure requirements regarding executive compensation in our periodic reports and proxy statements, and to exemptions from the requirements to hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will continue to be deemed a smaller reporting company until our public float exceeds $75 million on the last day of our second fiscal quarter in any fiscal year.

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Corporate Information

We were incorporated under the laws of the State of Washington in March 1989 as a wholly owned subsidiary of Immunex Corporation and began operations as an independent company in 1992 as Targeted Genetics Corporation.

In January 2011, we completed the acquisition of Biocontrol Ltd, which we refer to as Biocontrol, an antimicrobial biotechnology company based in the United Kingdom, with the goal of developing their phage therapy programs using funding from the sale of our legacy gene therapy assets. On February 22, 2011, we changed our name to AmpliPhi Biosciences Corporation.

In November 2012, we completed the acquisition of Special Phage Holdings Pty Ltd, a company based in Australia, which we refer to as SPH, pursuant to our offer to acquire all outstanding shares of SPH from its shareholders under the terms of a Shareholder Sale Agreement and a Managers Warranty Deed. SPH was formed in 2004 to address the rapidly escalating problem of antibiotic resistance through the development of a series of bacteriophage-based treatments.

We intend to reincorporate as AmpliPhi Biosciences Corporation in the State of Delaware.

Our principal executive offices are located at 4870 Sadler Road, Suite 300, Glen Allen, VA 23060. The telephone number at our principal executive office is (804) 205-5069. Our website address is *http://www.ampliphibio.com*. Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on our website or any such information in making your decision whether to purchase our common stock.

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THE OFFERING

Common stock covered by this prospectus

73,362,164 shares

Common stock outstanding as of January 10, 2014

271,135,285 shares

Use of proceeds

The Selling Stockholders will receive all of the proceeds from the sale of the shares offered for sale by them under this prospectus. We will not receive proceeds from the sale of the shares by the Selling Stockholders. See Use of Proceeds.

We may receive proceeds upon the cash exercise of warrants held by the Selling stockholders, the underlying shares of which are offered under this prospectus. Any proceeds of such warrant exercises will be used for general corporate purposes.

Risk factors

See the section entitled Risk Factors and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

Dividend policy

We currently intend to retain any future earnings to fund the development activities and operation of our business. Therefore, we do not currently anticipate paying cash dividends on our common stock.

Trading symbol

Our common stock is quoted on the OTC Pink market under the symbol APHB.

The number of shares of our common stock outstanding as of January 10, 2014 is 271,135,285, which consists of 182,535,505 shares of common stock outstanding as of January 10, 2014, and 88,599,780 shares of common stock issuable upon conversion of all outstanding shares of Series B Convertible Preferred Stock as of January 10, 2014 (assuming a conversion ratio equal to ten (10) common shares for each share of Series B Convertible Preferred Stock), and does not include the following:

- 25,555,000 shares of our common stock issuable upon the exercise of stock options outstanding under our 2012 Stock Incentive Plan, or the 2012 Plan, at a weighted-average exercise price of $0.18 per share;
- 9,353,323 shares of our common stock reserved for future issuance under the 2012 Plan;
- 166,000 shares of our common stock issuable upon the exercise of stock options outstanding under our Targeted Genetics Corporation Stock Incentive Plan, or the 2009 Plan, at a weighted-average exercise price of $0.90 per share;
- 1,304,760 shares of our common stock reserved for future issuance under the 2009 Plan;
- 40,000,000 shares of common stock reserved for future issuance under our 2013 Stock Incentive Plan, or the 2013 Plan; and
- 42,746,165 shares of our common stock issuable upon the exercise of outstanding warrants, at a weighted-average exercise price of $0.16 per share.

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RISK FACTORS

An investment in our common stock involves a high degree of risk. We operate in an industry that involves numerous risks and uncertainties. The risks and uncertainties described below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business. If any of the risks discussed below actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. This could cause the trading price of our common stock to decline, and you may lose all or part of your investment.

Risks Related to Our Business

We are seeking to develop antibacterial agents using bacteriophage technology, which has not resulted in any approved product on the market to date.

We are developing our product candidates with bacteriophage technology. We have not, nor to our knowledge has any other company, received regulatory approval from the U.S. Food and Drug Administration, or FDA or equivalent foreign agencies for a pharmaceutical drug based on this approach. While *in vitro* studies have characterized the behavior of bacteriophages in cell cultures and there exists a body of literature regarding the use of phage therapy in humans, the safety and efficacy of phage therapy in humans has not been extensively studied in well-controlled modern clinical trials. Most of the prior research on phage-based therapy was conducted in the former Soviet Union prior to and immediately after World War II and lacked appropriate control group design or lacked control groups at all. Furthermore, the standard of care has changed substantially during the ensuing decades since those studies were performed, making claims of improved cure rates open for debate. We cannot be certain that our approach will lead to the development of approvable or marketable drugs.

Developing phage-based therapies on a commercial scale will also require developing new manufacturing processes and techniques. We and our third-party collaborators may experience delays in developing manufacturing capabilities for our product candidates, and may not be able to do so at the scale required to conduct efficiently the clinical trials required to obtain regulatory approval of our products, or to manufacture commercial quantities of our products, if approved.

In addition, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of drugs based on these targeting approaches, which could lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates.

Delays in our clinical trials could result in us not achieving anticipated developmental milestones when expected, increased costs and delay our ability to obtain regulatory approval and commercialize our product candidates.

Delays in our ability to commence or enroll patients for our clinical trials could result in us not meeting anticipated clinical milestones and could materially impact our product development costs and delay regulatory approval of our product candidates. We do not know whether planned clinical trials will be commenced or completed on schedule, if

at all. Clinical trials can be delayed for a variety of reasons, including:

- delays in the development of manufacturing capabilities for our product candidates to enable their consistent production at clinical trial scale;
- delays in the commencement of clinical trials as a result of clinical trial holds or the need to obtain additional information to complete an Investigational New Drug Application (IND);
- delays in obtaining regulatory approval to commence new trials;
- adverse safety events experienced during our clinical trials;
- delays in obtaining clinical materials;
- slower than expected patient recruitment for participation in clinical trials; and
- delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval.

Delays in our clinical trials could result in us not achieving anticipateddevelopmental milestones when expected, inc

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If we do not successfully commence or complete our clinical trials on schedule, the price of our common stock may decline.

Preclinical studies and Phase 1 or 2 clinical trials of our product candidates may not predict the results of subsequent human clinical trials.

Preclinical studies, including studies of our product candidates in animal models of disease, may not accurately predict the result of human clinical trials of those product candidates. In particular, promising animal studies suggesting the efficacy of prototype phage products in the treatment of bacterial infections, such as *P. aeruginosa* may not predict the ability of these products to treat similar infections in humans. Our phage technology may be found not to be efficacious in treating bacterial infections alone or in combination with other agents, when studied in human clinical trials.

To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase 2 trials, does not ensure that later clinical trials will be successful. Our initial results from Phase 1/2 clinical trials also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Our product candidates must undergo rigorous clinical testing, the results of which are uncertain and could substantially delay or prevent us from bringing them to market.

Before we can obtain regulatory approval for a product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory agencies. Clinical trials of new drug candidates sufficient to obtain regulatory marketing approval are expensive and take years to complete.

We cannot be certain of successfully completing clinical testing within the time frame we have planned, or at all. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our product candidates, including the following:

our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;

the results obtained in earlier stage clinical testing may not be indicative of results in future clinical trials;

clinical trial results may not meet the level of statistical significance required by the FDA or other regulatory agencies;

enrollment in our clinical trials for our product candidates may be slower than we anticipate, resulting in significant delays and additional expense;

we, or regulators, may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and

the effects of our product candidates on patients may not be the desired effects or may include undesirable side effects or other characteristics that may delay or preclude regulatory approval or limit their commercial use, if approved.

Completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients, which is a function of many factors, including:

the therapeutic endpoints chosen for evaluation;
the eligibility criteria defined in the protocol;
the perceived benefit of the investigational drug under study;
the size of the patient population required for analysis of the clinical trial s therapeutic endpoints;

Our product candidates must undergo rigorous clinical testing, the results ofwhich are uncertain and could substant

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our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience;
our ability to obtain and maintain patient consents; and