

GENOCEA BIOSCIENCES, INC.
Form S-3/A
April 30, 2019

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

AMENDMENT NO. 1
TO
FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

GENOCEA BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)
Delaware 51-0596811
(State or other jurisdiction (I.R.S. Employer
of incorporation or organization) Identification No.)

100 Acorn Park Drive
Cambridge, Massachusetts 02140
(617) 876-8191
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

William D. Clark
President and Chief Executive Officer
Genocea Biosciences, Inc.
100 Acorn Park Drive
Cambridge, Massachusetts 02140
(617) 876-8191
(Name, address including zip code, and telephone number, including area code, of agent for service)

With copies to:

Marc A. Rubenstein, Esq.
Ropes & Gray LLP
Prudential Tower
800 Boylston St.
Boston, Massachusetts 02199
(617) 951-7000

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

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

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

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

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

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

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, 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 prospectus is not complete and may be changed. The selling stockholders may not sell these securities or accept an offer to buy these securities until the Securities and Exchange Commission declares the registration statement effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED APRIL 30, 2019
PRELIMINARY PROSPECTUS
GENOCEA BIOSCIENCES, INC.
25,599,979 Shares of Common Stock
11,712,494 Shares of Common Stock Issuable upon Exercise of Warrants

This prospectus relates to the resale or other disposition from time to time of up to (i) 25,599,979 shares of our common stock, par value \$0.001 per share (the "Common Stock"), and (ii) up to 11,712,494 shares of Common Stock upon the exercise of warrants by the selling stockholders identified in this prospectus, including their transferees, pledgees, donees or successors.

The selling stockholders may, from time to time, sell, transfer, or otherwise dispose of any or all of their securities from time to time on any stock exchange, market, or trading facility on which the securities are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. See "Plan of Distribution" which begins on page 11.

We are not offering any shares of our Common Stock for sale under this prospectus. We will not receive any of the proceeds from the sale of common stock by the selling stockholders. However, we will generate proceeds in the event of a cash exercise of the warrants by the selling stockholders. All expenses of registration incurred in connection with this offering are being borne by us. All selling and other expenses incurred by the selling stockholders will be borne by the selling stockholders.

Our common stock is quoted on the Nasdaq Capital Market under the symbol "GNCA." On April 29, 2019, the last reported sale price of our common stock as reported on the Nasdaq Capital Market was \$0.76 per share.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Investing in our securities involves risks. See "Risk Factors" on page 3, and any applicable prospectus supplement, 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 passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Prospectus dated , 2019

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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 or continuous offering process.

You should read this prospectus and the information and documents incorporated by reference carefully. Such documents contain important information you should consider when making your investment decision. See “Where You Can Find More Information” and “Incorporation of Documents by Reference” in this prospectus.

This prospectus may be supplemented from time to time to add, to update or change information in this prospectus. Any statement contained in this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in such prospectus supplement modifies or supersedes such 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 or incorporated by reference in this prospectus, any applicable prospectus supplement or any related free writing 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. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus. This prospectus is not an offer to sell securities, and it is not soliciting an offer to buy securities, in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or any prospectus supplement, as well as information we have filed with the SEC that is incorporated by reference, is accurate as of the date on the front of those documents only, regardless of the time of delivery of this prospectus or any applicable prospectus supplement, or any sale of a security. Our business, financial condition, results of operations and prospects may have changed since those dates.

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 “Where You Can Find More Information.”

Unless otherwise stated or the context requires otherwise, references in this prospectus to “Genocea,” the “company” or the “Company,” “we,” “us,” or “our” refer to Genocea Biosciences, Inc.

ABOUT THE COMPANY

Company Overview

We are a biopharmaceutical company that seeks to discover and develop novel cancer immunotherapies. We use our proprietary discovery platform, ATLAS, to profile CD4+ and CD8+ T cell (or cellular) immune responses to tumor antigens. We use insights arising from ATLAS to design novel cancer immunotherapies. We believe that ATLAS, which recreates each individual's T cell immune responses to their tumor in the laboratory, affords Genoccea advantages in the design of novel cancer immunotherapies relative to our peers, who we believe rely primarily on software and processes such as "machine learning" to predict immunotherapy targets.

Our most advanced program is GEN-009, a neoantigen (or personalized) cancer vaccine, for which we are conducting a Phase 1/2a clinical trial. The GEN-009 program uses ATLAS to identify neoantigens, or tumor mutations unique to each patient, for inclusion in each patient's GEN-009 vaccine. We are also advancing GEN-011, a neoantigen adoptive T cell therapy program as well as GEN-010, a next-generation neoantigen vaccine program.

Our principal executive offices are located at 100 Acorn Park Drive, Cambridge, MA 02140, and our telephone number is (617) 876-8191. Our website address is: www.genoccea.com. We have included our website address as a factual reference and do not intend it to be an active link to our website. The information that can be accessed through our website is not part of this prospectus, and investors should not rely on any such information in deciding whether to purchase our common stock.

RISK FACTORS

An investment in our common stock involves risks. Prior to making a decision about investing in our common stock, you should consider carefully the risks together with all of the other information contained or incorporated by reference in this prospectus, including any risks described in the section entitled “Risk Factors” contained in any supplements to this prospectus, in our Annual Report on Form 10-K for the year ended December 31, 2018, and in our subsequent filings with the SEC. Each of the referenced risks and uncertainties could adversely affect our business, prospects, operating results and financial condition, as well as adversely affect the value of an investment in our securities. Additional risks not known to us or that we believe are immaterial may also adversely affect our business, operating results and financial condition and the value of an investment in our securities.

DESCRIPTION OF PRIVATE PLACEMENT OF COMMON STOCK AND WARRANTS

On February 14, 2019, we completed a private placement financing transaction (the “Initial Closing”). Pursuant to a Subscription Agreement (the “Subscription Agreement”), we issued 25,599,979 shares (the “Shares”) of Common Stock, pre-funded warrants (the “Pre-Funded Warrants”) to purchase 4,250,000 shares of Common Stock (the “Pre-Funded Warrant Shares”), and warrants (the “Warrants”) to purchase up to 7,462,494 shares of Common Stock (the “Warrant Shares”). The Shares, Pre-Funded Warrants and Warrants (collectively, the “Units”) were sold at a purchase price of \$0.5026 per Unit. We received gross cash proceeds of approximately \$15,002,599, excluding transactions costs, fees and expenses, for the purchase of the Shares, Pre-Funded Warrant Shares and Warrant Shares. The purchasers of the Shares, Pre-Funded Warrants and Warrants were the selling stockholders named in this prospectus (the “Purchasers”).

Warrants and Pre-Funded Warrants
The material terms and provisions of the Warrants and the Pre-Funded Warrants to purchase shares of Common Stock are summarized below. This summary is subject to and qualified in its entirety by the form of warrant and pre-funded warrant, which were filed with the SEC as exhibits to the Company’s Annual Report on Form 10-K for the year ended December 31, 2018.

Exercisability. The holder may exercise the Warrants at any time or from time to time through February 14, 2024, unless the holder becomes a Non-Participating Purchaser, in which case it will forfeit any unexercised Warrants. The holder may exercise the Pre-Funded Warrants at any time or from time to time through February 14, 2039. As further described under “Selling Stockholders,” notwithstanding the foregoing, certain holders will be prohibited from exercising such warrants into shares of our common stock if, as a result of such exercise, the holder, together with its affiliates, would own more than a specific percentage of the total number of shares of our common stock then issued and outstanding. The Warrants and Pre-Funded Warrants are exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below).

Exercise Price. The exercise price upon exercise of each Warrant is \$0.5656 per share of Common Stock and the exercise price of each Pre-Funded Warrants is \$0.5026 per share of Common Stock, of which \$0.5025 per share was paid by the holder at the Initial Closing. The exercise price of the warrants is subject to appropriate adjustment in the event of stock dividends, subdivisions, stock splits, stock combinations, reclassifications or reorganizations affecting our common stock.

Payment of Exercise Price. The warrant holders have the option to provide payment of the exercise price of the shares being acquired upon exercise of the warrants (i) by wire transfer or cashier’s check, or (ii) by cashless exercise.

Transferability. Subject to applicable laws and the restriction on transfer set forth in the Warrant Agreement, the warrants may be transferred at the option of the holders upon surrender of the warrants to the warrant agent together with the appropriate instruments of transfer.

Change of Control Transactions. If, at any time while the Warrant or Pre-Funded Warrant is outstanding, there is a Change of Control, which generally includes a merger or consolidation resulting in the sale of 50% or more of the voting securities of the Company, the sale of all or substantially all of the assets or voting securities of the Company, or other change of control transaction, then the holder has the right thereafter to receive, upon exercise of the Warrant or Pre-Funded Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Change of Control if it had been, immediately prior to such Change of Control, the holder of the number of Warrant Shares then issuable upon exercise in full of the Warrant or Pre-Funded Warrant (the “Alternate Consideration”). If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Change of Control, then the holder will be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Change of Control.

Events of Failure. In the event that we fail to timely deliver shares of Common Stock to any holder, we are required to make whole any holder who purchases shares of Common Stock to deliver in satisfaction of a sale by such holder of shares of Common Stock issuable upon an exercise of the Warrants or the Pre-Funded Warrants that the holder anticipated receiving from the Company, as described in the Warrants and Pre-Funded Warrants.

Rights as a Stockholder. Except for the right to participate in certain dividends and distributions and as otherwise provided in the Warrants and the Pre-Funded Warrants or by virtue of a holder’s ownership of our common stock, the

holders of

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the Warrants and Pre-Funded Warrants do not have the rights or privileges of holders of our Common Stock, including any voting rights, until they exercise their warrants.

Waivers and Amendments. Any term of the Warrants and Pre-Funded Warrants may be amended or waived with our written consent and the written consent of the holder of such Warrant or Pre-Funded Warrant.

No Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of the Warrants or Pre-Funded Warrants. As to any fraction of a share which the holder would otherwise be entitled to purchase upon such exercise, we shall cause the warrant agent to, at our option, pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price of the Warrant or Pre-Funded Warrant per whole share or round such fractional share up to the nearest whole share.

Warrant Agent. Our warrant agent is Computershare Trust Company, N.A.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, any prospectus supplement and the other documents we have filed with the SEC that are incorporated herein by reference, contain forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. In particular, you should consider the numerous risks described in our Annual Report on Form 10-K for the year ended December 31, 2018 and any subsequent Quarterly Reports on Form 10-Q, each incorporated by reference in this prospectus, and in the “Risk Factors” section in the applicable prospectus supplement. See “Where You Can Find More Information.”

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. You should not rely upon forward-looking statements as predictions of future events. Unless required by law, we will not undertake and we specifically disclaim any obligation to release publicly the result of any revisions which may be made to any forward-looking statements to reflect events or circumstances after the date of such statements or to reflect the occurrence of events, whether or not anticipated. In that respect, we wish to caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made.

This prospectus and the other documents incorporated by reference herein include statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third party research, surveys and studies are reliable, we have not independently verified such data.

These risks and uncertainties include, among other things:

- our estimates regarding the timing and amount of funds we require to initiate clinical trials for GEN-009 and to continue our investments in immuno-oncology
- our estimate for when we will require additional funding
- our plans to commercialize GEN-009 and our other product candidates
- the timing of, and our ability to, obtain and maintain regulatory approvals for our product candidates
- the rate and degree of market acceptance and clinical utility of any approved product candidate
- the potential benefits of strategic partnership agreements and our ability to enter into strategic partnership arrangements
- our ability to quickly and efficiently identify and develop product candidates
- our commercialization, marketing and manufacturing capabilities and strategy
- our intellectual property position and
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing.

USE OF PROCEEDS

The selling stockholders will receive all of the net proceeds from sales of the Common Stock pursuant to this prospectus. However, in the case of Warrants and Pre-Funded Warrants issued to the selling stockholders pursuant to the Subscription Agreement, upon any exercise of the Warrants and Pre-Funded Warrants for cash, the selling stockholders would pay us an exercise price of \$0.5656 and \$0.01 per share of Common Stock, respectively, subject to any adjustment pursuant to the terms of the Warrants and Pre-Funded Warrants. We expect to use any such proceeds primarily to support the ongoing clinical study of GEN-009 and the development of other programs as well as for working capital and other general corporate purposes. The Warrants and Pre-Funded Warrants are also exercisable on a cashless basis by net exercise under certain conditions contained therein. If any of the Warrants or Pre-Funded Warrants are exercised on a cashless basis, we would not receive any cash payment from the applicable selling stockholder upon any such cashless exercise.

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SELLING STOCKHOLDERS

Pursuant to the Subscription Agreement, we agreed to file the registration statement of which this prospectus is a part to cover the resale of the shares of our Common Stock and the shares of Common Stock underlying the Warrants and Pre-Funded Warrants, and to keep such registration statement effective with respect to each selling stockholder until the date on which all of the shares of our Common Stock registered for resale under the registration statement have been disposed of in accordance with such registration statement, disposed of pursuant to Rule 144 under the Securities Act, or can be resold pursuant to Rule 144 without restriction or limitation (including without any limitation as to volume of sales and without the selling stockholder complying with any method of sale requirements or notice requirements under Rule 144). The shares issuable upon exercise of the Warrants and Pre-Funded Warrants will become eligible for sale by the selling stockholders under this prospectus only when the Warrants or Pre-Funded Warrants are exercised. We cannot predict when or whether any of the selling stockholders will exercise their Warrants or Pre-Funded Warrants.

We are registering the resale of the above-referenced shares to permit each of the selling stockholders identified below, or their permitted transferees or other successors-in-interest that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part, to resell or otherwise dispose of the shares in the manner contemplated under “Plan of Distribution” in this prospectus (as may be supplemented and amended). This prospectus covers the sale or other disposition by the selling stockholders of up to the total number of shares of Common Stock that have been issued to the selling stockholders pursuant to the Subscription Agreement, plus the total number of shares of Common Stock issuable upon exercise of the Warrants and Pre-Funded Warrants issued to the selling stockholders. Throughout this prospectus, when we refer to the shares of our Common Stock being registered on behalf of the selling stockholders, we are referring to the shares of our Common Stock and the shares underlying the Warrants and Pre-Funded Warrants issued to the selling stockholders pursuant to the Subscription Agreement, and when we refer to the selling stockholders in this prospectus, we are referring to the purchasers under the Subscription Agreement and, as applicable, their permitted transferees or other successors-in-interest that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part.

The selling stockholders may sell some, all or none of their shares. We do not know how long the selling stockholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale or other disposition of any of the shares. The shares of our Common Stock covered hereby may be offered from time to time by the selling stockholders.

When we refer to “selling shareholders” in this prospectus, we mean those persons listed in the table below, as well as their transferees, pledgees or donees or their successors. The information regarding shares beneficially owned after the offering assumes the sale of all shares offered by the selling shareholders. To our knowledge, subject to community property laws where applicable, each person named in the table has sole voting and investment power with respect to the shares of Common Stock set forth opposite such person’s name.

The following table sets forth the name of each selling stockholder, the number and percentage of our Common Stock beneficially owned by the selling stockholders as of March 31, 2019, the number of shares of our Common Stock that may be offered under this prospectus, and the number and percentage of our Common Stock beneficially owned by the selling stockholders assuming all of the shares of our Common Stock registered hereunder are sold. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to our Common Stock. Generally, a person “beneficially owns” shares of our Common Stock if the person has or shares with others the right to vote those shares or to dispose of them, or if the person has the right to acquire voting or disposition rights within 60 days. The number of shares of our Common Stock in the column “Number of Shares Offered” represents all of the shares of our Common Stock that a selling stockholder may offer and sell from time to time under this prospectus. For certain selling stockholders, the number of shares of Common Stock into which the Warrants and Pre-Funded Warrants beneficially held by such selling stockholder are exercisable are limited pursuant to the terms of the Warrants and Pre-Funded Warrants to a number of shares of Common Stock which would result in such selling stockholder having aggregate individual beneficial ownership of the total issued and outstanding shares of Common Stock over specified percentage thresholds (collectively, referred to as the “Beneficial Ownership

Limitation”).

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Name and Address	Prior to Offering			After Offering		
	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	Number of Shares Offered	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
New Enterprise Associates 16, L.P. 1954 Greenspring Drive, Suite 600 Timonium, MD 21093	49,935,336(1)	39.20 %	12,435,336	37,500,000	30.03 %	
S.R. One, Limited 980 Great West Road Brentford, Middlesex, TW8 9GS England	14,557,004(2)	12.67 %	12,435,336	2,121,668	1.89 %	
BVF Partners L.P. 44 Montgomery Street, 40 th Floor San Francisco, CA 94104	11,602,974(3)	9.99 %	8,704,735	7,614,455	6.63 %	
DAFNA Capital Management LLC 10990 Wilshire Boulevard, Suite 1400 Los Angeles, CA 90024	3,362,066(4)	2.96 %	2,487,066	875,000	*	
Lincoln Park Capital Fund, LLC 440 N. Wells Street, Suite 410 Chicago, IL 60654	1,750,000(5)	1.55 %	1,250,000	500,000	*	

*Represents less than 1%.

Based on a Schedule 13D filed with the SEC on February 14, 2019, consisting of 34,948,269 shares of common stock and warrants to purchase 14,987,067 shares of common stock. NEA Partners 16, L.P. ("NEA Partners 16") is the sole general partner of NEA 16. NEA 16 GP, LLC ("NEA 16 LLC") is the sole general partner of NEA

(1)Partners 16. The individual managers of NEA 16 LLC are Peter J. Barris, Forest Baskett, Ali Behbahani, Carmen Chang, Anthony A. Florence, Jr., Mohamad H. Makhzoumi, Joshua Makower, David M. Mott, Scott D. Sandell, Peter W. Sonsini and Paul Walker (collectively, the "Managers"). The Managers share voting and dispositive power with regard to the shares held directly by NEA 16.

(2)Based on a Schedule 13D filed with the SEC on February 25, 2019, consisting of 12,069,937 shares of common stock and 2,487,067 shares of common stock issuable upon the exercise of warrants. These shares and warrants are held directly by S.R. One, Limited, an indirect wholly-owned subsidiary of GlaxoSmithKline plc.

(3)Consists of securities purchased in connection with a private placement in February 2019 and based on a Schedule 13G filed with the SEC on February 14, 2019, which discloses shares as of December 31, 2018. Consists of 3,777,888 shares of common stock held of record by Biotechnology Value Fund, L.P. ("BVF"), 2,924,147 shares of common stock held of record by Biotechnology Value Fund II, L.P. ("BVF2"), 591,427 shares of common stock held of record by Biotechnology Value Trading Fund OS LP ("Trading Fund OS"), and 534,781 shares of common stock held of record by the Partners Managed Accounts ("Managed Accounts"). Also includes 3,774,731 shares of common stock issuable upon exercise of warrants held by the above referenced BVF entities. Excludes 4,716,216 shares of common stock issuable upon the exercise of warrants, which are not exercisable within 60 days of March 31, 2019 by virtue of the beneficial ownership limitation described below. The number of shares of common stock into which the warrants are convertible is limited to that number of shares of common stock which would result in the stockholders, together with its affiliates, having an aggregate beneficial ownership of no more than 9.99% of the total issued and outstanding shares of common stock. This beneficial ownership limitation may be increased or decreased to an amount not to exceed 19.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of warrants.

(4)Consists of (i) 1,352,964 shares of common stock and 863,241 shares of common stock issuable upon exercise of warrants held by DAFNA LifeScience, LP and (ii) 636,689 shares of common and 509,172 shares of common stock issuable upon the exercise of warrants held by DAFNA LifeScience Select LP. DAFNA Capital Management

LLC is the sole general partner of DAFNA LifeScience, LP and DAFNA LifeScience Select, LP. The Chief Executive Officer and Chief Inve