

PACIFIC BIOSCIENCES OF CALIFORNIA, INC.

FORM 8-K (Current report filing)

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Address	1305 O'BRIEN DRIVE MENLO PARK, CA, 94025
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Sector	Healthcare
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)
February 10, 2018

Pacific Biosciences of California, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-34899
(Commission
File Number)

16-1590339
(IRS Employer
Identification No.)

1305 O'Brien Drive
Menlo Park, California 94025
(Address of principal executive offices, including zip code)

(650) 521-8000
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

ITEM 5.02. DEPARTURE OF CERTAIN DIRECTORS OR CERTAIN OFFICERS; ELECTION OF DIRECTORS; APPOINTMENT OF CERTAIN OFFICERS; COMPENSATORY ARRANGEMENTS OF CERTAIN OFFICERS.

(b)

On February 10, 2018, the board of directors of Pacific Biosciences of California, Inc. (the “Company”) determined that Kathy Ordoñez, the Company’s Chief Commercial Officer and Executive Vice President, is an executive officer for purposes of Item 401(b) of Regulation SK and an officer for purposes of the requirements of Section 16 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and that Kevin Corcoran, the Company’s Senior Vice President, Market Development, no longer meets the definition of named executive officer or of a Section 16 officer under the Exchange Act. Mr. Corcoran will continue in his role as Senior Vice President, Market Development, and report to Ms. Ordoñez.

ITEM 8.01. OTHER EVENTS.

Commencement of Proposed Public Offering of Common Stock

On February 12, 2018, the Company issued a press release announcing the commencement of an underwritten public offering of its common stock pursuant to a shelf registration statement filed on Form S-3 (File No. 333-219642) with the Securities and Exchange Commission, which was declared effective August 18, 2017. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Disclosure update

The Company has updated its disclosure regarding its Legal Proceedings and Risk Factors. The revised disclosure is filed herewith as Exhibit 99.2 and incorporated herein by reference.

This Current Report on Form 8-K, including the exhibits hereto, shall not constitute an offer to sell or the solicitation of an offer to buy any securities of the Company, which is being made only by means of a written prospectus meeting the requirements of Section 10 of the Securities Act, nor shall there be any sale of the Company’s securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated February 12, 2018.
99.2	Legal Proceedings and Risk Factors.



Pacific Biosciences of California, Inc. Announces Proposed Public Offering of Common Stock

MENLO PARK, CA, February 12, 2018, Pacific Biosciences of California, Inc. (NASDAQ: PACB) today announced that it intends to offer and sell shares of its common stock in an underwritten public offering. Pacific Biosciences also intends to grant the underwriters a 30-day option to purchase up to an additional 15% of the number of shares of its common stock sold in the offering. The offering is subject to market and other conditions and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

Cantor Fitzgerald & Co. is acting as the sole book-running manager for the offering.

Pacific Biosciences intends to use the net proceeds from the offering for general corporate purposes, including capital expenditures and working capital. Pacific Biosciences may also use a portion of the net proceeds from the offering to acquire or invest in complementary businesses, technologies, product candidates or other intellectual property, although it has no present commitments or agreements to do so.

A shelf registration statement relating to the shares of common stock was previously filed with the Securities and Exchange Commission (the "SEC") and declared effective on August 18, 2017. A preliminary prospectus supplement and accompanying prospectus relating to the offering will be filed with the SEC and will be available on the SEC's website. Copies of the preliminary prospectus supplement (when available) and accompanying prospectus may be obtained from Cantor Fitzgerald & Co., Attention: Capital Markets, 499 Park Ave., 6th Floor, New York, New York 10022, or by e-mail at prospectus@cantor.com.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction. Any offer, if at all, will be made only by means of the prospectus supplement and accompanying prospectus forming a part of the effective registration statement.

About Pacific Biosciences of California, Inc.

Pacific Biosciences offers sequencing systems to help scientists resolve genetically complex problems. Based on its novel Single Molecule, Real-Time (SMRT[®]) Technology, Pacific Biosciences' products enable *de novo* genome assembly to finish genomes in order to more fully identify, annotate and decipher genomic structures; full-length transcript analysis to improve annotations in reference genomes, characterize alternatively spliced isoforms in important gene families, and find novel genes; targeted sequencing to more comprehensively characterize genetic variations; and real-time kinetic information for epigenome characterization. Pacific Biosciences' technology provides high accuracy, ultra-long reads, uniform coverage, and the ability to simultaneously detect epigenetic changes. PacBio[®] sequencing systems, including consumables and software, provide a simple, fast, end-to-end workflow for SMRT Sequencing.

“Safe Harbor” Statement Under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements within the meaning of the federal securities laws. These statements involve risks and uncertainties that could cause actual results to differ materially, including, but not limited to, whether or not Pacific Biosciences will be able to raise capital through the sale of shares of common stock or consummate the offering, the final terms of the offering, the satisfaction of customary closing conditions, prevailing market conditions, the anticipated use of the proceeds of the offering which could change as a result of market conditions or for other reasons, and the impact of general economic, industry or political conditions in the United States or internationally. Additional risks and uncertainties relating to the proposed offering, Pacific Biosciences and its business can be found under the heading “Risk Factors” in Pacific Biosciences’ most recent periodic, quarterly and annual reports filed with the SEC and in the preliminary prospectus supplement and accompanying prospectus relating to the offering to be filed with the SEC. Pacific Biosciences assumes no duty or obligation to update or revise any forward-looking statements for any reason.

Contact:
Attn: Investor Relations
Pacific Biosciences of California, Inc.
1305 O’Brien Drive
Menlo Park, California 94025
(650) 521-8450

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LEGAL PROCEEDINGS

On November 2, 2016, we filed a complaint against Oxford Nanopore Technologies Ltd., Oxford Nanopore Technologies, Inc. (“ONT Inc.”) and Metrichor, Ltd. (“Metrichor” and, together with ONT Inc., “ONT”) with the U.S. International Trade Commission (“USITC”) for patent infringement. On December 5, 2016, the USITC provided notice that an investigation had been instituted based on the complaint. We sought exclusionary relief with respect to several ONT products, including ONT’s MinION and PromethION devices. The complaint was based on our U.S. Patent No. 9,404,146, entitled “Compositions and methods for nucleic acid sequencing” which covers novel methods for sequencing single nucleic acid molecules using linked double-stranded nucleic acid templates, providing improved sequencing accuracy. On March 1, 2017, we filed an amended complaint to add a second patent in the same patent family, U.S. Patent No. 9,542,527, which was granted on January 10, 2017, to the investigation. We sought, among other things, an exclusion order permanently barring entry of infringing ONT products into the United States, and a cease and desist order preventing ONT from advertising and selling infringing products in the United States. On May 23, 2017, the Administrative Law Judge (“ALJ”) assigned to the matter issued an order construing certain claim terms of the asserted patents. On June 8, 2017, ONT filed a summary determination motion to terminate the proceedings based on the ALJ’s claim construction decision, and we did not oppose the motion. The ALJ granted the motion on July 19, 2017, and, on July 31, 2017, we filed a petition to review with the USITC to correct what we believe was an incorrect construction of the claims. On September 5, 2017, the USITC issued a notice granting our petition to review the ALJ’s claim construction decision. On February 7, 2018, the USITC issued a notice indicating that it had determined to adopt the ALJ’s claim construction and terminating the investigation. We plan to appeal the USITC’s ruling to the U.S. Court of Appeals for the Federal Circuit.

On February 2, 2017, we filed a claim in the High Court of England and Wales against Oxford Nanopore Technologies Ltd. (“ONT Ltd.”) and Metrichor for infringement of Patent EP(UK) 3 045 542, which is in the same patent family as the patents asserted in the USITC action referred to above. We are seeking remedies including injunctive relief, damages, and costs. On March 27, 2017, the defendants in the case filed their defense and counterclaim, denying infringement and seeking a declaration that the asserted patent is invalid. We filed our reply and defense to counterclaim on April 12, 2017. A case management conference was held on June 13, 2017. A trial is scheduled for May 2018 (not earlier than May 8). On August 31, 2017 we added a claim for infringement of a newly granted divisional, EP(UK) 3 170 904. On December 22, 2017, ONT Ltd. added to the action a request for declaration of non-infringement of its 1D² product. On January 12, 2018 we served reply to ONT’s request for a declaration of non-infringement, asserting infringement of both patents by ONT’s 1D² product.

On March 15, 2017, we filed a complaint in the U.S. District Court for the District of Delaware against ONT Inc. for patent infringement. The complaint is based on our U.S. Patent No. 9,546,400, entitled “Nanopore sequencing using n-mers” which covers novel methods for nanopore sequencing of nucleic acid molecules using the signals from multiple monomeric units. This patent was granted on January 17, 2017. We are seeking remedies including injunctive relief, damages and costs. On May 8, 2017, the defendants filed a motion to dismiss the complaint, alleging that the asserted patent claims recite patent ineligible subject matter. On November 9, 2017, the judge denied ONT’s motion to dismiss. The parties and court are currently working to define the case schedule.

On April 21, 2017, ONT Ltd. and Harvard University filed a claim against us in the High Court of England and Wales for infringement of Patent EP(UK) 1 192 453, a patent owned by Harvard University and entitled “Molecular and atomic scale evaluation of biopolymers,” and for which ONT Ltd. alleges it holds an exclusive license. ONT Ltd. and Harvard University are seeking remedies including injunctive relief, damages, and costs. On April 25, 2017, ONT Ltd. announced that it also had filed a claim against us in the District Court of Mannheim, Germany, for infringement of the German version of the patent. On November 2, 2017, we filed our statement of defense in the German infringement matter and we also filed a separate nullity action in Germany to establish that the EP 1 192 453 patent is invalid. On December 6, 2017, we filed a cross-complaint in the German infringement matter alleging ONT Ltd.’s infringement in Germany of our EP 3 045 542 patent. The trial date for the German infringement matter and cross-complaint is set for July 27, 2018. The trial date for the UK matter is expected to occur in approximately March 2019.

On September 25, 2017, we filed a complaint in the U.S. District Court for the District of Delaware against ONT Inc. for patent infringement. The complaint is based on our U.S. Patent No. 9,678,056 entitled “Control of Enzyme Translation in Nanopore Sequencing”, granted June 13, 2017, and U.S. Patent No. 9,738,929 entitled “Nucleic Acid Sequence Analysis”, granted August 22, 2017. We are seeking remedies including injunctive relief, damages and costs.

On December 14, 2017, the defendants filed a motion to dismiss the complaint, alleging that the asserted patent claims in the 9,738,929 patent recite patent ineligible subject matter. On January 5, 2018, we filed our opposition to this motion. The parties and court are currently working to define the case schedule.

Litigation is inherently unpredictable, and it is too early in the proceedings to predict the outcome of these lawsuits or any impact they may have on us. As such, the estimated financial effect associated with these complaints cannot be made as of this 8-K filing time. Litigation is a significant ongoing expense, recognized in sales, general and administrative expense, with an uncertain outcome, and has been in the past and may in the future be a material expense for the Company. Management believes this investment is important to protect the Company’s intellectual property position, even recognizing the uncertainty of the outcome.

From time to time, we may also be involved in a variety of other claims, lawsuits, investigations and proceedings relating to securities laws, product liability, patent infringement, contract disputes, employment and other matters that arise in the normal course of our business. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications. We record a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. We currently do not believe that the ultimate outcome of any of the matters described above is probable or reasonably estimable, or that these matters will have a material adverse effect on our business; however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of litigation and settlement costs, diversion of management resources and other factors.

RISK FACTORS

We are involved in legal proceedings to enforce our intellectual property rights.

Our intellectual property rights involve complex factual, scientific and legal questions. We operate in an industry characterized by significant intellectual property litigation. Even though we may believe that we have a valid patent on a particular technology, other companies have from time to time taken, and may in the future take, actions that we believe violate our patent rights. For example, we are involved in several legal proceedings for patent infringement with ONT, Oxford Nanopore Technologies Ltd. and Harvard University in several United States and European jurisdictions. We have received adverse rulings against us with respect to our complaint with the USITC in one of these proceedings, and there are no assurances that we can be successful in appealing or otherwise overturning any such rulings. Legal actions to enforce our patent rights have been, and will continue to be, expensive, and may divert significant management time and resources. Adverse parties from previous legal actions have brought, and may in the future bring, claims against us and/or our intellectual property. Litigation is a significant ongoing expense, recognized in sales, general and administrative expense, with an uncertain outcome, and has been, and may in the future be, a material expense for the Company. Our enforcement actions may not be successful, have given rise to legal claims against us and could result in some of our intellectual property rights being determined to be invalid or not enforceable. Furthermore, an adverse determination or judgement could lead to an award of damages against us, or the issuance of an injunction against us that could prevent us from selling any products found to be infringing the intellectual property rights of another party.

We have been, are currently, and could in the future be, subject to legal proceedings with third parties who may claim that our products infringe or misappropriate their intellectual property rights.

Our products are based on complex, rapidly developing technologies. We may not be aware of issued or previously filed patent applications that belong to third parties that mature into issued patents that cover some aspect of our products or their use. In addition, because patent litigation is complex and the outcome inherently uncertain, our belief that our products do not infringe third-party patents of which we are aware or that such third-party patents are invalid and unenforceable may be determined to be incorrect. As a result, third parties have claimed, and may in the future claim, that we infringe their patent rights and have filed, and may in the future file, lawsuits or engage in other proceedings against us to enforce their patent rights. For example, ONT and Harvard University have filed claims against us in the High Court of England and Wales and the District Court of Mannheim, Germany for patent infringement. We are aware of other issued patents and patent applications owned by third parties that could be construed to read on our products and services. Although we do not believe that our products or services infringe any valid issued patents, the third-party owners of these patents and applications may in the future claim that we infringe their patent rights and file lawsuits against us. In addition, as we enter new markets, our competitors and other third parties may claim that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. Furthermore, parties making claims against us may be able to obtain injunctive or other relief, which effectively could block our ability to develop further, commercialize, or sell products or services, and could result in the award of substantial damages against us. Patent litigation between competitors in our industry is common. Additionally, we have certain obligations to many of our customers and suppliers to indemnify and defend them against claims by third parties that our products or their use infringe any intellectual property of these third parties. In defending ourselves against any of these claims, we have in the past incurred, and could in the future incur, substantial costs, and the attention of our management and technical personnel could be diverted. For example, we previously incurred significant legal expenses to litigate and settle a complaint alleging patent infringement. Even if we have an agreement that indemnifies us against such costs, the indemnifying party may be unable to uphold its contractual obligations. To avoid or settle legal claims, it may be necessary or desirable in the future to obtain licenses relating to one or more products or relating to current or future technologies, which could negatively affect our gross margins. We may not be able to obtain these licenses on commercially reasonable terms, or at all. We may be unable to modify our products so that they do not infringe the intellectual property rights of third parties. In some situations, the results of litigation or settlement of claims may require us to cease allegedly infringing activities which could prevent us from selling some or all of our products. The occurrence of these events may have a material adverse effect on our business, financial condition or results of operations.

In addition, in the course of our business, we may from time to time have access or be alleged to have access to confidential or proprietary information of others, which, though not patented, may be protected as trade secrets. Others could bring claims against us asserting that we improperly used their confidential or proprietary information, or that we misappropriated their technologies and incorporated those technologies into our products. A determination that we illegally used the confidential or proprietary information or misappropriated technologies of others in our products could result in us paying substantial damage awards or being prevented from selling some or all of our products, which could materially and adversely affect our business.