AmpliPhi Biosciences Corp Form S-1 September 01, 2016

As filed with the Securities and Exchange Commission on September 1, 2016

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 (State or Other Jurisdiction of Incorporation or Organization) 2836

(Primary Standard Industrial Classification Code Number)

91-1549568

(I.R.S. Employer Identification Number)

3579 Valley Centre Drive, Suite 100 San Diego, California 92130 (858) 829-0829

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

M. Scott Salka Chief Executive Officer AmpliPhi Biosciences Corporation 3579 Valley Centre Drive, Suite 100 San Diego, California 92130 (858) 829-0829

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

Copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

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, as amended (the Securities Act), check the following box. o

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

If this Form is a 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.

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

Accelerated filer o Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered ⁽¹⁾	Proposed maximum aggregate offering price ⁽²⁾	Amount of registration fee
Common Stock, \$0.01 par value per share		
Warrants to purchase shares of common stock		
Total	\$ 10,000,000	\$ 1,007

The securities registered hereunder also include the shares of common stock as may be issued upon exercise of warrants registered hereby. Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional securities as may be issuable to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act.

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

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

Subject to completion, dated September 1, 2016

PRELIMINARY PROSPECTUS

Shares of Common Stock

Warrants to Purchase Shares of Common Stock

We are offering shares of our common stock and warrants to purchase an aggregate of shares of our common stock (and the shares of common stock that are issuable from time to time upon exercise of the warrants). Each share of common stock is being sold together with a warrant to purchase up to of a share of our common stock, at an exercise price of \$ per share. The warrants will be exercisable immediately and will expire years from the date of issuance. The shares of common stock and warrants can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance. Our common stock is listed on the NYSE MKT under the symbol APHB. On , 2016, the last reported sale price of our common stock on the NYSE MKT was \$ per share. There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for a listing of the warrants on any national securities exchange.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

	Per Share and	
	Accompanying	Total
	Warrant	
Public offering price ⁽¹⁾	\$	\$
Underwriting discounts and commissions ⁽²⁾	\$	\$
Proceeds, before expenses, to us	\$	\$

⁽¹⁾ The public offering price is \$ per share of common stock and \$0.01 per warrant to purchase of a share of common stock.

The offering is being underwritten on a firm commitment basis.

Investing in our securities involves a high degree of risk. See the section entitled Risk Factors beginning on page 8 of this prospectus and elsewhere in this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

⁽²⁾ In addition, we have agreed to reimburse the underwriters for certain expenses. See Underwriting beginning on page <u>54</u> of this prospectus for additional information.

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.

The underwriters expect to deliver the shares of common stock and warrants to purchasers on or about

, 2016.

Sole Book-Running Manager

Roth Capital Partners

Co-Manager

Griffin Securities, Inc.

The date of this prospectus is , 2016

Griffin Securities, Inc. 6

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

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PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus or incorporated by reference into this prospectus from our filings with the Securities and Exchange Commission, or SEC, listed in the section of the prospectus entitled Incorporation of Certain Information by Reference. Because it is only a summary, it does not contain all of the information that you should consider before purchasing our securities in this offering and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere or incorporated by reference into this prospectus. You should read the entire prospectus, the registration statement of which this prospectus is a part, and the information incorporated by reference herein in their entirety, including the Risk Factors and our financial statements and the related notes incorporated by reference into this prospectus, before purchasing our securities in this offering. Unless the context requires otherwise, references in this prospectus to AmpliPhi, we, us and our refer to AmpliPhi Biosciences Corporation together with its wholly owned subsidiaries.

Overview

Our Company

We are a biotechnology company focused on the discovery, development and commercialization of novel phage therapeutics. Phage therapeutics use bacteriophages, a family of viruses, to kill pathogenic bacteria. Phages have powerful and highly selective mechanisms of action that permit them to target and kill specific bacteria. We believe that phages represent a promising means to treat bacterial infections, especially those that have developed resistance to current therapies, including the so-called multi-drug-resistant or superbug strains of bacteria.

Our goal is to be the leading developer of phage therapeutics. We are combining our expertise in the manufacture of drug-quality bacteriophages and our proprietary approach and expertise in identifying, characterizing and developing naturally occurring bacteriophages with that of our collaboration partners in bacteriophage biology, synthetic biology and manufacturing, to develop second-generation bacteriophage products.

The extensive use of antibiotics since their discovery in the 1940s has resulted in drug resistance among many disease-causing bacteria. According to the U.S. Centers for Disease Control and Prevention, resistance to antibiotics threatens to reverse many of the key medical advances of the last half-century. Examples of clinically important microbes that are rapidly developing resistance to available antimicrobials include bacteria that cause skin, bone, lung and bloodstream infections (e.g., *S. aureus* and methicillin-resistant *S. aureus*, or MRSA), pneumonia and lung infections in both community and hospital settings and cystic fibrosis patients (e.g., *A. baumanii, P. aeruginosa,* and *K. pneumoniae*), meningitis (e.g., *S. pneumonia*), urinary tract and gastrointestinal infections (e.g., *E. coli* and *C. difficile*). As phages kill bacteria in ways entirely unlike the mechanisms used by traditional antibiotics, we believe that multi-drug resistant bacteria will be susceptible to phage therapy. Should resistant bacteria emerge or evolve, we believe it will remain possible to identify phages that can effectively kill these resistant bacteria. Furthermore, we have found that in some circumstances the selective pressure applied by phage use on antibiotic-resistant bacteria can result in those bacteria reverting back to being antibiotic sensitive.

Our lead product candidate is AB-SA01, for the treatment of *S. aureus* infections, including MRSA. We are currently conducting a Phase 1 clinical trial of AB-SA01 for the treatment of *S. aureus* in chronic rhinosinusitis patients and have completed enrollment of a second Phase 1 clinical trial to evaluate the safety of AB-SA01 when administered topically to the intact skin of healthy adults. We expect to report final data for both trials in the second half of 2016.

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We also have another product candidate in earlier stage development, AB-PA01 for the treatment of *P. aeruginosa* infections, and an additional discovery program, AB-CD01 for the treatment of *C. difficile* infections.

We are developing our phage product candidates using a proprietary discovery and development platform, which is designed for rapid identification, characterization and manufacturing of multiple phage therapeutics. Each product candidate combines several carefully chosen phages, which target a specific disease-causing bacteria such as *S. aureus*, *P. aeruginosa*, and *C. difficile*. We believe that the combination of our platform, our manufacturing capability, our understanding of the regulatory and development requirements of

Our Company 9

bacteriophage therapeutics, and the clinical and scientific expertise of our collaboration partners may enable the rapid advancement of phage therapeutics through the clinic and the regulatory approval process.

We have a collaboration agreement and a license agreement with the University of Leicester to develop a phage therapeutic that targets and kills certain types of *C. difficile*. Pursuant to the license agreement, we may be obligated to pay the University of Leicester a percentage royalty in the single digits and an aggregate of up to £575,000 in milestone payments.

In November 2015, our Australian subsidiary, AmpliPhi Australia Pty Ltd, entered into a clinical trial agreement with the University of Adelaide and the Queen Elizabeth Hospital, both of Adelaide, SA, Australia, for the conduct of a clinical trial of AB-SA01 in patients with chronic rhinosinusitis complicated by a *S. aureus* infection. Patient screening for this clinical trial commenced in late 2015. The first patient was dosed in January 2016 and we are now enrolling the final cohort. We expect to have the complete study report before the end of 2016.

In June 2013, we entered into a cooperative research and development agreement, or Research and Development Agreement, with the United States Army Medical Research and Materiel Command focusing on developing bacteriophage therapeutics to treat *S. aureus*, *E. coli* and *P. aeruginosa* infections. In May 2016, we initiated a Phase 1 clinical trial under a U.S. investigational new drug application, or IND, to evaluate the safety of AB-SA01 administered topically to the intact skin of 12 healthy adult volunteers. The trial is now fully enrolled and top-line results are expected by the end of the third quarter of 2016, with the complete study report expected by the end of

Risks Associated with Our Business

Our business and our ability to implement our business strategy are subject to numerous risks, as more fully described in the section entitled Risk Factors in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, incorporated herein by reference. You should read these risks before you invest in our securities. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, risks associated with our business include:

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. Even if this offering is successful, will need to raise additional capital in the future to continue operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations, and there will be substantial doubt about our ability to continue as a going concern.

We are seeking to develop antibacterial agents using bacteriophage technology, a novel approach, which makes it difficult to predict the time and cost of development. No bacteriophage products are currently approved for human therapeutics commercial use in the United States.

Our product candidates must undergo rigorous clinical testing, such clinical testing may fail to demonstrate safety and efficacy and any of our product candidates could cause undesirable side effects, which would substantially delay or prevent regulatory approval or commercialization.

We determined that we had a material weakness as of December 31, 2014 and December 31, 2015. If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable.

A complaint has been filed against us and the members of our board of directors by one of our principal stockholders.

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

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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.

If you purchase our securities in this offering, you will incur immediate and substantial dilution. We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Corporate and Other 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, 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.

In February 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, with the goal of combining SPH s research on addressing the rapidly escalating problem of antibiotic resistance through the development of a series of bacteriophage-based treatments into our own development programs.

In August 2015, we effected a 1-for-50 reverse split of our common stock. The share and per share information for transactions described in this prospectus that occurred prior to the reverse split have been adjusted to give retroactive effect to the reverse split.

Our principal executive offices are located at 3579 Valley Centre Drive, Suite 100, San Diego, California 92130. The telephone number at our principal executive office is (858) 829-0829. 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 securities in this offering.

This prospectus contains references to our trademarks and to trademarks and trade names belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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, or JOBS Act, enacted in April 2012. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

being permitted to present only two years of audited financial statements and only two years of related Management s Discussion and Analysis of Financial Condition and Results of Operations in the documents incorporated by reference into this prospectus;

not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;

reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and

exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may use these provisions until the last day of our fiscal year following the fifth anniversary of the first sale of our equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended, or the Securities Act, after we became a reporting company under the Securities Exchange Act of 1934, as amended, or the Exchange Act, pursuant to our registration statement on Form 10 (File No. 000-23930). However, if certain events occur prior to the end of such five-year period, including if we become a large accelerated filer, our annual gross revenues exceed \$1.0 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We are also a smaller reporting company as defined in Exchange Act and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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The Offering

Common stock offered by us in this offering

shares

Warrants offered by us in this offering

Warrants to purchase up to shares of common stock. Each share of our common stock is being sold together with of a warrant to purchase of a share of our common stock. Each warrant will have an exercise price of \$ per share, will be immediately exercisable and will expire on the anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants.

Common stock to be outstanding after this offering

shares (assuming none of the warrants issued in this offering are exercised).

Use of proceeds

We intend to use the net proceeds from this offering for general corporate purposes, including manufacturing expenses, clinical trial expenses, research and development expenses and general and administrative expenses. See Use of Proceeds.

Risk factors

You should read the Risk Factors section of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock and warrants in this offering.

National Securities Exchange Listing

Our common stock is listed on the NYSE MKT under the symbol APHB. We do not intend to list the warrants on any securities exchange or nationally recognized trading system.

The number of shares of our common stock to be outstanding after this offering is based on 11,120,394 shares of common stock outstanding as of June 30, 2016 and assumes:

the issuance by us of shares of common stock in this offering; and the issuance by us of shares of common stock in connection with the closing of this offering pursuant to the Common Stock Issuance Agreement, dated April 8, 2016, or the CSIA, by and between us and certain of our stockholders, based on an assumed public offering price per share of common stock in this offering of \$; and excludes, as of June 30, 2016:

739,021 shares of common stock issuable upon the exercise of outstanding stock options, at a weighted-average exercise price of \$6.81 per share;

1,650,179 shares of common stock reserved for future issuance under our 2016 Equity Incentive Plan, or the 2016 plan;

120,000 shares of common stock reserved for future issuance under our 2016 Employee Stock Purchase Plan, or the ESPP; and

2,443,479 shares of common stock issuable upon the exercise of outstanding warrants, at a weighted-average exercise price of \$5.87 per share.

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Consolidated Summary Financial Data

The following tables summarize certain of our historical financial data. We derived the consolidated summary statement of operations data for the years ended December 31, 2015 and 2014 from our audited consolidated financial statements incorporated by reference into this prospectus from our Annual Report on Form 10-K for the year ended December 31, 2015. The consolidated summary statement of operations data for the six months ended June 30, 2016 and 2015 and the consolidated summary balance sheet data as of June 30, 2016 were derived from our unaudited consolidated financial statements incorporated by reference into this prospectus from our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016. The unaudited consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements included in this prospectus and include, in our opinion, all adjustments, consisting only of normal recurring adjustments, necessary for the fair presentation of the financial information in those statements, including giving retroactive effect to the 1-for-50 reverse split of our common stock that was effected on August 7, 2015 for the presentation of per share information. Our historical results are not necessarily indicative of the results that may be expected in the future and results of interim periods are not necessarily indicative of the results for the entire year. The consolidated summary financial data should be read together with our consolidated financial statements and related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations incorporated by reference in this prospectus.

	Year Ended December 31,		Six Months Ended June 30,	
	2015	2014	2016	2015
Consolidated Statements of Operations Data				
Revenue	\$ 475,000	\$ 409,000	\$ 209,000	